

## Ask the Ethicist: FDA Panel's LASIK Guidelines

September 2008

**Q:** *I have a sizable LASIK practice with many satisfied patients. Admittedly, I also have several patients who claim side effects. I work closely with them to ameliorate those effects.*

*Last April, there was an FDA panel meeting on quality-of-life issues for refractive surgery patients. How should the panel recommendations be incorporated into my practice?*

**A:** The FDA panelists' recommendations are relatively simple: Strengthen the information you provide to patients about contraindications and potential side effects. This message can be done in advertising, screening procedures and the informed consent process. A few examples follow:

- Use photographs or illustrations to show how postoperative side effects like glare, starbursts and halos will appear. The panelists noted that these are side effects, not complications (i.e., many patients have these visual disturbances although they diminish with time). Explain that it is probable that certain side effects will occur.
- Unambiguously explain that there may be potentially problematic postoperative effects, such as inaccuracy in IOP readings and in calculating IOL power. Also be clear that LASIK patients made emmetropic in their youth will need reading glasses in middle age.
- Simplify descriptions of preexisting conditions that disqualify a candidate, such as ectatic conditions, autoimmune diseases, documented dry eye, extreme nearsightedness and large pupils.
- Inform patients that not everyone will have a "quick" and "painless" procedure that guarantees a "lifetime of no glasses," as LASIK is frequently marketed.

Of note, the FDA panel did not issue these recommendations as guidelines for physician advertising and said that inappropriate advertising would fall under Federal Trade Commission regulation. The panel acknowledged that issues of inadequate informed consent and improper patient screening may fall under medical malpractice statutes.

With respect to refractive advertising, be aware that inappropriate or overreaching advertising claims can be used to supplement a plaintiff's malpractice suit. It can be successfully argued that superlative claims for refractive procedures lured a patient into the physician's office, where the stated or implied promise of a particular result was unfulfilled. Civil damages awarded for such claims have no tort reform-enabled dollar cap. The awards can be staggeringly high.

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