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FDA NEWS RELEASE

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FDA warns against improper advertising, promotion of lasers intended for LASIK corrective eye surgery

The U.S. Food and Drug Administration today warned five eye care providers to stop the misleading advertising and promotion of refractive lasers used in eye surgery procedures such as LASIK. The FDA found that the providers' advertisements and promotional materials did not offer consumers adequate information about associated risks, as well as warnings and possible adverse events.

The five providers that received FDA Warning Letters are:

- 20/20 Institute Indianapolis LASIK, of Indianapolis
- Scott Hyver Visioncare Inc., of Daly City, Calif.
- Rand Eye Institute, of Deerfield Beach, Fla.
- Eye Center of Texas, of Bellaire, Texas
- Woolfson Eye Institute, of Atlanta

"Advertising by many eye care professionals who perform laser vision correction surgery provides patients with the risk information that they need to make informed decisions," said Steve Silverman, compliance director at FDA's Center for Devices and Radiological Health. "But providers whose advertising does not provide adequate risk information are finding out today that the FDA is serious about consumer protection."

Vision correction surgery with refractive lasers is intended to reduce a person's dependency on glasses or contact lenses. In refractive surgery, precise and controlled removal of corneal tissue by a special laser permanently reshapes the cornea (a part of the eye that helps focus light to create an image on the retina) and changes its focusing power. LASIK, which stands for Laser-Assisted In Situ Keratomileusis, is one type of vision correction surgery that uses refractive lasers to correct nearsightedness, farsightedness, and astigmatism.

The most common risks of LASIK vision correction surgery with refractive lasers include:

- dry eye syndrome, which can be severe;
- the possible need for glasses or contact lenses after surgery;
- visual symptoms including halos, glare, starbursts, and double vision, which can be debilitating; and
- loss of vision.

The FDA may take further regulatory action, such as seizure, injunction and civil money penalties, against providers who do not correct their advertising and promotion to address concerns raised by the FDA.

The FDA issued letters in [May 2009](#)¹ and [September 2011](#)² to eye care professionals nationwide explaining the agency's concerns about improper advertising and promotion of FDA-approved lasers. The FDA also issued letters in March 2012 to the [American Society of Cataract and Refractive Surgery](#)³ and the [American Academy of Ophthalmology](#)⁴, providing additional information about disclosing risk information in eye care professionals' advertisements and promotional materials concerning FDA-approved lasers intended for LASIK.

The FDA website includes information on the risks and benefits of [LASIK](#)⁵, and provides access to the labeling for FDA-approved lasers used in LASIK. The FDA encourages consumers considering LASIK to understand what might make them poor candidates for the procedure, the risks and limitations of the procedure and the particular laser that would be used to perform the procedure. The FDA also recommends that consumers consult an experienced eye care professional to know what to expect before, during, and after LASIK surgery.

The FDA reminds consumers that eye surgery such as LASIK is irreversible, that not all patients will achieve optimal results, and that some patients may need additional procedures.

For more information:

- [LASIK](#)⁶ information for consumers

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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