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Congressman Tom McClintock
4th District of California
2312 Rayburn Building
Washington, DC 20515

03/30/2019

Subject: Gender Identity language in H.R.5 Equality Act will lead to permanent medical and surgical harms to children and adolescents with gender dysphoria.

Dear Mr. Tom McClintock:

I am all for equality for our citizens. However the gender identity language in the Equality Act poses great risks to child and adolescent health. This has to do with experimental treatments for childhood gender dysphoria.

The NIH has granted $5.7 million to fund the research study "The Impact of Early Medical Treatment in Transgender Youth" [1]. This is a 5 year study which involves giving children with gender confusion puberty blocking hormones and cross sex hormones (meaning hormones of the opposite sex). These medications are not FDA approved for this condition and have many risks including causing sterility and cardiovascular disease [2,3]. These medications are being given not because of any objective test - but simply because of the child's self identification (i.e. gender identity) of being the opposite sex.

It has been known that the puberty blocking medications in this study are being given to kids as young as age 8. However, the youngest age for cross (opposite) sex hormones was originally set at 13 years old.

Through a Freedom of Information Act request, we were able to obtain the Protocol and Progress reports for this study. I found out something even more shocking- that in 2017

the youngest age for kids to receive cross sex hormones was reduced from age 13 to age 8.

Here is the relevant portion of the text (also see attached documents):

> "the minimum age for the cross-sex hormone cohort inclusion criteria was decreased from 13 to 8 to ensure that a potential participant who could be eligible for cross-sex hormones based on Tanner Staging [meaning stage of puberty] would not be excluded due to age alone."

This means that girls as young as age 8 are receiving testosterone, and boys as young as age 8 or 9 are receiving estrogen. Again, these dangerous medications are being given in this experiment to 3rd and 4th graders simply on the basis of their self described gender identity and not because of any objective testing (i.e. lab tests, genetic tests, MRI, etc).

Children and adolescents cannot consent to these dangerous medications, nor can their parents consent given the irreversible side effects. These medications lead to sterility, sexual dysfunction, increased risk of death from cardiovascular disease, and increased risk for cancers of the breast and ovaries [3]. We have written a letter to the editor of our premier endocrinology journal, JCEM, describing these risks (attached) [3].

While this information is horrendous, I am still waiting for more documents from a secondary FOIA request pertaining this NIH funded study. I have enclosed the relevant portion of the Progress Reports from 2017 showing the age reduction for cross sex hormones.

H.R.5 will lead to medical protocols like this being implemented nationwide, because children and adolescents will be treated on the basis of their feelings about their gender, rather than the physical reality of their biological sex. The consequences will be absolutely devastating to kids.

Thank you very much for reviewing this material. Please contact me with any questions.

Michael Laidlaw MD

Michael K. Laidlaw, MD

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3. Michael K Laidlaw; Quentin L Van Meter; Paul W Hruz; Andre Van Mol; William J Malone. Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline". The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 3, 1 March 2019, Pages 686–687, https://doi.org/10.1210/jc.2018-01925

A. COVER PAGE

Project Title: The Impact of Early Medical Treatment in Transgender Youth	
Grant Number: 5R01HD082554-03	**Project/Grant Period:** 08/01/2015 - 06/30/2020
Reporting Period: 07/01/2016 - 06/30/2017	**Requested Budget Period:** 07/01/2017 - 06/30/2018
Report Term Frequency: Annual	**Date Submitted:** 05/10/2017
Program Director/Principal Investigator Information: JOHANNA L OLSON , BS MS MD **Phone number:** (818) 679-6757 **Email:** jolson@chla.usc.edu	**Recipient Organization:** CHILDREN'S HOSPITAL OF LOS ANGELES 4650 Sunset Boulevard Mailstop #97 LOS ANGELES, CA 900276062 **DUNS:** 052277936 **EIN:** 1951690977A1 **RECIPIENT ID:** 8011-RGF009152-00
Change of Contact PD/PI: N/A	
Administrative Official: NAGHMA AHMAD 4650 Sunset Blvd, MS# 97 Los Angeles, CA 900276062 **Phone number:** 323-361-8560 **Email:** nahmad@chla.usc.edu	**Signing Official:** KAREN SUE NIEMEIER 4650 Sunset Blvd. #84 Los Angeles, CA 90027 **Phone number:** 3233616309 **Email:** kniemeier@chla.usc.edu
Human Subjects: Yes HS Exempt: No Exemption Number: Phase III Clinical Trial:	**Vertebrate Animals:** No
hESC: No	**Inventions/Patents:** No

F. CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

In order to completely capture the impact on all youth undergoing treatment with GnRH agonists, recruitment will be expanded to include those youth in Tanner 4 of development. In addition, the minimum age for the cross-sex hormone cohort inclusion criteria was decreased from 13 to 8 to ensure that a potential participant who could be eligible for cross-sex hormones based on Tanner Staging would not be excluded due to age alone. The Principal Investigators assert that this will not impact the data analysis and results of the research study.

Due to the substantial burden on participants for completing the DISC, the Principal Investigators and Co-Investigators decided to stop utilizing the DISC and implement the Mini International Neuropsychiatric Interview (M.I.N.I.) and the M.I.N.I. for Children and Adolescents (M.I.N.I. Kid), version 7.0.2 for DSM-5, as a replacement. This transition means that there is a portion of participants for whom we are missing the baseline diagnostic data due the time it takes for coordinating center and local IRBs to approve the transition in instruments.

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subjects

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F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline"

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Childhood gender dysphoria (GD) is not an endocrine condition, but it becomes one through iatrogenic puberty blockade (PB) and high-dose cross-sex (HDCS) hormones. The consequences of this gender-affirmative therapy (GAT) are not trivial and include potential sterility, sexual dysfunction, thromboembolic and cardiovascular disease, and malignancy (1, 2).

There are no laboratory, imaging, or other objective tests to diagnose a "true transgender" child. Children with GD will outgrow this condition in 61% to 98% of cases by adulthood (3). There is currently no way to predict who will desist and who will remain dysphoric. The degree to which GAT has contributed to the rapidly increasing prevalence of GD in children is unknown. The recent phenomenon of teenage girls suddenly developing GD (rapid onset GD) without prior history through social contagion is particularly concerning (4).

GnRH agonists are used in precocious puberty to delay the abnormally early onset of puberty to a physiologically normal age. The goal of PB in the healthy child, however, is to induce hypogonadotropic hypogonadism to "buy time" to confirm gender incongruence. In a study of PB in adolescents aged 11 to 17 years, 100% desired to continue GAT. They simply "bought" themselves lower bone density and the need for lifelong medical therapy (5).

Studies show that <5% of adolescents receiving GAT even attempt fertility preservation (6). Those started on PB at Tanner stage II, as recommended by current guidelines, will be blocked prior to sperm maturation and ovum release. They will have no prospect of biological offspring while on HDCS hormones and continuing on to gonadectomy.

The Endocrine Society's guidelines recommend elevating females' testosterone levels from a normal of 10 to 50 ng/dL to 300 to 1000 ng/dL, values typically found with androgen-secreting tumors. The ovaries of women given testosterone correspond to those found in PCOS, which itself is associated with increased ovarian cancer risk and metabolic abnormalities (1). Venous thromboembolism risk is elevated fivefold in males taking estrogen (2).

The health consequences of GAT are highly detrimental, the stated quality of evidence in the guidelines is low, and diagnostic certainty is poor. Furthermore, limited long-term outcome data fail to demonstrate long-term success in suicide prevention (7). How can a child, adolescent, or even parent provide genuine consent to such a treatment? How can the physician ethically administer GAT knowing that a significant number of patients will be irreversibly harmed?

Hypothesis-driven randomized controlled clinical trials are needed to establish and validate the safety and efficacy of alternate treatment approaches for this vulnerable patient population. Existing care models based on

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psychological therapy have been shown to alleviate GD in children, thus avoiding the radical changes and health risks of GAT (8). This is an obvious and preferred therapy, as it does the least harm with the most benefit.

In our opinion, physicians need to start examining GAT through the objective eye of the scientist-clinician rather than the ideological lens of the social activist. Far more children with gender dysphoria will ultimately be helped by this approach.

Acknowledgments

Disclosure Summary: Q.L.V.M. is a speaker for Abbvie and is involved in clinical research with Abbvie on Depot Lupron. The remaining authors have nothing to disclose.

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