

October 28, 2022

Testimony of Dr. Meredith McNamara before the Florida Boards of Medicine and Osteopathic Medicine on Proposals for Practice Standards for the Treatment of Gender Dysphoria

Mr. Chairman and members of the Florida Board of Medicine and the Florida Board of Osteopathic Medicine, thank you all for your invitation to testify today. My testimony addresses the Board's proposal to develop draft rule language related to practice standards for the treatment of gender dysphoria. I appreciate the opportunity to furnish the public record with truthful information regarding gender affirming care. I am honored to testify alongside Drs. Dayton and Jansen, whose expertise in gender affirming care, gender dysphoria and gender expansive identity I hold in high regard.

Please note that my testimony reflects my own professional judgment and is not the official position of my employer, Yale University.

I am a board-certified adolescent medicine physician and pediatrician, with an MD from Emory University, and I am an Assistant Professor at the Yale School of Medicine. I provide clinical care for youth ages 12 to 25 including transgender and gender expansive youth, and I have a Master of Science in Clinical Research.

I join you from Connecticut to address health policy matters in Florida because misinformation about gender affirming care poses a threat to the well-being of youth everywhere and the use of misinformation to set legal standards that have the potential to degrade medical authority.

On June 2, 2022, the Florida Agency for Health Care Administration ("AHCA") issued a purported scientific report (the "June 2 Report") concluding that standard medical care for gender dysphoria does not meet generally accepted medical standards and is experimental and investigational.¹ I am concerned that the Board may rely on this flawed report in crafting its own standard of care for gender dysphoria. Accordingly, my testimony addresses in detail the reasons why the Board should reject the conclusion that the June 2 report reaches.

To state the matter firmly and positively: standard medical care for gender dysphoria does meet generally accepted medical standards and is neither experimental nor investigational. Gender-affirming care for youth is supported by every relevant major medical association, including WPATH, the Endocrine Society, and the American Academy of Pediatrics. This medical consensus is based on a solid body of scientific evidence, with more than 16 studies confirming that standard medical treatments for gender dysphoria are safe and effective.

¹ Division of Florida Medicaid, Agency for Health Care Administration, Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria, June 2022, at https://www.ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf.

I am part of an interdisciplinary cohort of clinicians and subject matter experts who have performed the most in-depth analysis of Florida's AHCA report to my knowledge.² My testimony today summarizes portions of our analysis, but I urge the Board to read our report in its entirety.

The deeply flawed June 2 ACHA Report was commissioned by the state of Florida to provide cover for the deprivation of healthcare of approximately 9,000 transgender Floridians insured by Medicaid. The misinformation and flawed methodologies of this report are grave. The report makes false claims about the evidence regarding gender-affirming care and reaches an incorrect conclusion based on misuse of the scientific method and limited insight into nuances of clinical research. After a line-by-line examination of the June 2 Report, including all xx of its pages and appendices, I testify today that its conclusions are incorrect and scientifically unfounded. The June 2 Report purports to be a review of the scientific and medical evidence but is, in fact, fundamentally unscientific.

The fact is that the June 2 Report blatantly violates the basic tenets of scientific inquiry. The report makes false statements and contains glaring errors regarding science, statistical methods, and medicine. Ignoring established science and longstanding, authoritative clinical guidance, the report instead relies on biased and discredited sources, including purported “expert” reports that carry no scientific weight due to lack of expertise and bias.

The June 2 Report appears to be a scientific report, but its veneer hides a flawed analysis that ignores the scientific evidence and relies instead on pseudo-science, particularly purported “expert” reports that are biased, inept, and full of errors. The claimed “expert” reports are written by authors whose testimony has been disqualified in court and who have known ties to anti-LGBTQ advocacy groups.

A flawed literature review

A linchpin of the June 2 report is a so-called systematic review of systematic reviews that is deeply flawed and violates basic standards of research integrity. I will refer to this document, which appears as Appendix A to the June 2 Report, as “the state’s review”. This document is not published or peer-reviewed and its design and execution raise a number of red flags for bias, which I will outline.

First, neither of the two authors of the state’s review is a subject matter expert – one individual is a dentist and the other is a post-doctoral fellow in biostatistics. At a bare minimum, a systematic review of systematic reviews should be conducted by those who are qualified to critically assess the literature. I would not trust a dermatologist’s review of the literature on a neurosurgical procedure, for instance.

² See Meredith McNamara et al., A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria, July 8, 2022, available at https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/florida%20report%20final%20july%208%202022%20accessible_443048_284_55174_v3.pdf. This document is attached to my written testimony.

Second, the authors of the state’s review make no effort to engage with peers or subject matter experts. This circumvention of peer review violates foundational aspects of the scientific method and violates the standards established by the National Academy of Medicine for systematic reviews.³

Third, the state’s review exhibits bias. The authors uncritically assign equal weight to peer-reviewed studies and grey literature sources. I personally vetted the grey literature sources included and found them to be politically biased and from an anti-transgender website called SEGM.org. Additionally, the state’s review examines an arbitrarily truncated sample of the literature on gender-affirming care – sourcing only from 2020-early 2022, which also spans the worst public health emergency in a century which likely stalled the production and publication of non-COVID research. The authors do not justify this truncation.

Calls for RCTs

Moving on from the state’s flawed review, I’d like to share other examples of how the scientific method and basic medical terminology are misused in the June 2 Report. One key example is that state’s claim that the absence of randomized control trials negates evidence of the benefits of gender-affirming care. An RCT for GAC would never pass an institutional review board’s safety or ethical standards. If the Board feels strongly that RCTs are indeed the gold standard of medical evidence and that medical care not backed by RCTs should be restricted, the Board would have to consider banning statins, mammography, insulin for diabetes, penicillin and some minimally invasive surgeries. All of these types of medical care derive their evidence base from robust observational studies, not RCTs, and yet there are no calls to limit this care. This raises concerns about the exceptionalist standards that gender-affirming care are being held to.

Claims of “low-quality evidence”

The June 2 Report repeatedly and erroneously dismisses solid studies and clinical practice guidelines as “low quality.” Once again, the June 2 Report is (mis)using technical language in a way that is likely confusing to non-experts. Low quality evidence is a technical designation rather than terminology that should be viewed in lay terms. Low quality evidence can actually inform strong recommendations for clinical practice.

For instance, the Endocrine Society’s guidelines on obesity recommend that children consume fruits and vegetables rather than sweetened beverages such as juice. These recommendations are based on “low quality evidence” but have been adopted in widely in the counseling and treatment of pediatric obesity. Reye syndrome is a mysterious neurodegenerative disorder that has been tied to aspirin use in febrile children. Randomized control trials on aspirin in febrile children have not been done to replicate these findings, for obvious reasons. Thus, evidence

³ Committee on Standards for Systematic Reviews of Comparative Effectiveness Research, Institute of Medicine, Finding What Works in Health Care: Standards for Systematic Reviews, National Academies (Jill Eden et al., eds 2011), p. 48 (Standard 2.1.1 states that teams for systematic reviews should include expertise in pertinent clinical content areas). The Institute of Medicine is now known as the National Academy of Medicine.

recommending strongly against aspirin for treatment of pediatric fever is “low quality” but resoundingly supported in the medical community.

In fact, the technical rating system that is used to identify studies as “high quality” or “low quality” specifically states that technically “low quality” studies can and do provide a sound basis for clinical recommendations.⁴

It is thus simply a mistake – and a mischaracterization of medical research across fields of medicine – for the June 2 Report to conclude that the absence of RCTs means that there is “no evidence” for the efficacy of medical treatment for gender dysphoria. Medical research requires, instead, that researchers evaluate the design and conduct of specific observational studies and do so with an awareness of clinical context.⁵

Off-label

The June 2 Report reiterates throughout that puberty blockers are used off-label in the treatment of gender dysphoria. The state falsely supposes that this should prompt safety concerns and tight regulation. But, in fact, off-label use is so common in pediatrics that off-label drugs are prescribed in 30% of patient visits.

In palliative care, neonatology, addiction medicine, psychiatry, gynecology, and general pediatrics, off-label medication use is the cornerstone of essential treatments. In our report, we review key examples spanning from using steroids for croup, ondansetron for nausea and vomiting, birth control pills for heavy menstrual bleeding and sertraline for depression.

The key message here is that off-label does not equal off-evidence. Again, the exceptionally high burden of proof that gender-affirming care faces is unfair in the context of other accepted treatments that do not face similar scrutiny. Off-label use does not denote experimental treatment but use of this term by the state risks of stoking public fear.

Misuse and cherry-picking of research

⁴ See Howard Balshem et al., GRADE Guideline: 3. Rating the Quality, 64 J. Clinical Epidemiology P401-406 (2011), P402: “Although higher quality evidence is more likely to be associated with strong recommendations than lower quality evidence, a particular level of quality does not imply a particular strength of recommendation. Sometimes, low or very low quality evidence can lead to a strong recommendation.”

⁵ See Balshem et al., supra note 42 at 405 (“[W]e caution against a mechanistic approach toward the application of the criteria for rating the quality of the evidence up or down.... Fundamentally, the assessment of evidence quality is a subjective process, and GRADE should not be seen as obviating the need for or minimizing the importance of judgment or as suggesting that quality can be objectively determined”). See also the National Institute of Medicine (Institute of Medicine) Standards, supra note 34, at 176: (“We are disappointed when a systematic review simply lists the characteristics and findings of a series of single studies without attempting, in a sophisticated and clinically meaningful manner, to discover the pattern in a body of evidence. Although we greatly value meta-analyses, we look askance if they seem to be mechanistically produced without careful consideration of the appropriateness of pooling results or little attempt to integrate the finds into the contextual background.”)

⁶ <https://www.vice.com/en/article/m7gg54/florida-transgender-healthcare-minors>

Throughout the June 2 Report, individual studies are commonly misused, misquoted, and distorted. These poor practices are also apparent in how the report's authors handle the entire body of research establishing the benefits of gender-affirming care.

Leading researchers have expressed how the state of Florida mischaracterized results of their work.⁶ They were not contacted to verify that the state was correctly summarizing the results of their research. The report's authors drew inaccurate conclusions.

Some researchers had produced additional, larger studies that replicated or deepened their initial findings and deepened an understanding of the research questions at hand, but only their preliminary works were cited, despite later works being available to authors of the June 2 report.

Some peer-reviewed, published studies are singled out because authors of the June 2 report take issue with study design. One glaring example is a critique of a study that did not have a control group of youth without gender dysphoria to study the impact of gender-affirming care. This is an oft repeated and misguided style of critique is ignorant to general norms of clinical research. Control groups are not necessary to study the impact of an intervention. Millions of published studies have advanced medical care with observational research protocols. I, myself, have performed statistical analysis on and reviewed several observational studies where the independent effect of an intervention on an outcome was detected with a single cohort of participants. I'm concerned that this example highlights either the June 2 report's authors' poor qualifications for conducting such a potentially influential literature review or their purposeful leveling of baseless claims to confuse readers.

In some cases, a single line from the limitations section of a study is presented and treated as representative of the study's findings. Limitations sections are conventional and integral in investigators' presentation of their work, but they are not ever to be taken in isolation or at the exclusion of the study's findings. The authors' use of this practice is so flagrant that it is difficult to consider that it is not intentional.

Perhaps the most glaring, repeated, and troubling error in the June 2 report is the singling out and thoughtless dissection of single studies rather than engaging in the entire body of evidence as a whole. The June 2 Report fails to acknowledge the number of solid studies that all find that puberty blockers are effective. Indeed, at least 16 studies show that puberty blockers and hormones benefit patients with gender dysphoria, and the benefits have been documented across study designs, including retrospective report, cross sectional, longitudinal, and qualitative studies. I can see how this would be an effective way to dismiss consensus and throw fog up around the issues at hand – but it should not and cannot guide healthcare.

Operating outside the norms of science and medicine

The state attempts to dismiss medical consensus as “eminence-based medicine,” but this is a mistake. Consensus isn't eminence, it's the direct opposite: medical consensus, as reflected in the WPATH and Endocrine Society clinical practice guidelines and AAP recommendations, is grounded in the scientific evidence. Rather than engage with the content of their testimony, which my group has done in writing and this report is submitted for BOM review, I'd like to

highlight that the platform these individuals have been given represents a deeply unscientific approach to profound decisions that affect healthcare.

Comparison to practice outside the United States

Before legal interference beginning a year ago, the United States was not out-of-step with practice in other countries. No other country in the world has prohibited the provision of gender-affirming care for youth. Despite the picture painted by some, in Sweden, Finland, the United Kingdom and others, gender-affirming healthcare is available to any adolescent in whose clinician recommends it, as long as the required clinical, patient, and parental consents are obtained. I submit to the Board an amicus brief from Stonewall U.K. et al, which details an accurate account of gender-affirming care in other countries from those who provide it.

Conclusion

In conclusion, I would like to emphasize that **standard medical care for gender dysphoria does meet generally accepted medical standards and is neither experimental nor investigational. Nothing in the state of Florida's June 2 report** calls into question the solid medical evidence that underlies the consensus recommendations of WPATH, the Endocrine Society, and the AAP.

I urge the Board to read our report and not to rely on the June 2 report, which is full of misinformation and scientific errors. As physician-scientists, the members of this Board can give the June 2 report the critical scrutiny it deserves.

Thank you for your time.

Attachments

Brief of Amici Stonewall UK, et al., in Support of Plaintiffs-Appellees, Eknes-Tucker v. Governor of the State of Alabama, August 17, 2022, available at <https://www.splcenter.org/sites/default/files/documents/eknes-tucker-v-marshall-stonewall-uk-amicus.pdf>

Meredithe McNamara et al., A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria, July 8, 2022, available at https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/florida%20report%20final%20july%208%202022%20accessible_443048_284_55174_v3.pdf.