



Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

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Federal Trade Commission Stops Allegedly Misleading Representations for Lasik Eye Surgery

Future Claims of Benefits, Performance, Efficacy, and Safety Must Be Substantiated

The Federal Trade Commission today announced two complaints and proposed consent orders with two of the largest purveyors of laser-assisted in situ keratomileusis (LASIK) refractive eye surgery services, settling charges that their advertisements were not substantiated by scientific evidence. According to the Commission, the ads claimed that LASIK surgery - which is designed to improve the focusing power of the eye by changing the shape of the cornea, thereby reducing patients' dependance on glasses and contact lenses - would eliminate the need for glasses or contacts for life, eliminate the need for reading glasses, and eliminate the need for bifocals.

Under the terms of the proposed orders with the Commission, both companies, The Laser Vision Institute, LLC and its principals, Marco Musa, Max Musa, and Marc'Andrea Musa (collectively, LVI) and LCA Vision, Inc., doing business as LasikPlus (LCA), will be barred from making such claims in the future unless the claims can be substantiated. The cases mark the first actions the FTC has taken against the sellers of LASIK surgery services for making allegedly false and unsubstantiated claims.

"The Commission charged that these companies couldn't substantiate their claim that LASIK eye surgery would eliminate the need for glasses or contacts for life," said Howard Beales, Director of the FTC's Bureau of Consumer Protection. "Companies offering any medical procedure shouldn't need glasses to see this clearly: if you over-promise, the FTC will act."

The Commission's Complaints

According to the Commission's complaints, both LCA, based in Cincinnati, Ohio, and LVI, based in Lake Worth, Florida, violated Section 5 of the FTC Act by making unsubstantiated claims regarding the benefits, performance, and efficacy of the LASIK procedure. In addition, as detailed below, LVI allegedly made a false claim regarding "free"

Related Documents:

[*LCA-Vision, Inc. d/b/a*](#)

[*LasikPlus*](#), File Number 022-3098

[*The Laser Vision Institute,*](#)

[*LLC*](#), File Number 022-3053

Basic LASIK: Tips on LASIK Eye Surgery



LASIK consultations, and LCA made an unsubstantiated safety claim about LASIK services.

The FTC's complaint against LCA alleges that the company failed to substantiate claims that its LASIK surgery services eliminate the need for glasses and contacts for life, and that the procedure poses significantly less risk to patients' eye health than wearing contacts or glasses. In addition, the complaint contends that LCA did not have substantiation for its claim that its procedure eliminates the risk of glare and halving, a star-burst effect around lights at night, that can be caused by LASIK.

The Commission's complaint against LVI alleges that the company failed to substantiate claims that its LASIK surgery services eliminate the need for glasses and contacts for life, eliminate the need for reading glasses, and eliminate the need for bifocals. Further, according to the complaint, LVI falsely claimed that consumers would receive a free consultation to determine their candidacy for LASIK. Instead, after an initial meeting with an LVI representative during which the representative quoted a price for the procedure based on their preferred treatment, LVI allegedly required consumers to pay a \$300 deposit before they were told of the risks associated with the surgery, or if they were eligible candidates for the LASIK procedure. According to the FTC, the \$300 deposit was nonrefundable if, after the initial consultation, the consumers elected not to have the surgery. The FTC alleges that only \$200 of the deposit was returned to consumers who elected to undergo the surgery but subsequently were rejected for medical reasons.

Terms of the Proposed Orders

The Commission's proposed consent orders are designed to prevent the two companies from engaging in similar acts or practices in the future when advertising their LASIK services.

Regarding LCA, the proposed 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 or halving, 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. Further, the proposed order requires that future claims about the benefits, performance, efficacy, or safety of any refractive surgery be substantiated by competent and reliable scientific evidence, and permits only device claims approved by the FDA under any new medical device application.

Regarding LVI, the proposed 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. The same definition of "refractive surgery services" applies, as do the other terms of the order related to claims about such services. The proposed order also 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 such refractive surgery services determined; or 3) the information consumers will receive during a consultation for refractive surgery services.

Consumer Education

To help consumers who are interested in LASIK eye surgery, the FTC has prepared a document entitled "Basic LASIK: Tips on LASIK Eye Surgery." It is available free from the Commission's Consumer Response Center at the address provided below and can be found on the FTC's Web site at: www.ftc.gov/bcp/online/pubs/health/lasik.htm.

The document provides the primary facts related to LASIK surgery, including sections on what LASIK surgery is; whether a consumer is a good candidate; how to find a surgeon; what risks and complications may occur; what to expect before, during, and after surgery; and what alternatives are available. It also contains the phone numbers and addresses of a wide range of resources for information about LASIK, including the American Academy of Ophthalmology, the National Eye Institute, and the U.S. Food and Drug Administration.

Finally, when considering LASIK surgery, the FTC recommends that consumers keep the following in mind: First, like any surgery, LASIK has potential risks; talk to an eye doctor and then weigh the pros and cons of the procedure - consumers should not sign up with their "eyes wide shut." Second, LASIK is not intended to correct presbyopia, or "aging eyes," the condition that requires most people to need reading glasses by their mid-forties. Third, LASIK surgery cannot be reversed; consumers may need additional surgery - called "enhancements" - to get the best possible vision after LASIK. Accordingly, consumers should consult their eye doctor about what to expect after the operation. Finally, most insurance plans do not cover the LASIK procedure.

The Commission vote to file each complaint and settlement was 5-0. The Commission is accepting public comments on the proposed settlements until April 25, after which it will determine whether to make them final.

NOTE: The agreements referenced in this release are for settlement purposes only and do not constitute an admission of a law violation.

Copies of the complaints, consent agreements, and analyses to aid public comment are available from the FTC's Web site at <http://www.ftc.gov> and also from the FTC's Consumer Response Center, Room 130, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The FTC works for the consumer to prevent fraudulent, deceptive, and unfair business practices in the marketplace and to provide information to help consumers spot, stop, and avoid them. To file a complaint, or to get free information on any of 150 consumer topics, call toll-free, 1-877-FTC-HELP (1-877-382-4357), or use the complaint form at <http://www.ftc.gov>. The FTC enters Internet, telemarketing, identity theft, and other fraud-related complaints into Consumer Sentinel, a secure, online database available to hundreds of civil and criminal law enforcement agencies in the U.S. and abroad.

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(<http://www.ftc.gov/opa/2003/03/lasikads.htm>)