

Is the Assault on LASIK Justified?

BY ROBERT K. MALONEY, MD; JAY S. PEPOSE, MD, PhD; LOUIS E. PROBST, MD; MITCHELL C. SHULTZ, MD; AND J. TREVOR WOODHAMS, MD

Morris Waxler, PhD, is the former head of the FDA branch responsible for reviewing data on LASIK between 1996 and 2000, and LASIK was approved for use with multiple devices on his watch. Recently, Dr. Waxler told the media that the FDA's approval of the procedure was a mistake. He stated that he plans to file a citizen's petition urging the agency to take steps to stop what he calls "the epidemic of permanent vision problems" caused by LASIK.¹ His petition will reportedly implore the FDA to issue a public health advisory about the dangers associated with LASIK and implement stricter controls over LASIK device manufacturers and practitioners. What is your opinion of Dr. Waxler's statements and actions?

ROBERT K. MALONEY, MD

LASIK was approved by the FDA under Dr. Waxler only after the procedure fulfilled all of the agency's safety protocols and guidance documents. Now, Dr. Waxler is discussing the safety of LASIK based on his recollection of data that he reviewed 10 to 15 years ago. These data do not reflect the improvements that have developed as a result of 15 years of technological advances. Since Dr. Waxler left the FDA, his successors have authorized an additional 28 LASIK approvals and clearances upon thorough review of studies involving thousands of eyes. It is fair to say that few procedures in medicine have received as careful scrutiny or as

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- Robert K. Maloney, MD

many approvals by the FDA as LASIK. Additionally, Dr. Waxler has confused the discussion by combining severe, safety-related problems and subjective complaints, such as dry eye, under the general heading "injuries." This uses subjective complaints to inflate the number of overall complaints. It results in a disservice to the millions of patients whose lives were changed for the better by LASIK and to the relatively few patients with problems, who deserve to have their conditions clearly understood and effectively treated.

JAY S. PEPOSE, MD, PhD

LASIK represents the most commonly performed elective surgery in medicine and arguably the most studied. A recent meta-analysis of the world literature by Solomon et al² showed that LASIK is associated with a higher level of patients' satisfaction when compared with other elective procedures. This review included studies dating as far back as 1988. Now, there may be even higher levels of satisfaction, as there have been iterative, substantive advances that have further improved patients' safety and the predictability of outcomes. These include customized laser vision correction, pupil tracking and adjustment for pupil centroid shift, personalized nomograms, and more precise microkeratomes and femtosecond lasers, to name just a few. There are few fields that advance at the pace of laser refractive surgery, although it is sad to see that many newer innovations and clinical trials are now located outside the United States due to the type of draconian thinking expressed by Dr. Waxler.

When I was a resident at Johns Hopkins years ago, A. Edward Maumenee, MD, counseled me with tongue in cheek that his one surefire method to guarantee no complications or dissatisfied patients was never to operate. Dr. Waxler, it seems, would like to actually implement this plan and impose a moratorium on the most frequently performed elective procedure associated with the highest level of patients' satisfaction. Those of us who are involved in advancing ophthalmology through clinical trials know that there is some level of complaints from patients associated with every lens implant, with every drug and placebo, and even with unoperated control eyes. While all of us await and applaud further improvements to an already refined procedure, if Dr. Waxler's criteria for the approval of surgical devices were widely applied, cataract surgery would no longer be performed today, no one would benefit from an IOL, and Sir Harold Ridley would likely be posthumously stripped of his knighthood.

LOUIS E. PROBST, MD

Achieving the best results with the highest level of safety is everyone's goal for LASIK. The advanced wavefront and femtosecond technologies that have become available over the past decade have allowed this goal to come to fruition. Criticisms about LASIK performed 10 years ago with earlier technology that was approved by Dr. Waxler's department at the FDA seems both odd and counterproductive.

MITCHELL C. SHULTZ, MD

I believe that Dr. Waxler's arguments are inappropriate and create a dangerous environment for impeding medical progress. As an analogy, we allow 16-year-olds to get a driver's license in the state of California. Statistics suggest that a significant number of automobile-related fatalities are caused by drivers under the age of 25. Should we ban automobile manufacturers from making cars to prevent automobile accidents? Should we ban all drivers under the age of 25 from getting behind the wheel? LASIK performed by a competent surgeon on appropriate patients is a safe procedure. In my experience as a surgeon and expert witness, many bad outcomes could have been avoided with the proper selection of patients for the procedure. The practice of bad medicine is not a manufacturing issue but rather one of poor clinical decision making. Furthermore, should Dr. Waxler's petition be granted, I can only imagine the impact of such regulations on multifocal IOL technologies.

J. TREVOR WOODHAMS, MD

Dr. Waxler's ill-considered remarks should be understood within the context of the progressive political

agenda that seeks ultimately to regulate the practice of medicine at the federal, top-down level. After all, since even nearly miraculous, widely performed operations like LASIK have been shown to have undesirable side effects at least some of the time, any complaints whatsoever demonstrate the responsibility of the state to increase control. Considering the tort industry's success in pushing the agenda that all human activities need to be 100% safe and without side effects, it should be no surprise that a career federal bureaucrat would make such a patently absurd claim. ■

Section Editor John F. Doane, MD, is in private practice with Discover Vision Centers in Kansas City, Missouri, and he is a clinical assistant professor with the Department of Ophthalmology, Kansas University Medical Center in Kansas City, Kansas. Dr. Doane may be reached at (816) 478-1230; jdoane@discovervision.com.

Robert K. Maloney, MD, is the director of the Maloney Vision Institute in Los Angeles. Dr. Maloney may be reached at (310) 208-3937; info@maloneyvision.com.

Jay S. Pepose, MD, PhD, is the director of the Pepose Vision Institute and a professor of clinical ophthalmology and visual sciences at the Washington University School of Medicine in St. Louis. Dr. Pepose may be reached at (636) 728-0111; jpepose@peposevision.com.

Louis E. Probst, MD, is the national medical director of TLC The Laser Eye Centers in Chicago; Madison, Wisconsin; and Greenville, South Carolina. Dr. Probst may be reached at (708) 562-2020.

Mitchell C. Shultz, MD, is in private practice and is an assistant clinical professor at the Jules Stein Eye Institute, University of California, Los Angeles. Dr. Shultz may be reached at (818) 349-8300; izapeyes@gmail.com.

J. Trevor Woodhams, MD, is the surgical director of the Woodhams Eye Clinic in Atlanta. Dr. Woodhams may be reached at (770) 394-4000; twoodhams@woodhamseye.com.



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