

Waxler Regulatory Consultancy LLC

1920 Arlington Place
Madison, WI 53726-4002

608-219-7547
mwaxler@charter.net

January 16, 2012

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
WO 2200
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Jeffrey E. Shuren, M.D., J.D.
Director, Center for Devices and Radiological Health
Food and Drug Administration
WO 66, Room 5442
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Addendum to FDA-2011-P-0022

Dear Drs. Hamburg and Shuren,

Thank you for removing false information from FDA's LASIK website that misled thousands of Americans into believing that dry eyes, night vision loss, and other LASIK adverse events are rare at six months after surgery. Thousands of Americans suffer permanently from these adverse events due to false information supplied by FDA and amplified by the LASIK medical industrial complex.

Set the record straight. Make a public announcement regarding misleading information published about LASIK adverse events so that LASIK patients who continue to suffer from these problems are correctly informed about why they have these adverse effects. This announcement should include the accurate percentages of adverse events.

FDA was willing to provide the public with false LASIK data, but now appears unwilling to produce the correct adverse event percentages on its website. The agency has the correct LASIK adverse event percentages. Failure to provide the public with correct percentages of adverse events misleads prospective LASIK patients. Also, by not explicitly retracting and replacing false adverse event data FDA is giving license to the LASIK medical industrial complex to continue to use the false data to induce Americans to undergo LASIK.

LASIK centers continue to tell suffering LASIK patients that dry eyes, night vision problems, etc. do NOT occur after six months, citing false information planted on FDA's website. Patients are told these problems are rare, when in fact the actual and correct data show otherwise. Moreover, LASIK clinics often tell LASIK sufferers that the suffering is a personal defect, making them feel responsible for their own suffering. The writings of 28 year-old Vincent Wat prior to his suicide in 2008 are telling testimony (Attachment A).

I have some observations about the PROWL study. As the agency knows, the LASIK service at the Naval Medical Center San Diego (NMCS D) was created and run for many years by LASIK surgeons funded in part by manufacturers of LASIK devices and in part by private LASIK centers. The NMCS D LASIK center is a hub of the LASIK medical industrial complex. FDA should:

1. Ensure subjects are informed that the frequency of adverse events is more than 10% by providing correct data, and that complications such as dry eyes, night driving problems, etc. persist longer than one year.
2. Conduct independent data audits of published data.
3. Conduct examinations of corneal integrity, dry eyes, halos, etc. of all NMCS D LASIK patients by corneal experts who are not refractive surgeons.

I filed a petition (FDA-2011-P-0022) one year ago and the only response I have received is an acknowledgement that FDA has taken no action due to need for "further review and analysis". What additional information do you need? During this one-year period over 500 additional MedWatch reports of LASIK-related adverse events (product codes LZS and HNO) were submitted to the agency.

I am hopeful that you will continue to serve the public well. I would appreciate your staff contacting me to discuss FDA-2011-P-0022 and, in particular, this addendum.

Regards,



Morris Waxler, Ph.D.
President

Attachment A

The Clark County Nevada coroner's office confirmed the suicide of 28 year-old Vincent K. Wat of Las Vegas. Wat died on September 2, 2008. Below is a sample of Wat's writings on the LASIK patient forum at <http://lasik-flap.com/forum> using the pseudonym "notsubby".

September, 2007

I read a post by another guy. He talked about how he cried every day for 3 years. Three years? You guys are all made out of adamantite or somethin', 'cause I'd never last three years. I'm pretty sure I can't last another 3 months...

Yeah, so's for me, I gotta jump into the [LASIK reoperation] thing. I know bad things are gonna happen -- seems to be my lot in life, but what can ya do? While Siems, the doctor I saw, seems to think taking a taxi everywhere is a viable way to live life, I don't think I gotta tell ya that's not realistic...

I've only been in hell for 9 months...

*The only two choices are to live with it or to roll again. And again, and again, and hope the ride takes us somewhere. Risky? Sure. More s*** can go wrong? Definitely. Probably, even... But it's too late for us. We're already degenerate gamblers... So that's why I'm pro-surgery. It's the only way out, aside from a bridge.*

October, 2007

*I was doing some thinking. It would appear that the ethical thing to do is to kill ourselves. We cannot drive. The sun covers the road, and daytime headlights obscure children. It is not a question of IF we will kill someone, but WHEN. More and more, I think the day draws near. I have had too many close calls. I am pretty sure I actually contacted a pedestrian the other day, though it's hard to tell. Because I can't f***** see him. We have no future. Our end is preordained. I am something like \$70,000 in debt, and I cannot earn any money. No degree. No marketable skills. No moving to NYC and riding the subway. I do not want to die. I want to get married. I want to have kids. I want to contribute to society. But the tradeoff is that I will kill someone. It's not that I'm afraid to kill myself, it's that I don't want to. I want to do all the things that I've yet to do. But someone will die for it. Maybe more than one someone. This makes me and everyone like me... a monster. Yet I continue to live, knowing the inevitable. I can't even look at myself in the mirror anymore.*

February, 2008

And that doctor who says that the peeps who killed themselves had previously psychological problems, and that it was unrelated to LASIK... This is why no one likes the bourgeoisie. With their ties and white coats, they think they can get away with saying ridiculous things like that.

March 18, 2008

*It's that time. All other options have failed. Lenses, surgeries, it's all useless. Time to rip the s*** out and throw in a dead man's.*

Yeah, I met [REDACTED]. Had surgery from him, even. Piece of shit, through and through. I'd ask him ridiculous questions like "Have people ever had the surgery and it didn't get rid of the HOAs?" He'd reply, "No, never." Mofo can lie without even so much as blinkin'.

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January 21, 2012

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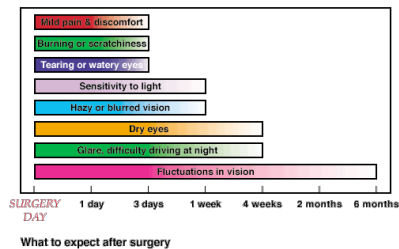
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Re: Addendum to FDA-2011-P-0022 – Correction

Dear Drs. Hamburg and Shuren:

I apologize for thanking the agency for removing false information from it's LASIK website since you have not removed it. FDA is still misleading Americans with false information about LASIK devices. The graph is at

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm061270.htm>



Americans have a right to know if this graph is false or true. If true FDA should say so and cite the data upon which the graph is based. Otherwise the agency appears to be participating in or covering up fraud and malfeasance.

Set the record straight. Is this graph true or false?

Regards,

Morris Waxler

Morris Waxler, Ph.D.
President