

## ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from The Laser Vision Institute, LLC and its principals, Marco Musa, Max Musa, and Marc' Andrea Musa (collectively, "LVI").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves alleged misleading representations about LASIK (laser assisted *in situ* keratomileusis) refractive surgery services designed to improve the focusing power of the eye by permanently changing the shape of the cornea (the clear covering of the front of the eye), thereby reducing patients' dependence on eyeglasses and contact lenses.

The complaint alleges that LVI failed to substantiate claims that its LASIK surgery services: (1) eliminate the need for glasses and contacts for life; (2) eliminate the need for reading glasses; and (3) eliminate the need for bifocals. Among other reasons, the complaint alleges that LASIK surgery does not eliminate most peoples' need for reading glasses.

According to the FTC complaint, LVI falsely claimed that consumers will receive a free consultation that determines their candidacy for LASIK. In fact, the complaint alleges that consumers receive a free, initial meeting with an LVI representative during which consumers receive a quoted price for the procedure based on their prescription and other desired services, and are required to pay a \$300 deposit before the risks and limitations of LASIK are disclosed to them and their candidacy is determined by a health care professional at a future time. The \$300 deposit is non-refundable if, after the consultation, consumers elect not to undergo the procedure. Consumers are refunded \$200 of the deposit if they are later rejected as medical candidates.

The proposed consent order contains provisions designed to prevent LVI from engaging in similar acts and practices in the future.

Part I of the order prohibits claims that LASIK surgery services or any other refractive surgery services: (1) eliminate the need for glasses and contacts for life; (2) eliminate the need for reading glasses; or (3) eliminate the need for bifocals, unless the claims are substantiated by competent and reliable scientific evidence. "Refractive surgery services" are defined as any surgical procedure designed to improve the focusing power of the eye by permanently changing the shape of the cornea.

Part II of the order requires that future claims about the benefits, performance, efficacy, or safety of any refractive surgery service be substantiated by competent and reliable scientific evidence.

Part III of the order prohibits LVI from misrepresenting: (1) that consumers will receive a free consultation that determines their candidacy for LASIK or any other refractive surgery services; (2) the cost to consumers to have their candidacy for refractive surgery services determined; or (3) the information consumers will receive during a consultation for refractive surgery services.

Part IV of the order permits device claims approved by the FDA under any new medical device application.

Parts V and VI of the order require LVI to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, and provide copies of the order to certain of its personnel.

Part VII of the order requires the corporate respondent to notify the Commission of changes in corporate structure.

Part VIII of the order requires the individual respondents to notify the Commission of their employment status in the eye care industry.

Part IX of the order requires LVI to file compliance reports with the Commission, and . Part X provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.