Waxler Regulatory Consultancy LLC

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March 12, 2012

Dear LASIK-injured patient,

Help stop LASIK. You are not alone. Thousands have been injured.

Join my Petition.

My name is Morris Waxler, PhD and I was the Branch Chief at the FDA from 1996 to 2000 who oversaw the original approval of the devices used for LASIK surgery in the USA.[1] Since that time, I have come to believe that the real risks associated with these devices are far higher than the FDA would have originally approved, had important data not been distorted or withheld.

On January 6, 2011 I petitioned the Food and Drug Administration (FDA) to issue a Public Health Advisory to halt the epidemic of LASIK injuries. I asked the Commissioner to take this action because LASIK makes healthy eyes sick. The petition can be found at

http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0022-0001

"Many thousands of eyes have been damaged beyond repair by LASIK devices since the 1990s. Approximately 700,000 eyes will receive refractive surgery with LASIK devices by the end of year 2011. Thus, more than four thousand six hundred (4,630) are projected to face blindness due to surgically thinned and bulging corneas (keratectasia).' This is an addition to the many thousands of LASIK patients already suffering from keratectasia. In addition, more than 70,000 LASIK patients (140,000 eyes) will suffer by the end of 2011 with persistent adverse effects including but not limited to night vision disturbances, dry eye, glare, and halos.[t] These LASIK-induced adverse events have occurred from using both early and late model LASIK technologies. Also, upwards of 43 percent of LASIK patients will be wearing corrective lenses 6 to 12 months after surgery and in about 7 years fifty-five percent will be unhappy with their vision and the number of eyes that lost 2 or more lines of visual acuity will have doubled.§"

The agency has taken no action on the petition. In fact the agency continues to promote LASIK using an industry graph showing the LASIK adverse event rate as less than 1.0% when it is really about 20.0%. In addition, there is growing evidence that LASIK causes corneal ectasia.

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[1] Resume attached.

Add your name to my petition so that the LASIK-industry-medical-FDA complex cannot hide the fact that you are one of many thousands whose eyes have been permanently damaged by LASIK. Ask family members to be co-petitioners. Ask the surgeon who gave you corneal transplants to be a co-petitioner. Ask the optometrist who is treating the devastating visual effects and the ophthalmologist who is treating your dry eyes or your corneal ectasia to be a co-petitioner. Ask your friends to be co-petitioners.

Contact me at morriswaxler@gmail.com to join others in becoming co-petitioners on FDA-2011-P-0022. Share as much information about your injury as you willing to share. Call me at 608-219-7547 between 2-4 PM CST to discuss limitations on disclosing your contact information, and the date, and name of LASIK clinic and surgeon who injured you, including, but not limited to:

1. **Anonymity**. Code name as needed.
2. **Confidentiality Agreement**. Do we need one?
3. **Narrative**. A one page narrative description of your eye injuries would be helpful.
4. **Resources**. Vision aids, consultation, other assistance.
5. **Notification of legal authorities**. For example, HHS Office of the Inspector General, State Attorneys General Offices and FDA Field Offices for investigation.

There is no fee for being a petitioner on FDA-2011-P-0022.

Please send your request to be a co-petitioner on FDA-2011-P-0022 to me at morriswaxler@gmail.com. Your pain and suffering does not have to be in vain. Be a voice to help others avoid LASIK. You are not alone.

Best regards,

Morris Waxler, Ph.D.

Resume

Morris Waxler, Ph.D.
Waxler Regulatory Consultancy LLC
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608-219-7547
morriswaxler@gmail.com
January 30, 2012

- Waxler Regulatory Consultancy has, and continues, to serve manufacturers of a wide-range of products, including but not limited to devices for blood storage, cancer diagnosis, dental treatment, pain relief, retinal evaluation, software diagnosis of medical problems, coated catheters, wound cleaners, menstrual cups, microbial detection, onychomycosis treatment, and implanted cardioverters.
- Completed five successful years with the FDA Consulting Practice at Godfrey & Kahn, a law firm in Madison, WI. Formulated regulatory strategies for a wide range of medical products including cardiovascular implants, combination products, ophthalmic devices, and antibiotic biologics. Also served for six months as compliance officer for a major manufacturer of cardiovascular devices to assure compliance with a Corporate Integrity Agreement with the Department of Health and Human Services.
- Successfully formulated and implemented regulatory strategies for more than 60 manufacturers of a wide range of medical products in 22 months at Hogan & Hartson, a law firm in Washington, D.C. The products included demineralized human bone, human cultured skin, tissue-based wound dressings, vascular and biliary stents, orthopedic and spinal implants, reagents, and many other products.
- Resolved through effective dialogue many scientific and regulatory conflicts between manufacturers and the Food and Drug Administration (FDA), both while at FDA and at Hogan & Hartson.
- Four years as an innovative manager at FDA regulating eye, ear, nose and throat devices.
- Successfully developed consensus within FDA on regulatory, engineering, and clinical guidance for manufacturers seeking marketing approval of lasers for refractive surgery.
- Eighteen years successful facilitation of organizational transitions within FDA.
- Two years experience successfully mediating workplace disputes within the Federal government.

PROFESSIONAL EXPERIENCE

Current – May 20, 2008 President, Waxler Regulatory Consultancy, LLC

Morris Waxler provides consulting services on FDA regulatory strategies, tactics and processes to developers and manufacturers of medical devices and combination products. These services include the preparation and evaluation of premarket notifications (approvals), requests for designation, quality systems for manufacturers, and FDA components of business plans. Morris also provides expert opinions on FDA regulation of medical devices to investors and in medical malpractice cases.

September 16, 2002 – October 31, 2007 FDA REGULATORY AFFAIRS SPECIALIST, GODFREY & KAHN, SC

Morris Waxler was a non-lawyer member of the FDA Consulting Practice. As the firm's FDA Regulatory Affairs Specialist, he provided consulting services to the firm's clients on regulatory strategies, tactics and processes for developers and manufacturers of medical devices, drugs, biologics and food products. Morris also provided investors in new products with independent assessment about the time and effort needed to meet FDA requirements. He provided due diligence regarding compliance with FDA requirements for companies during mergers and acquisitions.

September 21, 2000 – July 19, 2002 REGULATORY AFFAIRS SPECIALIST, HOGAN & HARTSON LLP

Formulated regulatory strategies for manufacturers planning to market medical products in the United States. These regulatory strategies included determining jurisdiction within FDA, identifying applicable regulations, evaluating relevant guidance, and identifying appropriate regulatory pathways to market. Executed regulatory strategies by reviewing and preparing appropriate documents for submission to FDA. The documents included requests for product designation, appeals of jurisdictional decisions, applications for approval of clinical studies, and applications for authorization to market the product. Helped manufacturers resolve disputes with the FDA regarding requirements to market new products and requirements to continue distributing existing products. Assisted manufacturers plan bench and animal studies in support of product-marketing submissions to FDA.

1996 - 2000 BRANCH CHIEF, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH), FDA

Managed a team of scientists in the evaluation of approximately one thousand medical device applications each year. Built consensus on key engineering and clinical criteria needed for marketing approval of lasers for refractive surgery. Increased the number of marketing applications approved for lasers to treat refractive errors from two to seventeen (eight different lasers). Widened the scope of refractive indications for marketed lasers from PRK to LASIK treatment and from treatment of a restricted range of

nearsightedness to treatment of a wide refractive range of nearsightedness, farsightedness, and astigmatism. Helped formulate actions that eliminated more than 100 illegal refractive lasers from the marketplace while maintaining the scientific and regulatory integrity of the pre-market approval process. Negotiated resolution of FDA disputes with ophthalmologists and manufacturers on clinical trials resulting in FDA approval of the VISX and Summit lasers for LASIK treatment of nearsightedness with astigmatism. Assisted in the re-engineering of customer service information systems.