FERDIC, INCORPORATED
P.O. BOX 20159
WICKENBURG, AZ 85358-5159
(928) 684-3112
(928) 684-5909 (Fax)

Dickinson's FDA WEBVIEW
(www.fdaweb.com)
Dickinson's FDA REVIEW
Dickinson's FDA UPDATE

April 19, 2010

Dean Andrew Kantis
Founder/Editor
www.LifeAfterLasik.com
"Hurt LASIK Patient Network"

Dear Mr. Kantis:

You have asked for my objective observations on the FDA approval and post-market surveillance of lasers used in the cosmetic vision enhancement surgical procedure known as LASIK.

After researching all of the publicly accessible FDA documentation and a large amount of non-FDA literature, including peer-reviewed journals, correspondence between informed parties, and federal court documents, it is my carefully considered opinion that:

(1) These lasers and associated hardware were respectively PMA-approved and 510(k)-cleared by FDA with egregiously insufficient evidence of their long-term safety and effectiveness for the LASIK indication.
(2) FDA developed an unwise working relationship with the American Society of Cataract and Refractive Surgery under which the falsely-based misperception that LASIK has a 95% post-surgical no-defects rate was perpetuated by the agency, seriously retarding the public realization that the defective vision rate is actually 20%-plus, or 20 times the incidence that FDA itself had said in a guidance document was tolerable.
(3) Although it performed a token enforcement action in 2009 involving inspection of some 20 LASIK-performing ambulatory surgical facilities and issuance of a cautionary letter to the profession about its obligation to include adverse event factors in members' advertising, FDA has not advised that it has conducted any effective follow-up to these activities. Failure to visibly follow-up in the face of multiple examples of continuing, even accelerating, violations in the LASIK surgery industry is clear evidence of insincerity on FDA's part and is suggestive that its unwise alliance with the ASCRS (see preceding observation) is continuing.
(4) FDA's 2009 decision to collaborate with the Department of Defense in a longterm study of LASIK's quality-of-life issues puts it in a conflict-of-interest situation with the Department of the Navy, which conducts the majority of LASIK procedures on active-duty Defense personnel for military purposes; personnel performing these procedures have been accused of covering up adverse events and being biased in favor of the procedure, citing data that may not be relevant to the civilian population most at-risk for experiencing LASIK adverse events.
(5) There is sufficient adverse-event information in the public record for FDA to issue a lay-language public warning about LASIK advising that one in every five people who undergo this procedure will experience lifelong, sometimes delayed, vision problems that may be so disabling that other medical conditions will be caused, such as depression and suicidality.

I hope the foregoing observations are helpful.

Sincerely,

James G. Dickinson

James G. Dickinson
Editor and President