LUPRON VICTIMS HUB

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OPEN LETTER TO FDA
March 17, 2014

Department of Health and Human Services
Food and Drug Administration
Michelle Eby, Pharm. D.
Consumer Safety Officer
Office of Executive Programs
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD. 20993

Dear Ms. Eby,

I am writing with regards to your November 13, 2013 response to Dr. David Redwine, who forwarded a 300-page 'Lupron Review' ('Leuprolide – the "D" is Silent') to the FDA in 2011.

Your 2013 response noted "an extensive and careful review of [Dr. Redwine's] submission and have concluded that the information and analyses [he] provided do not change our risk-benefit assessment for Lupron Depot for the treatment of endometriosis. … no regulatory action is needed … ."

Under the Freedom of Information Act, I am requesting to receive any and all information on this "extensive and careful review" conducted by the FDA during 2011-2013.

Can you please forward to me a copy of the minutes of all meetings, including the names of participants, and the dates and times of meetings, and any reports generated. Can you please also forward an elaboration of FDA's conclusion that no regulatory action is needed.

Also, and most significantly, I am asking that you specifically address the issues of fraudulent data and altered outcomes that were raised by Dr. Redwine's Review, but were unmentioned and unaddressed in your response. To review just one example of fraudulent data and altered outcomes, Dr. Redwine identified that an analyses of raw data in clinical trial M84-042 revealed "62.5 % of study subjects had not regained baseline estrogen levels by one year after stopping Lupron … [which is] definitive evidence

of long-term damage to ovarian function." As you are aware, TAP/Abbott/AbbVie claims in its Lupron label that treatment-induced hypoestrogenism "is reversible upon discontinuation of therapy"[1] .

Please address with particularity this 'discrepancy', in light of reports (since the 1990's) of premature menopause and infertility experienced by young women post-Lupron. And please provide a copy of the FDA's review, if any, conducted on M84-042 data during 2011–2013, along with conclusion(s).

What post-marketing surveillance has taken place for Lupron for female indications? Please forward any and all information available on post-marketing surveillance of Lupron for female indications. If no post-marketing surveillance data is available, please explain how the FDA concludes that its risk-benefit assessment of Lupron is 'unchanged' following evaluation of Dr. Redwine's 'Lupron Review'.

I am aware of the FDA's 2010 review of Lupron/GnRHa's risks to men, and the subsequent label changes which added the "risk of diabetes, heart attack, sudden cardiac death, and stroke"[2] . This FDA safety review identified there are "no known comparable studies that have evaluated the risks of diabetes and heart disease in women and children taking GnRHa's."

In 2008, the National Women's Health Network believed that the FDA "should review the safety and efficacy of Lupron® for both its approved and off-label uses. ... a registry should be established to monitor the drug's effect on women, as well as on any children exposed to Lupron®." [3]

Can you please answer whether or not there now exists a registry and/or comparable studies in women and children? If there still remains "no known comparable studies" evaluating the risk of Lupron/GnRHa's to women and children, or a registry, please explain the reason(s) why this is so.

As the Consumer Safety Officer, could you please also answer a few other questions?

I have been made aware of a MedWatch report, filed on May 28, 2013, reporting a homicide while on Lupron Depot 3.75 mgs and in a dissociative state – however there appears to be no report by the FDA acknowledging this homicide[4] ,[5]. Can you please explain why FDA databases have apparently not acknowledged this reported adverse event of "homicide while on Lupron"?

Also, I have been made aware of the deaths of two young women while on Lupron who similarly have not been included in FDA's AERS database. One woman died November 7, 2006; and in a review of AERS data requested under FOIA, no report of this death was noted. The second woman died July 31, 2012; and likewise[6], no death is identified within FDA's Lupron/leuprolide AERS reports.

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[1] http://www.rxabbvie.com/pdf/lupron3_75mg.pdf
[2] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm210549.htm
[3] http://nwhn.org/lupron%C2%AE-%E2%80%93-what-does-it-do-women%E2%80%99s-health
[4] http://www.ehealthme.com/ds/lupron/homicide
[5] http://www.druginformer.com/~mark/druginformer/side_effect_details/lupron/homicide.html
[6] Click link for "'Export Last 12 months' data" @ http://www.drugcite.com/?q=LUPRON#showLearnMore (no death for a 22 year old female is reported)

If you could please provide attention and answers to the above questions, I would be greatly appreciative. And as stated above, this information is requested under the Freedom of Information Act.

Sincerely,

Lynne Millican

cc National Women's Health Network; Cynthia Pearson, Executive Director – www.nwhn.org .
Boston Women's Health Book Collective; Judy Norsigian, Executive Director – www.ourbodiesourselves.org .
National Organization for Women, Terry O'Neill, President – www.now.org
Center for Bioethics & Culture Network; Jennifer Lahl, Director, R.N. – www.cbc.network.org, www.eggsploitation.com .
Alliance for Humane Biotechnology; Diane Beeson Ph.D., Founding Member – http://humanebiotech.org .
'The Justice Club'; Rose Colombo, Founder - http://rose4justice.com/ .
Public Citizen; Robert Weissman, President – www.citizen.org .
Libby Hopton - http://www.mindbodygreen.com/wc/libby-hopton .
Dr. David B. Redwine – www.endopaedia.info .
Dr. David Healy, Prof. of Psychiatry - http://davidhealy.org/AbbVie/