

# *Waxler Regulatory Consultancy LLC*

*1920 Arlington Place  
Madison, WI 53726-4002*

*608-219-7547  
morriswaxler@gmail.com*

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Dear LASIK Injured Patients,

Some of you have been telling me that the Food and Drug Administration (FDA) is unresponsive to MEDWATCH reports of injuries, that they have provided no feedback, and have not contacted you for additional information. I share your frustration. The agency is ignoring me also. The agency has taken no action regarding my January 2011 Petition requesting the agency

- ❖ Withdraw approval (PMA) for all LASIK devices
- ❖ Issue a Public Health Advisory with a voluntary recall of LASIK devices

I have agreed to submit information to FDA for one LASIK-injured patient who has contacted me. I will submit it as an addendum to my Petition. So far she has not sent me the information. Her information will be public and will include:

- Her name and contact information
- Date of LASIK surgery
- Name of surgeon
- Name of LASIK clinic
- Name of LASIK device manufacturer (if known).
- Description of adverse events (AE), including
  - Post-op onset time
  - Duration of AE
  - Characteristics (dry eye, ectasia, pain, blurry, night driving problems, etc)
- MEDWATCH Report date and number (if applicable).

I will not investigate her report but will edit it for clarity. I will be a conduit of information from her to FDA in the faint hope that the agency will respond and act responsibly.

I am willing to be a conduit for information from any LASIK-injured patient who is willing to be publically identified. Please send information about your injury to me at [morriswaxler@gmail.com](mailto:morriswaxler@gmail.com) and I will make it an addendum to the Petition.

I am hopeful that transparency on the part of LASIK-injured patients will provide incentive for the agency to reciprocate. Please help yourself to this opportunity to encourage the agency to issue a Public Health Advisory and withdraw approval of LASIK devices.

Best regards,

A handwritten signature in cursive script that reads "Morris Waxler".

Morris Waxler