Advertising Premium IOLs

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Ophthalmologists have both a legal and ethical obligation to truthfully advertise their services. This article will address issues to be aware of in advertising premium IOLs and the implications for coverage when improper advertising occurs. Much of this information was adapted from the American Academy of Ophthalmology 2008 Policy Statement: *Guidelines for Refractive Surgery Advertising.*

Both the Federal Trade Commission Act and the Federal Food, Drug, and Cosmetic Act prohibit false and deceptive or misleading advertising. The FTC has primary jurisdiction over the advertising of health care services, over-the-counter drugs, and devices. The FDA has jurisdiction over product labeling for prescription drugs and medical devices, and advertising of prescription drugs and medical devices that a licensed practitioner must authorize for sale, distribution, or use. Note that patient information brochures, seminars, and videos may be considered advertising.

State licensing authorities also regulate physician advertising and can impose disciplinary action against physicians who engage in false and deceptive advertising. In addition, every state has general laws and rules against false and misleading commercial claims. The American Academy of Ophthalmology has ethics rules which apply to advertising issues as well, most directly, Rule 13. *Communications to the Public.*

Under FDA regulations, advertising FDA-approved devices by brand name and model is permissible as long as a brief statement of the device's intended uses and all relevant warnings, precautions, contraindications, and side effects are provided in the advertisement. Ads do not need to incorporate all informed consent disclosures, but they must not contradict them. If the device's FDA premarket approval orders include requirements that promotional materials contain specific risk information, those must be adhered to.

There are additional precautions to take when advertising FDA-approved premium IOLs that the ophthalmologist may use off-label. While it is legal under the "practice of medicine" exception for physicians to use FDA-approved devices off-label, advertising this use is prohibited.

The FTC requires that advertisers have a "reasonable basis" for advertising claims at the time they are made. 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, preferably those that have been peer reviewed or replicated in other studies.

If using a testimonial, the particular patient's experience must be typical or representative of the experiences generally achieved by the physician's patients, or else a clear and conspicuous disclosure of the results generally achieved by the users of the product or device must be included. Note that some states prohibit the use of patient testimonials.

As with LASIK advertisements, ophthalmologists should avoid ads that begin: "Throw Away Your Glasses" or have images with the same message. Even if the ad text states that the premium IOL "may correct your presbyopia and nearsightedness and may eliminate your need for glasses or contacts," consumers are still likely to infer from the dramatic opening statement or image that if they select cataract or refractive surgery with use of a premium IOL, they will achieve perfect vision and be free of any need for glasses. Since the surgeon cannot guarantee this outcome, the claim is subject to legal challenge.

Another advertising pitfall is the use of statements such as, "We use premium IOLs so you get the best results." This implies that premium IOLs produce better results than standard IOLs (or other procedures). Such a statement should be avoided unless the physician has competent and reliable scientific evidence to support it.

A statement that you can legally make is: "The Food and Drug Administration has determined that the premium IOLs we use are safe and effective for cataract surgery." The Federal Food, Drug and Cosmetic Act was amended to allow references to the FDA-approved status of medical devices in advertisements.

Aside from action by the FDA, FTC, state agency, or the ophthalmologist's professional society(ies), false or misleading advertising could lead to lawsuits against the physician by patients alleging lack of informed consent or fraud. In turn, this could result in uninsured risk as a result of the denial of the claim or termination of coverage by the ophthalmologist's malpractice insurer.

Patients may prevail in a claim of lack of informed consent where aggressive advertising has occurred. The patient may allege that the overstated benefits misled him or her into agreeing to undergo the surgery without fully understanding or appreciating the consequences and alternatives. In this way, the advertisement destroys the validity of an otherwise properly executed consent form.

OMIC's underwriting requirements for refractive surgery (which includes the use of premium IOLs for refractive lens exchange) state that advertisements must not be misleading, and must not make statements that guarantee results or cause unrealistic expectations. Violation of these underwriting requirements may cause termination of the policy or denial of coverage of a claim based on the violation. In addition, Exclusion III.B.1 of the policy provides that OMIC will defend insureds against allegations of medical malpractice that include false, misleading, or deceptive advertising or other fraudulent acts, but not if the claim is based solely on the advertising or fraud claim. Even then, the policy will not cover damages or supplementary payments for such claims.