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Finally, under the FTC Act, deception can occur through omission of information when that information is necessary to prevent an affirmative representation from being misleading, or simply by remaining silent, if doing so constitutes an implied but false representation. Not all omissions are deceptive, even if providing the information would benefit consumers. An omission is considered deceptive only if the absence of the information causes the advertisement to convey an inaccurate impression about a material fact.

Under FTC law, therefore, advertisements, promotional brochures, informational tapes, seminars and other forms of marketing of RK or PRK to consumers should not contain express or implied claims that are false or unsubstantiated, or omissions of material information. In particular, claims that convey an inaccurate impression about the safety, efficacy, success or other benefits of PRK would raise deception concerns. For example, an unqualified claim for PRK that patients can "throw away their eyeglasses" would be suspect because the FDA has approved the excimer laser only for the treatment of mild to moderate nearsightedness and not to treat other refractive vision deficiencies. Likewise, the same claim made for RK would also be questionable because published, multi-center studies indicate that RK does not eliminate the need for corrective lenses for all refractive vision deficiencies. Even a more limited claim, suggesting only that patients who are nearsighted, with no other refractive vision deficiencies, can "throw away their eyeglasses" may also be deceptive, without further qualification, if, after surgery, a significant number of patients require eyeglasses for best vision, for reading, or under particular circumstances, such as for night driving.

Similarly, claims regarding success rates, long-term stability or predictability of outcome would also need to be substantiated by competent and reliable scientific evidence. It is important to keep in mind that the fact that the FDA has approved the excimer laser for use in PRK does not by itself necessarily provide adequate substantiation for all specific claims about the success of the procedure.

Finally, representations made about the safety or efficacy of RK or PRK, may, in certain circumstances, require disclosures of material information about health risks or limitations associated with the surgery to prevent deception. For example, an advertisement containing express or implied representations that the surgery is safe may also need to contain information about any significant risks associated with the surgery, and, for PRK, with the particular laser in use.

Questions about this letter may be directed to the FTC's Service Industry Practices, Bureau of Consumer Protection staff at (202) 326-3319 (Walter Gross) or (202) 326-3291 (Matt Daynard) or the FTC's Boston Regional Office staff at (617) 424-5960 (Paul Block or Colleen Lynch).

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