Medical Update: Lasik Surgery

Eye Openers: Why FDA Looks the Other Way on Safety & Severe Side Effects

Lasik eye surgery is widespread, but its popularity masks a darker side—severe side effects that can cause pain and loss of sight. Furthermore, critics say Food and Drug Administration downplays or ignores safety concerns.

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Brides-to-be who surfed the Internet in spring 2015 might have come across wedding suggestions from Christenbury Eye Center. Among the "beauty services" that the center suggested for June brides was Lasik eye surgery. The pitch: Lasik (laser-assisted in situ keratomileusis) enables brides to avoid the camera-flash glare that's on eyeglasses in pictures and the possibility of losing a contact lens while snorkeling on a Caribbean honeymoon.

Touting an irreversible surgery on your eyes as a "beauty service" is an example of how surgeons have underplayed, ignored and even hidden intentionally from consumers and authorities the risks of Lasik, says critic and Food and Drug Administration whistleblower Morris Waxler. "It's treated like having your hair coiffed or your eyebrows tweezed and as something that has essentially no risk at all. People are being sold a bill of goods," says Waxler, who led FDA's ophthalmological-devices unit in 1998 when FDA approved the first devices to perform Lasik.

In Lasik, an eye surgeon uses a laser to cut a flap in the cornea and reshape it to correct refractive errors, such as nearsightedness, farsightedness and astigmatism. Lasik averages $2,000 per eye and is elective surgery, which means that it typically isn't covered by insurance, according to David Harmon of Market Scope, which is an ophthalmic market-research company.

When injured Lasik patients contacted Waxler after he retired, he looked back at the issue and decided that he made a mistake in ushering these devices to market. He says he was misled by Lasik surgeons and device-makers, who continue to enjoy the protection of FDA at the expense of patient health.

According to Cleveland Clinic's Dr. Ronald Krueger, who is a leading Lasik

surgeon, Lasik is the most common elective surgery in the country. In the United States, Lasik is performed on about 650,000 eyes annually, according to Harmon. Although studies appear to show that Lasik is safe and successful for the vast majority of consumers, interviews with Waxler, two other former FDA officials and 24 ophthalmologists, optometrists, injured patients and personal-injury lawyers tell a troubling tale of the darker side of an industry that generates about $1.3 billion in the United States each year.

Two former FDA employees say Lasik-device approvals were based on shoddy science and overlooked side effects that proved to be more severe than originally were represented. Interviews reveal that FDA subsequently failed to address its missteps in any significant way while surgeons misled consumers and failed to provide them with an accurate profile of the risks that they assume.

Keeping an Eye on Lasik Business Practices

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Consumers should know that when it comes to Lasik, the true rate of risk is unknown because of flaws in reporting adverse events and the paucity of long-term studies. What's more, incomplete informed-consent processes and questionable business practices blur the line between practicing medicine and seeking profit.

EYES SHUT. Waxler's petition that asked FDA to withdraw its approval of excimer lasers—the medical device that's used to reshape corneas—to perform Lasik was denied by the agency in 2014. Waxler tells Consumers Digest that he offered FDA access to files that show that surgeons hid evidence of Lasik injuries. FDA told Waxler that it hasn't found any evidence to indicate that the devices aren't reasonably safe and effective. Waxler says no one from FDA contacted him about his files.

In May 2015, 1,073 injured Lasik patients and their advocates sent to FDA a letter that asked the agency to reconsider Waxler's petition. The letter included stories of disability, derailed careers and even suicides that activists have presented to FDA for years. FDA, in response to our questions, tells us that it "takes adverse events concerning Lasik seriously. The FDA will continue to monitor postmarket data related to Lasik devices and the promotional claims made about these devices." In other words, the agency promises nothing.

Further, refractive surgeons who perform Lasik say Waxler's petition to FDA is based on old science from the early days of Lasik. Changes in surgical procedures and patient-screening technology led to dramatically improved outcomes, says Dr. Eric Donnenfeld, who is a refractive surgeon and a past president of American Society of Cataract and Refractive Surgeons. Based on his experience as a former FDA official and an expert witness, Waxler says he has a difficult time trusting any claims about the procedure's safety and efficacy or the science that's produced, reviewed and published by refractive surgeons.

Donnenfeld questions Waxler's motives, pointing out that Waxler has been engaged as a paid expert witness in Lasik personal-injury cases. Waxler tells us that his high-profile opposition to Lasik and paid expert work actually cost him business and income, because he derives most of his income from advising device-makers on how to deal with FDA.

Paula Cofer, who is an injured Lasik patient and activist, says FDA's motives and defense of the Lasik industry should be questioned, particularly because the agency issues warnings for products that cause far fewer documented adverse events than Lasik has. She says FDA never responded to injured Lasik patients' petitions, even for lesser measures, such as warning the public

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about the risk of permanent vision-impairing side effects from the procedure.

FLAWED APPROACH. Opponents of Lasik say cutting and reshaping the cornea—the procedure itself—is the fundamental problem.
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"When it comes to Lasik, it isn't that the agency has dropped the ball, it's that they never even moved it," says Larry Pilot, who looked into the Lasik issue as a former FDA director of compliance for medical devices.

FDA released preliminary results of its Patient-Reported Outcomes with Lasik (PROWL) study in October 2014 as evidence that the agency is attending to patient concerns. The study found that 4 percent of patients had visual symptoms that were "very" or "extremely" bothersome and that 1 percent had difficulty performing, or were unable to perform, their usual activities after Lasik. Four percent were dissatisfied with their vision. However, activists' expectations for a serious look at the side effects of Lasik were dashed when FDA said PROWL's goal was only to design a questionnaire that other researchers could use to assess Lasik outcomes. That's contrary to the agency's announcement in 2009 that the purpose of the study was to assess patient outcomes.

Refractive surgeons tout the positive results as evidence of Lasik's overall safety. However, FDA tells us that its sample study size—262 and 312 subjects in the two arms of the study—was too small to get an accurate rate of these side effects. In fact, that sample size is larger than what FDA accepted for most clinical trials of Lasik devices!

A review of the most recent studies that were presented to FDA for laser-device approval in 2011 and 2013, as well as medical literature about Lasik, shows that the procedure has become safer and more effective since it was introduced. Critics agree, but they believe that the cutting and reshaping of the cornea—the procedure itself—is the fundamental problem.

They also say this is part of a pattern that has played out for years: New devices are approved for Lasik based on short-term data, and surgeons insist that the procedures for which the devices are used are safe. When long-term data emerge that reveal safety issues, surgeons dismiss it, saying no one uses the old technology anymore.

This turns paying customers into guinea pigs in an ongoing medical experiment, Lasik opponents say. In any event, it's clear that refractive surgeons are selling a procedure based on short-term results.

ADVERSE EVENTS. Waxler and Everette Beers, who is a former FDA deputy director of the ophthalmic-device division, say a flaw in the approval process allowed the industry to convince FDA to downgrade adverse events to mere complications, which is how the side effects continue to be classified today. As such, more-common problems, such as impaired night vision, extreme dry eye and blurry vision—all of which can be severe and in some cases disabling—don't count against the 1 percent "adverse event" rate that FDA made clear was the acceptable limit.

"Night-vision problems are more serious than anyone ever thought they were initially," says Beers, who considers it a "shame" that Lasik devices were approved in the first place. "They should be a serious adverse event, not just a

complication."

Waxler says political and industry pressure had a lot to do with FDA's willingness essentially to look the other way when it came to the side effects. "The heat from Congress was tremendous, and the agency didn't want to have a fight with the high-powered ophthalmological group. We tried to accommodate their interests," he says. "Who got hurt were the patients. Patients don't have a voice at the agency. Patients are an afterthought."

LOOK TWICE. When activists urged Lasik patients to report adverse reactions directly, the number of negative outcomes in Food and Drug Administration's database soared. *Shutterstock*

Dry eye can be severe or disabling in some cases. Dr. Anat Galor, who is a surgeon at Bascom Palmer Eye Institute, says an estimated 20 percent to 30 percent of Lasik patients have painful and itchy (but manageable) dry eye, but 5 percent of patients have severe dry eye. Severe dry eye is permanent and extremely uncomfortable and can require the constant use of eye drops and moisture goggles. Nearly 1 percent of patients, Galor says, are unable to function as a result. Galor and Dr. Perry Rosenthal, who is the founder of Boston EyePain Foundation, say that in extreme cases, dry eye is a neuropathic pain syndrome that's brought on by Lasik. Both researchers published papers in medical journals in 2015 about this rare but debilitating phenomenon.

Even if rare, the consequences of lost vision and pain can be profound. According to Cofer, seven Lasik patients committed suicide because of disastrous outcomes, at least two others attempted suicide and countless cases of suicidal thoughts have been reported by Lasik patients who had bad outcomes. Activists say the depth of these patients' suffering merits a better response from FDA and surgeons.

When it comes to the benefits of Lasik, misinformation also is common: If your goal is never to use glasses again, you'll be disappointed. Activists say doctors rarely are upfront about information—gleaned from the few long-term studies that exist—that shows that Lasik regresses, or wears off, over time. Further, because of the eyes' natural aging, you still are likely to require reading—if not corrective—glasses as you age.

KEEPING TABS. Careful records of how often that adverse events happen in the real world help to construct a safety profile for a procedure. However, not only is what constitutes an "adverse event" with regard to Lasik being called into question, but surgeons and manufacturers also have been remiss in reporting adverse events. This means that the safety of Lasik likely is inflated.

Take the case of a devastating side effect that's called *post-Lasik ectasia*, in which a Lasik-weakened cornea buckles and causes vision that's so distorted that it renders a patient legally blind. We spoke with the office manager of a leading cornea specialist, two lawyers who specialize in cases that involve Lasik and injured patient activists who tell us that it's common for patients who suffer from post-Lasik ectasia to be told by their doctor that they instead have keratoconus, which has similar symptoms. Because it's a naturally occurring disorder, keratoconus wouldn't have to be reported as an adverse event. However, if a patient had Lasik and shows these symptoms, it really is post-Lasik ectasia, experts tell us, so calling it something else is an attempt to dodge reporting an adverse event.

Lawyer Todd Krouner says he never had a Lasik-related case in which the surgeon reported any adverse event. Available medical literature reports that post-Lasik ectasia occurs in about 0.66 percent of Lasik cases, but, Krouner asks, “How do you know that is true if not even the leaders in the industry are reporting it to the FDA?”

Waxler says that as an expert witness in personal-injury lawsuits, he saw files that were maintained by surgeons of adverse events, including some during clinical trials, that never were reported to FDA. Waxler offered this information to FDA’s Office of Criminal Investigations in his petition but says he never got a response. When we asked FDA about this, the agency, instead of addressing the handling of Waxler’s petition, responded that anyone is free to submit information that’s related to misconduct to the office of compliance.

In 2009, FDA started to crack down on the reporting problem by issuing warning letters to 35 facilities that didn’t have adequate reporting systems in place for adverse events. Around the same time, patient advocates began to push injured patients to report their own negative outcomes.

Our review of FDA’s adverse-event-reporting database revealed 499 reports of adverse events in 2015, through May. In 2014, the database had 1,801 reports. Most reports were filed by patients, not surgical centers or manufacturers. Before 2007, the totals were in the dozens, or low hundreds, according to an analysis that was performed by activists on older data that aren’t available on FDA’s website. Activists’ analysis reveals that, through 2011, 55 percent of the reports were filed by patients.

FLAWED TRIALS. Waxler and Beers say the clinical trials that were used to apply for FDA approval of Lasik devices had flaws that call into question whether the procedure should have been approved from the beginning. They say the studies often included too few subjects. FDA’s guidance for Lasik trials says 300–400 subjects should be sufficient to detect adverse events. Given that the adverse-event ceiling was small—1 percent—using only 300 subjects means that if a trial had a 1 percent adverse-event rate, the true rate, given typical margins of error, could be as high as 2.89 percent. In other words, the actual adverse-event rate could be nearly three times FDA’s 1 percent allowable-risk rate. Given the margin for error, a larger sample size would have allowed for more-accurate results.

What’s even more troubling, however, is that the vast majority of studies didn’t even have 300 subjects. Our review of the clinical-trial data upon which the approval of 31 laser devices for Lasik were approved since 1998 found that only six of these included at least 300 subjects.

Another flaw in the trials, Beers and Waxler say, was poor subject retention. By the end of several trials, for a variety of reasons, significant percentages of subjects weren’t included in the evaluations. The trial sponsors said these patients weren’t “eligible” for evaluation, not that they had been “lost to follow-up,” but the end result is the same: They weren’t included in the final evaluations. This makes the findings much less reliable, or completely meaningless in some cases, such as the one in which we found 76 percent of patients weren’t evaluated at the end of the trial. We asked FDA about this, and the agency insists that “patient accountability was adequate” for all of the approved lasers. However, when we pointed out that FDA’s own guidance for these trials says attrition rates shouldn’t exceed 10 percent, FDA told us that the guidance was a nonbinding suggestion.

Donnenfeld says it’s difficult to retain patients in trials, because they often don’t come back for their visits. “You know why they don’t come back for follow-up? Because they are happy,” he says. “The unhappy ones come back to the

doctor."

Waxler heard that reasoning when he was at FDA, but after seeing evidence that facilities hid adverse events, he no longer buys it. "We made the assumption that these are the guys in the white coats and that they are the bigger experts who had their patients' best interest at heart," Waxler says. "The lack of skepticism on my part is pretty outrageous when I think about it."

What's even more outrageous is that consumers still aren't able to get a clear picture on something that might affect their irreplaceable eyesight.

Catherine Elton is a freelance journalist who writes frequently about health issues. Among other topics for Consumers Digest, she investigated mammography, pediatric genetic testing and the overprescription of antidepressants.

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