

July 8, 2022

VIA E-MAIL AND WEBSITE

Simone Marsteller, Secretary
Tom Wallace, Deputy Secretary for Medicaid
Florida Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, FL 32308
MedicaidRuleComments@ahca.myflorida.com

Re: Rule No. 59G-1.050: General Medicaid Policy

Dear Secretary Marsteller and Deputy Secretary Wallace:

We are writing to submit a public comment on a proposed amendment to Section 59G-1.050 of the Florida Administrative Code (the “Proposed Rule”), which, if adopted, would deny medical treatment to transgender individuals.¹ The Proposed Rule would apply to Medicaid members of any age and would deny coverage for puberty blockers, hormones, “sex reassignment surgeries,” and “any other procedures that alter primary or secondary sexual characteristics.”²

We are a group of seven scientists and a law professor, and we are deeply dismayed by the content of the Proposed Rule, which will deny long-established, effective, and evidence-based medical care to thousands of Florida Medicaid patients.³ We are also distressed as scientists and stewards of public health by the shoddy quality of the purported scientific report offered to justify the Proposed Rule. The report, issued by the Florida Agency for Health Care Administration (“AHCA”) on June 2, 2022 (hereinafter, “June 2 Report”), disregards well-established clinical practice guidelines and scientific research showing that standard medical treatments for gender dysphoria are “consistent with generally accepted professional medical standards” and are not “experimental or investigational.”⁴

As discussed in depth below, we strongly oppose the adoption of the Proposed Rule. The Proposed Rule would violate the sex discrimination protections provided by the U.S. and Florida Constitutions and the federal statute that governs Medicaid by discriminating against transgender people on the basis of their sex, transgender status, and gender identity.⁵ We are confident that other comments will focus in depth on the legal authorities that pre-empt the Proposed Rule.

¹ 48 Fl. Admin. Reg. 2461 (June 17, 2022). The Notice of Development of Rulemaking was published in 48 Fl. Admin. Reg. 2270 (June 3, 2022) without any specification of the subject of the rulemaking.

² The Proposed Rule would add new subsection (7) to Fl. Admin. Code Section 59G-1.050. See 48 Fl. Admin. Reg. 2461 (June 17, 2022).

³ Our comments reflect our views and not those of the University of Alabama, the University of Texas, or Yale University.

⁴ 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 (“June 2 Report”).

⁵ See *Bostock v. Clayton County*, 590 U.S. ___ (2020); *Kadel v. Folwell, M.D. N.C.*, Mem. Op. 6-10-22 (applying *Bostock* to public health plan coverage); 42 U.S.C. 18116 (requiring nondiscrimination in Medicaid plans).

Our comments focus instead on the absence of any persuasive scientific or medical justification for the Proposed Rule. The June 2 Report purports to be a review of the scientific and medical evidence but is, in fact, fundamentally unsound from a scientific perspective. The June 2 Report disregards established scientific knowledge, ignores longstanding clinical practice recommendations developed by authoritative bodies of medical experts, and unaccountably dismisses the medical recommendations of more than 20 medical societies.

As scientists, we are alarmed that Florida's health care agency has adopted a purportedly scientific report that so blatantly violates the basic tenets of scientific inquiry. The report contains glaring errors regarding science, statistical methods, and medicine. Ignoring established science, the report instead relies on biased and discredited sources, stereotyping, and purported "expert" reports that carry no scientific weight.

These fundamental flaws thoroughly discredit the conclusions of the June 2 Report, with two legal consequences. First, the complete absence of scientific foundation for the Proposed Rule renders it an arbitrary and capricious use of rulemaking power. Second, the Florida AHCA cannot characterize the Proposed Rule as a valid interpretation of the existing Florida regulations on generally accepted professional medical standards, because the June 2 Report fails to satisfy Florida's own regulatory requirements for scientific review.⁶

The seven scientists in our group hold academic appointments at the University of Alabama, the University of Texas Southwestern, and Yale University. (The law professor is a tenured professor at the Yale Law School.) We include three Ph.D child and adolescent psychologists and four M.D. physicians with specialties in pediatric endocrinology, child and adolescent psychiatry, and adolescent medicine. All seven are also clinicians who treat transgender youth on a daily basis. Among us, we have accumulated more than 57 years of clinical practice and have treated more than 2,100 transgender youth. We received no funding for our work and have no conflicts of interest to declare.

We are writing to comment on the Proposed Rule because we are concerned that it will harm transgender people in Florida and set a misleading and dangerous national precedent. We are committed to the integrity of science and law, and we strongly oppose legal actions that, like the Proposed Rule and the June 2 Report, claim the authority of science but provide only biased and misleading information. Youth, families, and medical providers in Florida deserve a higher standard of protection and service from their government.

In this comment letter, we focus on the science governing the treatment of gender dysphoria. Our observations are relevant to the treatment of both youth and adults. For example, we show that the June 2 Report falsely claims that the evidence for medical treatment for gender dysphoria does not meet generally accepted professional medical standards and is experimental. We also show that the June 2 report relies on purported "expert" reports that appear to be highly biased and with undisclosed conflicts of interest. To keep our comments focused and manageable in length, the one issue that we do not address is the science of genital surgery used to treat gender dysphoria, which is typically not performed before the age of majority. We are confident that the

⁶ See Fl. Admin. Code Section 59G-1.035(1) and (4).

evidence base for surgical procedures is sound, and we are confident that others will address the June 2 Report's erroneous claims regarding surgery.

Throughout our comments, we refer to our companion report, *A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria*, which is attached as Appendix A. The report goes into greater detail on many of the points we raise here.

Background

The AHCA appears to have taken a belt-and-suspenders approach to denying Medicaid coverage for standard medical treatment for gender dysphoria: the agency appears to be pursuing two legal strategies simultaneously. The June 2 Report reflects the first strategy, which frames the denial of care as an interpretation of the existing Florida Medicaid coverage regulations.⁷ The Florida Medicaid program covers only health services that are “medically necessary” and excludes services that do not meet “generally accepted professional medical standards or are “experimental or investigational.” The existing regulations permit the AHCA to determine when health services are consistent with generally accepted professional medical standards (GAPMS).

Specifically, the existing regulations authorize the Florida Deputy Secretary for Medicaid to make a final coverage determination; however, the Deputy Secretary does not have unfettered interpretive authority. The Florida Administrative Code sets out a detailed process, which requires the AHCA to prepare a report that considers scientific evidence including “evidence-based clinical practice guidelines” and “published reports and articles in the authoritative medical and scientific literature related to the health service (published in peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations).”⁸ The June 2 Report purports to be such a report. It is titled a “Generally Accepted Professional Medical Standards Determination” and concludes that standard medical treatments for gender dysphoria “do not conform to GAPMS and are experimental and investigational.”⁹

The AHCA has also pursued, simultaneously, a second legal strategy by publishing the Proposed Rule on June 17. The Proposed Rule makes no reference to the June 2 Report and contains no independent justification for the rule. The Proposed Rule would add a new subsection to Section 59G-1.050 of the Florida Administrative Code, Section (7), which would deny Medicaid coverage in Florida for medical care for gender dysphoria. The Proposed Rule would apply to Medicaid members of any age and would deny coverage for puberty blockers, hormones, “sex reassignment surgeries,” and “any other procedures that alter primary or secondary sexual characteristics.”¹⁰ According to the Notice of Proposed Rule published in the Florida Administrative Register, a public hearing will be held on July 8, 2022, and public comments on the Proposed Rule may be submitted through that date.¹¹

⁷ See June 2 Report, p. 2 (noting that the Secretary of the Florida Agency for Health Care Administration requested the report from the Florida Division of Medicaid pursuant to Section 59G-1.035 of the Florida Administrative Code,

⁸ Fl. Admin. Code Section 59G-1.035(4).

⁹ The report makes specific reference to these rules. June 2 Report, p. 2.

¹⁰ 48 Fl. Admin. Reg. 2461 (June 17, 2022).

¹¹ See id. and the instructions at https://www.flrules.org/Gateway/View_notice.asp?id=25979915.

Analysis

In our comments below, we show that there is no scientific justification for the Proposed Rule and no scientific justification for the conclusions drawn in the June 2 Report.

1. The Proposed Rule would deny Florida Medicaid coverage for standard medical care for gender dysphoria, which is supported by a robust scientific consensus, meets generally accepted professional medical standards, and is neither experimental nor investigational.

The conclusion of the June 2 report – that medical treatments for gender dysphoria “do not conform to [generally accepted professional medical standards] and are experimental and investigational”¹² -- is demonstrably false.

Medical care for the treatment of gender dysphoria, which for youth under the age of majority can include gonadotropin releasing hormone agonists (“GnRHa” or puberty blockers) and hormone therapy, has been vetted and approved by international bodies of experts based on the scientific evidence. Two authoritative bodies of scientists, the World Professional Association for Transgender Health (WPATH) and The Endocrine Society, have published extensive clinical practice guidelines for treating gender dysphoria.¹³ These clinical guidelines are based on rigorous, structured processes. Each involves the work of a committee of scientific experts and peer review by additional experts. The guidelines are based on careful reviews of the scientific literature and are revised periodically to reflect scientific developments.

These longstanding clinical practice guidelines have been used by clinicians for decades. WPATH issued its initial guidelines in 1979 and updated them in 1980, 1981, 1990, 1998, 2001, and 2012. The eighth version remains in process, and it incorporates systematic literature reviews and ample opportunities for peer review and revision.¹⁴ The original Endocrine Society guidelines were published in 2009 and updated in 2017.¹⁵

Reflecting this scientific and medical consensus, medical care for gender dysphoria has been confirmed as standard care by every relevant medical organization in the United States, including the American Academy of Pediatrics, the American Psychological Association, and the American Academy of Child and Adolescent Psychiatry.¹⁶ In 2022, these organizations united

¹² June 2 Report, p. 2.

¹³ See Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, World Professional Association for Transgender Health (7th version, 2012), at <https://www.wpath.org/publications/soc> (“WPATH (2012)”); Wylie C. Hembree, et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, 102(11) J. Clin. Endocrinol. Metab. 3869-3903 (2017) (“Endocrine Society (2017)”).

¹⁴ See World Professional Association for Transgender Health (WPATH), Methodology for the Development of Standards of Care 8 (Soc 8), at <https://www.wpath.org/soc8/Methodology>.

¹⁵ Endocrine Society (2017), supra note 13.

¹⁶ Jason Rafferty, Committee on Psychosocial Aspects of Child and Family Health; Committee on Adolescence; Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness, Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents, 142(4) Pediatrics E20182162 (2018); American Psychological Association, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, 70(9) American Psychologist 832-64 (2015); Stewart L. Adelson, Practice Parameter on

with the American Medical Association, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and other groups to file an amicus brief representing a total of 20 major medical societies. The brief reaffirms that puberty blockers and hormone treatments for gender dysphoria are standard medical care and opposes legal measures that would limit patient access to this standard care.¹⁷

The weight and volume of these endorsements, across diverse medical specialties, sharply contradicts the June 2 Report's conclusion and undermines any purported scientific justification for the Proposed Regulation.

As further evidence, it is critical to note that the medications used to treat gender dysphoria are used commonly and safely in cisgender patients. Puberty blockers are the main treatment for central precocious puberty. Estrogen is prescribed for patients of all ages to manage fertility and reduce heavy menstrual bleeding (to give just two examples of its many uses). Testosterone is prescribed to address hypogonadism, and spironolactone (androgen blockade) is used to treat hirsutism and acne.

The Florida Medicaid program covers all these uses without question. The program authorizes physicians to tailor treatments to cisgender patients' needs and trusts patients (and, in the case of children, their parents) to make informed decisions. The Proposed Rule would deny coverage only for gender dysphoria, discriminating against transgender patients.

2. The June 2 Report appears to be a scientific report, but its veneer hides a flawed analysis that ignores the scientific evidence and relies on pseudo-science that does not meet Florida's own standards for review. The June 2 Report provides no scientific foundation for the Proposed Rule and fails to meet Florida's own regulatory requirements for Medicaid coverage determinations.

The Florida report dismisses or ignores the WPATH and Endocrine Society clinical practice guidelines and the science that underlies them and instead relies on five attached documents that, the report claims, constitute "clinical and technical expert assessments."¹⁸

Despite their billing as "expert" reports, the attachments to the June 2 report are unpublished, non-peer-reviewed documents written by authors with questionable claims to expertise and with red flags for undisclosed author bias. These documents should be given no weight in a serious scientific process.

The June 2 Report purports to be a coverage determination pursuant to Fl. Admin. Code Section 59G-1.035, but its reliance on these five documents constitutes a gross violation of the process set out in that regulation. The regulation requires that the AHCA consult actual scientific evidence, including "evidence-based clinical practice guidelines" and "*published* reports and

Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents, 51(9) J. Am. Acad. Child & Adolescent Psychiatry, 957-974 (2012).

¹⁷ Brief of Amicus Curiae American Academy of Pediatrics and Additional National and State Medical and Mental Health Organizations in Support of Plaintiffs' Motion for Temporary Restraining Order and Preliminary Injunction, Eknes-Tucker v. Ivey (later redesignated Eknes-Tucker v. Abbott), May 5, 2022, at <https://www.aamc.org/media/60556/download>.

¹⁸ June 2 Report, p. 2.

articles in the authoritative medical and scientific literature related to the health service (published in *peer-reviewed* scientific literature generally recognized by the relevant medical community or practitioner specialty associations).”¹⁹

The June 2 Report reads like a roadmap for how to violate these rules. The report disregards the evidence-based clinical practice guidelines published by WPATH and The Endocrine Society and relies entirely on the five attachments, which are not published, are not peer-reviewed, and are written by inexperienced and biased authors.

A. The purported “expert” documents attached to the June 2 Report are unpublished and not peer-reviewed, and they are written by authors whose expertise has been successfully challenged in legal proceedings and whose professional histories raise red flags for bias.

None of the documents attached to the June 2 Report meet standard criteria for expert scientific investigations, because none is published or peer reviewed. Publication and peer review are fundamental to science, as they ensure that a scientist’s data and conclusions are open to scrutiny from scientific experts.

Florida’s own standards for the determination of medical necessity recognize this point when they state that determinations of Medicaid coverage must consult “*published* reports and articles in the authoritative medical and scientific literature related to the health service (*published in peer-reviewed scientific literature* generally recognized by the relevant medical community or practitioner specialty associations).”²⁰ It is thus both unscientific and a violation of the regulations for the June 2 Report to rely on unpublished documents as its principal evidence base.

Further, the attachments raise red flags for author bias. The June 2 Report does not disclose how these “experts” were identified or by what criteria their expertise was assessed. The opacity of the Florida AHCA process for identifying experts is particularly troubling because at least four of the five experts have strong indications of bias. Further, the qualifications and credibility of two of the experts have been successfully challenged in litigation.²¹ The endorsement of these individuals as Florida’s banner “experts” raises the appearance of bias – that the AHCA sought a pre-ordained outcome, not a true scientific perspective.

Adding to these red flags for bias, none of the authors of the attachments provide a statement of funding and conflicts of interest. This omission violates a strong norm in scientific writing, which requires authors to declare any professional or financial arrangements that could call into question their independence of judgment.²² That strong norm also requires authors to disclose

¹⁹ Fl. Admin. Code Section 59G-1.035(4).

²⁰ Fl. Admin. Code Section 59G-1.035(4).

²¹ See Stephen Caruso, A Texas Judge Ruled That This Doctor Was Not an Expert, *Pennsylvania Capital-Star*, Sept. 15, 2020 (reporting that van Meter was disqualified as an expert in a Texas divorce case, now sealed).

²² For example, the conflict of interest rules for JAMA, one of the premier medical journals in the United States and the world state that “[a]uthors are expected to provide detailed information about all relevant financial interests, activities, relationships, and affiliations (other than those affiliations listed in the title page of the manuscript) including, but not limited to, employment, affiliation, funding and grants received or pending, consultancies, honoraria or payment, speakers’ bureaus, stock ownership or options, expert testimony, royalties, donation of

whether projects have been funded and if so, by whom and whether the authors have engaged in expert testimony. Without these statements, the Florida AHCA and the public cannot detect biases that could affect the integrity of these written products.

These are more than theoretical concerns: *four of the attachments have notable indicators of conflicts of interest and bias.* (Note that these are the only four we examined in detail, and so we do not imply that the other one is free from such bias.)

The author of the document provided as Attachment E is Quentin van Meter, whose history indicates bias and lack of expertise. Although the AHCA presents van Meter as an expert in medical treatment for gender dysphoria, at least one court barred him from providing expert testimony on the issue.²³ Van Meter is the president of the American College of Pediatricians (the “ACP”), which presents itself as a scientific group (and might be confused, by a non-expert, with the authoritative American Academy of Pediatrics). The ACP is, in fact, a political group that opposes same-sex marriage,²⁴ supports mental health providers practicing conversion therapy,²⁵ and describes gender dysphoria as “confusion.”²⁶ Troublingly, the van Meter attachment, proffered by the AHCA as a scientific report, contains several passages of uncredited, verbatim language that appears in a “position statement” published by the ACP.²⁷ The van Meter attachment appears to be a re-use of paid testimony rather than an original product.²⁸

James Cantor’s document, presented as Attachment D to the June 2 Report, also faces serious questions about bias and lack of expertise. In a 2022 case, a federal court took a skeptical view of Cantor’s purported expertise, giving his testimony little weight because Cantor has “no clinical experience in treating gender dysphoria in minors and no experience monitoring patients receiving drug treatments for gender dysphoria.”²⁹ Cantor’s document is nearly identical to what

medical equipment, or patents planned, pending, or issued.” JAMA Network, Instructions for Authors, visited June 22, 2022, at <https://jamanetwork.com/journals/jama/pages/instructions-for-authors#SecConflictsofInterestandFinancialDisclosures>

²³ Caruso, supra note 21.

²⁴ Den Trumbull, Defending Traditional Marriage, American College of Pediatricians (2013), <https://acpeds.org/position-statements/defending-traditional-marriage>. See Jack Turban, The American College of Pediatricians is an Anti-LGBTQ Group, Psychology Today, May 8, 2017.

²⁵ Christopher Rosik and Michelle Cretella, Psychotherapy for Unwanted Homosexual Attraction Among Youth, American College of Pediatricians (2016), <https://acpeds.org/position-statements/psychotherapy-for-unwanted-homosexual-attraction-among-youth>.

²⁶ Michelle Cretella, Gender Dysphoria in Children, American College of Pediatricians (2018), <https://acpeds.org/position-statements/gender-dysphoria-in-children> (site visited June 22, 2022). The author of the ACP position paper is Michelle Cretella, who was publicly rebuked by the Society for Adolescent Health and Medicine, the leading society for adolescent medicine in the United States, for “pushing political and ideological agendas not based on science and facts.” [https://www.adolescenthealth.org/Advocacy/Advocacy-Activities/2017-Activity/Senate-Bill-439-\(2\).aspx](https://www.adolescenthealth.org/Advocacy/Advocacy-Activities/2017-Activity/Senate-Bill-439-(2).aspx)

²⁷ The similarity was shown by a Word comparison of the van Meter report provided as Attachment E to the June 2 Report with a “position statement” published on the ACP website, with authorship credit given on the website to Michelle Cretella. See Michelle Cretella, Gender Dysphoria in Children, supra note 26.

²⁸ The van Meter document attached to the June 2 Report is substantially identical to his expert declaration in *Adams v. School Board of St. Johns County, Florida*. <https://files.eqcf.org/wp-content/uploads/2017/12/41-D-AMENDED-Notice-Documents-iso-Response-to-PI.pdf>.

²⁹ Opinion and Order, *Eknes-Tucker v. Marshall*, 2:22-CV-184-LCB, M.D. Alabama, May 13, 2022.

appears to be paid testimony in another case, where Cantor's declaration was used to support legislation barring transgender athletes from sports teams,³⁰ Troublingly, Cantor's appearance in that case seems to have been funded by the Alliance Defending Freedom ("ADF"),³¹ a religious and political organization that opposes legal protections for transgender people and same-sex marriage³² and defends the criminalization of gay sex.³³

Romina Brignardello-Petersen is one of two authors of the document provided as Attachment C to the June 2 Report. Although Brignardello-Petersen claims to have no research interests in medical care for transgender youth,³⁴ she has conducted research for the Society for Evidence-Based Gender Medicine ("SEGM").³⁵ Although SEGM claims to be an international medical society, it is, in fact, an advocacy group that opposes standard medical care for gender dysphoria. The SEGM has no publications or conferences and seems to consist solely of a website. The group appears to be run by a small group of people with limited or no scientific credentials and the website presents a cherry-picked collection of studies and narrative content that is full of scientific errors.³⁶

Patrick Lappert, whose document is attached to the June 2 Report as Attachment F, has been disqualified as an expert in a recent federal court decision in North Carolina.³⁷ The judge found that the evidence "calls Lappert's bias and reliability into serious question" and noted that Lappert has worked closely with ADF and has actively lobbied for legal bans on medical care for

³⁰The case is *BPJ v. West Virginia State Board of Education*, and the Alliance Defending Freedom takes credit for it here: <https://adfmmedia.org/case/bpj-v-west-virginia-state-board-education>. Cantor's declaration appears here: <https://adfmmedialegalfiles.blob.core.windows.net/files/BPJ-CantorDeclaration.pdf>

³¹ The ADF seems to take credit for the case in this press conference notice: <https://adfmmedia.org/case/bpj-v-west-virginia-state-board-education>

³² Marriage is the Future, American College of Pediatricians, <https://adflegal.org/issues/marriage/overview> (site visited July 2, 2022). Content on the page includes this statement: "Marriage is about equality and diversity. It's about joining the two equally important and diverse halves of humanity represented in men and women."

³³ Southern Poverty Law Center, Dangerous Liaisons, July 10, 2013, <https://www.splcenter.org/20130709/dangerous-liaisons> [visited July 2, 2022].

³⁴ Like the van Meter and Cantor attachments, the BPW document provides no express statement of conflicts of interest. The BPW document does offer a statement of "credentials and expertise," in which she declares that "her research interests are not in this area," meaning apparently research on medical care for gender dysphoria. BPW Document, p. 1.

³⁵ BPW document, p. 1. For one example of the purported research that Brignardello-Petersen apparently assisted in, see Alison Clayton et al., Commentary: the Signal and the Noise – Questioning the Benefits of Puberty Blockers for Youth with Gender Dysphoria – A Commentary on Rew et al. (2021), *Child and Adolescent Mental Health*, Dec. 22, 2021, at <https://acamh.onlinelibrary.wiley.com/doi/10.1111/camh.12533>. In the "Acknowledgements" section, the authors state, "We would also like to thank the Society for Evidence-based Gender Medicine (SEGM) for providing access to several experts who helped shape this commentary and ensure its accuracy. Specifically, we would like to thank Dr. Romina Brignardello Petersen [sic] for contributing her methodological expertise."

³⁶ Susan Boulware et al., Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims (April 28, 2022), at 28-29 (Appendix A) available at <https://medicine.yale.edu/childstudy/policy-and-social-innovation/lgbtq-youth/>.

³⁷ *Kadel v. Folwell*, 1:19CV272, M.D. N.C. June 10, 2022. The judge ruled that Lappert was not qualified to "render opinions about the diagnosis of gender dysphoria, its possible causes, the efficacy of the DSM, the efficacy of puberty blocking medication or hormone treatments, the appropriate standard of informed consent for mental health professionals or endocrinologists, or any opinion on the non-surgical treatments." Lappert was also disqualified from opining on "the efficacy of randomized clinical trials, cohort studies, or other longitudinal, epidemiological, or statistical studies of gender dysphoria."Id.

transgender youth.³⁸ The judge gave no weight to Lappert's testimony about informed consent, finding that it was unsupported by scientific evidence.³⁹ The judge also found that "Lappert has provided the Court with no data or methodology used to draw his conclusion that surgical treatment for gender dysphoria has "never been generally accepted by the relevant scientific community."⁴⁰

B. The linchpin of the June 2 Report is the analysis by Brignardello-Petersen and Wiercioch (the "BPW document"), provided as Attachment C, which purports to be a comprehensive review of the scientific literature but, in fact, is extremely narrow in scope and so flawed in its analysis that it merits no scientific weight at all.

The BPW document, like the other attachments to the June 2 Report, is an unpublished, non-peer-reviewed document. It is written by inexpert authors who construct an arbitrarily truncated sample and adopt a method that violates scientific guidelines and produces a biased result. The authors describe their findings in deceptive language and jargon predictably mislead the reader. Our review shows that *nothing in the BPW document calls into question the scientific foundations of the WPATH and the Endocrine Society clinical practice guidelines.*

The BPW document seems scientific on its face, because it uses technical jargon and includes numerous tables and charts. But a closer examination shows that it violates established standards for medical research and shows signs of being engineered to produce a pre-ordained and inaccurate result.

The bottom line is that, contrary to the BPW document's claims, there is a large body of reliable scientific literature that supports standard medical treatment for gender dysphoria.

(1) The BPW document lacks scientific credibility due to the authors' lack of relevant qualifications and their ties to an activist group.

The BPW document purports to be a systematic review of the scientific literature on medical treatment for gender dysphoria, but it is full of errors and omissions, resulting in a biased and misleading result. Here, we describe just three of the notable defects that undercut entirely the document's claim to objectivity and sound method. We provide additional detail on these errors in the Appendix to these comments.

First, *neither of the BPW authors are experts* in medical care for gender dysphoria, either as researchers or clinicians. One author (Brignardello-Petersen) has not previously studied the subject, except in her work for the ideological organization SEGM.org, noted just above. Her only clinical experience appears to be in dentistry.⁴¹ The other author (Wiercioch) is a junior researcher (a postdoctoral fellow) with no prior research or clinical experience in this field.⁴²

³⁸ Id.

³⁹ Id., pp. 29-30.

⁴⁰ Id., p. 31.

⁴¹ Romina Brignardello bio, at <https://experts.mcmaster.ca/display/brignarr> [visited July 2, 2022]

⁴² Google Scholar, Wojtek Wiercioch, visited June 22, 2022, https://scholar.google.com/citations?user=vdi3r_AAAAAJ&hl=en

The authors' lack of interest and experience renders the BPW work inexperienced rather than objective, and it violates the National Academy of Medicine standards for systematic reviews.⁴³ By analogy, one would not rely on, say, two dermatologists to conduct a review of the scientific literature on neurosurgery and to make recommendations for clinical practice.

Second, not only is the study not formally peer-reviewed, the BPW authors violate scientific norms and standards by *failing to engage at all with their peers or with actual experts* in the subject matter.⁴⁴ The BPW authors appear not to have published their protocol in advance or otherwise to have submitted their protocol for peer review.

Third, the BPW document raises red flags for opinion bias. Buried in the methodology pages of the BPW document is the fact that the authors include the fringe website SEGM.org.⁴⁵ As noted above, the group's website posts are not peer-reviewed or published, and its cherry-picked content is assembled by activists and is often full of errors.⁴⁶ Troublingly, this is the group to which one of the authors, Brignardello-Petersen, has ties, as noted above.

(2) The BPW document violates scientific standards for evaluating medical evidence. The picture that emerges is of a rushed and inexperienced report with indications of bias.

The BPW document has a patina of scientific expertise. It invokes the respected GRADE standards for rating the quality of studies, and it occupies many pages with tables and technical specifications. When a reader looks past the jargon, however, the BPW authors adopt a method that violates scientific standards and appears to be jury-rigged to reach a foregone conclusion. The authors convey their conclusions in misleading language. *Contrary to the BPW authors' claims, their study does not call into question the scientific and clinical importance of the established science that supports medical care for gender dysphoria.*

The BPW analysis incorporates numerous decisions that bias the results, and the authors describe their findings in grossly misleading terms. To begin, the BPW document reviewed only a small sample of the relevant scientific literature. In the introduction, the BPW authors initially claim to have reviewed 61 systematic reviews of medical treatment for gender dysphoria.⁴⁷ But buried in

⁴³ 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). Background: The Institute of Medicine, now called the National Academy of Medicine, is one of three branches of the National Academies of Science, Engineering, and Medicine. The National Academy of Science dates to 1963 and was established by Congress; the Institute of Medicine was established as a separate entity in 1970 and serves as the nation's leading authority on scientific research and knowledge. National Academy of Medicine, *About the National Academy of Medicine*, website visited June 22, 2022, <https://nam.edu/about-the-nam/>. The standards for systematic reviews were published in 2011, responding to a Congressional request to set benchmarks for high-quality systematic reviews that could reliably guide physicians and health-care providers in making informed, scientific judgments about health care.

⁴⁴ For additional detail, see the Appendix.

⁴⁵ BPW document, Methods section, p. 2.

⁴⁶ See Boulware et al., *supra* note 36, pp. 28-29 (Appendix A).

⁴⁷ BPW document, Introduction Section, p. 2.

the middle of the document is the admission that the analysis is based on a sample of 27 systematic reviews, not 61 as claimed.⁴⁸

Troublingly, the authors also embed in the middle of their technical document an unjustified decision to limit their analysis to studies published from 2020 to the present. The authors disclose that they “prioritized” studies from the last 30 months (two full years plus four months in 2022), but they do not defend that priority. The reader is left to wonder whether this truncation served only to help the authors produce their analysis in a very short time frame.

Further, the BPW authors mechanically apply a series of rating systems (AMSTAR and GRADE) for assessing the quality of scientific evidence, but their use violates key principles for using these systems. Based on this mechanical review of truncated sources, the BPW analysis reaches the conclusion that there is little or no evidence for the benefits of medical care for gender dysphoria.⁴⁹

But the BPW analysis is deceptive, because it dismisses nearly all existing studies of medical treatment for gender dysphoria as “low quality,” without explaining that this is a highly technical term and not a natural-language condemnation of the studies. By contrast, the GRADE system, which the authors purport to use, is quite clear about its quality rating systems and its limitations.⁵⁰ We provide additional detail on the authors’ misuse and deceptive statements in the Appendix.

The key point is that “low quality” in this context is a technical term and not a condemnation of the evidence, because “low quality” studies regularly guide important aspects of clinical practice. Indeed, the GRADE system, which the BPW document claims to use, specifically notes that GRADE should not be used to dismiss observational studies or to give absolute priority to RCTs:

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.*⁵¹

The methodology adopted by the BPW document will thus, predictably, conclude that any body of scientific literature that does not contain RCTs is “low” in quality. The 30 pages that it takes the authors to lay out their methodology is thus extremely misleading: a knowledgeable reader

⁴⁸ BPW document, Results Section, p. 1.

⁴⁹ For example, the BPW document states that there is *no evidence* about the effect of puberty blockers compared to not using puberty blockers. In other words, no studies compared the outcomes between a group of people with gender dysphoria using puberty blockers and another group of people with gender dysphoria not using them. Therefore, it is unknown whether people with gender dysphoria who use puberty blockers experience more improvement in gender dysphoria, depression, anxiety, and quality of life than those with gender dysphoria who do not use them. BPW document, Results section, p. 4.

⁵⁰ See Howard Balshem et al., GRADE Guideline: 3. Rating the Quality, 64 *J. Clinical Epidemiology* P401-406 (2011), Table 3, p. 404

⁵¹ Balshem et al., *supra* note 50, at 402 (emphasis added).

would know that if there are few or no RCTs in the literature, then the BPW technical conclusion is foregone, and, as importantly, is not a sound guide for clinical recommendations.

Put in simpler terms, if we coded apples as “high quality fruit” and bananas as “low quality fruit,” then any fruit bowl that has only bananas would predictably be technically coded as “low quality.” But that technical conclusion conveys very little information without context. For example, if no apples exist, then bananas may be a nutritious choice.

The drafters of the GRADE system emphasize that technically “low quality” evidence can support a strong clinical treatment recommendation. For example, pediatricians now agree – and every parent has been told -- that children should not be given aspirin for fevers. This recommendation is based on observational studies that showed an association between aspirin treatment during viral illnesses and the development of Reyes syndrome (a rapid and progressive disease of neurological dysfunction that can be fatal). Based on those studies, it would be unethical to conduct an RCT giving some children aspirin, and so the strong, consensus treatment recommendation is based entirely on “low quality” studies.⁵²

The critical fact is that RCTs are not, and cannot be, the gold standard for medical research on gender dysphoria, due to strong ethical constraints. Medical care has long been shown, by reliable scientific methods, to address gender dysphoria and improve mental health: as we have repeatedly noted, these treatments have been recommended by rigorous clinical practice guidelines issued by WPATH and the Endocrine Society and endorsed by every major medical organization. Given this medical consensus, which is based on solid scientific evidence, it would be unethical to conduct an RCT that involved denying standard medical care to a control group of individuals.

It is thus simply a mistake – and a mischaracterization of medical research – to conclude that the absence of RCTs means that there is “no evidence” for the efficacy of medical treatment for gender dysphoria.

3. The June 2 Report reflects a faulty understanding of statistics, medical regulation, and scientific research, and it repeats discredited claims and engages in speculation and stereotyping without scientific evidence. The report therefore provides no scientific support for the Proposed Rule or for an interpretation of existing Florida Medicaid standards.

The June 2 Report provides no credible scientific support for the Proposed Rule, because its analysis is full of errors and misstatements. In this section, we offer seven examples, all of which are documented in more detail in the Appendix to these comments.

A. The June 2 Report repeatedly and erroneously dismisses solid studies as “low quality.” If Florida’s Medicaid program applied the June 2 Report’s approach to all medical procedures equally, it would have to deny coverage for widely-used medications like statins (cholesterol-lowering drugs taken by millions of older Americans) and common medical procedures like mammograms and routine surgeries.

⁵² Balsheim et al., supra note 50, at 402.

In its opening words, the June 2 Report makes an error that is repeated throughout the document: “Studies presenting the benefits to mental health, including those claiming that the services prevent suicide, are either low or very low quality and rely on unreliable methods such as surveys and retrospective analyses, both of which are cross-sectional and highly biased.”

As we document in Section 2.B., above, it is an outright mistake to conclude that a study in the technical category of “low quality” is unreliable or poor evidence for clinical practice.⁵³ We provide additional analysis of the misuse of this language in the June 2 Report in the Appendix.

It is quite common for consensus medical practices to be supported only by technically “low quality” but respected observational studies – without RCTs. For example, the famous Framingham Heart Study provided the framework for clinical practice guidelines that support the use of statins, a cholesterol-lowering drug that is effective in preventing cardiovascular death.⁵⁴

The statins example shows that the June 2 Report rests on a fundamental misunderstanding of medical research and clinical practice. If the Florida Medicaid program actually adopted the standard of evidence urged by the June 2 report, the program would not cover statins, which are prescribed to 28% of adults over the age of 40.⁵⁵ Other common practices that would have to be reconsidered under this logic include post-menopausal hormone replacement therapy (which reduces lifetime risk of heart attacks and stroke) and mammography screening for breast cancer.

The same point is true of the technically “low quality” evidence base for many surgical procedures, including minimally invasive gall bladder surgery, which has a solid evidence base in observational studies. We think it unlikely that Florida’s Medicaid program will begin to refuse to pay for statins, mammograms, and routine surgeries. If not, then the June 2 Report and the Proposed Rule reflect an untenable and discriminatory double standard.

B. The June 2 Report disregards robust clinical research studies and instead relies on sources with no scientific credibility. The report’s analysis fails to satisfy Florida’s own regulatory standards for Medicaid coverage decisions and provides no scientific foundation for the Proposed Rule.

The June 2 Report repeatedly cites sources with little or no scientific credibility – including journalism, a student blog, a website, and letters to the editor – rather than peer-reviewed empirical research, in violation of Florida’s own regulatory standards.⁵⁶ At the same time, the

⁵³ Balslem et al., supra note 50, at 404 (“Well-conducted studies may be part of a body of evidence rated low quality because they only provide indirect or imprecise evidence for the question of interest.”)

⁵⁴ Neil J. Stone, et al., 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults, 129(25) *Circulation* S1-S45 (2014).

⁵⁵ Joseph A. Salami et al., National Trends in Statin Use and Expenditures in the U.S. Adult Population From 2002 to 2013, 2(1) *JAMA Cardiology* 56-65 (2017).

⁵⁶ Sources from journalism include Jon Brown, Medical Textbook Strips Gender Dysphoria Definition after Being Cited by Florida, Fox News, May 8, 2022, at 8 <https://www.foxnews.com/politics/textbook-strips-gender-dysphoria-definition-cited-florida> [visited July 3, 2022]; Lawrence S. Mayer and Paul McHugh, Sexuality and Gender: Finding from the Biological, Psychological, and Social Science, *The New Atlantis* (Fall 2016), https://www.thenewatlantis.com/wp-content/uploads/legacy-pdfs/20160819_TNA50SexualityandGender.pdf [visited July 3, 2022]. The citation to the student blog is Hong Phuong Nhi Le, *Eminence-Based Medicine vs. Evidence-Based Medicine*, Students 4 Best Evidence

report makes baseless or exaggerated criticisms of solid studies. Here, we offer only brief examples, with additional illustrations in the Appendix showing how selective and ungrounded criticism permeates the June 2 Report and further undermines its scientific credibility.

For example, the June 2 report attacks a 2015 study by Costa et al., claiming that the study design is flawed because it did not include a control group of adolescents without gender dysphoria.⁵⁷ This point is incorrect: as the Appendix to this report explains, the Costa et al. study did include an appropriate control group.

In addition to glaring technical errors, the June 2 Report's criticism of Costa makes an even more fundamental error: the June 2 report levels baseless criticisms at a single study *and fails to acknowledge that the weight of the literature as a whole strongly supports the same results Costa et al. report*. Scientific knowledge is, importantly, cumulative. It is thus entirely misleading – and unscientific – to dismiss the effectiveness of puberty blockers by criticizing studies in isolation. Put simply, the June 2 Report fails to acknowledge the number of solid studies that all find that puberty blockers are effective.⁵⁸ 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.⁵⁹

The June 2 Report also grossly misleads the reader in its discussion of a study by Chen et al. in 2020⁶⁰ and a study by DeSanctis et al. in 2019.⁶¹ The Appendix discusses these examples at

[blog], <https://s4be.cochrane.org/blog/2016/01/12/eminence-based-medicine-vs-evidence-based-medicine/#:~:text=What%20is%20eminence-based%20medicine> [visited July 3, 2022]. The website is SEGM.org, which we discuss in the text in Section 2. Citations to letters and opinion pieces include, inter alia, Andre van Mol, et al., Gender-Affirmation Surgery Conclusion Lacks Evidence, 177(8) Am. J. Psychiatry 765-766 (2020); Michael Laidlaw, et al., The Right to Best Care for Children Does Not Include the Right to Medical Transition, 19(2) Am. J. Bioethics 75-77 (2019); Michael Laidlaw, et al., Letter to the Editor: “Endocrine Treatment of Dysphoric/Gender Incongruent Persons: An Endocrine Society Clinical Practice Guideline,” 104(3) J. Clinical Endocrinology and Metabolism 686-687 (2018); Andre van Mol, et al., Gender-Affirmation Surgery Conclusion Lacks Evidence, 177(8) Am. J. Psychiatry 765-766 (2020).

⁵⁷ June 2 Report, p. 15 (“Costa et al did not create a third group that lacked a gender dysphoria diagnosis to serve as a control”). The Costa study is Rosalia Costa et al., Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria, 12 (11) J. Sexual Medicine P2206-2214 (2015) (hereinafter, “Costa et al. (2015).”)

⁵⁸ See Luke R. Allen, et al., Well-Being and Suicidality Among Transgender Youth after Gender-Affirming Hormones, 7(3) Clinical Practice in Pediatric Psychology 302-11 (2019); Amy E. Green, et al., Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth, 70(4) J. Adolescent Health 643-649 (2022); Jack L. Turban, et al., Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145(2) Pediatrics e20191725 (2020); Maureen D. Connolly, et al., The Mental Health of Transgender Youth: Advances in Understanding, 59(5) J. Adolescent Health 489-95 (2016); Gemma L. Witcomb et al., Levels of Depression in Transgender People and its Predictors: Results of a Large Matched Control Study with Transgender People Accessing Clinical Services, J. Affective Disorders (2018)..

⁵⁹ For citations, see Boulware et al., supra note 36, at n. 43.

⁶⁰ Diane Chen, et al., Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Pubertal Suppression in Transgender Youth, Transgender Health 246-257 (2020).

⁶¹ Vincenzo De Sanctis, et al., Long-Term Effects and Significant Adverse Drug Reactions (ADRs) Associated with the Use of Gonadotropin-Releasing Hormone Analogs (GnRHa) for Central Precocious Puberty: a Brief Review of Literature, 90(3) Acta Biomed. 345-359 (2019).

length. As a final example, the June 2 Report criticizes a 2019 preliminary study by Kuper et al. without acknowledging the existence of a more extensive 2020 study by Kuper et al.⁶² The earlier study presented data on the mental health of adolescents when initially presenting for care; only the later study presented full data that demonstrated the benefit of treatment.

C. The June 2 Report mistakenly claims that puberty blockers and hormones are experimental because they are used “off-label” and not approved by the FDA. In fact, off-label use, when supported by scientific evidence, as here, is extremely common in medical practice and especially in pediatrics.

The June 2 Report repeatedly notes that the FDA has not approved the use of puberty blockers and hormones for the treatment of gender dysphoria in minors.⁶³ The report infers that lack of FDA approval renders a treatment unauthorized and experimental, but this is false. Once again, the June 2 Report (mis)uses technical language to confuse readers.

The term “off-label” has a very specific meaning: a drug is off-label if the FDA has not approved a particular medication for a particular use in a specific population. The off-label use of medications for children is common and often necessary, because an “overwhelming number of drugs” have no FDA-approved instructions for use in pediatric patients.⁶⁴

The lack of FDA approval does not imply that the use of medications should be restricted. There is a consensus in the medical community that off-label use is necessary because of limits imposed by burdensome and expensive regulatory processes. Pharmaceutical companies often lack financial incentives to support research required for FDA approval for specific use in children.⁶⁵

The American Academy of Pediatrics, recognizing these facts, specifically authorizes the off-label use of drugs:

The purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, *the term “off-label” does not imply an improper, illegal, contraindicated, or investigational use.* Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient.⁶⁶

⁶² June 2 Report, p. 16. The earlier Kuper et al. study is Laura E. Kuper et al., Baseline Mental Health and Psychosocial Functioning of Transgender Adolescents Seeking Gender-Affirming Hormone Therapy, 40(8) J. Dev. Behav. Pediatr. 589-596 (2019). The later study is Laura E. Kuper et al., Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy, 145(4) Pediatrics e20193006 (2020).

⁶³ June 2 Report, pp. 8, 14, 15, 19.

⁶⁴ Boulware et al, supra note 36, quoting Kathleen A. Neville, et al., American Academy of Pediatrics Committee on Drugs, Off-label use of drugs in children, 133(3) Pediatrics 563-7 (2014) (“AAP Committee on Drugs”).

⁶⁵ AAP Committee on Drugs (2014), supra note 64.

⁶⁶ AAP Committee on Drugs (2014), supra note 64 (emphasis added). See also Lenneke Schrier, et al., Off-label Use of Medicines in Neonates, Infants, Children, and Adolescents: a Joint Policy Statement by the European Academy of Paediatrics and the European Society for Developmental Perinatal and Pediatric Pharmacology, 179(5) Eur. J. Pediatr 839-845 (2020).

Off-label use is so common in pediatrics that off-label drugs are prescribed in 20% of patient visits.⁶⁷ We discuss numerous examples in the Appendix, but a few familiar examples provide illustrations of day-to-day, off-label use in pediatrics.⁶⁸

As many parents know, the use of steroids for croup is a life-saving treatment that is off-label. The medication helps toddlers get through severe, potentially airway-obstructing illnesses safely. Ondansetron (Zofran) is used off-label for nausea and vomiting to prevent dehydration.

In psychiatry, some of the most commonly-prescribed medications for youth are off label. For example, selective serotonin reuptake inhibitors (SSRIs) are used to treat major depressive disorder in adolescents and have been shown to be effective, even though several are off-label.⁶⁹ Another common example is clonidine, which is FDA-approved for attention deficit hyperactivity disorder (ADHD) but is used off-label for anxiety, insomnia, and post-traumatic stress disorder (PTSD).⁷⁰

Finally, the June 2 Report notes that testosterone is a controlled substance and is subject to risk of abuse, but, once again, this is misleading. The inclusion of testosterone on the schedule of controlled substances reflects the misuse of the drug by some individuals and communities (e.g., weightlifters and athletes who may use the drug to build muscle). The classification does not in any way imply that physicians should not dispense the drug if medically necessary. No special license is necessary for prescribing the medication, which is routinely prescribed to cisgender men with testosterone deficiency.

D. The June 2 Report falsely claims that medical care for gender dysphoria is provided to a large percentage of children who will come to regret their treatment. In fact, patients with gender dysphoria have vanishingly low rates of regret regarding their medical treatment.

The June 2 Report attempts to cast doubt on medical treatment for gender dysphoria by repeating the debunked claim that most transgender teens ultimately reject their transgender identity. Below, we analyze two related claims made in the report and show why both are refuted by sound evidence. We provide additional detail in the Appendix.

First, the report claims that “the majority of young adolescents who exhibit signs of gender dysphoria eventually desist and conform to their natal sex.”⁷¹ This is false. We have refuted this claim in detail in prior work. The key point is that *adolescents with gender dysphoria rarely find*

⁶⁷ Diya Hoon, et al., Trends in Off-Label Drug Use in Ambulatory Settings: 2006-2015, 144(4) Pediatrics 1-10 (2019) (emphasis added).

⁶⁸ These examples are drawn from the list of off-label uses in AAP Committee on Drugs (2014) and reflect our clinical experience in major hospitals and clinics.

⁶⁹ For AACAP guidelines, see Boris Birmaher and David Brent, Practice Parameter for the Assessment and treatment of Children and Adolescents with Depressive Disorders, 46(110 J. Am. Acad. Child and Adolescent Psychiatry P1503-1526 (2007).

⁷⁰ Rama Yasaei and abdolreza Saadabadi, Clonidine, National Library of Medicine (2022), at <https://www.ncbi.nlm.nih.gov/books/NBK459124/> [visited July 4, 2022].

⁷¹ June 2 Report, p. 14.

*that their dysphoria resolves without treatment.*⁷² Because medical treatment for gender dysphoria begins only in adolescence, and only if medically necessary, medical treatment is thus provided only to a group known to be quite stable in their gender identity.

Second, the June 2 report claims that many transgender people regret their medical treatment. This is false. We provide a detailed discussion in the Appendix, but the scientific evidence is clear: solid studies show very low percentages of regret (typically under 1%) among transgender people who receive medical treatment for gender dysphoria. For example, Bustos et al. (2021) found regret expressed by one percent or fewer of transgender patients who underwent gender-affirming surgery, and Danker et al. (2018) report a rate of far less than 1%, as do Wiepjes et al. (2015).⁷³

E. The June 2 Report repeats discredited claims that “social contagion” is leading teens to become transgender. Scientific evidence refutes this claim, which is based on a single, discredited study whose results have not been replicated by more rigorous studies.

The June 2 Report claims that “social factors (e.g., peer influences and media) may be contributing factors to gender dysphoria,”⁷⁴ citing as evidence a single, discredited study by Littman. We have addressed this claim at length in other work and note that the study incorporated such serious methodological errors that the journal of publication required an extensive correction because of the article’s misstatements.⁷⁵

Littman’s sensationalist hypothesis has been widely covered in the press, but no clinical studies have found that rapid-onset gender dysphoria exists. Further, no professional organization has recognized “rapid-onset gender dysphoria” as a distinct clinical condition or diagnosis.

Most recently, an April 2022 study of 173 youth presenting at Canadian gender clinics *found no evidence of rapid-onset dysphoria or social contagion*. The researchers posited that if “rapid onset” gender dysphoria were a real phenomenon, then teens who had more recently begun identifying as transgender would (per the Littman hypothesis) also be more likely to report online support and engagement in their gender identity. They might also (per Littman’s hypothesis) be more likely to struggle with mental health concerns.

An April 2022 study of 173 youth found no such correlations, strongly undercutting the “rapid-onset” hypothesis endorsed by the June 2 report. The researchers controlled for age and sex assigned at birth and looked for correlations with recent gender knowledge (defined as less than one to two years having passed since “you realized your gender was different from what other people called you”). Recent gender knowledge was *not* significantly associated with depressive symptoms, psychological distress, past diagnoses with comorbid mental health issues or neurodevelopmental disorders, or self-harm. Nor was it associated with having gender-

⁷² Boulware et al., *supra* note 36, at 17-19.

⁷³ *Id.*

⁷⁴ June 2 Report, p. 12.

⁷⁵ Boulware et al., *supra* note 36, at 20-21 (internal citations omitted).

supportive online friends, general support from online friends or transgender friends, or gender support from parents.⁷⁶

Data do substantiate that younger people today are more likely to identify as transgender than are older people, but this does not substantiate the idea of social contagion. The increase may be due to a cohort effect associated with the increasing social acceptance of gender diversity (i.e., older people grew up in a much more restrictive and transphobic social environment). In fact, adolescent presentation of transgender identity is often observed and should not be pathologized.⁷⁷

Further, the data do not show a massive wave of transgender identity even among teens. A 2022 study by the Williams Institute found that, using an expansive definition of “transgender,” about 0.5% of adults now identify as transgender, while 1.4% of youth aged 13-17 do, or about 300,000 young people.⁷⁸ This is not a large percentage or a large absolute number.

The June 2 Report’s social contagion claim also disregards the enormous social pressure on teenagers to adopt a cisgender identity; transgender teens face significant discrimination and violence by asserting their gender identity and report very high rates of bullying at school.⁷⁹ Further, the evidence shows that teens (like adults) tend to use social media for emotional support and to access a helpful peer group that may not be available in person.⁸⁰

Ultimately, however, the social contagion hypothesis is irrelevant to the question whether medical care for gender dysphoria is effective. As we have noted, medical treatments are not offered to all gender-questioning youth. Instead, the WPATH and Endocrine Society standards recommend drug therapies for transgender adolescents whose interdisciplinary medical team has determined that they have lasting and intense gender dysphoria and that treatment is medically necessary.

F. The June 2 Report claims that inappropriate medical care is provided to adolescents with gender dysphoria who also have anxiety, depression, and other mental health conditions. These assertions are unsupported by evidence and disregard evidence-based clinical practice guidelines that provide sound guidance for treating complex cases.

The June 2 Report speculates that because “a high proportion” of youth receiving medical care for gender dysphoria also have a behavioral health disorder, “available research raises

⁷⁶ Greta R. Bauer, et al., 243 J. Pediatrics 224-227 (2022).

⁷⁷ In the largest U.S. sample of transgender adults, over half reported first starting to realize that they were transgender in adolescence (57% ages 11-20) and roughly half (47%) started to disclose their identity during this time frame. Sandy E. James, et al., The Report of the 2015 U.S. Transgender Survey, National Center for Transgender Equality (2015).

⁷⁸ Jody L. Herman, et al., How Many Adults and Youth Identify as Transgender in the United States?, U.C.L.A. School of Law, Williams Institute (2022).

⁷⁹ See, Joseph G. Kosciw, et al., The 2019 National School Climate Survey, GLSEN (2019), https://www.glsen.org/sites/default/files/2021-04/NSCS19-FullReport-032421-Web_0.pdf [visited July 3, 2020].

⁸⁰ Ashley Austin, et al., It’s My Safe Space: The Life-Saving Role of the Internet in the Lives of Transgender and Gender Diverse Youth 21(1) Int’l J. Transgender Health 33-44 (2020); Ellen Selkie, et al., Transgender Adolescents’ Uses of Social Media for Social Support, 66(3) J. Adolescent Health 275-280 (2020).

questions as to whether the [individuals'] distress is secondary to pre-existing behavioral health disorders and not gender dysphoria.”⁸¹ In simpler terms, the June 2 Report speculates that perhaps gender dysphoria is not real but is, rather, an imagined by-product of underlying mental illness.

A close examination shows that this claim has no foundation in science; it rests on unexamined and harmful stereotypes and unaccountably dismisses the scientific knowledge and clinical skill of child and adolescent psychologists and psychiatrists. Here, we briefly explain why the June 2 Report's speculations are scientifically unfounded. We provide further detail on these points in the Appendix.

The June 2 Report implicitly posits that behavioral health disorders cause gender dysphoria, but this hypothesis is completely unsupported by scientific evidence, which strongly suggests that the direction of causation runs the other way. It is well-established that being transgender leads to mental health concerns because of the social stress and discrimination of being transgender in our society.⁸² Although the effects of gender minority stress are well-known, the June 2 Report makes no mention of the literature.

Further, the co-occurrence of psychological distress among individuals with gender dysphoria provides no reason for denying care. Any population of individuals – cisgender or transgender -- will include some with mental health concerns. In response, the WPATH and Endocrine Society guidelines include a careful psychological assessment of each adolescent as part of the process for determining whether medical treatment for gender dysphoria is appropriate.

Importantly, experts in child and adolescent psychiatry, child psychology, and adolescent medicine have established that youth – including youth with mental health conditions -- can make complex medical decisions. The scientific literature specifically demonstrates that transgender youth with co-occurring mental health conditions can competently participate in medical decision-making.⁸³

G. The June 2 Report speculates, without evidence, that psychotherapy alone is as effective as medical treatment for gender dysphoria. This claim contradicts the findings of solid scientific studies.

The June 2 Report argues, without scientific evidence, that youth with gender dysphoria should not be offered medical treatment but instead should only receive psychotherapy, an approach that

⁸¹ June 2 Report, p. 6.

⁸² Rylan J. Testa, et al., Development of the Gender Minority Stress and Resilience Measure, 2(1) *Psychology of Sexual Orientation and Gender Diversity* 65-77 (2015); Rylan J. Testa, et al., Suicidal Ideation in Transgender People: Gender Minority Stress and Interpersonal Theory Factors, 126(1) *J. Abnormal Psychology* 125-36 (2017); Alexandri M. Delozier, et al., Health Disparities in Transgender and Gender Expansive Adolescents: A Topical Review from a Minority Stress Framework, 45(8) *J. Pediatric Psychology* 842-847 (2020); Jessica Hunter, et al., Gender Minority Stress in Trans and Gender Diverse Adolescents and Young People, 26(4) *Clinical Child Psychology and Psychiatry* 1182-1195 (2021).

⁸³ Lieke J. Vrouenraets, et al., Assessing Medical Decision-Making Competence in Transgender Youth, 148(6) *Pediatrics* e2020049643 (2021).

it mistakenly terms “watchful waiting.”⁸⁴ This statement is false. Here we provide an overview of the actual science, with more detail in the Appendix.

Several solid, recent studies have demonstrated that medical care for gender dysphoria has positive effects on mental health that are not associated with psychotherapy alone. Costa et al. in 2015 found that puberty blockers improve psychosocial functioning in teens with gender dysphoria, compared to teens who receive psychotherapy but not blockers.⁸⁵ In a 2022 study, Tordoff et al. clearly found that youth with gender dysphoria reported better outcomes if they received puberty blockers, even after controlling for the effects of psychotherapy.⁸⁶ A 2020 study by Laura Kuper et al. also shows that hormone treatment for gender dysphoria is effective above and beyond the benefits of psychotherapy and psychiatric medications.⁸⁷

Conclusion

Our analysis demonstrates that the June 2 Report carries no scientific weight. The report disregards established clinical guidelines and peer-reviewed studies and instead relies on purported “expert” reports that raise major red flags for lack of expertise, close ties to advocacy groups, and financial conflicts of interest. The report makes repeated errors about scientific research and medical regulation, and it engages in ungrounded speculation and stereotyping.

Accordingly, the Proposed Rule is ungrounded in scientific research and is arbitrary and capricious. Further, because the June 2 report violates Florida’s own standards for scientific review, it cannot support the Proposed Rule as an interpretation of the existing Florida regulatory scheme.

We respectfully submit this letter of comment for your consideration.

Very truly yours,

Anne L. Alstott

Anne L. Alstott
Jacquin D. Bierman Professor, Yale Law School
Professor, Yale Child Study Center

⁸⁴ For example, at p. 12, the June 2 Report asks, “[S]hould conventional behavioral health services be utilized without proposing treatments that pose irreversible effects [i.e., drug therapies]? Would that approach not provide additional time to address underlying issues before introducing therapies that pose permanent effects {i.e., the watchful waiting approach}?” At p. 20, the June 2 Report misuses the term “watchful waiting” to describe the denial of medical care to adolescents with gender dysphoria, and the report miscites its own purported expert report. The Cantor document discusses “watchful waiting” meaning the denial of social transition to prepubertal children, not the denial of medical treatment to adolescents. Cantor document, p. 10-11.

⁸⁵ Costa et al., *supra* note 57.

⁸⁶ Diana M. Tordoff et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care*, 5(2) JAMA Network Open e220978 (2022).

⁸⁷ Laura E. Kuper, et al., *Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy*, 145(4) Pediatrics e20193006 (2020).

With co-authors:

Hussein Abdul-Latif, M.D., Professor of Pediatrics and Pediatric Endocrinology, University of Alabama at Birmingham

Susan D. Boulware, M.D., Associate Professor of Clinical Pediatrics (Endocrinology), Yale School of Medicine; Director Clinical Operations, Section of Pediatric Endocrinology; Medical Director, Yale Pediatric Gender Program

Rebecca Kamody, PhD (Clinical Psychology), Assistant Professor, Yale School of Medicine: Child Study Center, Pediatrics, and Psychiatry

Laura Kuper PhD (Clinical Psychology), ABPP, Assistant Professor in Psychiatry, University of Texas Southwestern; Child and Adolescent Psychologist, Children's Medical Center Dallas

Meredith McNamara, M.D., M.S., FAAP, Assistant Professor of Pediatrics (Adolescent Medicine), Yale School of Medicine

Christy Olezeski, PhD (Clinical Psychology), Associate Professor of Psychiatry, Yale Child Study Center and Pediatrics, Yale School of Medicine; Director, Yale Pediatric Gender Program

Nathalie Szilagy, M.D., Instructor, Yale Child Study Center, Yale Pediatric Gender Program; Director, Greenwich Child and Adolescent Psychiatry, Greenwich Center for Gender & Sexuality

Appendix

July 8, 2022

A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria

Meredithe McNamara, M.D., M.S. (Clinical Research), FAAP, Assistant Professor of Pediatrics (Adolescent Medicine), Yale School of Medicine

Hussein Abdul-Latif, M.D., Professor of Pediatrics and Pediatric Endocrinology, University of Alabama at Birmingham

Susan D. Boulware, M.D., Associate Professor of Clinical Pediatrics (Endocrinology), Yale School of Medicine; Director Clinical Operations, Section of Pediatric Endocrinology; Medical Director, Yale Pediatric Gender Program

Rebecca Kamody, PhD (Clinical Psychology), Assistant Professor, Yale School of Medicine: Child Study Center, Pediatrics, and Psychiatry

Laura Kuper PhD (Clinical Psychology), ABPP, Assistant Professor in Psychiatry, University of Texas Southwestern; Child and Adolescent Psychologist, Children's Medical Center Dallas

Christy Olezeski, PhD (Clinical Psychology), Associate Professor of Psychiatry, Yale Child Study Center and Pediatrics, Yale School of Medicine; Director, Yale Pediatric Gender Program

Nathalie Szilagyi, M.D., Instructor, Yale Child Study Center, Yale Pediatric Gender Program; Director, Greenwich Child and Adolescent Psychiatry, Greenwich Center for Gender & Sexuality

Anne L. Alstott, J.D., Jacquin D. Bierman Professor, Yale Law School; Professor, Yale Child Study Center*

Introduction

On June 2, 2022, the Florida Agency for Health Care Administration (“AHCA”) issued a purported scientific report (hereinafter, “June 2 Report”) concluding that standard medical care

* The authors have received no funding for this report or for our public comments on Florida’s proposed Medicaid rule. We have no conflicts of interest to declare. Dr. Olezeski prepared paid expert testimony in a case for the Federal Public Defender for the District of Connecticut. We thank Melisa Olgun for excellent research assistance.

for gender dysphoria does not meet generally accepted medical standards and is experimental and investigational.⁸⁸

We are a group of seven scientists and a law professor, and we have concluded, after a careful examination of the June 2 Report, 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.

We are alarmed that Florida's health care agency has adopted a purportedly scientific report that so 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.

So repeated and fundamental are the errors in the June 2 Report that it seems clear that the report is not a serious scientific analysis but, rather, a document crafted to serve a political agenda.

The AHCA has offered the June 2 Report as justification for a proposed rule that would deny Florida Medicaid coverage for gender dysphoria to people of all ages (the "Proposed Rule").⁸⁹ We strongly oppose the Proposed Rule and have documented our reasons in public comments submitted to the AHCA on July 8, 2022. This report provides our detailed reasons for concluding that the June 2 Report provides no scientific support for Florida's proposed action.

Executive Summary

As we note in our comments on the Proposed Rule, we strongly oppose Florida's proposal to deny Medicaid coverage to standard medical care for gender dysphoria. In this report, we show that the June 2 Report is so thoroughly flawed and biased that it deserves no scientific weight. Although our focus is on the science, we also note that the Proposed Rule would violate the sex discrimination protections provided by the U.S. and Florida Constitutions and the federal statute that governs Medicaid by discriminating against transgender people on the basis of their sex, transgender status, and gender identity.⁹⁰

In this report, we examine closely the "scientific" claims made in the June 2 Report, and we show that its basic conclusion is incorrect. Medical treatment for gender dysphoria does meet generally accepted professional medical standards and is not experimental or investigational. We also show that the June 2 report reflects a faulty understanding of statistics, medical regulation, and scientific research. The report ignores solid scientific evidence and instead

⁸⁸ 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 ("June 2 Report").

⁸⁹ 48 Fl. Admin. Reg. 2461 (June 17, 2022).

⁹⁰ See *Bostock v. Clayton County*, 590 U.S. ___ (2020); *Kadel v. Folwell*, M.D. N.C., Mem. Op. 6-10-22 (applying *Bostock* to public health plan coverage); 42 U.S.C. 18116 (requiring nondiscrimination in Medicaid plans).

repeats discredited claims, cites to sources with no scientific merit, and engages in unfounded speculation based on stereotypes rather than science.

Specifically, we show that:

- Contrary to the June 2 Report’s repeated claims, medical care for gender dysphoria is supported by a robust scientific consensus, meets generally accepted professional medical standards, and is neither experimental nor investigational.
- 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, inexpert, 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.
- Nothing in the June 2 Report calls into question the scientific foundations of standard medical care for gender dysphoria. The June 2 Report makes unfounded criticisms of robust and well-regarded clinical research and instead cites sources with little or no scientific merit, including journalism, a blog entry, letters to the editor, and opinion pieces.
- The linchpin of the June 2 Report is an analysis by two epidemiologists that claims to undermine the scientific evidence supporting medical care for gender dysphoria. Their analysis is extremely narrow in scope, inexpert, and so flawed that it merits no scientific weight at all.
- The June 2 Report repeatedly and erroneously dismisses solid studies as “low quality.” If Florida’s Medicaid program applied the June 2 Report’s approach to all medical procedures equally, it would have to deny coverage for widely-used medications like statins (cardioprotective cholesterol-lowering drugs taken by millions of older Americans) and common medical procedures like mammograms and routine surgeries.

I. Contrary to the June 2 Report’s repeated claims, medical care for gender dysphoria is supported by a robust scientific consensus, meets generally accepted professional medical standards, and is neither experimental nor investigational.

The conclusion of the June 2 report – that medical treatments for gender dysphoria “do not conform to [generally accepted professional medical standards] and are experimental and investigational”⁹¹ – is demonstrably false.

Medical care for the treatment of gender dysphoria, which for youth under the age of majority can include gonadotropin releasing hormone agonists (“GnRHa” or puberty blockers) and hormone therapy, has been vetted and approved by international bodies of experts based on the scientific evidence. Two authoritative bodies of scientists, the World Professional Association for Transgender Health (WPATH) and The Endocrine Society, have published extensive clinical practice guidelines for treating gender dysphoria.⁹² These clinical guidelines are based on

⁹¹ June 2 Report, p. 2.

⁹² See Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, World Professional Association for Transgender Health (7th version, 2012), at <https://www.wpath.org/publications/soc> (“WPATH (2012)”); Wylie C. Hembree, et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent

rigorous, structured processes that include a committee of scientific experts and peer review by additional experts. The guidelines are based on careful reviews of the scientific literature and are revised periodically to reflect scientific developments.

These longstanding clinical practice guidelines have been used by clinicians for decades. WPATH issued its initial guidelines in 1979 and updated them in 1980, 1981, 1990, 1998, 2001, and 2012. The eighth version remains in process, and it incorporates systematic literature reviews and ample opportunities for peer review and revision.⁹³ The original Endocrine Society guidelines were published in 2009 and updated in 2017.⁹⁴

Reflecting this scientific and medical consensus, medical care for gender dysphoria has been confirmed as standard care by every relevant medical organization in the United States, including the American Academy of Pediatrics, the American Psychological Association, and the American Academy of Child and Adolescent Psychiatry.⁹⁵ In 2022, these organizations united with the American Medical Association, the American College of Obstetricians and Gynecologists, and other groups to file an amicus brief representing a total of 20 major medical societies. The brief reaffirms that puberty blockers and hormone treatments for gender dysphoria are standard medical care and opposes legal measures that would limit patient access to this standard care.⁹⁶

The weight and volume of these endorsements, across diverse medical specialties, sharply contradicts the June 2 Report's conclusions.

II. 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. The report heavily relies on five purported "expert" documents that are biased, inexperienced, and full of errors.

The Florida report dismisses or ignores the WPATH and Endocrine Society clinical practice guidelines and the science that underlies them and instead relies on five attached documents that, the report claims, constitute "clinical and technical expert assessments."⁹⁷

Persons: An Endocrine Society Clinical Practice Guideline, 102(11) J. Clin. Endocrinol. Metab. 3869-3903 (2017) ("Endocrine Society (2017)").

⁹³ See World Professional Association for Transgender Health (WPATH), Methodology for the Development of Standards of Care 8 (Soc 8), at <https://www.wpath.org/soc8/Methodology>.

⁹⁴ Endocrine Society (2017), supra note 5.

⁹⁵ Jason Rafferty, Committee on Psychosocial Aspects of Child and Family Health; Committee on Adolescence; Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness, Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents, 142(4) Pediatrics E20182162 (2018); American Psychological Association, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, 70(9) American Psychologist 832-64 (2015); Stewart L. Adelson, Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents, 51(9) J. Am. Acad. Child & Adolescent Psychiatry, 957-974 (2012).

⁹⁶ Brief of Amicus Curiae American Academy of Pediatrics and Additional National and State Medical and Mental Health Organizations in Support of Plaintiffs' Motion for Temporary Restraining Order and Preliminary Injunction, Eknes-Tucker v. Ivey (later redesignated Eknes-Tucker v. Abbott), May 5, 2022, at <https://www.aamc.org/media/60556/download>.

⁹⁷ June 2 Report, p. 2.

Despite their billing as “expert” reports, the attachments to the June 2 report are unpublished, non-peer-reviewed documents written by authors with questionable claims to expertise and with red flags for undisclosed author bias. These documents should be given no weight in a serious scientific process.

A. The purported “expert” documents attached to the June 2 Report carry no scientific weight. They are unpublished and not peer-reviewed, and they are written by authors whose expertise has been successfully challenged in legal proceedings and whose backgrounds raise red flags for bias.

None of the documents attached to the June 2 Report meet standard criteria for expert scientific investigations, because none is published or peer reviewed. Publication and peer review are fundamental to science, as they ensure that a scientist’s data and conclusions are open to scrutiny from scientific experts.

Florida’s own standards for the determination of medical necessity recognize this point when they state that determinations of Medicaid coverage must consult “*published* reports and articles in the authoritative medical and scientific literature related to the health service (*published in peer-reviewed scientific literature* generally recognized by the relevant medical community or practitioner specialty associations).”⁹⁸ It is thus both unscientific and a violation of the regulations for the June 2 Report to rely on the unpublished documents as its principal evidence base.

Further, the attachments all raise red flags for author bias. The June 2 Report does not disclose how these “experts” were identified or by what criteria their expertise was assessed. The opacity of the Florida AHCA process for identifying experts is particularly troubling because at least four of the experts have strong indications of bias. Further, the qualifications and credibility of two of the experts have been successfully challenged in litigation.⁹⁹ Two of the expert reports duplicate, word-for-word (or with very slight edits) testimony that was offered, apparently for pay, in litigation. Both have connections to advocacy organizations that oppose LGBTQ rights across the board. The endorsement of these individuals as Florida’s banner “experts” raises the appearance of bias – that the AHCA sought a pre-ordained outcome, not a true scientific perspective.

Adding to these red flags for bias, none of the authors of the attachments provide a statement of funding and conflicts of interest. This omission violates a strong norm in scientific writing, which requires authors to declare any conflicts of interest; these include any professional or financial arrangements that could call into question their independence of judgment.¹⁰⁰ That

⁹⁸ Fl. Admin. Code Section 59G-1.035(4).

⁹⁹ See Stephen Caruso, A Texas Judge Ruled That This Doctor Was Not an Expert, *Pennsylvania Capital-Star*, Sept. 15, 2020 (reporting that van Meter was disqualified as an expert in a Texas divorce case, now sealed).

¹⁰⁰ For example, the conflict of interest rules for JAMA, one of the premier medical journals in the United States and the world state that “[a]uthors are expected to provide detailed information about all relevant financial interests, activities, relationships, and affiliations (other than those affiliations listed in the title page of the manuscript) including, but not limited to, employment, affiliation, funding and grants received or pending, consultancies, honoraria or payment, speakers’ bureaus, stock ownership or options, expert testimony, royalties, donation of medical equipment, or patents planned, pending, or issued.” JAMA Network, Instructions for Authors, visited June

strong norm also requires authors to disclose whether projects have been funded and if so, by whom and whether the authors have engaged in expert testimony. Without these statements, the Florida AHCA and the public cannot detect biases that could affect the integrity of these written products.

These are more than theoretical concerns: at least four of the attachments have notable indicators of conflicts of interest and bias. (Note that these are the only four we examined in detail, and so we do not imply that the other one is free from such bias.)

The author of the document provided as Attachment E is Quentin van Meter, whose history indicates bias and lack of expertise. Although the AHCA presents van Meter as an expert in medical treatment for gender dysphoria, at least one court barred him from providing expert testimony on the issue.¹⁰¹ Van Meter is the president of the American College of Pediatricians (the “ACP”), which presents itself as a scientific group (and might be confused, by a non-expert, with the authoritative American Academy of Pediatrics). The ACP is, in fact, a political group that opposes same-sex marriage,¹⁰² supports mental health providers practicing conversion therapy,¹⁰³ and describes childhood gender dysphoria as “confusion.”¹⁰⁴ Troublingly, the van Meter attachment, proffered by the AHCA as a scientific report, contains several passages of uncredited, verbatim language that appears in a “position statement” published by the ACP.¹⁰⁵ The van Meter attachment appears to be a re-use of paid testimony rather than an original product.¹⁰⁶

James Cantor’s document, presented as Attachment D to the June 2 Report, also faces serious questions about bias and lack of expertise. In a 2022 case, a federal court took a skeptical view of Cantor’s purported expertise, noting that “the Court gave [Cantor’s] testimony little weight because he admitted, inter alia, to having no clinical experience in treating gender dysphoria in minors and no experience monitoring patients receiving drug treatments for gender dysphoria.”¹⁰⁷

22, 2022, at <https://jamanetwork.com/journals/jama/pages/instructions-for-authors#SecConflictsofInterestandFinancialDisclosures>

¹⁰¹ Caruso, supra note 12.

¹⁰² Den Trumbull, *Defending Traditional Marriage*, American College of Pediatricians (2013), <https://acpeds.org/position-statements/defending-traditional-marriage>. See Jack Turban, *The American College of Pediatricians is an Anti-LGBTQ Group*, *Psychology Today*, May 8, 2017.

¹⁰³ Christopher Rosik and Michelle Cretella, *Psychotherapy for Unwanted Homosexual Attraction Among Youth*, American College of Pediatricians (2016), <https://acpeds.org/position-statements/psychotherapy-for-unwanted-homosexual-attraction-among-youth>.

¹⁰⁴ Michelle Cretella, *Gender Dysphoria in Children*, American College of Pediatricians (2018), <https://acpeds.org/position-statements/gender-dysphoria-in-children> (site visited June 22, 2022).. The author of the ACP position paper is Michelle Cretella, who was publicly rebuked by the Society for Adolescent Health and Medicine, the leading society for adolescent medicine in the United States, for “pushing political and ideological agendas not based on science and facts.” [https://www.adolescenthealth.org/Advocacy/Advocacy-Activities/2017-Activity/Senate-Bill-439-\(2\).aspx](https://www.adolescenthealth.org/Advocacy/Advocacy-Activities/2017-Activity/Senate-Bill-439-(2).aspx)

¹⁰⁵ The similarity was shown by a Word comparison of the van Meter report provided as Attachment E to the June 2 Report with a “position statement” published on the ACP website, with authorship credit given on the website to Michelle Cretella. See Michelle Cretella, *Gender Dysphoria in Children*, supra note 17.

¹⁰⁶ The van Meter document attached to the June 2 Report is substantially identical to his expert declaration in *Adams v. School Board of St. Johns County, Florida*. <https://files.eqcf.org/wp-content/uploads/2017/12/41-D-AMENDED-Notice-Documents-iso-Response-to-PI.pdf>.

¹⁰⁷ *Opinion and Order, Eknes-Tucker v. Marshall*, 2:22-CV-184-LCB, M.D. Alabama, May 13, 2022.

Cantor's document is nearly identical to what appears to be paid testimony in another case, where Cantor's declaration was used to support legislation barring transgender athletes from sports teams,¹⁰⁸ Troublingly, Cantor's appearance in that case seems to have been funded by the Alliance Defending Freedom ("ADF"),¹⁰⁹ a religious and political organization that opposes legal protections for transgender people and same-sex marriage¹¹⁰ and defends the criminalization of sexual activity between partners of the same sex.¹¹¹ Because Cantor provides no conflicts of interest disclosure, readers cannot ascertain whether Florida AHCA also paid for Cantor's report and whether Florida officials were aware that the Cantor report reused his work for (apparently) the ADF.

Romina Brignardello-Petersen is one of two authors of the document provided as Attachment C to the June 2 Report. Although Brignardello-Petersen claims to have no research interests in medical care for transgender youth,¹¹² she has conducted research for the Society for Evidence-Based Gender Medicine ("SEGM").¹¹³ Although SEGM claims to be an international medical society, it is actually an activist group that opposes standard medical care for gender dysphoria. The SEGM has no publications or conferences and seems to consist solely of a website created by a small group of people with limited or no scientific credentials or clinical experience. The site presents a cherry-picked collection of studies and narrative content that is full of scientific errors.¹¹⁴

Patrick Lappert, whose document is attached to the June 2 Report as Attachment F, has been disqualified as an expert in a recent federal court decision in North Carolina.¹¹⁵ The judge found

¹⁰⁸The case is *BPJ v. West Virginia State Board of Education*, and the Alliance Defending Freedom takes credit for it here: <https://adfmedia.org/case/bpj-v-west-virginia-state-board-education>. Cantor's declaration appears here: <https://adfmedialegalfiles.blob.core.windows.net/files/BPJ-CantorDeclaration.pdf>

¹⁰⁹ The ADF seems to take credit for the case in this press conference notice: <https://adfmedia.org/case/bpj-v-west-virginia-state-board-education>

¹¹⁰ Marriage is the Future, American College of Pediatricians, <https://adflegal.org/issues/marriage/overview> (site visited July 2, 2022). Content on the page includes this statement: "Marriage is about equality and diversity. It's about joining the two equally important and diverse halves of humanity represented in men and women."

¹¹¹ Southern Poverty Law Center, *Dangerous Liaisons*, July 10, 2013, <https://www.splcenter.org/20130709/dangerous-liaisons> [visited July 2, 2022].

¹¹² Like the van Meter and Cantor attachments, the BPW document provides no express statement of conflicts of interest. The BPW document does offer a statement of "credentials and expertise," in which she declares that "her research interests are not in this area," meaning apparently research on medical care for gender dysphoria. BPW Document, p. 1.

¹¹³ BPW document, p. 1. For one example of the purported research that Brignardello-Petersen apparently assisted in, see Alison Clayton et al., *Commentary: the Signal and the Noise – Questioning the Benefits of Puberty Blockers for Youth with Gender Dysphoria – A Commentary on Rew et al.* (2021), *Child and Adolescent Mental Health*, Dec. 22, 2021, at <https://acamh.onlinelibrary.wiley.com/doi/10.1111/camh.12533>. In the "Acknowledgements" section, the authors state, "We would also like to thank the Society for Evidence-based Gender Medicine (SEGM) for providing access to several experts who helped shape this commentary and ensure its accuracy. Specifically, we would like to thank Dr. Romina Brignardello Petersen [sic] for contributing her methodological expertise."

¹¹⁴ Susan Boulware et al., *Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims* (April 28, 2022), at 28-29 (Appendix A) available at <https://medicine.yale.edu/childstudy/policy-and-social-innovation/lgbtq-youth/>.

¹¹⁵ *Kadel v. Folwell*, 1:19CV272, M.D. N.C. June 10, 2022. The judge ruled that Lappert was not qualified to "render opinions about the diagnosis of gender dysphoria, its possible causes, the efficacy of the DSM, the efficacy of puberty blocking medication or hormone treatments, the appropriate standard of informed consent for mental health professionals or endocrinologists, or any opinion on the non-surgical treatments." Lappert was also

that evidence “calls Lappert’s bias and reliability into serious question” and noted that Lappert has worked closely with ADF and has actively lobbied for legal bans on medical care for transgender youth.¹¹⁶ The judge gave no weight to Lappert’s testimony about informed consent in that case, finding that it was unsupported by scientific evidence.¹¹⁷ The judge also found that “Lappert has provided the Court with no data or methodology used to draw his conclusion that surgical treatment for gender dysphoria has “never been generally accepted by the relevant scientific community.”¹¹⁸

B. The linchpin of the June 2 Report is the analysis by Brignardello-Petersen and Wiercioch (the “BPW document”), provided as Attachment C, which purports to be a comprehensive review of the scientific literature on medical treatment for gender dysphoria but, in fact, is extremely narrow in scope and so flawed in its analysis that it merits no scientific weight.

The BPW document, like the other attachments to the June 2 Report, is an unpublished, non-peer-reviewed document. It claims to conduct a systematic review of the relevant scientific literature, but in fact, it is written by inexpert authors who construct an arbitrarily truncated sample and adopt a method that violates scientific guidelines and produces a biased result. The authors describe their findings in deceptive language and jargon predictably mislead the reader. Our review shows that *nothing in the BPW document calls into question the scientific foundations of the WPATH and the Endocrine Society clinical practice guidelines.*

The BPW document seems scientific on its face, and it may be impressive to non-experts, because it uses technical jargon and includes numerous tables and charts. But a closer examination shows that it violates established standards for medical research and shows signs of being engineered to produce a pre-ordained and inaccurate result: the false claim that there is no scientific evidence base for medical treatment for gender dysphoria. Contrary to the authors’ claims, there is a large body of reliable scientific literature that supports standard medical treatment for gender dysphoria and spans decades.

The bottom line is that, contrary to the BPW document’s claims, there is a large body of reliable scientific literature that supports standard medical treatment for gender dysphoria.

(1) The BPW document lacks scientific credibility due to the authors’ lack of relevant qualifications and their ties to an activist group.

The BPW document purports to be a systematic review of the scientific literature on medical treatment for gender dysphoria. But the document, like the other attachments to the June 2 Report, is not published or peer-reviewed, and its design and execution raise numerous red flags for bias. Here, we describe just four of the notable defects that undercut entirely the document’s claim to objectivity and sound method.

disqualified from opining on “the efficacy of randomized clinical trials, cohort studies, or other longitudinal, epidemiological, or statistical studies of gender dysphoria.” Id.

¹¹⁶ Id.

¹¹⁷ Id., pp. 29-30.

¹¹⁸ Id., p. 31.

First, neither of the BPW authors are experts in medical care for gender dysphoria, either as researchers or clinicians. One author (Brignardello-Petersen) has not previously studied the subject, except in her work for the ideological organization SEGM.org, noted just above. Her only clinical experience appears to be in dentistry.¹¹⁹ The other author (Wiercioch) is a junior researcher (a postdoctoral fellow) with no prior research or clinical experience in this field.¹²⁰

The authors' lack of interest and experience renders the BPW work inexpert rather than objective, and it violates the National Academy of Medicine (formerly, Institute of Medicine) standards for systematic reviews.¹²¹ By analogy, one would not rely on, say, two dermatologists to conduct a review of the scientific literature on neurosurgery and to make recommendations for clinical practice.

Second, not only is the study not formally peer-reviewed, the BPW authors violate scientific norms and standards by *failing to engage at all with their peers or with actual experts in the subject matter*. As experts in research methodology should know, any sound systematic review should propose explicit and reproducible methods to methodically summarize the existing literature; the protocol (i.e., the research design) is then published to solicit input and criticisms from potential users of the review and experts in the field.¹²² Peer review of the literature review and publication of the protocol are not optional or merely window-dressing; they reflect bedrock commitments of the scientific method. These processes help ensure that the authors of any review understand the existing research and craft a research design that will usefully build on and add to prior work.

The BPW document violates these standards, raising questions about whether this was a rushed study designed to serve a political agenda – rather than a considered, comprehensive, scientific enterprise. The BPW document does not contain a review of the existing literature, and it does not acknowledge the WPATH and Endocrine clinical practice guidelines, which are themselves based on careful systematic reviews. The BPW authors appear not to have published their protocol in advance or otherwise to have submitted their protocol for peer review. That is, there is no indication that they vetted their research design in consultation with subject-matter experts.

¹¹⁹ Romina Brignardello bio, at <https://experts.mcmaster.ca/display/brignarr> [visited July 2, 2022]

¹²⁰ Google Scholar, Wojtek Wiercioch, visited June 22, 2022, https://scholar.google.com/citations?user=vdi3r_AAAAAJ&hl=en

¹²¹ 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). Background: The Institute of Medicine, now called the National Academy of Medicine, is one of three branches of the National Academies of Science, Engineering, and Medicine. The National Academy of Science dates to 1963 and was established by Congress; the Institute of Medicine was established as a separate entity in 1970 and serves as the nation's leading authority on scientific research and knowledge. National Academy of Medicine, About the National Academy of Medicine, website visited June 22, 2022, <https://nam.edu/about-the-nam/> The standards for systematic reviews were published in 2011, responding to a Congressional request to set benchmarks for high-quality systematic reviews that could reliably guide physicians and health-care providers in making informed, scientific judgments about health care.

¹²² Committee on Standards for Systematic Reviews of Comparative Effectiveness Research, Institute of Medicine, *supra* note 34, at pp. 72-75.

Third, the BPW document raises red flags for opinion bias. Buried in the methodology pages of the BPW document is the fact that the authors uncritically include politically biased “grey literature” sources, giving them equal weight to peer-reviewed, published literature. Specifically, the authors include in their search the fringe website SEGM.org.¹²³ As noted above, the group’s website posts are not peer-reviewed or published, and its content is assembled by a small group of activists with few or no expert credentials and is often full of errors.¹²⁴ Troublingly, this is the group to which one of the authors, Brignardello-Petersen, has ties, as noted above.

(2) The BPW document examines a truncated sample of the literature and adopts a methodology that violates scientific standards for evaluating medical evidence. The authors compound this bias by describing their results using overstated and deceptive language. The picture that emerges is of a rushed and inexperienced report with indications of bias.

The BPW document has a patina of scientific expertise. It invokes the respected GRADE standards for rating the quality of studies, and it occupies many pages with tables and technical specifications. When a reader looks past the jargon, however, the BPW authors adopt a method that actually violates GRADE standards and appears to be jury-rigged to reach a foregone conclusion. The authors then convey their conclusions in misleading language. *Contrary to the BPW authors’ claims, their study does not call into question the scientific and clinical importance of the established science that supports medical care for gender dysphoria.*

The BPW analysis incorporates numerous decisions that bias their results, and they make numerous misleading statements. First, the BPW document reviewed only a small sample of the relevant scientific literature. In the introduction, the BPW authors initially claim to have reviewed 61 systematic reviews of medical treatment for gender dysphoria.¹²⁵ But buried in the middle of the document is the admission that the analysis is based on a sample of 27 systematic reviews, not 61 as claimed.¹²⁶ The result is that the BPW analysis excludes a great deal of relevant evidence, and the authors provide no rationale for this “prioritization,” as they call it. Troublingly, although the BPW document claims to be conducting a review of the literature that analyzes existing systematic reviews, the 27 studies they analyze are not all systematic reviews. Three of the 27 are mislabeled as systematic reviews but are actually practice bulletins, unpublished protocols or unlocatable.

Troublingly, the authors also embed in the middle of their document an *unjustified decision to limit their analysis to studies published from 2020 to the present, and their project has strong indications that it was rushed work.* The authors disclose that they “prioritized” studies from the last 30 months (two full years plus four months in 2022), but they do not defend that priority.

¹²³ BPW document, Methods section, p. 2.

¹²⁴ See Boulware et al., supra note 27 pp. 28-29 (Appendix A).

¹²⁵ BPW document, Introduction Section, p. 2.

¹²⁶ BPW document, Results Section, p. 1.

The reader is left to wonder whether this truncation served only to help the authors produce their analysis in what was apparently a very short time frame.¹²⁷

The truncation of the literature sample to the period from 2020 to early 2022 is worrisome because that period coincides with the worst global public health emergency in generations. The pandemic disrupted many institutions, straining the health care system and putting immense pressure on clinicians. It is likely that the pandemic stalled the production and publication of non-COVID research during this period, calling into sharp question the BPW authors' sampling strategy.

The BPW sample is also questionable because the authors choose, without justification, a small subsection of databases to search and have likely missed important literature as a result. Specifically, they chose not to source from other important databases such as Embase, PsycInfo, Web of Science, Scopus, or Cochrane. They also limited their scope to works published in English only, an exclusion that can introduce bias.

Second, the BPW authors misused and mechanically applied a well-regarded rating system known as AMSTAR, which is intended to evaluate the methodological strength of systematic reviews. They misused this rating system because their so-called group of systematic reviews included documents that cannot correctly be included (practice bulletins, unpublished protocols, and unlocatable documents) and thus led to a negative bias. The BPW error is further amplified because the authors used the flawed results of the AMSTAR phase to inform their next level of analysis, the GRADE system (which assesses the quality of medical evidence of pooled systematic reviews). Based on this flawed and purely mechanical review of truncated sources, the BPW analysis reaches the conclusion that there is little or no evidence for the benefits of medical care for gender dysphoria.¹²⁸

The BPW analysis is highly deceptive, because it dismisses nearly all existing studies of medical treatment for gender dysphoria as "low quality," without explaining that this is a highly technical term and not a natural-language condemnation of the studies. By contrast, the GRADE system, which the authors purport to use, is quite clear about its quality rating systems and its limitations.¹²⁹ In general, only randomized controlled trials (RCTs) are coded as "high" quality evidence in the GRADE system. A randomized controlled trial is a study that divides patients randomly into a control group (no treatment) and a treatment group. In contrast, an observational study records information about patients in a real-world setting that is more reliably generalizable, e.g., a cohort of patients seen at a clinic. Under the GRADE guidelines, observational studies are coded as "low" in quality.

¹²⁷ The authors disclose that they conducted their initial literature searches – the first step in the review process – at the end of April 2022. BPW document, Methods section, p. 2.

¹²⁸ For example, the BPW document states that there is *no evidence* about the effect of puberty blockers compared to not using puberty blockers. In other words, no studies compared the outcomes between a group of people with gender dysphoria using puberty blockers and another group of people with gender dysphoria not using them. Therefore, it is unknown whether people with gender dysphoria who use puberty blockers experience more improvement in gender dysphoria, depression, anxiety, and quality of life than those with gender dysphoria who do not use them. BPW document, Results section, p. 4.

¹²⁹ See Howard Balshem et al., GRADE Guideline: 3. Rating the Quality, 64 J. Clinical Epidemiology P401-406 (2011), Table 3, p. 404

The key point is that “low quality” in this context is a technical term and not a condemnation of the evidence, because “low quality” studies regularly guide important aspects of clinical practice. Indeed, the GRADE system, which the BPW document claims to use, specifically notes that GRADE should *not* be used to dismiss observational studies or to give absolute priority to RCTs:

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.*¹³⁰

The methodology adopted by the BPW document will thus, predictably, conclude that any body of scientific literature that does not contain RCTs is “low” in quality. Had BPW begun, as they should have, with a literature review of the evidence on puberty blockers and hormones, they would have seen that the evidence consists primarily of observational studies (for the good reasons discussed below). Thus, the 30 pages that it takes the authors to lay out their methodology is misleading: a knowledgeable reader would know that if there are few or no RCTs in the literature, then the BPW technical conclusion is foregone and, as importantly, is not a sound guide for clinical recommendations.

Put in simpler terms, if we coded apples as “high quality fruit” and bananas as “low quality fruit,” then any fruit bowl that has only bananas would predictably be technically coded as “low quality.” But that technical conclusion conveys very little information without context. For example, if no apples exist, then bananas may be a nutritious choice.

The drafters of the GRADE system emphasize that technically “low quality” evidence can support a strong clinical treatment recommendation. For example, pediatricians now agree that children should not be given aspirin for fevers. This recommendation is based on observational studies that showed an association between aspirin treatment during viral illnesses and the development of Reyes syndrome (a rapid and progressive disease of neurological dysfunction that can be fatal). Based on those studies, it would be unethical to conduct an RCT giving some children aspirin, and so the strong, consensus treatment recommendation is based entirely on “low quality” studies.¹³¹

The critical fact is that RCTs are not, and cannot be, the gold standard for medical research on gender dysphoria. In the context of treatments for gender dysphoria, randomized controlled trials would often be inappropriate for ethical reasons. Medical care has long been shown, by reliable scientific methods, to address gender dysphoria and improve mental health: as we have repeatedly noted, these treatments have been recommended by rigorous clinical practice guidelines issued by WPATH and the Endocrine Society and endorsed by every major medical organization. Given this medical consensus, which is based on solid scientific evidence, it would be unethical to conduct an RCT that involved denying standard medical care to a control group of individuals.

¹³⁰ Balshem et al., *supra* note 42, at 402 (emphasis added).

¹³¹ *Id.*

Similar ethical issues, along with practical barriers, leave many areas of consensus medicine supported by observational studies and not RCTs. Many surgical procedures, for example, are not supported by RCTs.¹³² Nor are standard protocols for lowering cholesterol using statins, one of the most widely-prescribed drugs in the United States. (See Section III.A of this report.)

It is thus simply a mistake – and a mischaracterization of medical research across fields of medicine – 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.¹³³

In sharp contrast to BPW, this is precisely what the authors of the Endocrine Society did in their 2017 clinical guidelines, which use the GRADE system but, in addition, carefully discuss the characteristics of the studies supporting each treatment guideline.¹³⁴ The Endocrine Society discloses the GRADE rankings for each treatment recommendation in order to be transparent about the evidence base for each of its recommendations. Then, following National Academy of Medicine (formerly, Institute of Medicine) standards for clinical practice guidelines, they proceed to a qualitative review of the evidence, place the evidence in clinical context, and discuss openly the values at stake in making a clinical practice recommendation.¹³⁵

III. The June 2 Report reflects a faulty understanding of statistics, medical regulation, and scientific research, and it repeats discredited claims and engages in speculation and stereotyping without scientific evidence.

The June 2 Report is full of errors and misstatements. Disregarding solid scientific evidence, the report relies on debunked studies and sheer speculation, and it levels criticisms at solid evidence that betray a poor understanding of medical research and statistics.

A. The June 2 Report repeatedly and erroneously dismisses solid studies as “low quality.” If Florida’s Medicaid program applied the June 2 Report’s approach to all medical procedures equally, it would have to deny coverage for widely-used medications like statins (cholesterol-lowering drugs taken by millions of older Americans) and common medical procedures like mammograms and routine surgeries.

¹³² See, e.g., Peter McCulloch, et al., Randomised Trials in Surgery: Problems and Possible Solutions, 324 (7351) BMJ 1448-1451 (2002).

¹³³ 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.”)

¹³⁴ Endocrine Society (2017), supra note 5.

¹³⁵ Id.

In its opening words, the June 2 Report makes an error that is repeated throughout the document: “Studies presenting the benefits to mental health, including those claiming that the services prevent suicide, are either low or very low quality and rely on unreliable methods such as surveys and retrospective analyses, both of which are cross-sectional and highly biased.”

As we document in Section II.B., above, it is an outright mistake to conclude that a study in the technical category of “low quality” is unreliable or poor evidence for clinical practice.¹³⁶ Thus, it is frank error for the June 2 Report to dismiss well-done, scientifically important studies because they rank as “low quality” using specialized, technical terms.

Like the BPW document, the June 2 Report thus relies on a deceptive use of technical terminology that is at odds with the standards used in medical research. It simply is not – and cannot be – the case that all clinical recommendations must be based on RCTs. Many areas of medicine do not lend themselves to ethical and practical RCTs. It is unethical to conduct an RCT when randomizing a patient to a control group would cause harm by denying treatments of known efficacy. For example, it would be unethical to conduct an RCT on the treatment of juvenile diabetes by randomizing some participants to receive insulin and others to receive no treatment.¹³⁷

It is quite common for the medical community to adopt important, consensus clinical practices supported by observational studies alone. For example, observational studies, notably the famous Framingham Heart Study, provided the framework for clinical practice guidelines in prevention and treatment of cardiovascular disease. In 2013, the American College of Cardiology and the American Heart Association issued updated clinical practice guidelines on the treatment of cholesterol to reduce heart disease risk in adults (the “Cholesterol Guidelines”).¹³⁸ These authoritative guidelines have been widely used in clinical practice but are based not only on RCTs but on a great deal of observational evidence, including studies technically ranked as “low quality.”¹³⁹ Concretely, many of the original treatment recommendations regarding statins are based on observational studies, not RCTs.¹⁴⁰ The authors of the Cholesterol Guidelines, very much like the Endocrine Society authors, are quite careful to grade their evidence. But they do not rest their treatment guidelines on a mechanical assessment of technical quality. Instead, they (like the Endocrine Society) carefully explain why particular bodies of evidence should be given weight in clinical decisionmaking.

The cholesterol example shows that the June 2 Report rests on a fundamental misunderstanding of medical research and clinical practice. If the Florida Medicaid program actually adopted the standard of evidence urged by the June 2 report, the program would not cover statins (drugs to

¹³⁶ Balshem et al., *supra* note 42, at 404 (“Well-conducted studies may be part of a body of evidence rated low quality because they only provide indirect or imprecise evidence for the question of interest.”)

¹³⁷ RCTs have other limitations as well. For example, RCTs often have strict exclusionary criteria that recruit healthier and more homogenous study populations than observational studies. Thus, this can lead to results that are not easily generalizable in real-world settings.

¹³⁸ Neil J. Stone, et al., 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults, 129(25) *Circulation* S1-S45 (2014).

¹³⁹ *Id.*, Tables 3 and 4.

¹⁴⁰ Syed S. Mahmood, et al., The Framingham Heart Study and the Epidemiology of Cardiovascular Disease: a Historical Perspective, 383 *Lancet* 999-1008 (2014).

lower cholesterol) for many patients, which are prescribed to 28% of adults over the age of 40 and are one of the most effective ways to prevent cardiovascular death.¹⁴¹ Other common practices that would have to be reconsidered under this logic include: post-menopausal hormone replacement therapy (which reduces lifetime risk of heart attacks and stroke) and mammography screening for breast cancer.

The same point is true of the technically “low quality” evidence base for many surgical procedures, including minimally invasive gall bladder surgery, which have long since had a foundational grounding in observational studies. We think it unlikely that Florida’s Medicaid program will begin to refuse to pay for statins, mammograms, and routine surgeries. If not, then the June 2 Report reflects an untenable and discriminatory double standard.

Thus, the June 2 Report not only relies on the biased and methodologically flawed evidence in the BPW document, as documented in Section II above; it also misuses scientific terminology in an effort to mislead readers and to support the unwarranted conclusion that medical treatment for gender dysphoria is “experimental.”

B. The June 2 Report disregards robust clinical research studies and instead relies on letters to the editor and opinion pieces. The report’s analysis fails to satisfy Florida’s own regulatory standards for Medicaid coverage decisions and does not undermine the scientific research that supports medical treatment for gender dysphoria.

The June 2 Report repeatedly cites sources with little or no scientific credibility – including journalism, a student blog, a website, and letters to the editor – rather than peer-reviewed empirical research.¹⁴² At the same time, the report makes baseless or exaggerated criticisms of solid studies. The report’s objections to these studies incorporate mistakes about basic statistics and often misrepresent the aims and findings of studies. Here, we offer several examples, but the problem of selective and ungrounded criticism permeates the June 2 Report and further undermines its scientific credibility.

¹⁴¹ Joseph A. Salami et al., National Trends in Statin Use and Expenditures in the U.S. Adult Population From 2002 to 2013, 2(1) JAMA Cardiology 56-65 (2017).

¹⁴² Sources from journalism include Jon Brown, Medical Textbook Strips Gender Dysphoria Definition after Being Cited by Florida, Fox News, May 8, 2022, at 8 <https://www.foxnews.com/politics/textbook-strips-gender-dysphoria-definition-cited-florida> [visited July 3, 2022]; Lawrence S. Mayer and Paul McHugh, Sexuality and Gender: Finding from the Biological, Psychological, and Social Science, The New Atlantis (Fall 2016), https://www.thenewatlantis.com/wp-content/uploads/legacy-pdfs/20160819_TNA50SexualityandGender.pdf [visited July 3, 2022]. The citation to the student blog is Hong Phuong Nhi Le, Eminence-Based Medicine vs. Evidence-Based Medicine, Students 4 Best Evidence [blog], <https://s4be.cochrane.org/blog/2016/01/12/eminence-based-medicine-vs-evidence-based-medicine/#:~:text=What%20is%20eminence-based%20medicine> [visited July 3, 2022]. The website is SEGM.org, which we discuss in the text in Section II.B and Section III.A. Citations to letters and opinion pieces include, inter alia, Andre van Mol, et al., Gender-Affirmation Surgery Conclusion Lacks Evidence, 177(8) Am. J. Psychiatry 765-766 (2020); Michael Laidlaw, et al., The Right to Best Care for Children Does Not Include the Right to Medical Transition, 19(2) Am. J. Bioethics 75-77 (2019); Michael Laidlaw, et al., Letter to the Editor: “Endocrine Treatment of Dysphoric/Gender Incongruent Persons: An Endocrine Society Clinical Practice Guideline,” 104(3) J. Clinical Endocrinology and Metabolism 686-687 (2018); Andre van Mol, et al., Gender-Affirmation Surgery Conclusion Lacks Evidence, 177(8) Am. J. Psychiatry 765-766 (2020).

For example, the June 2 report attacks a 2015 study by Costa et al., claiming that the study design is flawed because it did not include a control group of adolescents without gender dysphoria.¹⁴³ This point is simply incorrect. The Costa study was designed to measure the impact of puberty blockers on gender dysphoria. To do so, the authors validly compared outcomes in teens with dysphoria who received treatment with blockers and those who did not. They were able to do this ethically because the control group of teens (who received psychotherapy but not puberty blockers) were not yet eligible for blockers or were eligible but chose to delay or forgo blockers. The study found that puberty suppression was associated with improvements in psychosocial functioning.

The Costa study is, despite the June 2 Report's claims, a solid methodology. In the context of this study, adding a third "control group" of teens without gender dysphoria would serve no scientific purpose. Further, the June 2 Report also criticizes Costa for "rel[ying] heavily on self-assessments."¹⁴⁴ But this is a wildly off-base criticism. Costa et al. measure psychosocial functioning using a widely-used and accepted instrument, the Children's Global Assessment Scale. Psychological research typically relies on such assessments, which are carefully constructed and psychometrically validated. This is one example of the June 2 Report's poor understanding of research in psychology and medicine.

In addition to these glaring errors, the June 2 Report's criticism of Costa makes an even more fundamental error: the June 2 report levels baseless criticisms at a single study *and fails to acknowledge that the weight of the literature as a whole strongly supports the same results that Costa et al. report*. Scientific knowledge is, importantly, cumulative. It is thus entirely misleading – and unscientific – to dismiss the effectiveness of puberty blockers by criticizing studies in isolation. Put simply, the June 2 Report fails to acknowledge the number of solid studies that all find that puberty blockers are effective.¹⁴⁵ 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.¹⁴⁶

To take another example, the June 2 Report grossly misleads the reader in its discussion of a study by Chen et al. in 2020.¹⁴⁷ The report cherry-picks quotes from Chen et al. to the effect

¹⁴³ June 2 Report, p. 15 ("Costa et al did not create a third group that lacked a gender dysphoria diagnosis to serve as a control"). The Costa study is Rosalia Costa et al., Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria, 12 (11) J. Sexual Medicine P2206-2214 (2015) (hereinafter, "Costa et al. (2015)").

¹⁴⁴ Id.

¹⁴⁵ See Luke R. Allen, et al., Well-Being and Suicidality Among Transgender Youth after Gender-Affirming Hormones, 7(3) Clinical Practice in Pediatric Psychology 302-11 (2019); Amy E. Green, et al., Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth, 70(4) J. Adolescent Health 643-649 (2022); Jack L. Turban, et al., Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145(2) Pediatrics e20191725 (2020); Maureen D. Connolly, et al., The Mental Health of Transgender Youth: Advances in Understanding, 59(5) J. Adolescent Health 489-95 (2016); Gemma L. Witcomb et al., Levels of Depression in Transgender People and its Predictors: Results of a Large Matched Control Study with Transgender People Accessing Clinical Services, J. Affective Disorders (2018).

¹⁴⁶ For citations, see Boulware et al., supra note 27, at n. 43.

¹⁴⁷ Diane Chen, et al., Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Puberty Suppression in Transgender Youth, Transgender Health 246-257 (2020).

that "the effects of pubertal suppression warrant further study" and the "full consequences of suppressing endogenous puberty are not yet understood."¹⁴⁸

These criticisms are misapplied, because the Chen article is not a substantive study of the effects of puberty blockers. It is, instead, a consensus parameter, which is an article that uses a structured methodology to consult experts to develop a research agenda for future studies. It is expected that the Chen piece would focus on what is not yet known, or what is not completely known, because it is attempting to identify research topics and approaches. Notably, and contrary to the June 2 Report's claims, Chen et al. recognize that existing evidence suggests that puberty blockers improve mental health functioning.

More generally, the June 2 Report's misleading characterization of Chen et al. reflects a basic lack of knowledge about scientific research. All research is flawed, including all RCTs: there simply is no perfect study in any area of medicine. The task of the scientist is to be rigorous in assessing what we know and to work to improve knowledge, incrementally, by conducting additional studies that build on earlier work. Thus, it is commonplace for authors to conclude medical research studies by calling for further research. Chen et al.'s statements are not indictments of puberty blockers – they are conventional acknowledgments of the value of further study that drives scientific inquiry and innovation.

The June 2 Report also contains a misleading account of the study by DeSanctis et al. The DeSanctis article reviews the literature on the use of puberty blockers (GnRHa's) for children diagnosed with central precocious puberty. De Sanctis finds that blockers are generally "safe and well-tolerated in children and adolescents" and that most drug reactions were mild.¹⁴⁹ The June 2 Report misleadingly and without foundation cites the De Sanctis piece as "[raising] questions about whether off-label use to treat a psychological condition [gender dysphoria] is worth the risks."¹⁵⁰ This attribution is bizarre, because De Sanctis et al. actually *support* the use of puberty blockers (by finding them safe and with only rare side effects) and do not offer any evidence at all to suggest that the risks are higher in the treatment of gender dysphoria.

As a final example, the June 2 Report criticizes a 2019 preliminary study by Kuper et al. without acknowledging the existence of a 2020 study by Kuper et al.¹⁵¹ The earlier study presented data on the mental health of adolescents when initially presenting for care; only the later study presented full data that demonstrated the benefit of treatment.

C. The June 2 Report mistakenly claims that puberty blockers and hormones are experimental because they are used "off-label" and not approved by the FDA. In fact,

¹⁴⁸ June 2 Report, p. 15.

¹⁴⁹ Vincenzo De Sanctis, et al., Long-Term Effects and Significant Adverse Drug Reactions (ADRs) Associated with the Use of Gonadotropin-Releasing Hormone Analogs (GnRHa) for Central Precocious Puberty: a Brief Review of Literature, 90(3) Acta Biomed. 345-359 (2019).

¹⁵⁰ June 2 Report, p. 16.

¹⁵¹ June 2 Report, p. 16. The earlier Kuper et al. study is Laura E. Kuper et al., Baseline Mental Health and Psychosocial Functioning of Transgender Adolescents Seeking Gender-Affirming Hormone Therapy, 40(8) J. Dev. Behav. Pediatr. 589-596 (2019). The later study is Laura E. Kuper et al., Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy, 145(4) Pediatrics e20193006 (2020).

off-label use, when supported by scientific evidence, as is the case here, is extremely common in medical practice and especially in pediatrics.

The June 2 Report repeatedly notes that the FDA has not approved the use of puberty blockers and hormones for the treatment of gender dysphoria in minors.¹⁵² The report infers that lack of FDA approval renders a treatment unauthorized and experimental, but this is false.

Once again, the June 2 Report is (mis)using technical language in a way that is likely confusing to non-experts. The term “off-label” has a very specific meaning: a drug is off-label if the FDA has not specifically approved a particular medication for a particular use in a specific population. The off-label use of medications for children is quite common and often necessary, because an “overwhelming number of drugs” have no FDA-approved instructions for use in pediatric patients.¹⁵³

The lack of FDA approval does not imply that the use of medications should be restricted. There is a consensus in the medical community that off-label use reflects a product of burdensome and expensive regulatory processes. Pharmaceutical companies often lack financial incentives to support research required for FDA approval for specific use in children.¹⁵⁴

The American Academy of Pediatrics, recognizing these facts, specifically authorizes the off-label use of drugs:

The purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, *the term “off-label” does not imply an improper, illegal, contraindicated, or investigational use.* Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient.¹⁵⁵

Off-label use is so common in pediatrics that off-label drugs are prescribed in 20% of patient visits.¹⁵⁶ Combined hormonal contraceptives or progesterone-only contraceptive methods, which are approved on-label for contraception, are also used off-label to treat heavy menstrual bleeding, which could be due to a bleeding disorder, a delay in normal pubertal maturity or variety of other conditions; they are also used off-label for premenstrual dysphoria disorder and polycystic ovarian syndrome.

¹⁵² June 2 Report, pp. 8, 14, 15, 19.

¹⁵³ Boulware et al, supra note 27, quoting Kathleen A. Neville, et al., American Academy of Pediatrics Committee on Drugs, Off-label use of drugs in children, 133(3) Pediatrics 563-7 (2014) (“AAP Committee on Drugs”).

¹⁵⁴ AAP Committee on Drugs (2014), supra note 66.

¹⁵⁵ Id. (emphasis added). See also Lenneke Schrier, et al., Off-label Use of Medicines in Neonates, Infants, Children, and Adolescents: a Joint Policy Statement by the European Academy of Paediatrics and the European Society for Developmental Perinatal and Pediatric Pharmacology, 179(5) Eur. J. Pediatr 839-845 (2020).

¹⁵⁶ Diya Hoon, et al., Trends in Off-Label Drug Use in Ambulatory Settings: 2006-2015, 144(4) Pediatrics 1-10 (2019) (emphasis added).

A host of familiar examples provide illustrations of day-to-day, off-label use in pediatrics.¹⁵⁷ The use of steroids for croup is a life-saving treatment that is off-label. The medication helps toddlers get through severe, potentially airway-obstructing illnesses safely. Ondansetron (Zofran) is used off-label for nausea and vomiting to prevent fluid loss, as children are particularly vulnerable to severe dehydration.

Off-label use is also common in pediatric compassionate care, and frequently the on-label use is very different from the off-label use. Gabapentin, for example, is used on-label for the treatment of seizures but used off-label for neuropathic or mixed pain. Ketamine and fentanyl are used on-label in anesthesia but off-label for pain relief, for example, to manage chronic pain in palliative care and in patients with cancer.

In neonatal medicine, off-label medications are routinely used to treat the smallest and most fragile babies. Caffeine is used off-label to treat apnea (i.e., idiopathic respiratory arrest) of prematurity and phenobarbital is used off-label to treat neonatal seizures. More routinely, in general pediatric care, pantoprazole is a proton pump inhibitor (PPI) used to treat acid reflux. It is used off-label in neonates with gastroesophageal reflux disease who do not respond to traditional first-line treatments. It is used successfully to help infants gain adequate weight in the first four to six months of life if they do not respond to using different types of bottles, slow flow nipples, or more frequent and lower volume feedings.

In addiction medicine, routine medications like supplemental nicotine patches are off-label; they are not approved for use in those younger than 18 but are used successfully in vaping/smoking cessation, so much so that the AAP has issued guidelines on how to use and dose them. Bupropion is used on-label as an antidepressant and off-label for smoking cessation. Buprenorphine (suboxone) is used on-label in those 16 or older with opioid use disorder but used off-label in those who are younger; this medication prevents overdose death and allows those struggling with addiction to safely recover.

In psychiatry, some of the most commonly-prescribed medications for youth are off label. For example, selective serotonin reuptake inhibitors (SSRIs) are used to treat major depressive disorder and generalized anxiety in adolescents and have been shown to be effective, even though several of these including sertraline and escitalopram) are off-label.¹⁵⁸ Other common examples include clonidine, which is FDA-approved for attention deficit hyperactivity disorder (ADHD) but is also used off-label for anxiety, insomnia, and post-traumatic stress disorder (PTSD).¹⁵⁹

Finally, the June 2 Report also notes that testosterone is a controlled substance and is subject to risk of abuse, but, once again, this is misleading. The inclusion of testosterone on the schedule of controlled substances reflects the misuse of the drug by some individuals and

¹⁵⁷ These examples are drawn from the list of off-label uses in AAP Committee on Drugs (2014) and reflect our clinical experience in major hospitals and clinics.

¹⁵⁸ For AACAP guidelines, see Boris Birmaher and David Brent, Practice Parameter for the Assessment and treatment of Children and Adolescents with Depressive Disorders, 46(110 J. Am. Acad. Child and Adolescent Psychiatry P1503-1526 (2007).

¹⁵⁹ Rama Yasaei and Abdolreza Saadabadi, Clonidine, National Library of Medicine (2022), at <https://www.ncbi.nlm.nih.gov/books/NBK459124/> [visited July 4, 2022].

communities (e.g., weight lifters and athletes who may use the drug to build muscle). The classification does not in any way imply that physicians should not dispense the drug if medically necessary. No special license is necessary for prescribing the medication, which is routinely prescribed to cisgender men with testosterone deficiency as well as to transgender men.

D. The June 2 Report falsely claims that medical care for gender dysphoria is provided to a large percentage of children who will come to regret their treatment. In fact, patients with gender dysphoria have vanishingly low rates of regret regarding their medical treatment.

The June 2 Report attempts to cast doubt on medical treatment for gender dysphoria by repeating the debunked claim that most transgender teens ultimately reject their transgender identity. Below, we analyze two related claims made in the report and show why both are refuted by sound evidence.

First, the report claims that “the majority of young adolescents who exhibit signs of gender dysphoria eventually desist and conform to their natal sex.”¹⁶⁰ This is false. We have refuted this claim in detail in prior work (addressing similar claims made to support medical treatment bans in Texas and Alabama). The key point is that *adolescents with gender dysphoria rarely find that their dysphoria resolves without treatment*.¹⁶¹ Because medical treatment for gender dysphoria begins only in adolescence, and only if medically necessary for gender dysphoria, medical treatment is thus provided only to a group known to be quite stable in their gender identity.

The authoritative WPATH and Endocrine Society clinical practice guidelines contain measures to ensure that medical treatment is administered only when medically necessary.¹⁶² As part of the process of diagnosis and treatment, clinicians take care to explain to the youth and their parents the risks and the benefits of medical treatment as well as the risks and benefits of no medical interventions.

Second, the June 2 report claims, without citation, that “roughly 8% [of transgender people] decide to return to their natal sex” for reasons ranging “from treatment side effects to more self-exploration that provided insight on individuals' gender dysphoria.”¹⁶³ The 8% figure is not large, but it is nevertheless an overstatement of the percentages found in the scientific literature: solid studies show very low percentages of regret (typically under 1%) among transgender people who receive medical treatment for gender dysphoria.

The June 2 report offers as general evidence for its claims about regret only a 2021 study by Littman.¹⁶⁴ But the Littman study cannot establish how prevalent it is for transgender individuals to reject their transgender identity. Indeed, the Littman study does not even purport

¹⁶⁰ June 2 Report, p. 14.

¹⁶¹ Boulware et al., *supra* note 27, at 17-19.

¹⁶² WPATH (2012) and Endocrine Society (2017), *supra* note 5.

¹⁶³ *Id.*

¹⁶⁴ Lisa Littman, *Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners*, 50 *Archives of Sexual Behavior* 3353-3369 (2021).

to show the percentage of transgender people who “detransition.” Instead, it simply asked 100 people who self-identified as “detransitioners” about their reasons. Using Littman’s study as evidence of widespread regret is akin to saying that giant pandas (an endangered species) are common because, if we search, we can find 100 of them.

Furthermore, the Littman study used a biased sampling and survey methodology: survey was anonymous; its participants were solicited from (among other venues) anti-transgender social media groups.

Finally, the June 2 Report makes a flagrant error in conflating “detransition” with “regret.”¹⁶⁵ In addition, the Littman study is unscientific in describing a likely very diverse group of people as “detransitioners.” She defines detransition as “discontinuing medications, having surgery to reverse the effects of transition, or both.” Littman’s definition is highly misleading, because transgender people may have many reasons to discontinue medication. One might continue to live socially in a gender role that is not the one assigned at birth and yet, by Littman’s criteria, be counted as a “detransitioner.” In our clinical practice, we have seen youth who discontinued hormone therapy because the effects had addressed their dysphoria; these patients were nonbinary, but Littman’s method would mistakenly count them as “detransitioners.”

By contrast, the June 2 report disregards a very large and far more nuanced and important 2021 study by Turban et al., which shows that transgender people who do return to live as the sex assigned at birth may not permanently do so and are, by their own report, influenced largely by “external factors, such as pressure from family, nonaffirming school environments, and sexual assault.”¹⁶⁶ The study found that only a minority of survey participants “reported that detransition was due to internal factors, including psychological reasons, uncertainty about gender identity, and fluctuations in gender identity.” Indeed, as the authors note, these psychological experiences “*did not necessarily reflect regret* regarding past gender affirmation, and were presumably temporary, as all of these respondents subsequently identified as transgender/gender diverse, an eligibility requirement for study participation.”¹⁶⁷

The June 2 Report also ignores a recent study, Olson et al. (2022), who find that after an average of 5 years of social transition, only 2.5% of youth identified as cisgender.¹⁶⁸

Studies that actually focus on regret consistently find that transgender people only rarely regret their medical treatments.¹⁶⁹ For example, Bustos et al. (2021) found regret expressed by one

¹⁶⁵ See generally Jack L. Turban, et al., Factors Leading to “Detransition” Among Transgender and Gender Diverse People in the United States: A Mixed-Methods Analysis, 8(4) *LGBT Health* 273-280 (2021) (noting that “the term ‘detransition’ has at times been conflated with regret, particularly with regard to medical and surgical affirmation”).

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ Kristina R. Olson, et al., Gender Identity Five Years After Social Transition, *Pediatrics* (preprint, May 2022).

¹⁶⁹ Valeria P. Bustos, et al., Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence, 9(3) *Plastic and Reconstructive Surgery - Global Open* e3477 (2021); Sara Danker, et al., Abstract: A Survey Study of Surgeons’ Experience with Regret and/or Reversal of Gender-Confirmation Surgeries, 6(9 Supp.) *Plastic and Reconstructive Surgery* 189 (2018); Chantal M. Wiepjes, et al., The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets, 15(4) *J. Sex Med.* 582-590 (2018); see also Yolanda L.S. Smith, et al., Sex Reassignment: Outcomes and Predictors of Treatment for Adolescent and Adult Transsexuals, 35(1) *Psychological Medicine* 89-199 (2005).

percent or fewer of transgender patients who underwent gender-affirming surgery, and Danker et al. (2018) report a rate of far less than 1%, as do Wiepjes et al. (2015).¹⁷⁰

E. The June 2 Report repeats discredited claims that “social contagion” is leading teens to become transgender. The issue, although sensationalized in the June 2 Report, is ultimately irrelevant to medical treatment, which is provided only after a multidisciplinary assessment and after a finding that gender dysphoria is persistent and medical treatment is warranted.

The June 2 Report claims that “social factors (e.g., peer influences and media) may be contributing factors to gender dysphoria,”¹⁷¹ citing as evidence a single, discredited study by Littman. We have addressed this study at length in other work and note that

WPATH, among other authorities, has taken a skeptical view of Littman’s claim, and the study has been criticized for serious methodological errors, including the use of parent reports instead of clinical data and the recruitment of its sample of parents from anti-transgender websites. The journal of publication required an extensive correction of the original Littman article because of its misstatements. Such a correction in reputable, peer-reviewed academic journals is taken only when a panel of experts, in retrospect, came to recognize the methodological flaws of the original study and concluded that it would be unscientific to allow the originally published findings to stand.”¹⁷²

Littman’s sensationalist hypothesis has been widely covered in the press, but no clinical studies have found that rapid-onset gender dysphoria exists. Further, no professional organization has recognized “rapid-onset gender dysphoria” as a distinct clinical condition or diagnosis.

Most recently, an April 2022 study of 173 youth presenting at Canadian gender clinics *found no evidence of rapid-onset dysphoria or social contagion*. The researchers posited that if “rapid onset” gender dysphoria were a real phenomenon, then teens who had more recently begun identifying as transgender would (per the Littman hypothesis) also be more likely to report online support and engagement in their gender identity. They might also (per Littman’s hypothesis) be more likely to struggle with mental health concerns.

An April 2022 study of 173 youth found no such correlations, strongly undercutting the “rapid-onset” hypothesis endorsed by the June 2 report. The researchers controlled for age and sex assigned at birth and looked for correlations with recent gender knowledge (defined as less than one to two years having passed since “you realized your gender was different from what other people called you”). Recent gender knowledge was *not* significantly associated with depressive symptoms, psychological distress, past diagnoses with mental health issues or neurodevelopmental disorders, or self-harm. Nor was it associated with having gender-supportive online friends, general support from online friends or transgender friends, or gender support from parents.¹⁷³

¹⁷⁰ Id.

¹⁷¹ June 2 Report, p. 12.

¹⁷² Boulware et al., *supra* note 27, at 20-21 (internal citations omitted).

¹⁷³ Greta R. Bauer, et al., 243 J. Pediatrics 224-227 (2022).

Data do substantiate that younger people today are more likely to identify as transgender than are older people, but this does not substantiate the idea of social contagion. The increase may be due to the increasing social acceptance of gender diversity (i.e., older people grew up in a more transphobic social environment). In fact, adolescent presentation of transgender identity is often observed and should not be pathologized. In the largest U.S. sample of transgender adults, over half reported first starting to realize that they were transgender in adolescence (57% ages 11-20) and roughly half (47%) started to disclose their identity during this time frame.¹⁷⁴

Further, the data do not show a massive wave of transgender identity even among teens. A 2022 study by the Williams Institute found that, using an expansive definition of “transgender,” about 0.5% of adults now identify as transgender, while 1.4% of youth aged 13-17 do, or about 300,000 young people.¹⁷⁵ This is not a large percentage or a large absolute number.

Underlying the June 2 Report’s claim about social contagion is a set of imagined stereotypes – that teenagers do not know their own gender identity and readily change their gender identity based on peer influence and social media. But these stereotypes contradict the scientific understanding of gender identity formation. Studies of so-called “conversion” or “reparative” therapy, for example, finds that transgender identity is highly resistant to change even in the face of concerted efforts by medical authorities versed in psychological methods. Studies find that conversion therapy is ineffective in altering gender identity and is psychologically damaging.¹⁷⁶

F. The June 2 Report claims that inappropriate medical care is provided to adolescents with gender dysphoria who also have anxiety, depression, and other mental health conditions. These assertions are unsupported by scientific evidence and disregard evidence-based clinical practice guidelines that provide sound guidance for treating complex cases.

The June 2 Report speculates that because “a high proportion” of youth receiving medical care for gender dysphoria also have a behavioral health disorder, “available research raises questions as to whether the [individuals’] distress is secondary to pre-existing behavioral health disorders and not gender dysphoria.”¹⁷⁷ In simpler terms, *the June 2 Report speculates that perhaps gender dysphoria is not real but is, rather, an imagined by-product of underlying mental illness.* A close examination shows that this claim has no foundation in science; it rests on unexamined and harmful stereotypes and unaccountably dismisses the scientific knowledge and clinical skill of child and adolescent psychologists and psychiatrists.

¹⁷⁴ Sandy E. James, et al., *The Report of the 2015 U.S. Transgender Survey*, National Center for Transgender Equality (2015).

¹⁷⁵ Jody L. Herman, et al., *How Many Adults and Youth Identify as Transgender in the United States?*, U.C.L.A. School of Law, Williams Institute (2022).

¹⁷⁶ A survey of the scientific literature by the U.S. Department of Health and Human Services finds that “none of the existing research supports the premise that mental or behavioral health interventions can alter gender identity or sexual orientation.” Substance Abuse and Mental Health Services Administration, *Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth*, U.S. Department of Health and Human Services, HHS Publication No. (SMA) 15-4928 (2015), p. 1.

¹⁷⁷ June 2 Report, p. 6.

First, the June 2 Report implicitly posits a causal hypothesis that behavioral health disorders cause gender dysphoria. This hypothesis is entirely devoid of scientific evidence. Indeed, the scientific evidence strongly suggests that the direction of causation runs the other way. It is well-established that being transgender leads to mental health concerns because of the social stress and discrimination of being transgender in a society that is strongly oriented to cisgender identity and disapproving of transgender identity.¹⁷⁸ In our society, transgender individuals experience a great deal of discrimination, hostility, and physical violence. Quite simply, it is unsafe to be transgender in this current hostile climate.¹⁷⁹ Accumulation of existential fear and threatening experiences can manifest as physical and mental conditions. Thus, one would expect – and studies confirm – that transgender people, on average, have worse physical and mental health than cisgender people.

Although the effects of gender minority stress are well-known, the June 2 Report makes no mention of the literature. Instead, it indulges in speculation based, apparently, on the stereotyping of transgender people as confused and dysfunctional. The June 2 Report posits that individuals with mental health concerns cannot be trusted to understand their own gender identity. This is a highly prejudicial stance and one that disregards the key role of psychologists and psychiatrists, who have developed sensitive and effective approaches to treating adolescents with gender dysphoria and mental health concerns.¹⁸⁰

Second, the co-occurrence of psychological distress among individuals with gender dysphoria provides no reason for denying care. Any population of individuals – cisgender or transgender – will include some with mental health concerns, and the WPATH and Endocrine Society guidelines recognize that there is a higher prevalence of anxiety, depression and post-traumatic stress disorder among transgender youth than among cisgender youth. In response, the guidelines set out practices that include a careful psychological assessment of each adolescent as part of the process for determining whether medical treatment for gender dysphoria is appropriate and likely to have benefits that outweigh risks.

The Endocrine Society guidelines specifically recommend that mental health professionals should be able to diagnose gender dysphoria and distinguish it from other “conditions that have similar features (*e.g.*, body dysmorphic disorder).” In addition, the mental health provider should be prepared to diagnose psychiatric conditions, provide or refer for treatment, and to “psychosocially assess the person’s understanding, mental health, and social conditions that can

¹⁷⁸ Rylan J. Testa, et al., Development of the Gender Minority Stress and Resilience Measure, 2(1) *Psychology of Sexual Orientation and Gender Diversity* 65-77 (2015); Rylan J. Testa, et al., Suicidal Ideation in Transgender People: Gender Minority Stress and Interpersonal Theory Factors, 126(1) *J. Abnormal Psychology* 125-36 (2017); Alexandrai M. Delozier, et al., Health Disparities in Transgender and Gender Expansive Adolescents: A Topical Review from a Minority Stress Framework, 45(8) *J. Pediatric Psychology* 842-847 (2020); Jessica Hunter, et al., Gender Minority Stress in Trans and Gender Diverse Adolescents and Young People, 26(4) *Clinical Child Psychology and Psychiatry* 1182-1195 (2021).

¹⁷⁹ See, e.g., Rebecca L. Stotzer, Violence Against Transgender People: A Review of United States Data, 14(3) *Aggression and Violent Behavior* 170-179 (2009).

¹⁸⁰ See John F. Strang, et al., Initial Clinical Guidelines for Co-Occurring Autism Spectrum Disorder and Gender Dysphoria or Incongruence in Adolescents, 47(1) *J. Clinical Child & Adolescent Psychology* 105-115 (2016).

impact gender-affirming hormone therapy.”¹⁸¹ In our clinical practice, we also ensure that youth and their caregivers have the information and support necessary to fully understand the risks, benefits, and outcomes of treatment. That is, we not only provide assessment but also fill in any gaps in understanding and support the decision-making process.

Our experience in clinical practice reflects these guidelines. Any consultation for medical treatment for gender dysphoria includes a mental health assessment. Further, the treatment plan for each adolescent is then individualized to reflect the risks and benefits of treatment and the risks and benefits of no treatment. Consistent with the WPATH guidelines, as clinicians, we ensure that the mental health concerns are not interfering with our ability to assess gender dysphoria and youth assent to treatment.

Third, the June 2 Report implicitly claims that any mental health disorder impairs a minor’s ability to provide informed assent and, somehow, also invalidates the informed consent of their guardian. Experts in child and adolescent psychiatry, child psychology, and adolescent medicine have established that youth can make complex medical decisions. Further, the literature specifically demonstrates that transgender youth with co-occurring mental health conditions can competently participate in decision-making.¹⁸² With guidance from mental health providers, parents, and physicians, teens can be part of a decision process that helps them explore their identity and make nuanced decisions about the benefits and risks of medical treatment.¹⁸³ Indeed, these processes of exploration and decision-making are central goals of, and central tasks for, trained mental health providers who work with teens.

G. The June 2 Report speculates, without evidence, that psychotherapy alone is as effective as medical treatment for gender dysphoria. This claim contradicts the findings of solid scientific studies, which show that medical care is more effective than psychotherapy alone.

The June 2 Report argues, without scientific evidence, that youth with gender dysphoria should not be offered medical treatment but instead should only receive psychotherapy, an approach that it mistakenly terms “watchful waiting.”¹⁸⁴

¹⁸¹ Endocrine Society (2017), supra note 5.

¹⁸² Lieke J. Vrouenraets, et al., Assessing Medical Decision-Making Competence in Transgender Youth, 148(6) Pediatrics e2020049643 (2021).

¹⁸³ Beth A. Clark and Alice Virani, “This wasn’t a Split-Second Decision”: An Empirical Ethical Analysis of Transgender Youth Capacity, Rights, and Authority to Consent to Hormone Therapy, 18 J. Bioethical Inquiry 151-164(2021); Vrouenrats, et al., supra note 95; Megan S. O'Brien, Critical Issues for Psychiatric Medication Shared Decision Making with Youth and Families, 92(3) Families in Society 310-316 (2011); Mary Ann McCabe, Involving Children and Adolescents in Medical Decision Making: Developmental and Clinical Considerations 21(4) J. Pediatric Psychology 505-516 (1996).

¹⁸⁴ For example, at p. 12, the June 2 Report asks, “[S]hould conventional behavioral health services be utilized without proposing treatments that pose irreversible effects [i.e., drug therapies]? Would that approach not provide additional time to address underlying issues before introducing therapies that pose permanent effects {i.e., the watchful waiting approach}?” At p. 20, the June 2 Report misuses the term “watchful waiting” to describe the denial of medical care to adolescents with gender dysphoria, and the report miscites its own purported expert report. The Cantor document discusses “watchful waiting” meaning the denial of social transition to prepubertal children, not the denial of medical treatment to adolescents. Cantor document, p. 10-11.

The report offers no actual evidence for this denial of standard medical care. Its recommendation rests, instead, on an unfounded and mistaken criticism of the existing literature. The Cantor document, attached to the AHCA report as Appendix C, states that several studies “successfully identified evidence of [mental health] improvement [due to medical treatment for gender dysphoria], *but because patients received psychotherapy along with medical services, which of those treatments caused the improvement is unknowable.*”¹⁸⁵

This statement is false. Medical treatment for gender dysphoria has been shown to lead to positive effects on mental health that are not associated with psychotherapy alone. Costa et al. in 2015 found that puberty blockers improve psychosocial functioning in teens with gender dysphoria, compared to teens who receive psychotherapy but not blockers.¹⁸⁶ Costa’s study was designed to include a control group of teens with gender dysphoria who did not receive blockers.

In a 2022 study, Tordoff et al find that puberty blockers and hormone therapy are associated with significant improvements in depression and suicidality in a population of transgender and nonbinary youths aged 13 to 20.¹⁸⁷ The authors showed the independent effects of medications such as puberty blockers and hormones on depression, anxiety, and gender dysphoria. They controlled for temporal trends and other confounding factors, expressly including whether the teen received “ongoing mental health therapy other than for the purpose of a mental health assessment to receive a gender dysphoria diagnosis.”¹⁸⁸ Put simply, Tordoff et al. clearly found that youth with gender dysphoria reported better outcomes if they received puberty blockers, even after controlling for the effects of psychotherapy.

Similarly, in a 2020 study, Laura Kuper et al. found that gender-affirming hormone therapy made a large improvement in adolescents’ body-related distress and led to small to moderate improvement in symptoms of depression and anxiety.¹⁸⁹ Kuper et al. specifically collected data on psychotherapy and the use of psychiatric medications and expressly controlled for both. Thus, Kuper et al.’s study shows that hormone treatment for gender dysphoria is effective above and beyond the benefits of psychotherapy and psychiatric medications.

¹⁸⁵ Cantor document, p. 13.

¹⁸⁶ Costa et al., *supra* note 56.

¹⁸⁷ Diana M. Tordoff et al., Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care, 5(2) JAMA Network Open e220978 (2022).

¹⁸⁸ *Id.*

¹⁸⁹ Laura E. Kuper, et al., Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy, 145(4) Pediatrics e20193006 (2020).