LUPRON VICTIMS HUB

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FDA
Media Relations Director
Lyndsay Meyer
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10903 New Hampshire Ave
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Dear Ms. Meyer,

This letter is written in response to your comment in a 9-19-19 article ("Why Thousands of Women are Swapping [Lupron] for Cannabis" - https://www.missgrass.com/wellness/lupron-and-cannabis/?fbclid=IwAR3V28RrBDetRaPT7ynVS62qF0bebs5qlis_YbLPkMLV3fkcwietOcWVWxo) in which no comment from the FDA was provided concerning the issue of fraudulent clinical trial data having been supplied to FDA in Lupron's 1990 endometriosis approval.

Can the FDA please address this issue?

As stated in above article: "[Millican] points to a report that says the FDA was deceived with fraudulent clinical trial data when they approved Lupron for treatment of endometriosis. … ", yet the FDA's response to this article does not address this issue.

By way of background: In 2011, Dr. David Redwine submitted a 300-page 'Lupron Review' to the FDA ("Leuprolide - the "D" is Silent"), alerting and informing the FDA of the fraudulent data and altered outcomes he discovered within the 1980's endometriosis clinical trials' raw data. In 2013 the FDA responded to this review, and determined "no regulatory action is needed" – without any acknowledgment or reply to the issue of submitted clinical trial data having been fraudulent and having contained altered outcomes.

To cite one shocking result of Dr. Redwine's intensive review of the raw data in clinical trial M84-042 (detailed in his 2011 report to FDA): "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." The claim in Lupron's label for the 1990 FDA approval (and to this day) is that treatment-induced hypoestrogenism "is reversible upon discontinuation of therapy" – however, the company's own raw data does not support any such conclusion.

Prior to its 2011 submission, I extensively reviewed Dr. Redwine's report. Moreover, in 2002 as an RN/paralegal, I also examined the endometriosis clinical trials' data. Unlike Dr. Redwine, who had hundreds of hours for scrutiny, my inspection of the raw data was limited to several days – however, my brief audit nonetheless yielded examples of highly suspect data notations and other alarming information. Therefore, I can definitively reinforce the veracity of Dr. Redwine's report, and have every reason to trust his conclusions.

Dr. Redwine's review, in short, identifies a scandalous and chilling scheme that has far and wide-reaching implications – which should be of The Utmost concern to the FDA. Although the endometriosis clinical trials' data are under a court seal, the FDA has the ability to access and review this raw data. As a matter of public health, this FDA review should have been done following receipt of Dr. Redwine's 2011 report.

But to the best of my knowledge, the FDA has yet to address this extremely disturbing and most consequential situation. For this reason, I am requesting that the FDA provide a response specifically addressing this issue. And it would be appreciated if you could please refrain from providing the typical pat response habitually issued by the FDA ("commitment to ensure all drugs are safe and effective, benefit-risk assessment, monitoring of safety after approval, etc.).

As a taxpayer and a Lupron victim, I - as well as millions of women suffering from endometriosis and/or Lupron's adverse effects - deserve an explanation of the appalling evidence indicating Lupron's 1990 endometriosis FDA approval was based upon fraudulent data and altered outcomes. And we also warrant an answer as to why the FDA appears to have avoided and abandoned its duty to protect women by simply ignoring these most troublesome circumstances.

Respectfully,

Lynne Millican