

LASIK Victims Ramp Up Protests at FDA, Capitol Hill

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In a battery of new letters to FDA and its Capitol Hill overseers, protesters who say they have been permanently damaged by LASIK vision-correction surgery escalated their campaign this week to have the agency upgrade patient disclosures and warnings in the labeling of devices used and initiate inspections at ambulatory surgical facilities that, they allege, routinely fail to report adverse events to the agency. They say the letter campaign is to be followed by visits to key lawmakers this month and demonstrations outside FDA headquarters.

Following on a [5/26 petition](#) to the agency seeking a medical device reports (MDR) enforcement effort by the agency, the letters complain that CDRH director **Daniel G. Schultz** has failed to follow through on promises he made in a [letter 11 months ago](#) to injured LASIK patient **Michael Patterson**, of Atlanta, GA. Other than a [recent letter](#) from CDRH compliance director **Tim Ulatowski** cautioning LASIK professionals about promotional claims, Schultz has made no substantive changes and "the inhumane breaches of the FDA regulations continue," Patterson complains in a [6/1 letter to Schultz](#). A laid-off Northrop Grumman systems analyst and IT specialist, Patterson copied the letter widely to Capitol Hill overseers and to new FDA commissioner **Margaret Hamburg**.

The letter, and others like it from other eye-damaged patients in his network, complains about FDA continuing to "endorse (and fund) a plan to conduct a prospective quality of life after LASIK study in collaboration with biased LASIK surgeons who have clear financial conflicts of interest and who are under pressure from members of their professional societies to improve their LASIK profits." Patterson's letter contends that a "group of LASIK victims (PhDs, MDs, etc.) has offered to conduct a study for \$50,000 to \$100,000 total via a nonprofit organization and only asks the government to help obtain access to the patients (as required for any study)."

Patterson also alleges that LASIK surgeons regularly reuse 510(k)'d microkeratome blades for cutting pre-LASIK corneal flaps, contrary to CDRH public declarations that the devices are approved for single-use only. He and other LASIK victims say the industry has been concealing the fact that the corneal flaps never completely heal, permanently weaken the eye, expose LASIK patients to a lifetime of infection and blindness risks, and that intending LASIK patients are routinely deprived of adequate informed-consent documents, including an FDA-mandated Patient Information Booklet.

In a 6/2 letter to Schultz, Fort Lauderdale, FL-based microjet [aircraft broker Dean Kantis](#), another network member, took the CDRH director to task for not pursuing under-reporting ambulatory surgical facilities. In his 7/22/08 letter to Patterson, Kantis wrote, Schultz had agreed with the concern about under-reporting "and stated that you were considering ways to address this important issue. You stated that FDA 'has inspected three LASIK user facilities' since 2000. Why were not more facilities inspected? What is the current number of LASIK user facilities that have been inspected? Are any inspections scheduled?"

"We believe the FDA has failed to address the important public health concern of under-reporting of LASIK adverse events," Kantis added.

In two separate statements on this report 6/3. FDA press officer **Mary Long** told us that the agency's "plans for examining issues related to Lasik include an inspections component. While we can't provide specifics on our investigations before they happen, I

can tell you that they include inspections of hospitals and user facilities for adverse event reporting." An earlier comment that sidestepped the protesters' conflicted quality-of-life study, microkeratome blade reuse and patient disclosure allegations said:

"The FDA's Web site documents potential risks to patients from LASIK. There are links to approved lasers, which lead also to the brochures that should be provided to patients.

"The FDA has an integral role in the design and execution of the study to evaluate prospective quality of life after LASIK. This study will be done in accordance with the rules governing FDA and NEI clinical trials. The FDA will objectively evaluate the information collected, and the outcomes of the study will be made public. The results of this study could lead to modification of FDA's LASIK Web site, revised patient and physician labeling, and educational outreach.

"We are currently collaborating with the National Eye Institute (NEI) on a pilot study to validate the Web-based administration of previously validated paper versions of ophthalmic health-related questionnaires. Web-based administration of such questionnaires will help facilitate the pivotal study of patient-reported outcomes after LASIK. The pilot study is the first of its kind in the area of ophthalmology.

"Subjects with ocular surface disease and subjects with a normal ocular surface are being enrolled. People interested in participating in the pilot study at the NEI of the National Institutes of Health (NIH) in Bethesda, MD, and getting a free screening for dry eye and other ocular surface diseases, can learn more about the study by going to <http://clinicaltrials.gov/ct2/show/NCT00678860?term=NCT00678860&rank=1>."

Source: www.FDAWeb.com