

Clinical trial for dissatisfied LASIK patients discussed

SAN FRANCISCO – The American Society of Cataract and Refractive Surgery and the American Academy of Ophthalmology, in conjunction with the U.S. Food and Drug Administration and the National Eye Institute, will evaluate unsatisfactory LASIK outcomes. The groups have assembled a joint task force charged with formulating a viable study design to identify dissatisfied post-LASIK patients, define their significant symptoms and evaluate the influence of those symptoms on quality of life, according to a joint press release from ASCRS and AAO.

The collaboration marks the first time the FDA has called for counsel from external organizations concerning the design of such a study, the release said.

Richard L. Lindstrom, MD, immediate past president of ASCRS and a PRIMARY CARE OPTOMETRY NEWS Editorial Board member, is co-chair of the ASCRS task force on LASIK.

Encouraged by FDA petitions

urging for an effective freeze on nonessential eye surgeries, the FDA initially approached ASCRS in fall 2006 for assistance in designing the post-LASIK quality-of-life trial. Although the FDA did not deem the majority of requests worthy of new investigation, the agency permitted the petitioners to present testimony at a special meeting of the Ophthalmic Devices Panel that was to take place in April.

During the meeting, delegates from the Ophthalmic Devices Panel were to review concerns related to poor outcomes after LASIK and implantation of phakic IOLs and consider their effects on patients' quality-of-life, according to the release.

The joint task force has not yet made a final decision regarding the necessity and design of the study.

"Ultimately, joint task force recommendations will be put to the governing boards of the ASCRS and AAO to consider. Then, it will fall to the regulatory agencies to determine what, if any, steps need to be taken," the release said. P