



POLICY STATEMENT

Guidelines for Refractive Surgery Advertising

A joint statement of the American Academy of Ophthalmology, the American Society of Cataract and Refractive Surgery and the International Society of Refractive Surgery of the American Academy of Ophthalmology.

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 prohibits false and deceptive advertising, as do similar state laws. The Federal Food, Drug and Cosmetic Act also prohibits false and misleading advertisements for restricted medical devices, including Federal Drug Administration (FDA)-approved lasers used for LASIK surgery. Advertising that is literally true but that conveys a misleading impression to reasonable consumers may be unlawful. Claims made implicitly in advertising, as well as those made explicitly, 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. Ophthalmologists are responsible for unlawful or deceptive claims made during testimonials that are used in their promotion and advertising materials. In addition, the FDA's premarket approval orders might contain certain conditions of approval that could include requirements that physicians or companies provide specific risk information in promotional materials.

The FTC has primary jurisdiction over advertising of health care services, over-the-counter drugs, and devices. The FDA has jurisdiction over product labeling for prescription drugs and medical devices. It also has jurisdiction over the advertising of prescription drugs and restricted medical devices.

One issue of current interest concerns physicians' advertising of FDA-approved medical devices for use in "off-label" surgical applications. A physician's decision to use an FDA-approved and legally marketed device on a patient for any condition or disease within a legitimate physician-patient relationship (e.g., using the excimer laser outside the scope of the approved labeling) is considered to be within the practice of medicine exception. 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 the off-label use of these specific FDA-approved devices is prohibited and is not protected under the practice of medicine exception. Off-label use may be described in peer-review articles and textbooks.

Under FDA regulations, advertising of FDA-approved devices (e.g., excimer lasers) by brand name and model to the public is permissible as long as the physician, manufacturer, and distributor provide a brief statement of the device's intended uses and all relevant warnings, precautions, contraindications, and side effects in the advertisement. Informed consent is regulated by the states. In addition, the FTC can assert jurisdiction over statements made in informed consent forms.

State licensing authorities also regulate physician advertising and can impose disciplinary action against physicians who make claims of superior quality of care or otherwise engage in false and deceptive advertising. In addition, every state has general laws and rules against false and misleading commercial claims. Physicians should familiarize themselves with applicable state laws and regulations in this area.

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 with respect to these laws. Under the Federal Trade Commission Act, Internet ads also are viewed as advertising. Privileged discussions between physicians and their patients are generally not regulated by the FTC, but they 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 other medical treatment options. In addition, the FDA has a definition for labeling and its jurisdiction extends over certain materials (e.g., a patient brochure) that the FTC might consider advertising for its own jurisdictional purposes. In such situations, physicians and companies are responsible for complying with both agencies' requirements.

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 are held to a higher standard than those who advertise consumer products that are not health related, particularly with respect to surgical procedures. 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, this will usually require "competent and reliable" scientific evidence that may include the physician's own outcomes alone or in combination with other clinical studies, depending on the claim. 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 expressed 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 them.

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 of the results generally achieved by the users of the product or device. 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 check their state laws 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 considering the expert endorsement.

Advertising Claims

Prospective refractive surgery patients have differing needs and expectations, and they 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 read, "Throw Away Your Glasses!"* A reasonable consumer could 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 were to undergo 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 to be as unqualified as the claim in Example 1, in light of the more prominent headline or drawing. 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 reduce your dependence on 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 reasons cited for Examples 1 and 2.

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 FDA 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 nonscanning ones, and such a statement should be avoided unless the physician has 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 the physician has 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 the following: "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 noninvasive procedure. It is not appropriate to claim or suggest expressly or through use of euphemisms such as "treatment," "therapy," "vision correction," or "enhancement" that PRK is anything other than an invasive surgical procedure.

While it may be appropriate to differentiate between refractive procedures in order to inform consumers, it should be done in a way so as not to be misleading; PRK and LASIK 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.

Permanence and Predictability Claims

Example 1: An ad states, "Achieve permanent vision correction with refractive surgery!" A reasonable consumer could assume "permanent" to mean that their postsurgical refractive result will remain stable throughout their lifetime. The FTC staff has raised questions about the possibility of regression, drift, and instability long-term. It has objected to permanency claims because it believes 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 postsurgical 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, preoperatively, 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 ensure 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:

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

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