

ADVISORY OPINION OF THE CODE OF ETHICS

Subject: Advertising Claims Containing Certain Potentially Misleading Phrases

Issues Raised: In what circumstances is it deceptive to claim that certain ophthalmic

procedures are "safe," "harmless," or "painless"; that treatments will "cure" patients; or that ophthalmologists are "pioneers," "leaders," or

"world famous"?

Applicable Rule: Rule 13. Communications to the Public

Background

Like all physicians, ophthalmologists have an obligation to present themselves and the services they offer in a manner that is neither inaccurate nor misleading. This principle of ethical conduct is regulated by state law, the Food and Drug Administration, and the Federal Trade Commission.

An ophthalmologist's misrepresentation of his or her qualifications or the nature of an ophthalmic procedure is an ethical violation, because a successful physician-patient relationship is built on trust and confidence. The relationship carries with it the assumption that the physician has provided the patient with an accurate assessment of his or her problem, an appropriate recommendation for treatment, and an honest representation of the physician's ability to carry out that therapy. Because patients may be relatively uninformed on issues related to health and health care, it is imperative that practitioners avoid misrepresentations that would deny the patient information needed for making truly informed decisions.

First Inquiry

Facts - Dr. A, a member of the American Academy of Ophthalmology, has an extremely active practice that consists largely of cataract surgery, and he has placed an advertisement in several local papers announcing his practice. The ads include the statements that "my state-of-the-art laser technique for cataract or glaucoma is safe, and painless" and that "we will cure your visual problem." A colleague is concerned that these ads may be deceptive to patients and has inquired whether they are consistent with the Code of Ethics.

Resolution - To call a procedure safe is to make one of three possible claims. It means (1) that the procedure is absolutely safe (i.e., there are no risks), (2) that the procedure is comparatively safe when compared with alternative procedures for the same problem, or (3) that it is safer than surgery for another problem. If the first meaning is intended, the statement clearly is false, since all surgical procedures, including cataract surgery, carry some degree of risk, even if the risk in a particular case is low.

If the second meaning is intended, the ad is also deceptive unless the procedure is demonstrably safer than alternative techniques for cataract surgery. If this is so, the advertiser should have credible clinical evidence to support that claim. Such a claim may be difficult to prove, because the safety of a procedure often varies with the circumstances (e.g., the medical status and characteristics of the individual patient).

If the third meaning is intended, the advertiser simply means to convey the fact that his cataract surgery is safer than surgery in general (e.g., triple-bypass heart surgery). Without further explanation, this is a deceptive comparison.

Because the safety of a surgical procedure is necessarily a qualified concept, simply using a word such as "safe" is likely to deceive prospective patients. The failure to qualify the claim of safety is particularly objectionable, because a variety of phrases could easily be used to communicate the safety/risk

relationship (e.g., "relatively safe," "safe for most patients," or "among the safer types of surgery").

The Academy is also concerned that many potential patients may understand the unqualified word "safe" to refer to some consensus and possibly to a government-approved standard of adequate safety, similar to the Food and Drug Administration's determination that a prescription drug is safe and effective. Because using an unqualified word such as "safe" is likely to be misunderstood as implying absolute safety, and because doing so suggests a benefit of a procedure without discussing risks, it is likely to violate Rule 13 of the Code of Ethics.

Similarly, the term "painless" with respect to an ophthalmic surgical procedure is seldom accurate and is usually deceptive. To say that an operation is painless is misleading if the statement refers to only part of the entire surgical treatment. The discomfort that occurs at the time of surgery can be minimized or in many cases eliminated by the use of local or general anesthetics. However, since anesthetics may involve an injection or installation of an irritating topical agent, the statement is not literally true. Second, it is not uncommon for patients to feel some discomfort in the postoperative period. Third, possible complications such as glaucoma, infections, or inflammation of tissue can cause pain such that a painless course of treatment cannot be ensured. To a patient, the statement that a surgical procedure is painless almost surely means that the entire experience—preparation, surgery, and recovery—is painless. Such a statement is almost always misleading.

The reference to using the laser may be a deception to attract patients who fear conventional surgery. which they may associate with pain. This distinction is usually deceptive. Likewise, use of the term "cure" with reference to ophthalmic problems is often deceptive. To cure a condition means that as a consequence of treatment, the condition no longer exists and will not recur for any reason. For example, to perform a trabeculectomy or laser trabeculoplasty on a patient with primary open-angle glaucoma cannot be said to cure the glaucoma. First, the visual incapacitation caused by any pre-existing glaucomatous nerve damage will continue. Second, the surgical procedure may not lower the pressure adequately to obviate the need for supplemental medication. Third, intraocular pressure may not be lowered adequately even with the use of medications postoperatively, and visual field loss may continue. In addition, glaucoma procedures may undergo late failure even after years of functioning well. All of these situations mean that the patient continues to need testing, examination, and ongoing care, even if the intraocular pressure is lowered to the point where further visual field loss is halted. In other words, the patient continues to have primary open-angle glaucoma for the rest of his or her life. In the case of cataract surgery, the lens implant is an exogenous prosthetic device that approximates, but does not replace, the function of the human lens. Thus, in order not to be misleading, the term "cure" should almost always be further explained and qualified to give the patient an accurate understanding of his or her prospects for improvement.

The Academy is not prepared to say that all ads that contain the words "safe," "painless," or "cure" are deceptive. In this case, the ad using these terms appears to be inconsistent with Rule 13; the terms were used without other qualifications or explanations and applied to surgical procedures that are associated with risks of pain, complications, and incomplete success. The degree to which the claims may be true varies greatly and no substantiation is provided.

Second Inquiry

Facts - Dr. B is a well-respected cataract surgeon with an expanding practice in a small city in a Sunbelt state. On several occasions he has offered his services to a charitable organization that has sponsored him and other eye professionals to travel to less developed countries to perform eye surgery for one week per year. Dr. B has not published any papers in refereed journals, but he has lectured at continuing medical education seminars on three occasions. Generally, he lectures on the success he has had in using a particular brand of intraocular lens and on his low rate of postoperative complications. Although his practice is largely local, he does operate from time to time on visitors from abroad, particularly from Latin America. In order to market his practice, Dr. B places advertisements in local newspapers each Sunday. The ads state in relevant part, "If you need cataract surgery, don't you want a top surgeon? Call Dr. B, a world-renowned surgeon. Dr. B has pioneered certain advances in cataract surgery and participated in developments in the field. He has lectured on his accomplishments to medical groups across the country. You'll be in experienced hands."

Another ophthalmologist in the same city as Dr. B has inquired whether this advertisement contravenes

the Academy's Code of Ethics.

Resolution - This advertisement appears to be misleading in several respects. First, only a very small fraction of all physicians can justifiably claim to be world renowned by the consensus meaning of the term. These may include some physicians who have authored widely used texts or who have made significant, independently validated contributions to the care of patients. As such, it is the very elusiveness of measures of fame that makes invoking them misleading when trying to lure patients. Merely traveling extensively, presenting addresses at professional meetings, or treating patients from abroad does not mean that a physician is world famous. To so indicate is to exploit the inherent imprecision of the concept of fame to mislead patients. There can be little question that such claims are employed in order to give patients the impression that the surgeon meets some objective, high level of competence, skill, or recognition—that may not exist with respect to the advertiser. The same is true of Dr. B's advertising himself as a top surgeon. To be literally true, "top" must refer to an objective and verifiable criterion in which the surgeon actually exceeds all others.

Saying that one has pioneered certain advances in cataract surgery is also deceptive in this case. Such a phrase clearly connotes a significant, independently validated breakthrough, not a minor alteration or refinement of conventional procedures. Simply being one of many investigators for one type of intraocular lens, using one piece of equipment, or using a slightly modified surgical procedure does not justify use of a hyperbolic term such as "pioneered." Since all surgery requires some degree of innovation, a surgeon cannot meaningfully claim to be an originator or developer of a technique or product simply because he or she has modified in some minor way what existed before.

Use of the phrase "participated in developments in the field" suffers from a related but different flaw. Read literally, it means virtually nothing, because the words "developments" and "field" are undefined. Its use to suggest an accomplishment is therefore illusory; by performing surgery and maintaining patient records, every surgeon participates in development in the sense of seeing outcomes upon which alterations or advances in surgical techniques are based. This is roughly the same as the vague assertion that every human being participates in the historic evolution of mankind. To advertise using such phrases thus appears to be misleading unless the ophthalmologist has personally contributed significant advances that have been adopted by colleagues. This does not appear to be true of Dr. B. Thus, Dr. B appears to have acted unethically by engaging in advertising that is designed and intended to deceive patients.

In summary, use of the terms "safe," "harmless," "painless," "cure," "pioneer," "leader," "world famous," and similar such words should be used with caution, and they should only refer to truthful and verifiable qualities of the ophthalmologist and his or her treatments.

Applicable Rule

"Rule 13. Communications to the Public. Communications to the public must be accurate. They must not convey false, untrue, deceptive, or misleading information through statements, testimonials, photographs, graphics, or other means. They must not omit material information without which the communications would be deceptive. Communications must not appeal to an individual's anxiety in an excessive or unfair way, and they must not create unjustified expectations of results. If communications refer to benefits or other attributes of ophthalmic procedures that involve significant risks, realistic assessments of their safety and efficacy must also be included, as well as the availability of alternatives and, where necessary to avoid deception, descriptions and/or assessments of the benefits or other attributes of those alternatives. Communications must not misrepresent an ophthalmologist's credentials, training, experience or ability, and must not contain material claims of superiority that cannot be substantiated. If a communication results from payment by an ophthalmologist, this must be disclosed unless the nature, format, or medium makes it apparent."

Other References

"Rule 2. Informed Consent. The performance of medical or surgical procedures shall be preceded by appropriate informed consent. When obtaining informed consent, pertinent medical facts and recommendations consistent with good medical practice must be presented in understandable terms to the patient or to the person responsible for the patient. Such information should include alternative

modes of treatment, the objectives, risks, and possible complications of such a treatment, and the consequences of no treatment. The operating ophthalmologist must personally confirm with the patient or patient surrogate their (his or her) comprehension of this information."

"Rule 9. Medical and Surgical Procedures. An ophthalmologist must not misrepresent the service that is performed or the charges made for that service. An ophthalmologist must not inappropriately alter the medical record."

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