LASIK: A Fight FDA Can't Ethically Win

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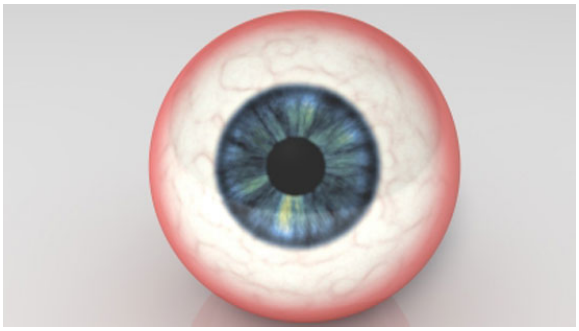
By Jim Dickinson



What happens when an irresistible force meets an immovable object? Although logic says the two cannot exist at the same time, FDA may be about to find out, as it did in 1988, when persistent street demonstrators forced it to adopt emergency regulations slashing the review time for AIDS drugs.

This time, short of actual street demonstrations, the unreformed agency faces an equally persistent though numerically much smaller community of LASIK victims determined to force it to warn the public about an unacceptably high ratio of permanent injuries from the heavily promoted procedure.

As with the AIDS encounter 26 years ago, FDA still does not want to do what the activists want it to do. It is bound by its sluggish institutional culture to not read the writing on the wall, partly because of the character of the people who wrote it and partly because of political discouragement from above.

In the present case of laser-assisted in situ keratomileusis (LASIK), dozens of patients claiming they were permanently injured by the procedure have banded together on the Internet to exchange information and pressure FDA to take strong action against LASIK marketers.

One of them, volatile Florida microjet broker Dean Kantis, apparently made himself so unpopular at CDRH by launching flamboyant allegations of criminality by named CDRH officials that he says his e-mails go unanswered and he has been insulted and hung-up on on the telephone by CDRH people.

The LASIK activists were joined in 2011 by Morris Waxler, the retired CDRH branch director who in 1999 led the reviews that approved excimer laser PMAs for the LASIK indication and who later recanted. From retirement, he petitioned the agency for their withdrawal based on his recalculation of adverse events that were more than 20 times greater than sponsors admitted in the PMAs.

Last year, after 30 months of stalling, FDA denied Waxler's petition, saying it had not met "statutory standards" (21 USC 515(e)(1) and 21 *CFR* 814.46(a)) and, anyway, the agency didn't believe LASIK was as dangerous as Waxler said. The denial cited published literature predominantly from LASIK practitioners' profession-controlled publications that have refused to publish articles critical of LASIK.

The activists, like their AIDS counterparts a quarter-century before, were not about to give up. In addition to forging a productive informal relationship with a knowledgeable non-FDA government expert who could help them, in December they took a new tack with a petition seeking an FDA black-box warning on LASIK laser labeling.

"With millions of people having undergone laser eye surgery with such frequent problems," the petitioners wrote, "it follows that there is an epidemic of visual symptoms/night vision problems and dry eyes caused by this unnecessary surgery. Unless the FDA immediately begins to provide adequately strong black-box warnings about the risks and adverse effects of laser eye surgery, the epidemic will continue to grow. There

have already been several reports of LASIK-related suicide and countless reports of suicidal ideation. A black-box warning would help reduce the number of such negative outcomes and therefore falls well within the FDA's mandate of protecting and promoting public health."

Doubtless, this petition will meet the same fate Waxler's did, probably sometime after the 2016 elections.

However, the activists' new relationship with an FDA collaborator on LASIK at the National Eye Institute (NEI), Rick Ferris, has the outward appearance of providing them with the steel they need to turn FDA obstructionism around.

Ferris, it turns out, was on the FDA advisory committee that reviewed the first LASIK PMAs starting in 1998. He also represented NEI on the more-than-$1-million joint FDA-NEI-Department of Defense (DoD) LASIK Quality of Life Collaboration Project that last October reported preliminary results of two patient-satisfaction surveys among military and civilian personnel that were broadly positive for LASIK. (That's the verbally cited cost LASIK activists say was given them by NEI's Rick Ferris. The U.S. Department of Defense said in an e-mail it didn't keep track of its costs in the project, Ferris declined to answer an e-mail on NEI's costs, and FDA said it had allocated $1.1 million to the overall project.)

All of this experience has apparently made Ferris unhappy with the way the LASIK indication was approved and subsequent events—although not as unhappy as Waxler. For example, the first lasers approved for LASIK, made by Summit Technology and VisX, were supported by safety data from only 75% of patients reached for follow-up at three months postoperation and only 63% at six months when the prevailing standard was 90% or better at 1 to 2 years postop, as recorded in the official transcript of the committee meeting.

According to extensive e-mails between Ferris and LASIK activist Michael Patterson, the NEI physician voted in the FDA advisory committee against the LASIK indication and is currently working to improve patient informed consent.

Patient informed consent is a key issue because LASIK activists say they were not given the FDA-required patient information booklet that is a condition of PMA approval (for LASIK manufacturers, not for state-regulated LASIK ophthalmic surgeons). In 2006, CDRH quietly dropped LASIK PMA approval letter language requiring manufacturers to provide practitioners with the patient booklets.

Ferris expects to accomplish improved LASIK patient consent, according to his e-mails, through his participation in a final report with FDA and DoD counterparts on the joint-collaboration project's two studies, to be published "in the spring." In one e-mail to Patterson, Ferris seemed to acknowledge that LASIK approvals had not been done properly, partly due to informed consent deficiencies: "I can't fix the past but I am trying to get data for future consents."

That, it turns out, was the whole rationale for the joint LASIK Quality of Life Collaboration Project—not to deliver a definitive assessment of real-world post-LASIK quality of life as advertised by FDA in its 2009 announcement, but to develop a scientifically sound survey instrument or questionnaire that could be used in the future to measure real-world post-LASIK quality of life.

The e-mails also revealed a significant activist disillusionment with CDRH's Office of the Ombudsman, which for years since director Les Weinstein retired has demonstrated no publicly visible positive results, and to which other offices routinely refer LASIK complainers.

Ferris's admitted inability to "fix the past"—a past that he, Waxler, and current CDRH director of ophthalmic devices Malvina Eydelman all contributed to—has been taken as a challenge by the LASIK activists.

In e-mail exchanges in January they were energized by the idea of pursuing the alleged wrongdoing they had uncovered in the clinical trials underpinning the original LASIK laser approvals, wrongdoing first uncovered by Waxler long after he had left FDA.

They call it "fraud"—something that if shown should be sufficient to reverse the device approvals. But, as FDA's petition denial letter to Waxler put in cold black-and-white, he hadn't met the "statutory standard" of proof (at least in FDA lawyers' eyes).

Even if he had, or even if the activists today can, the statute of limitations has run out. For this type of crime at the federal level, it is five years from the beginning of the criminal act.

While prosecuting original wrongdoers might be a blind alley now, the tirelessness of the activists' other Internet-based efforts—now spanning nearly seven years of complaints and questions to FDA—parallel the ultimately successful efforts of AIDS activists during the Reagan Administration, when most people were unaware of the Internet.

Even if the original LASIK PMAs' now-discredited adverse events data were true (less than 1% incidence), that is the same incidence rate that AIDS has in the United States. Waxler's recalculation places the actual LASIK rate at nearly 22%.

Add to the equation the fact that LASIK is a medically unnecessary procedure that leaves a permanent physical injury—a U-shaped cut in the corneal surface that never heals—and you have a battle that, assuming the activists keep up the pressure, FDA is highly unlikely to win on ethical grounds.

Industry money backed by superior political connections, however, might reverse those odds.

Jim Dickinson is MD+DI's contributing editor.

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