# HB 449 and the Dangers of Lupron

**REP DAW** 

## What this bill does:

 Creates a grant to study the use of certain medications used in transgender procedures for minors

## Why this bill is necessary:

- ${f \cdot}$  Lupron is being used off label, meaning it is not FDA-approved to treat gender dysphoria  $^1$ 
  - Lupron (Leuprolide Acetate) is only approved for endometriosis, fibroids, precocious puberty, and as a chemotherapy drug for prostate cancer <sup>2</sup>
- Symptoms can be debilitating, sometimes not appearing for months<sup>3</sup>
  - Symptoms include osteoporosis, fibromyalgia, blindness, sterility, depression, menopause-like symptoms<sup>4</sup>
- Over 27,000 Adverse Event Reports have been filed against Lupron
  - $\bullet$  Over 14,000 of these reports are classified as "serious" with approx. 2,000 deaths reported  $^5$

<sup>&</sup>lt;sup>1</sup> FDA. gov <sup>2</sup> FDA. gov <sup>3</sup> NWHN. org, drugs. com <sup>4</sup> FDA. gov, drugs. com <sup>5</sup> fis. FDA. gov

# Darcy Spears - KTVN

**Link Here** 



#### Statement from Dr. Redwine

- Dr. Redwine is a (now retired) endocrinologist and OB-GYN who specialized in endometriosis and who practiced for over 30 years
- Excerpt from his statement:

"During my career, I had the opportunity to speak with and operate on over 600 patients who had been treated with Lupron for pain due to endometriosis. Clearly the medicine does nothing to the disease, but more worrisome are the long-term effects of Lupron on ovarian function that patients would mention to me. As a medical expert in a product liability lawsuit against Lupron (Klein v Abbott), I had the opportunity to review thousands of pages of in-house medical studies consisting of tabulations of raw data and their evaluation in reports which eventually became the basis for FDA approval of Lupron for endometriosis in 1990 and also the basis for medical journal article publications. One of the earliest in-house studies found that by one year after stopping Lupron, 62% of patients had not regained baseline estrogen production. This fact was not presented in the medical journal publication of the time, so practitioners are not aware of this evidence of long-term ovarian dysfunction. Indeed, the product label and a medical publication of the time imply that normal ovarian function is restored in most by 2 months after stopping Lupron. Proper informed consent for Lupron therapy is impossible to obtain because the occurrence of ovarian dysfunction long after stopping Lupron remains hidden behind a court protective order. Beyond the hidden data on ovarian function, I found in my review of the in-house studies that there were many examples of protected violations and other means of making the regults more favorable to Lupron than the data protocol violations and other means of making the results more favorable to Lupron than the data would allow. But deception is simply how drug companies operate. The future is like a black box. When any medicine is approved and prescribed, a great social experiment begins which will eventually define efficacy and safety in the light of day, not within the protective walls of a drug company. Lupron is a powerful drug with unanticipated long-term adverse consequences in a sizable fraction of patients. Its off-label use for gender dysphoria is controversial and seems questionable in my opinion."

## Why this bill is necessary now

- Number of Female to Male transgender minors in Utah going through medical transition<sup>1</sup>
  - 2015:5
  - 2016: 32
  - 2017:96
  - 2018: 189
  - 2019: 553
    - 10000% increase over the last 5 years

<sup>&</sup>lt;sup>1</sup> Controlled Substance Database

### **More Resources**

- https://www.drugs.com/lupron.html
- https://www.accessdata.fda.gov/drugsatfda\_docs/label/2018/020708s035lbl.pdf
- <a href="https://www.drugs.com/sfx/lupron-side-effects.html">https://www.drugs.com/sfx/lupron-side-effects.html</a>
- https://www.accessdata.fda.gov/drugsatfda\_docs/nda/2018/205054Orig1s000MultidisciplineR.pdf
- https://www.nwhn.org/lupron-what-does-it-do-to-womens-health/
- https://www.consumeraffairs.com/news/new-report-describes-dangers-of-giving-lupron-to-kids-020317.html
- https://www.nwhn.org/lupron-what-does-it-do-to-womens-health/
- https://www.consumeraffairs.com/news/new-report-describes-dangers-of-giving-lupron-to-kids-020317.html
- https://www.pbs.org/newshour/health/women-fear-drug-they-used-to-halt-puberty-led-to-health-problems
- https://www.ktnv.com/news/investigations/more-women-come-forward-with-complaints-about-lupron-side-effects
- https://www.wsbtv.com/news/local/georgia-woman-says-drug-used-to-treat-endometriosis-led-to-series-of-health-problems/859263892/
- https://rxisk.org/lupron-a-nightmare-produced-in-abbvie/
- <u>http://www.hormonesmatter.com/lupron-thyroid-broken-scales-justice/</u>
- https://www.hormonesmatter.com/lupron-precocious-puberty-parents-patients-speak/
- https://www.statnews.com/2017/02/02/lupron-puberty-children-health-problems/
- Neuropsychologic dysfunction in women following leuprolide acetate induction of hypoestrogenism.
- Memory complaints associated with the use of gonadotropin-releasing hormone agonists: a preliminary study
- SCOTUS Klein v TAP Pharmaceuticals -
- GPRD Study of GnRH Analogs and Depression/Suicide
- Court documents from Paulsen v AbbVie
- https://www.lieffcabraser.com/2019/08/abbvie-medical-fraud-lawsuit-highlights-growing-nationwide-concern-with-big-pharma-paying-doctors-to-get-new-customers/
- https://news.bloomberglaw.com/product-liability-and-toxics-law/abbott-abbvie-continue-to-face-lupron-bone-joint-damage-suit
- https://www.nytimes.com/2001/10/04/business/2-drug-makers-to-pay-875-million-to-settle-fraud-case.html
- https://www.thepharmaletter.com/article/tap-to-pay-875-million-in-lupron-case
- http://lupronvictimshub.com
- https://www.change.org/p/barack-obama-lift-gag-on-unpublished-lupron-research-turn-off-the-poison-tap/u/16584095