From: Matthew Benson
To: zzzz Feedback, BOM_MeetingMaterials; Vazquez, Paul
Subject: Board of Medicine Letter
Date: Monday, September 26, 2022 9:22:51 AM
Attachments: 2022-09-25-Letter to FL Board Med Gender Dysphoric Youth Final.pdf

Dear Paul,

Attached is a letter signed by 7 physicians licensed in Florida who are all board certified pediatric endocrinologists . Also signing are two advanced practice registered nurses who work in our endocrinology clinic.

Respectfully Yours ,

Matthew R. Benson , MD

An Open Letter to the Florida Board of Medicine

Regarding the Proposed Rules to Limit the Use of Hormonal and Surgical Care for Gender Variant Youth

September 23rd, 2022

To: Department of Health
Board of Medicine
4052 Bald Cypress Way Bin C-03
Tallahassee, FL 32399-3253
Phone: (850) 488-0595
Fax: (850) 488-0596
Email: NewsMedia@flhealth.gov

From: Board Certified Pediatric Endocrinologists in the state of Florida

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An Open Letter to the Florida Board of Medicine

To Whom it May Concern:

We write to you in response to your planned public meetings on September 30th, 2022, in Tallahassee, FL to discuss proposed rules and regulations regarding the medical care of gender variant youth.

First, we agree that all children deserve the best evidence-based medical treatments. This extends to children who are diverse in their gender expression and those so distressed by their bodies that they are diagnosed with gender dysphoria. Children, like all people, are complex beings with immense value, dignity and worth. As pediatric endocrinologists and pediatric endocrine nurse practitioners, and some of us also clinical scientists involved in pediatric research, we are deeply concerned that the current scientific evidence for "gender-affirming" care, which heavily relies on the off-label use of puberty blockers and cross-sex hormones, is simply lacking. There are limited data from prospective, controlled trials, which are the gold-standard by which we judge any therapeutic intervention. The Endocrine Society issued updated guidelines addressing the care of transgender individuals in 2017 and rated the evidence as mostly low quality and largely expert opinion [1, 2], which is among the lowest level of medical evidence.

Yet, the American Academy of Pediatrics (AAP) have nonetheless issued their own policies [3] that recommend what is described 'gender affirming therapies' in early adolescence, which is notably undefined precisely in the AAP policy statement but could be as young as 10-13 years of age. The AAP policy also calls for the use of puberty blockers (GnRH analogues) until 16 years of age [3]. This has led to a rapid proliferation of a myriad of clinics and programs where many of these children are prescribed these therapies on demand with little to no in-depth assessment of the psychological needs of these youngsters. The AAP and others, however, have stifled debate and honest critiques in this critical topic, even though data are lacking on the long-term safety and efficacy of the prescribed treatments, often labeling any honest dissent in gender dysphoria-related treatments as "extremist" (https://www.aap.org/en/news-room/aap-voices/why-we-stand-up-for-transgender-children-and-teens/). Sweden, Finland, France and UK are already restricting the use of puberty blockers and cross-sex hormones in children less than 18 years of age, concluding that the science and research regarding optimal treatments for children diagnosed with gender dysphoria is far from settled (https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf). We believe this should also be the approach in the U.S. until more robust data are published in the peer-review literature.

We commend the development of the largest longitudinal interventional trial funded by the NIH in 2015 in U.S. transgender youth known as the Trans Youth Care Study (TYC) (R01HD082554). This two-year prospective trial enrolled 497 subjects by 2018, of whom 95 are receiving puberty blockers, 316 subjects are receiving cross-sex hormones and ~86 are receiving no hormones at all. This critically important trial is taking place in four of the largest pediatric gender clinics in the USA (Los Angeles, San Francisco, Chicago, and Boston). While the researchers have published twice regarding their plans to track anthropometric, physiologic, and mental health outcomes in 2019 [4, 5], the actual outcomes data have not yet been published, now four years after these studies were initiated. It is noteworthy, that TYC investigators used as a justification for the study, the significant gaps in knowledge regarding medical therapies in gender dysphoric children [4]. In their 2019 publication, *Impact of Early Medical Treatment for Transgender Youth: Protocol for the Longitudinal, Observational Trans Youth Care Study,* the authors wrote about the 30-year experience of the "Dutch Model," on which the so called 'gender affirmative' model is based, stating the following:

> "Although these guidelines [the Endocrine Society's] have informed care at academic and community centers across the United States, they are based on extremely limited data. Furthermore, there is minimal available data examining the long-term physiologic and metabolic consequences of gender-affirming hormone treatment in youth. This represents a critical gap in knowledge that has significant implications for clinical practice across the United States."

They then went on to observe that gender-affirming hormones are now prescribed at younger ages than used in the Dutch Model and concede that "there are only minimal data supporting the earlier use of gender-affirming hormones in transgender adolescents." [4]. Yet, the AAP asserts hormonal interventions to be "evidence-based" already. This assertion by the AAP is incorrect, resulting in hundreds of clinics in the USA implementing these treatment pathways carte blanche outside of well-regulated and well-designed research protocols.

We have witnessed children being prescribed cross-sex hormones after a single brief visit to clinics, at times by physician and non-physician providers with limited expertise and minimal to no involvement by well-trained psychologists. This is deeply alarming since these are unproven medical interventions with serious potential risks including lifelong medicalization as seen in studies of transgender adults. Among transgender adults, long-term cross-sectional data suggests that for a substantial number, their quality of life remains immensely difficult even after medical transition [6]. Cross-sectional studies in transgender adults in Sweden, for example, have demonstrated persistently high rates of suicide, depression and premature death when compared to the general population. The survival curves in this retrospective Swedish cohort over a 30-year period, did not observe changes in mortality until about 10 years after these "gender affirmative surgeries" [6]. To date, we have no long-term prospective data in gender-diverse children in the literature who have received hormonal therapies in childhood.

To understand the state of evidence, the Florida Department of Health commissioned two researchers from McMaster University where the term "evidence-based medicine" was coined, for a systematic review of available evidence (https://ahca.myflorida.com/letkidsbekids/). The review included sixty-one systematic reviews of transgender research, including two studies of puberty blockers, four of cross-sex hormones and eight of surgery, which were of adequate quality and therefore worthy to inform an evidence-based decision-making determination. The review concluded that "this evidence alone is not sufficient to support using or not using these treatments."

Given the absence of solid scientific data, we recommend the implementation of a judicious pause in hormonal interventions in gender dysphoric youth in the State of Florida in general medical practice. We also support that such interventions should only be ethically permitted in the context of high-quality research protocols approved by an IRB, overseen by a data safety monitoring board and capable of producing quality data prospectively targeting long-term pre-determined outcomes. This recommendation is congruent with the new policy of the National Board of Health and Welfare in Sweden and at the Karolinska Institute in Stockholm (https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf), and to the restructuring and new guidelines for gender dysphoria clinics being implemented by Dr. Hilary Cass in the UK, after her systematic review for the National Health Service (https://cass.independent-review.uk/publications/interim-report/).

We also support the expansion of competent expert psychological support with rapid implementation of nonjudgmental exploratory psychodynamic therapy in gender-dysphoric youth [7-11].

As we thoughtfully debate the science of these medical treatments, we must be clear that violence in any form cannot be condoned or tolerated whether against those providers treating children with

gender dysphoria with hormonal treatments, nor against those that, like us, prefer a more conservative approach in children (https://www.childrenshospitals.org/news/newsroom/2022/08/cha-supports-the-health-and-wellbeing-of-transgender-youth). Any such threat should be reported immediately to the Florida Department of Law Enforcement (1-855-FLA-SAFE).

It is a sad commentary that it has become politically incorrect to raise any issues of concern when dealing with children and adolescents with gender dysphoria and transgender youth and that raising any such concerns gets automatically labeled as transphobic. This has silenced many physicians who thoroughly agree with our expressed concerns but that also fear retaliation.

We believe children and adolescents that are gender dysphoric and that identify themselves as transgender require respect and support in a non-judgmental, non-discriminatory way. We also believe these children can seldom make these overwhelming, life-changing decisions regarding hormone use and surgery, many of them irreversible, at such an early age. We are now seeing young adults that are openly expressing regret, while detransitioning in a variety of ways. These observations highlight the need for holistic examination of the individual gender-dysphoric person and their environment, to better understand their dysphoria in its full context while providing adequate time be given before any irreversible decisions are made.

A group of physicians, psychologists, risk-management experts, ethicists, and lay people on a medical board should be able to assess the evidence, while also advising on a proper standard of care as opposed to legislative and political bodies. These decisions are too critical and important for young children to make as they cannot easily comprehend the long-term ramifications.

Lastly, without adequate oversight and regulation by the Board of Medicine, the financial costs of the current approach could be large. More importantly, we must address the human suffering not alleviated by hormonal therapies or surgeries in these vulnerable youth. We appreciate the Florida Board of Medicine's careful consideration of our concerns.

Sincerely,

Matthew R. Benson, MD
Jacksonville, FL

Larry A. Fox, MD
Jacksonville, FL

Reham Hasan, MD
Jacksonville, FL

Nelly Mauras, MD
Jacksonville, FL

Monica Mortensen, DO
Jacksonville, FL

Lournaris Torres-Santiago, MD
Jacksonville, FL

Lydia Snyder, MD
Jacksonville, FL

Joe Permuy, MSN, APRN
Jacksonville, FL

Kaley Carroll, BSN, MSN, APRN, CPN-PC
Jacksonville, FL

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******The scientific assessments of the data expressed in this letter are those of the author(s), and not necessarily those of their employers, hospitals, medical schools, or health-care systems.******