CDRH Disowns Statutory Authority Over LASIK Ads 01/31/2011

Twenty months after CDRH's then director of compliance, **Timothy Ulatowski**, cautioned the nation's eye care professionals not to make misleading or unsubstantiated claims in their advertisements about the effectiveness of lasers used in LASIK surgery, the Center has conducted no follow-up and last week announced it has no jurisdiction over LASIK ads.

"These lasers," wrote Ulatowski back then, "are restricted medical devices that have been approved for particular uses and have risks associated with their use. Advertising and promotional materials for FDA-approved lasers used during LASIK procedures must be truthful, properly substantiated and not misleading.

"A restricted device is misbranded under the Federal, Food, Drug, and Cosmetic Act (Act) if its advertising is false or misleading (21 USC 352(q)). In determining whether the advertisement is misleading, the FDA takes into account not only representations made or suggested by statement, word, or design, but also the extent to which the advertisement fails to reveal facts material in the light of such representations, or material with respect to consequences which may result from the use of the device to which the advertisement relates under the conditions of use prescribed in the advertisement (21 USC 321(n))."

Fast-forward 20 months to last Friday (1/28), when CDRH ombudsman **David S. Buckles** told LASIK victim and activist **Paula Cofer**: "I've investigated the matter you raised regarding the advertising practices cited in your message. Because the advertising practices apparently to do not relate to medical products per se, but rather are advertising for the provision of services, we do not have jurisdiction in this matter. My understanding is that these issues are handled as 'service industry claims' by the Federal Trade Commission."

Cofer, an FDA advisory panel patient representative, had sent CDRH compliance director **Steven Silverman** what she called a "blatantly deceptive" Web site link by Florida-based Brandon Eye Associates, and Silverman passed her off to Buckles, who has no enforcement authority.

In her request to Silverman, Cofer wrote that the Web site's front page banner headline, "*Kiss Your Contacts and Glasses Goodbye* is misleading and deceptive. There is no disclaimer that some patients may need to continue wearing glasses or contact lenses, and there is no mention of risks, side effects, and contraindications.

"This is an example of the typical hype and failure to disclose risks that is prevalent in LASIK advertising on the Internet," Cofer's email to Silverman went on. "We, the injured LASIK patient community, have complained about this for years, but I have not seen a change in the way LASIK is advertised. Former director of compliance, Timothy Ulatowski, sent a letter on 5/22/2009 to eye care professionals in what appeared to be a crack down on false and misleading LASIK ads. Since that time, it's only gotten worse. There are thousands of LASIK ad violators on the Internet.

"As injured LASIK patients, what should we do when we see this type of illegal ad? Will anything be done by the FDA if we take the time to report them?

"I await a response."

Another victim and activist, **Dean Kantis**, says he has sent CDRH "hundreds" of violative LASIK ads, to no effect. Has FDA investigated any of them, and if so, with what result? Buckles says "we are not in a position to disclose the status or even the existence of compliance and enforcement actions that are being contemplated or are in progress."

Meanwhile, nearly 300 people have signed an online forum supporting a petition filed earlier this month by former CDRH ophthalmic devices director **Morris Waxler**, seeking an immediate ban on the procedure because of its unacceptable adverse events rate.

FDA did not respond to two requests for its input on this report.

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