

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 LCA-Vision, Inc. d/b/a *LasikPlus* (“LCA”).

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 allegedly 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.

According to the FTC complaint, LCA failed to have substantiation for the claims that its LASIK surgery services: (1) eliminate the need for glasses and contacts for life; and (2) pose significantly less risk to patients' eye health than wearing glasses or contacts. Among other reasons, LASIK surgery does not eliminate most peoples' need for reading glasses, and the relative risks of LASIK surgery and wearing contact lenses over time are not readily comparable. The complaint further alleges that LCA did not have substantiation for its claim that its LASIK surgery services eliminate the risk of glare and haloing, a starburst effect around lights at night, that can be caused by the LASIK procedure.

The proposed consent order contains provisions designed to prevent LCA 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) pose significantly less risk to patients' eye health than wearing glasses or contacts; or (3) eliminate the risk of glare and haloing, 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 permits device claims approved by the FDA under any new medical device application.

Parts IV, V, VI, and VII of the order require LCA to keep copies of relevant advertisements

and materials substantiating claims made in the advertisements, to provide copies of the order to certain of its personnel, to notify the Commission of changes in corporate structure, and to file compliance reports with the Commission. Part VIII 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.