THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

DECLARATION OF ATTORNEY JENNIFER ALTMAN IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, Jennifer Altman, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am over the age of eighteen and make this declaration from my own personal knowledge. If called as a witness, I could and would testify competently to the matters stated herein.

2. I am an attorney with Pillsbury Winthrop Shaw Pittman in Miami, Florida, and I have been retained by Plaintiffs as co-counsel in the above-captioned matter.

3. I make this Declaration in support of Plaintiffs' Motion for Preliminary Injunction

4. Attached as **Exhibit A** is a true and correct copy of *Treatment of Gender*

Dysphoria for Children and Adults, issued by the Florida Department of Health on April 20, 2022, *available at* https://tinyurl.com/3xkhvk96.

5. Attached as **Exhibit B** is a true and correct copy of *Gender-Affirming Care and Young People*, published by the U.S. Dep't of Health & Human Servs. in March 2022, *available at* https://tinyurl.com/2yck4yxt.

6. Attached as **Exhibit C** is a true and correct copy of Brittany S. Bruggeman, et al., *Opinion: We 300 Florida health care professionals say the state gets transgender guidance wrong | Open letter*, TAMPA BAY TIMES (Apr. 27, 2022), *available at* https://tinyurl.com/bdhskwyj.

7. Attached as **Exhibit D** is a true and correct copy of AHCA Secretary Marstiller's Letter to Deputy Secretary Tom Wallace dated April 20, 2022, *available at* https://tinyurl.com/2k6xext8.

8. Attached as **Exhibit E** is a true and correct copy of the report titled *Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria* ("GAPMS Memo"), published by the Florida Agency for Health Care Administration ("AHCA") on June 2, 2022, *available at* https://tinyurl.com/3z385js4.

9. Attached as **Exhibit F** is a true and correct copy of *A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria* (July 8, 2022), *available at* https://tinyurl.com/4dwtzk3u.

10. Attached as **Exhibit G** is a true and correct copy of Stephen Caruso, *A Texas Judge Ruled That This Doctor Was Not an Expert*, PENNSYLVANIA CAPITAL-STAR (Sept. 15, 2020), *available at* https://tinyurl.com/5n7pwspb.

11. Attached as **Exhibit H** is a true and correct copy of Alison Clayton et al., *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), *available at* https://tinyurl.com/2dxv9ce7.

12. Attached as **Exhibit I** is a true and correct copy of the AHCA's Notice of Proposed Rule dated June 17, 2022, *available at* https://tinyurl.com/2v9aawwd.

13. Attached as **Exhibit J** is a true and correct copy of *Letter from the Endocrine Society to the AHCA* (July 8, 2022), *available at* https://tinyurl.com/dehkktxb.

14. Attached as **Exhibit K** is a true and correct copy of *Letter from the American Academy of Pediatrics et al. to AHCA Deputy Secretary Tom Wallace* (July 7, 2022), *available at* https://tinyurl.com/yhfte8df.

15. Attached as **Exhibit L** is a true and correct copy of *Letter from Anne L. Alstott et al. to AHCA Secretary Marstiller* (July 8, 2022), *available at* https://tinyurl.com/3ryrkb22.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 12, 2022

By: */s/ Jennifer Altman*

Jennifer Altman (Fl. Bar No. 881384)
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EXHIBIT A

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Ron DeSantis
Governor

Joseph A. Ladapo, MD, PhD
State Surgeon General

Vision: To be the Healthiest State in the Nation

Treatment of Gender Dysphoria for Children and Adolescents

April 20, 2022

The Florida Department of Health wants to clarify evidence recently cited on a fact sheet released by the US Department of Health and Human Services and provide guidance on treating gender dysphoria for children and adolescents.

Systematic reviews on hormonal treatment for young people show a trend of low-quality evidence, small sample sizes, and medium to high risk of bias. A paper published in the International Review of Psychiatry states that 80% of those seeking clinical care will lose their desire to identify with the non-birth sex. One review concludes that "hormonal treatments for transgender adolescents can achieve their intended physical effects, but **evidence regarding their psychosocial and cognitive impact is generally lacking**."

According to the Merck Manual, “gender dysphoria is characterized by a strong, persistent cross-gender identification associated with anxiety, depression, irritability, and often a wish to live as a gender different from the one associated with the sex assigned at birth.”

Due to the lack of conclusive evidence, and the potential for long-term, irreversible effects, the Department's guidelines are as follows:

- Social gender transition should not be a treatment option for children or adolescents.
- Anyone under 18 should not be prescribed puberty blockers or hormone therapy.
- Gender reassignment surgery should not be a treatment option for children or adolescents.
    - Based on the currently available evidence, "encouraging mastectomy, ovariectomy, uterine extirpation, penile disablement, tracheal shave, the prescription of hormones which are out of line with the genetic make-up of the child, or puberty blockers, are all clinical practices which run an **unacceptably high risk of doing harm**."
- Children and adolescents should be provided social support by peers and family and seek counseling from a licensed provider.

These guidelines do not apply to procedures or treatments for children or adolescents born with a genetically or biochemically verifiable disorder of sex development (DSD). These disorders include, but are not limited to, 46, XX DSD; 46, XY DSD; sex chromosome DSDs; XX or XY sex reversal; and ovotesticular disorder.

The Department’s guidelines are consistent with the federal Centers for Medicare and Medicaid Services age requirement for surgical and non-surgical treatment. These guidelines are also in line with the guidance, reviews, and recommendations from Sweden, Finland, the United Kingdom, and France.

Parents are encouraged to reach out to their child’s health care provider for more information.

EXHIBIT B

OASH | Office of Population Affairs

Gender-Affirming Care and Young People

What is gender-affirming care?

Gender-affirming care is a supportive form of healthcare. It consists of an array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people.

For transgender and nonbinary children and adolescents, early gender-affirming care is crucial to overall health and well-being as it allows the child or adolescent to focus on social transitions and can increase their confidence while navigating the healthcare system.

Why does it matter?

Research demonstrates that gender-affirming care improves the mental health and overall well-being of gender diverse children and adolescents.[1] Because gender-affirming care encompasses many facets of healthcare needs and support, it has been shown to increase positive outcomes for transgender and nonbinary children and adolescents. Gender-affirming care is patient-centered and treats individuals holistically, aligning their outward, physical traits with their gender identity.

Gender diverse adolescents, in particular, face significant health disparities compared to their cisgender peers. Transgender and gender nonbinary adolescents are at increased risk for mental health issues, substance use, and suicide.[2,3] The Trevor Project's 2021 *National Survey on LGBTQ Youth Mental Health* found that 52 percent of LGBTQ youth seriously considered attempting suicide in the past year.[4]

A safe and affirming healthcare environment is critical in fostering better outcomes for transgender, nonbinary, and other gender expansive children and adolescents. Medical and psychosocial gender affirming healthcare practices have been demonstrated to yield lower rates of adverse mental health outcomes, build self-esteem, and improve overall quality of life for transgender and gender diverse youth.[5,6] Familial and peer support is also crucial in fostering similarly positive outcomes for these populations. Presence of affirming support networks is critical for facilitating and arranging gender affirming care for children and adolescents. Lack of such support can result in rejection, depression and suicide, homelessness, and other negative outcomes.[7,8,9]

Common Terms:
(in alphabetical order)

Cisgender: Describes a person whose gender identity aligns with their sex assigned at birth.

Gender diverse or expansive: An umbrella term for a person with a gender identity and/or expression broader than the male or female binary. Gender minority is also used interchangeably with this term.

Gender dysphoria: Clinically significant distress that a person may feel when sex or gender assigned at birth is not the same as their identity.

Gender identity: One's internal sense of self as man, woman, both or neither.

Nonbinary: Describes a person who does not identify with the man or woman gender binary.

Transgender: Describes a person whose gender identity and or expression is different from their sex assigned at birth, and societal and cultural expectations around sex.

Additional Information

- Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline
- Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents | American Academy of Pediatrics
- Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming People | World Professional Association for Transgender Health

HHS Office of Population Affairs
Web: opa.hhs.gov | Email: opa@hhs.gov
Twitter: @HHSPopAffairs | YouTube: HHSOfficeofPopulationAffairs

Gender-Affirming Care and Young People

Affirming Care	What is it?	When is it used?	Reversible or not
Social Affirmation	Adopting gender-affirming hairstyles, clothing, name, gender pronouns, and restrooms and other facilities	At any age or stage	Reversible
Puberty Blockers	Using certain types of hormones to pause pubertal development	During puberty	Reversible
Hormone Therapy	Testosterone hormones for those who were assigned female at birth Estrogen hormones for those who were assigned male at birth	Early adolescence onward	Partially reversible
Gender-Affirming Surgeries	"Top" surgery – to create male-typical chest shape or enhance breasts "Bottom" surgery – surgery on genitals or reproductive organs Facial feminization or other procedures	Typically used in adulthood or case-by-case in adolescence	Not reversible

Resources

- Discrimination on the Basis of Sex | HHS Office of Civil Rights
- Lesbian, Gay, Bisexual, and Transgender Health | Healthy People 2030
- Lesbian, Gay, Bisexual, and Transgender Health: Health Services | Centers for Disease Control and Prevention
- National Institutes of Health Sexual & Gender Minority Research Office
- Family Support: Resources for Families of Transgender & Gender Diverse Children | Movement Advancement Project
- Five Things to Know About Gender-Affirming Health Care | ACLU
- Gender-Affirming Care is Trauma-Informed Care | The National Child Traumatic Stress Network
- Gender-Affirming Care Saves Lives | Columbia University
- Gender Identity | The Trevor Project
- Genderspectrum.org
- Glossary of Terms | Human Rights Campaign
- Health Care for Transgender and Gender Diverse Individuals | ACOG
- Transgender and Gender Diverse Children and Adolescents | Endocrine Society

[1] Green, A. E., DeChants, J. P., Price, M. N., & Davis, C. K. (2021). Association of Gender-Affirming Hormone Therapy With Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth. *Journal of Adolescent Health*, 70(4). https://doi.org/https://doi.org/10.1016/j.jadohealth.2021.10.036

[2] Rimes, K., Goodship N., Ussher, G., Baker, D. and West, E. (2019). Non-binary and binary transgender youth: Comparison of mental health, self-harm, suicidality, substance use and victimization experiences. *International Journal of Transgenderism*, 20 (2-3); 230-240.

[3] Price-Feeney, M., Green, A. E., & Dorison, S. (2020). Understanding the mental health of transgender and nonbinary youth. *Journal of Adolescent Health, 66*(6), 684–690. https://doi.org/10.1016/j.jadohealth.2019.11.314

[4] Trevor Project. (2021). *National Survey on LGBTQ Youth Mental Health 2021*. Trevor Project. https://www.thetrevorproject.org/survey-2021/.

[5] Wagner J, Sackett-Taylor AC, Hodax JK, Forcier M, Rafferty J. (2019). Psychosocial Overview of Gender-Affirmative Care. *Journal of pediatric and adolescent gynecology,* (6):567-573. doi: 10.1016/j.jpag.2019.05.004. Epub 2019 May 17. PMID: 31103711.

[6] Hughto JMW, Gunn HA, Rood BA, Pantalone DW. (2020). Social and Medical Gender Affirmation Experiences Are Inversely Associated with Mental Health Problems in a U.S. Non-Probability Sample of Transgender Adults. *Archives of sexual behavior*, 49(7):2635-2647. doi: 10.1007/s10508-020-01655-5. Epub 2020 Mar 25. PMID: 32215775; PMCID: PMC7494544.

[7] Brown, C., Porta, C. M., Eisenberg, M. E., McMorris, B. J., & Sieving, R. E. (2020). Family relationships and the health and well-being of transgender and gender-diverse youth: A critical review. *LGBT Health*, *7*, 407-419. https://doi.org/10.1089/lgbt.2019.0200

[8] Seibel BL, de Brito Silva B, Fontanari AMV, Catelan RF, Bercht AM, Stucky JL, DeSousa DA, Cerqueira-Santos E, Nardi HC, Koller SH, Costa AB. (2018). The Impact of the Parental Support on Risk Factors in the Process of Gender Affirmation of Transgender and Gender Diverse People. *Front Psychol*, 27;9:399. doi: 10.3389/fpsyg.2018.00399. Erratum in: Front Psychol. 2018 Oct 12;9:1969. PMID: 29651262; PMCID: PMC5885980.

[9] Sievert ED, Schweizer K, Barkmann C, Fahrenkrug S, Becker-Hebly I. (2021). Not social transition status, but peer relations and family functioning predict psychological functioning in a German clinical sample of children with Gender Dysphoria. *Clin Child Psychol Psychiatry*, 26(1):79-95. doi: 10.1177/1359104520964530. Epub 2020 Oct 20. PMID: 33081539.

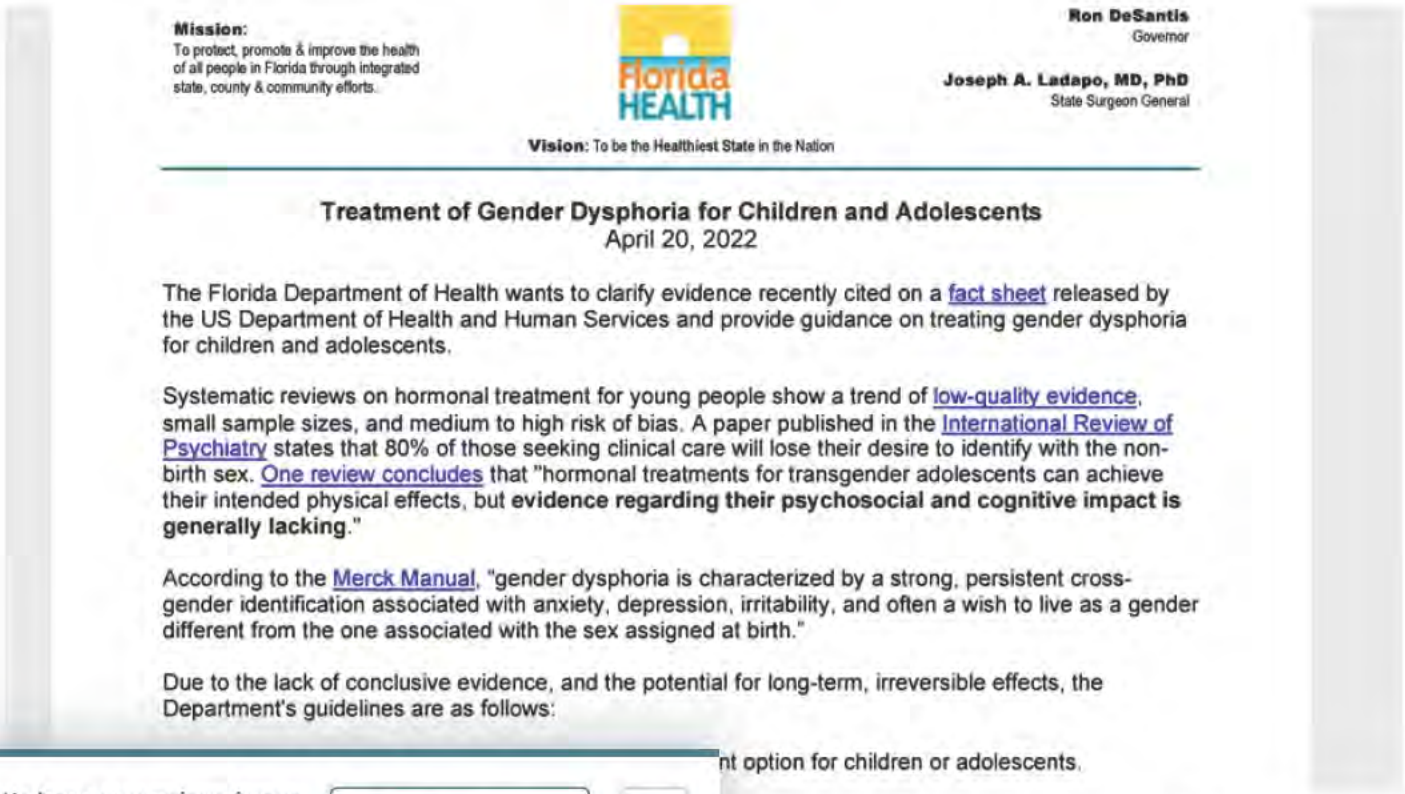
EXHIBIT C

Tampa Bay Times

OPINION

We 300 Florida health care professionals say the state gets transgender guidance wrong | Open letter

The state cherry-picks and misreads the studies to come to the wrong conclusions and endanger transgender youth.



Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

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Treatment of Gender Dysphoria for Children and Adolescents
April 20, 2022

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Systematic reviews on hormonal treatment for young people show a trend of low-quality evidence, small sample sizes, and medium to high risk of bias. A paper published in the International Review of Psychiatry states that 80% of those seeking clinical care will lose their desire to identify with the non-birth sex. One review concludes that "hormonal treatments for transgender adolescents can achieve their intended physical effects, but **evidence regarding their psychosocial and cognitive impact is generally lacking**."

According to the Merck Manual, "gender dysphoria is characterized by a strong, persistent cross-gender identification associated with anxiety, depression, irritability, and often a wish to live as a gender different from the one associated with the sex assigned at birth."

Due to the lack of conclusive evidence, and the potential for long-term, irreversible effects, the Department's guidelines are as follows:

nt option for children or adolescents.

on "Treatment of Gender Dysphoria for Children and
is guidance, saying it "misrepresents the weight of the

Tampa Bay Times

Published Apr. 27 | Updated Apr. 27

We write as a group of more than 300 Florida health care professionals who care for transgender and gender diverse youth. We have one common goal: to provide the best quality, evidence-based, individualized and compassionate care for our patients. Ultimately, we strive to empower each patient to achieve their optimal physical, mental, emotional and social health, and we want each person to feel that they are accepted and valued for who they are.

The recent statement issued by the Florida Department of Health entitled "Treatment of Gender Dysphoria for Children and Adolescents" misrepresents the weight of the evidence, does not allow for personalized patient and family-centered care, and would, if followed, lead to higher rates of youth depression and suicidality.

The Florida Department of Health guidance categorically recommends against social and medical gender transition for any patient under the age of 18. This directly contradicts existing guidelines from the American Academy of Pediatrics, the Endocrine Society, the American Academy of Child and Adolescent Psychiatry and the World Professional Association for Transgender Health. These national and international guidelines are the result of careful deliberation and examination

ricians, endocrinologists, psychologists

evidence," their statement fails to follow their own recommendations. Specifically, the Florida Department of Health cites a selective and non-representative sample of small studies and reviews, editorials, opinion pieces and commentary to support several of their substantial claims. When citing high-quality studies, they make conclusions that are not supported by the authors of the articles. And while they state that their guidance is consistent with recommendations from Sweden, Finland, the United Kingdom and France, in fact, none of these countries recommends against social gender transition, and all provide a path forward for patients in need of medical intervention. This stands in marked contrast to the categorical ban recommended by the Florida Department of Health.

Current national guidelines recommend developmentally appropriate, patient- and family-centered, and nuanced care that promotes children and adolescents' self-worth. Evaluation and treatment includes thorough assessment by

multidisciplinary teams including mental health professionals and medical providers and may include social or medical transition if indicated and desired by the patient and family.

that are 5 to 7 times higher and rates of
an that of the cisgender population.

supporting a child or adolescent to express themselves fully and honestly.

Professional guidelines do not recommend initiation of puberty blocking medications prior to the onset of puberty, and their use has been linked to reduced rates of depression and suicidality. Similarly, guidelines recommend initiation of gender-affirming hormonal treatment only after multidisciplinary teams have a and the desire of the patient and

so as to provide informed consent alongside their guardians, which is present in most by age 16. Treatment is linked to improved body satisfaction and rates of depression. Genital surgeries are not recommended for patients under 18, and masculinizing chest surgeries only after patients meet strict criteria and can give truly informed consent alongside their guardians. In all cases, these decisions are made with great thoughtfulness and cannot be dealt with in a one-size-fits-all approach.

While we need research to further improve care for transgender and gender diverse youth, taking away social support and medical care is not the answer. We urge the professionals at the Florida Department of Health to reconsider its guidance in favor of a more individualized, patient- and family-centered, and compassionate approach.

Sincerely,

Brittany S. Bruggeman, MD, FAAP, Assistant Professor of Pediatric Endocrinology, University of Florida College of Medicine

Kristin Dayton, MD, Director, UF Youth Gender Program, Assistant Professor of Pediatric Endocrinology University of Florida College of Medicine

Alejandro Diaz, MD Chief, Division of Pediatric Endocrinology Nicklaus Children's Hospital

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Co-signed by:

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Sakina Sojar, MD

Louise Spierre, MD

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Peter S. Staats, MD

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Mori Stern, MD

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Abby Wagner, MD

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Erika Wert, MD

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Rachel Whynott, MD, FACOG

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Salym Winter, LCSW

William E. Winter, MD

Alea Wise, LMHC, RPT, NCC

Lisa Wolcott, LCSW

JD Wright, PhD

Nancy Wright, MD

Patricia Xirau-Probert, PhD

Eunhui Yoon, PhD, NCC, NCYC

Elisa Zenni, MD

UP NEXT: Elon Musk and Sean Hannity made it a bad Monday for freedom | Column

MORE FOR YOU

Some doctors stopping treatment for transgender youth in Florida

EXHIBIT D

RON DESANTIS
GOVERNOR

SIMONE MARSTILLER
SECRETARY

April 20, 2022

Tom Wallace
Deputy Secretary for Medicaid
Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, FL 32308

Dear Deputy Secretary Wallace:

On April 20, 2022, the Florida Department of Health released guidance on the treatment of gender dysphoria for children and adolescents.[1] The Florida Medicaid program does not have a policy on whether to cover such treatments for Medicaid recipients diagnosed with gender dysphoria. Please determine, under the process described in Florida Administrative Code Rule 59G-1035, whether such treatments are consistent with generally accepted professional medical standards and not experimental or investigational. Pursuant to Rule 59G-1035(5), I look forward to receiving your final determination.

Sincerely,

Simone Marstiller
Secretary

[1] *See* https://www.floridahealth.gov/newsroom/2022/04/20220420-gender-dysphoria-press-release.pr.html (last visited Apr. 20, 2022).

EXHIBIT E

Florida Medicaid

Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria

June 2022

Ron DeSantis, Governor
Simone Marstiller, Secretary

Contents

Introductory Remarks and Abstract

Generally Accepted Professional Medical Standards

The Secretary of the Florida Agency for Health Care Administration requested that the Division of Florida Medicaid review the treatment of gender dysphoria for a coverage determination pursuant to Rule 59G-1.035, Florida Administrative Code (F.A.C.) (See Attachment A for the Secretary's Letter to Deputy Secretary Tom Wallace). The treatment reviewed within this report included "sex reassignment treatment," which refers to medical services used to obtain the primary and/or secondary physical sexual characteristics of a male or female. As a condition of coverage, sex reassignment treatment must be "consistent with generally accepted professional medical standards (GAPMS) and not experimental or investigational" (Rule 59G-1.035, F.A.C., see Attachment B for the complete rule text).

The determination process requires that "the Deputy Secretary for Medicaid will make the final determination as to whether the health service is consistent with GAPMS and not experimental or investigational" (Rule 59G-1.035, F.A.C.). In making that determination, Rule 59G-1.035, F.A.C., identifies several factors for consideration. Among other things, the rule contemplates the consideration of "recommendations or assessments by clinical or technical experts on the subject or field" (Rule 59G-1.035(4)(f), F.A.C.). Accordingly, this report attaches five assessments from subject-matter experts:

- **Attachment C:** Romina Brignardello-Petersen, DDS, MSc, PhD and Wojtek Wiercioch, MSc, PhD: *Effects of Gender Affirming Therapies in People with Gender Dysphoria: Evaluation of the Best Available Evidence*. 16 May 2022.
- **Attachment D:** James Cantor, PhD: *Science of Gender Dysphoria and Transsexualism*. 17 May 2022.
- **Attachment E:** Quentin Van Meter, MD: *Concerns about Affirmation of an Incongruent Gender in a Child or Adolescent*. 17 May 2022.
- **Attachment F:** Patrick Lappert, MD: *Surgical Procedures and Gender Dysphoria*. 17 May 2022.
- **Attachment G:** G. Kevin Donovan, MD: *Medical Experimentation without Informed Consent: An Ethicist's View of Transgender Treatment for Children*. 16 May 2022.

Abstract

Available medical literature provides insufficient evidence that sex reassignment through medical intervention is a safe and effective treatment for gender dysphoria. 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. Rather, the available evidence demonstrates that these treatments cause irreversible physical changes and side effects that can affect long-term health.

Five clinical and technical expert assessments attached to this report recommend against the use of such interventions to treat what is categorized as a mental health disorder (See attachments):

- **Health Care Research:** Brignardello-Petersen and Wiercioch performed a systematic review that graded a multitude of studies. They conclude

that evidence supporting sex reassignment treatments is low or very low quality.

- **Clinical Psychology:** Cantor provided a review of literature on all aspects of the subject, covering therapies, lack of research on suicidality, practice guidelines, and Western European coverage requirements.
- **Plastic Surgery:** Lappert provided an evaluation explaining how surgical interventions are cosmetic with little to no supporting evidence to improve mental health, particularly those altering the chest.
- **Pediatric Endocrinology:** Van Meter explains how children and adolescent brains are in continuous phases of development and how puberty suppression and cross-sex hormones can potentially affect appropriate neural maturation.
- **Bioethics:** Donovan provides additional insight on the bioethics of administering these treatments, asserting that children and adolescents cannot provide truly informed consent.

Following a review of available literature, clinical guidelines, and coverage by other insurers and nations, Florida Medicaid has determined that the research supporting sex reassignment treatment is insufficient to demonstrate efficacy and safety. In addition, numerous studies, including the reports provided by the clinical and technical experts listed above, identify poor methods and the certainty of irreversible physical changes. Considering the weak evidence supporting the use of puberty suppression, cross-sex hormones, and surgical procedures when compared to the stronger research demonstrating the permanent effects they cause, these treatments do not conform to GAPMS and are experimental and investigational.

Health Service Summary

Gender Dysphoria

Frequently used to describe individuals whose gender identity conflicts with their natural-born sex, the term gender dysphoria has a history of evolving definitions during the past decades (Note: This report uses the term "gender" in reference to the construct of male and female identities and the term "sex" when regarding biological characteristics). Prior to the publication of the *Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders* (DSM-V), the American Psychiatric Association (APA) used the diagnosis of gender identity disorder (GID) to describe individuals who sought to transition to the opposite gender. However, behavioral health clinicians sought a revision after determining that using GID created stigma for those who received the diagnosis. This is despite the APA having adopted GID to replace the previous diagnosis of transsexualism for the exact same reason (APA, 2017).[1]

When crafting its new definition and terminology, the APA sought to remove the stigma of classifying as a disorder the questioning of one's gender identity by focusing instead on the psychological distress that such questioning can evoke. This approach argues that individuals seeking behavioral health and transition services are doing so due to experiencing distress and that gender non-conformity by itself is not a mental health issue. This led to the adoption of gender dysphoria in 2013 when the APA released the DSM-V. In addition to using a new term, the APA also differentiated the diagnosis between children and adolescents and adults, listing different characteristics for the two age groups (APA, 2017).

According to the DSM-V, gender dysphoria is defined as "the distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender." As for the criteria to receive the diagnosis, the APA issued stricter criteria for children than adolescents and adults. For the former, the APA states that a child must meet six out of eight behavioral characteristics such as having "a strong desire to be of the other gender or an insistence that one is the other gender" or "a strong preference for cross-gender roles in make-believe or fantasy play." The criteria for adults and adolescents are less stringent with individuals only having to meet two out of six characteristics that include "a strong desire to be the other gender" or "a strong desire to be rid of one's primary and/or secondary sexual characteristics." The APA further notes that these criteria can also apply to young adolescents (DSM-V, 2013).

In 2021, the Merck Manual released a slightly different definition for gender dysphoria, citing that the condition "is characterized by a strong, persistent cross-gender identification associated with anxiety, depression, irritability, and often a wish to live as a gender different from the one associated with the

[1] The concept of gender being part of identity and disconnected from biological sex originated during the mid-twentieth century and was publicized by psychologist John W. Money. His research asserted that gender was a complete social construct and separate from biology, meaning that parents and/or caregivers could imprint on a young child (under three years) the identity of a boy or girl. In 1967, Money's theories led to a failed experiment on twin boys where physicians surgically transitioned one to appear as a girl. The twin that underwent sex reassignment never fully identified as a female. However, Money never publicly acknowledged this and reported the experiment as a success. Furthermore, he promoted his conclusions across the scientific community, concealing what actually unfolded. As a result, Money's ideas on gender fluidity served as a basis for performing procedures on children with hermaphroditic features or genital abnormalities. The case reveals how the understanding of a concept (e.g., gender) at any given time can lead to incorrect medical decisions with irreversible consequences (Gaetano, 2015).

sex assigned at birth." Additionally, the Merck Manual further states that "gender dysphoria is a diagnosis requiring specific criteria but is sometimes used more loosely for people in whom symptoms do not reach a clinical threshold" (Merck Manual, 2021). This definition is largely consistent with the DSM-V but does not emphasize the distress component to the same extent.[2]

Like other behavioral health diagnoses classified in the DSM-V, gender dysphoria has the following subtypes:

- **Early-Onset Gender Dysphoria:** This subtype begins during childhood and persists through adolescence into adulthood. It can be interrupted by periods where the individual does not experience gender dysphoria signs and may classify as homosexual (DSM-V, 2013).
- **Late-Onset Gender Dysphoria:** Occurring after puberty or during adulthood, this subtype does not begin until late adolescence and can emerge following no previous signs of gender dysphoria. The APA attributes this partially to individuals who did not want to verbalize their desires to transition (DSM-V, 2013).

Further studies have identified additional subtypes of gender dysphoria. In 2018, Lisa Littman introduced the concept of a rapid-onset subtype. Classified as rapid-onset gender dysphoria (ROGD), it features characteristics such as sudden beginnings during or following puberty. However, it differs from the DSM-V definitions because ROGD is associated with other causes such as social influences (e.g., peer groups, authority figures, and media). In other words, adolescents who had no history of displaying typical gender dysphoria characteristics go through a sudden change in identity following intense exposure to peers and/or media that heavily promotes transgender lifestyles (Littman, 2018). While more long-term studies are needed to confirm whether ROGD is a temporary or long-term condition, Littman's study has initiated discussions regarding potential causes of gender dysphoria as well as introduced a potential subtype.

Additionally, the frequent use of gender dysphoria in clinical and lay discourse has led to a fracturing of the definition. Studies on the topic frequently do not apply the DSM-V's criteria for the diagnosis and overlook certain key features such as distress. In a 2018 review by Zowie Davy and Michael Toze, the authors evaluated 387 articles that examine gender dysphoria and noted stark departures from the APA's definition. They further asserted that the APA intended to "reduce pathologization" by establishing a new definition for gender dysphoria in the DSM-V. This in turn would reduce diagnoses, although as Davy and Toze note, the tendency for the literature to diverge from the APA's definition may result in increased numbers of individuals classified as having gender dysphoria when they do not meet the DSM-V's criteria (Davy and Toze, 2018). This further raises the question of whether individuals are receiving potentially irreversible treatments for the condition when they might not actually have it.

The current usage of gender dysphoria is the result of discussions spanning across decades as demonstrated in the past editions of the DSM. Until 2013, the APA considered having gender identity issues a mental disorder by itself regardless of the presence of psychological distress. That perspective has since shifted to only consider the adverse psychological effects of questioning one's gender as a disorder. In addition, the APA considers gender as part of one's identity, which is not subject to a diagnosis. Whether the APA has shifted its terminology and criteria for gender identity issues due to

[2] Following the release of the Florida Department of Health's guidelines for treating gender dysphoria, Merck removed its definition for "gender dysphoria" from the Merck Manual (Fox News, 2022).

emerging clinical data or cultural changes is another question. In 1994, the APA replaced transsexualism with gender identity disorder as part of the "effort to reduce stigma" (APA, 2017). This raises questions about what influences decisions to revise definitions and criteria; is it social trends or medical evidence?

Behavioral Health Issues Co-Occurring with Gender Dysphoria

Because gender dysphoria pertains directly to the distress experienced by an individual who desires to change gender identities, secondary behavioral health issues can co-occur such as depression and anxiety. If left untreated, these conditions can lead to the inability to function in daily activities, social isolation, and even suicidal ideation. Studies do confirm that adolescents and adults with gender dysphoria report higher levels of anxiety, depression, and poor peer relationships than the general population (Kuper et al, 2019). Other associated conditions include substance abuse, eating disorders, and compulsivity. A significant proportion of individuals with gender dysphoria also have autism spectrum disorder (ASD) (Saleem and Rizvi, 2017). Although the number reporting secondary issues is increased, individuals diagnosed with gender dysphoria do not necessarily constitute the entire population that is gender non-conforming (i.e., does not identify with natal sex), and no information is available breaking down the percentage of those who are non-conforming with gender dysphoria and those who are non-conforming with no distress. Additionally, available research raises questions as to whether the distress is secondary to pre-existing behavioral health disorders and not gender dysphoria. This is evident in the number of adolescents who reported anxiety and depression diagnoses prior to transitioning (Saleem and Rizvi, 2017).

Furthermore, conventional treatments for secondary behavioral health issues are available. These include cognitive behavioral therapy, medication, and inpatient services. The APA reports that treatments for these are highly effective with 80% to 90% of individuals diagnosed with depression responding positively (APA, 2020). In addition, a high percentage of adolescents diagnosed with gender dysphoria had received psychiatric treatment for a prior or co-occurring mental health issue. A 2015 study from Finland by Kaltiala-Heino et al noted that 75% of children seeking sex reassignment services had been treated by a behavioral health professional (Kaltiala-Heino et al, 2015).

Diagnosing Gender Dysphoria

Prior to the publication of the DSM-V, diagnosing individuals experiencing gender identity issues followed a different process. Behavioral health clinicians could assign the diagnosis based on gender non-conformance alone. That has changed since 2013. Today, non-conforming to one's gender is part of personal identity and not a disorder requiring treatment. This change has led professional associations to shift the diagnostic criteria for gender dysphoria to focus on the distress caused by shifting identities (DSM-V, 2013).

For adolescents, the APA identifies "a marked incongruence between one's experienced/expressed gender and natal sex, of at least 6 months' duration" as the core component of gender dysphoria (DSM-V, 2013). What the APA does not elucidate is the threshold for "marked." This raises questions as to whether practitioners exercise uniformity when applying the diagnostic criteria or if they do so subjectively. For example, the WPATH's *Standards of Care for the Health of Transsexual, Transgender, and Gender Non-Conforming People* provides guidance on the processes mental health practitioners should use when assessing for gender dysphoria but offers no benchmarks for meeting diagnostic criteria (WPATH, 2012).

Such processes include evaluating for gender non-conforming behaviors and other co-existing mental disorders like anxiety or depression. This involves not only interviewing the adolescent but also the family in addition to reviewing medical histories. WPATH also asserts that gender dysphoria assessments need to account for peer relationships, academic performance, and provide information of potential treatments. This last component is necessary because it might affect an individual's choices regarding transitioning, particularly if the information does not correspond to the desired outcome (WPATH, 2012).

The diagnosis of gender dysphoria is a relatively recent concept in mental health, being the product of decades of discussion and building upon previous definitions. Instead of treating gender non-conformity as a disorder, behavioral health professionals acknowledge it as part of one's identity and focus on addressing the associated distress. Considering the new criteria, this changes the dynamics of the population who would have qualified for a diagnosis before 2013 and those who would today. Given that desiring to transition into a gender different from natal sex no longer qualifies as a disorder, behavioral health professionals are treating distress and referring adolescents and adults to therapies that are used off-label and pose irreversible effects.

Current Available Treatments for Gender Dysphoria

At present, proposed treatment for gender dysphoria occurs in four stages, beginning with psychological services and ending with sex reassignment surgery. As an individual progresses through each stage, the treatments gradually become more irreversible with surgical changes being permanent. Because of the increasing effects, individuals must have attempted treatment at the previous stage before pursuing the next one (Note: late adolescents and adults have already completed puberty and do not require puberty blockers). Listed in order, the four stages are as follows:

- **Behavioral Health Services:** Psychologists and other mental health professionals are likely the first practitioners individuals with gender dysphoria will encounter. In accordance with clinical guidelines established by the World Professional Association for Transgender Health (WPATH)[3], behavioral health professionals are supposed to "find ways to maximize a person's overall psychological well-being, quality of life, and self-fulfillment." WPATH further discourages services for attempting to change someone's gender identity. Instead, it instructs practitioners to assess for the condition and readiness for puberty blockers or cross-sex hormones while offering guidance to function in a chosen gender. WPATH does assert that the clinicians do need to treat any other underlying mental health issues secondary or co-occurring with gender dysphoria (WPATH, 2012). However, the organization provides conflicting guidance because it also advises practitioners to prescribe cross-sex hormones on demand (Levine, 2018).
- **Puberty Suppression:** Used only on individuals in the earliest stages of puberty (Tanner stage 2), preventing pubertal onset provides additional time to explore gender identities before the physical characteristics of biological sex develop. This treatment is intended to reduce distress and anxiety related to the appearance of adult sexual physical features. To suppress puberty, pediatric endocrinologists inject gonadotropin releasing hormone (Gn-RH) at specific intervals (e.g., 4 weeks or 12 weeks). The Gn-RH suppresses gonadotropin receptors that allow for the

[3] The World Professional Association for Transgender Health asserts that it is a professional organization. However, it functions like an advocacy group by allowing open membership to non-clinicians (WPATH, 2022).

development of primary and secondary adult sexual characteristics. Prior to receiving puberty suppression therapy, individuals must have received a diagnosis of gender dysphoria and have undergone a mental health evaluation (Kyriakou et al, 2020).

- **Cross-Sex Hormones:** For adults and late adolescents (16 years or older), the next treatment phase recommended is taking cross-sex hormones (e.g., testosterone or estrogen) to create secondary sex characteristics. In men transitioning into women, these include breast development and widening around the pelvis. Women who transition into men experience deeper voices, redistribution of fat deposits, and growing facial hair. According to the Endocrine Society, late adolescents who qualify for cross-sex hormones must have a confirmed diagnosis of gender dysphoria from a mental health practitioner with experience treating that population. Some physical changes induced by these hormones are irreversible (Endocrine Society, 2017).
- **Sex Reassignment Surgery:** Sometimes referred to as "gender affirming" surgery, this treatment does not consist of just one procedure but several, depending on the desires of the transitioning individual. Primarily, sex reassignment procedures alter the primary and secondary sexual characteristics. Men transitioning into women (trans-females) undergo a penectomy (removal of the penis), orchiectomy (removal of the testes), and vulvoplasty (creation of female genitals). Other procedures trans-females may undergo include breast augmentation and facial feminization. For women that transition into men (trans-males), procedures include mastectomy (removal of the breasts), hysterectomy (removal of the uterus), oophorectomy (removal of the ovaries), and phalloplasty (creation of male genitals). Because of the complexities involved in phalloplasty, many trans-males do not opt for this procedure and limit themselves to mastectomies. Additionally, the effects of sex reassignment surgery, such as infertility, are permanent (WPATH, 2012).

While some clinical organizations assert that they are the standard of care for gender dysphoria, the U.S. Food and Drug Administration (FDA) currently has not approved any medication as clinically indicated for this condition (Unger, 2018). Although puberty blockers and cross-sex hormones are FDA approved, the FDA did not approve them for treating gender dysphoria, meaning that their use for anything other than the clinical indications listed is off-label (American Academy of Pediatrics, 2014). As for surgical procedures, the FDA does not evaluate or approve them, but it does review all surgical devices (FDA, 2021). In addition, the Endocrine Society concedes that its practice guidelines for sex reassignment treatment does *not* constitute a "standard of care" and that its grades for available services are low or very low (Endocrine Society, 2017).[4]

[4] Disagreement over how to treat gender dysphoria, gender identity disorder, and transsexualism has persisted since sex reassignment surgery first became available in the 1960s. In a 2006 counterargument, Paul McHugh highlights how individuals seeking surgery had other reasons that extended beyond gender identity, including sexual arousal and guilt over homosexuality. In addition, he asserts that undergoing sex reassignment procedures did not improve a patient's overall behavioral health and that providing a "surgical alteration to the body of these unfortunate people was to collaborate with a mental disorder rather than to treat it" (McHugh, 2006).

Literature Review: Introduction

Currently, an abundance of literature and studies on gender dysphoria is available through academic journals, clinical guidelines, and news articles. Similar to other mental health issues, the material addresses a broad range of topics consisting of available treatments, etiology (i.e., causes), risks, benefits, and side effects. Although most stories reported by the media indicate that treatments such as cross-sex hormones and sex reassignment surgery are the most effective, research reveals that numerous questions still exist. These include what are the long-term health effects of taking cross-sex hormones, what are the real causes of gender dysphoria, and how many individuals that transition will eventually want to revert to their natal sex. Additionally, much of the available research is inconclusive regarding the effectiveness of sex reassignment treatments with multiple studies lacking adequate sample sizes and relying on subjective questionnaires. While much of the scientific literature leans in favor of cross-sex hormones and surgery as options for improving the mental health of individuals with gender dysphoria, it does not conclusively demonstrate that the benefits outweigh the risks involved, either short or long-term. What studies do reveal with certainty is that sex reassignment surgery and cross-sex hormones pose permanent effects that can result in infertility, cardiovascular disease, and disfigurement. All of this indicates that further research is necessary to validate available treatments for gender dysphoria. Thus, physicians, who recommend sex reassignment treatment, are not adhering to an evidence-based medicine approach and are following an eminence-based model.

The following literature review addresses the multiple facets of this condition and presents areas of ongoing debate and persisting questions. Beginning with the condition's etiology and continuing with evaluations of puberty blockers, cross-sex hormones, and surgery, the review explains each area separately and in context of gender dysphoria at large. Additionally, the review provides an analysis on available research on mental health outcomes as well as the condition's persistence into adulthood. Taken as a whole, the available studies demonstrate that existing gender dysphoria research is inconclusive and that current treatments are used to achieve cosmetic benefits while posing risky side effects as well as irreversible changes.

Literature Review: Etiology of Gender Dysphoria

What causes gender dysphoria is an ongoing debate among experts in the scientific and behavioral health fields. Currently, the research indicates that diagnosed individuals have higher proportions of autism spectrum disorder (ASD), history of trauma or abuse, fetal hormone imbalances, and co-existing mental illnesses. Also, experts acknowledge that genetics may factor into gender dysphoria. Another potential cause is social factors such as peer and online media influence. At the moment, none of the studies provides a definite cause and offer only correlations and weakly supported hypotheses. In addition, evidence favoring a biological explanation is highly speculative. However, the research does raise questions about whether treatments with permanent effects are warranted in a population with disproportionately high percentages of ASD, behavioral health problems, and trauma.

In a 2017 literature review by Fatima Saleem and Syed Rizvi, the authors examine gender dysphoria's numerous potential causes and the remaining questions requiring further research. In conclusion, the pair indicate that associations exist between the condition and ASD, schizophrenia, childhood abuse, genetics, and endocrine disruption chemicals but that more research is needed to improve understanding of how these underlying issues factor into a diagnosis. Throughout the review, Saleem and Rizvi identify the following as potential contributing elements to the etiology of gender dysphoria:

- **Neuroanatomical Etiology:** During fetal development, the genitals and brain develop during different periods of a pregnancy, the first and second trimesters respectively. Because the processes are separate, misaligned development is possible where the brain may have features belonging to the opposite sex. The authors identify one study where trans-females presented with a "female-like putamen" (structure at the base of the brain) when undergoing magnetic resonance imaging (MRI) scans.[5]
- **Psychiatric Associations:** Saleem and Rizvi identify multiple studies reporting that individuals with gender dysphoria have high rates of anxiety and depressive disorders with results ranging as high as 70% having a mental health diagnosis. In addition, the pair note that schizophrenia may also influence desires to transition. However, the review does not assess whether the mental health conditions are secondary to gender dysphoria.
- **Autism Spectrum Disorder:** Evidence suggests a significant percentage of individuals diagnosed with gender dysphoria also have ASD. The authors note that the available studies only establish a correlation and do not identify mechanisms for causation.
- **Childhood Abuse:** Like the above causes, Saleem and Rizvi note that those with gender dysphoria tended to experience higher rates of child abuse across all categories, including neglect, emotional, physical, and sexual.
- **Endocrine Disruptors:** Although this cause still requires substantial research, it is a valid hypothesis regarding how phthalates found in plastics can create an imbalance of testosterone in fetuses during gestation, which can potentially lead to gender dysphoria. The authors point to one study that makes this suggestion.

[5] Research on neuroanatomical etiology for gender dysphoria remains highly speculative due to limitations of brain imaging (Mayer and McHugh, 2016). In addition, neuroscience demonstrates that exposures to certain environments and stimuli as well as behaviors can affect brain changes (Gu, 2014). Furthermore, available research indicates that male and female brains have different physical characteristics but cannot be placed in separate categories due to extensive overlap of white/grey matter and neural connections (Joel et al, 2015).

Saleem and Rizvi's review reveal that gender dysphoria's etiology can have multiple factors, most of which require treatments and therapies not consisting of cross-sex hormones or surgery. (Saleem and Rizvi, 2017).

Out of the research on the condition's etiology, a large portion focuses on the correlation with ASD. One of the more substantial studies by Van der Miesen et al published in 2018 evaluates 573 adolescents and 807 adults diagnosed with ASD and compares them to 1016 adolescents and 846 adults from the general population. The authors' findings note that adolescents and adults with ASD were approximately 2.5 times more likely to indicate a desire of becoming the opposite sex. Although the methodology used to reach this conclusion consisted of surveys where respondents had a choice of answering "never," "sometimes," or "often," the results correspond with those of similar studies. Van der Miesen et al also indicate that most responses favoring a change in gender responded with "sometimes." Additionally, the authors do not state how many in their sample group actually had a gender dysphoria diagnosis. (Van der Miesen et al, 2018).

Another study by Shumer et al from 2016 utilizes a smaller sample size (39 adolescents) referred to an American hospital's gender clinic. Unlike Van der Miesen et al's research, Shumer et al evaluate subjects with a diagnosis of gender dysphoria for possible signs of ASD or Asperger's syndrome. Their findings revealed that 23% of patients presenting at the clinic would likely have one of the two conditions. Possible explanations for the high percentage are the methods used to gather the data. Shumer et al requested a clinical psychologist to administer the Asperger Syndrome Diagnostic Scale to the parents of the sample patients, four of whom already had an ASD diagnosis. The authors conclude that the evidence to support high incidence of gender dysphoria in individuals with ASD is growing and that further research is needed to determine the specific cause (Shumer et al, 2016).

Research indicating a strong correlation between ASD and gender dysphoria is not the only area where new studies are emerging. Discussions about the effects of prenatal testosterone levels are also becoming more prevalent. One such example is Sadr et al's 2020 study that looks at the lengths of the index and ring fingers (2D:4D) of both left and right hands of 203 individuals diagnosed with gender dysphoria. The authors used this method because prenatal testosterone levels can affect the length ratios of 2D:4D. By comparing the ratios of a group with gender dysphoria to a cohort from the general population, Sadr et al could assess for any significant difference. Their results indicated a difference in trans-females who presented with more feminized hands. For trans-males, the difference was less pronounced. The results for both groups were slight, and the meta-analysis that accompanies the study notes no statistically significant differences in multiple groups from across cultures. However, Sadr et al further assert that the evidence strongly suggests elevated prenatal testosterone levels in girls and reduced amounts in boys may contribute to gender dysphoria, requiring additional research (Sadr et al, 2020).

In addition to biological factors and correlations with ASD, researchers are exploring psychological and social factors to assess their role in gender dysphoria etiology. This literature examines a range of potential causative agents, including child abuse, trauma, and peer group influences. One such study by Kozlowska et al from 2021 explores patterns in children with high-risk attachment issues who also had gender dysphoria. The authors wanted to assess whether past incidents of abuse, loss, or trauma are associated with higher rates of persons desiring to transition. As a basis, Kozlowska et al cite John Bowlby's research on childhood brain development, noting that the process is not linear and depends

heavily on lived experiences. The study further acknowledges that biological factors combined with life events serve as the foundation for the next developmental phase and that early poor-quality attachment issues increase the risk for psychological disorders in adolescence and adulthood. Such disorders include mood and affective disorders, suicidal ideations, and self-harm. Kozlowska et al also cite other studies that indicate a high correlation between gender dysphoria and "adverse childhood events" and further assert that the condition "needs to be conceptualized in the context of the child's lived experience, and the many different ways in which lived experience is biologically embedded to shape the developing brain and to steer each child along their developmental pathway" (Kozlowska et al, 2021).

For their study, Kozlowska et al recruited 70 children diagnosed with gender dysphoria and completed family assessments going back three generations. This in-depth level was necessary to ascertain any and all events that could affect a child's developmental phases. Additionally, the researchers individually assessed the diagnosed children. To establish comparisons, Kozlowska et al performed assessments on a non-clinical group and a mixed-psychiatric group. Their results demonstrate that children with gender dysphoria have significantly higher rates of attachment issues as well as increased reports of "adverse childhood events" such as trauma (e.g., domestic violence and physical abuse). Furthermore, the authors indicate that a high proportion of families reported "instability, conflict, parental psychiatric disorder, financial stress, maltreatment events, and relational ruptures." These results led Kozlowska et al to conclude that gender dysphoria can be "associated with developmental pathways – reflected in at-risk patterns of attachment and high rates of unresolved loss and trauma – that are shaped by disruptions to family stability and cohesion." The study also cites that treatment requires "a comprehensive biopsychosocial assessment with the child and family, followed by therapeutic interventions that address, insofar as possible, the breadth of factors that are interconnected with each particular child's presentation" (Kozlowska et al, 2021).

This recent study raises questions regarding the medical necessity of gender dysphoria treatments such as puberty blockers and cross-sex hormones for adolescents. If high percentages of children diagnosed with gender dysphoria also have histories of trauma and attachment issues, should conventional behavioral health services be utilized without proposing treatments that pose irreversible effects? Would that approach not provide additional time to address underlying issues before introducing therapies that pose permanent effects (i.e., the watchful waiting approach)?

Aside from the notion that childhood abuse and adversity can potentially cause gender dysphoria, other possible explanations such as social factors (e.g., peer influences and media) may be contributing factors. Research on rapid onset gender dysphoria (ROGD) links this phenomenon to peer and social elements. In an analysis utilizing parent surveys, Lisa Littman asserts that the rapid rise of ROGD is not associated with the traditional patterns of gender dysphoria onset (i.e., evidence of an individual's gravitation to the opposite sex documented over multiple years) but rather exposure to "social and peer contagion." Littman uses this term in the context of definitions cited in academic literature, stating that "social contagion is the spread of affect or behaviors through a population" and that "peer contagion is the process where an individual and peer mutually influence each other in a way that promotes emotions and behaviors that can potentially undermine their own development or harm others." Examples of the latter's negative effects include depression, eating disorders, and substance abuse. What prompted this study is a sudden increase of parents reporting their daughters declaring themselves to be transgender without any previous signs of gender dysphoria. Littman also indicates

that these parents cite that their daughters became immersed in peer groups and social media that emphasized transgender lifestyles (Littman, 2018).

In addition to identifying characteristics of ROGD, the study examines social media content that provides information to adolescents regarding how to obtain cross-sex hormones through deception of physicians, parents, and behavioral health professionals. Such guidance includes coaching on how to fit a description to correspond to the DSM-V and pressures to implement treatment during youth to avoid a potential lifetime of unhappiness in an undesirable body. Littman further states that "online content may encourage vulnerable individuals to believe that non-specific symptoms and vague feelings should be interpreted as gender dysphoria." The study also notes that none of the individuals assessed using the parental surveys qualified for a formal diagnosis using the DSM-V criteria (Littman, 2018).

The survey responses revealed similar data to Kozlowska et al's study with 62.5% of the adolescents having a mental health or neurodevelopmental disorder. Furthermore, the responses indicate a rapid desire to bypass behavioral health options and pursue cross-sex hormones. 28.1% of parents surveyed stated that their adolescents did not want psychiatric treatments. One parent even reported that their daughter stopped taking prescribed anti-depressants and sought advice only from a gender therapist. Littman's research further reveals that 21.2% of parents responded that their adolescent received a prescription for puberty blockers or cross-sex hormones at their first visit (Littman, 2018). These responses indicate that practitioners do not uniformly follow clinical guidelines when making diagnoses or prescribing treatment.

In the discussion, Littman proposes two hypotheses for the appearance of ROGD. The first states that social and peer contagion is one of the primary causes, and the second asserts that ROGD is a "maladaptive coping mechanism" for adolescents dealing with emotional and social issues. While the surveyed parents did not report early signs of gender dysphoria, a majority noted that their daughters had difficulty in handling negative emotions. Littman concludes that ROGD is distinct from gender dysphoria as described in the DSM-V and that further research is needed to assess whether the condition is short or long-term (Littman, 2018). What the study does not explore, but raises the question, is what proportion of those being treated for gender dysphoria are adolescents with ROGD.

Littman's study along with the others reveal that the causes of gender dysphoria are still a mystery and could have multiple biological and social elements. Because of this ongoing uncertainty, treatments that pose irreversible effects should not be utilized to address what is still categorized as a mental health issue. That allows adequate opportunity for individuals to receive treatment for co-existing mental disorders, establish their gender dysphoria diagnoses, and understand how cross-sex hormones and surgery will alter the appearance of their bodies as well as long-term health.

Literature Review: Desistance of Gender Dysphoria and Puberty Suppression

The World Professional Association for Transgender Health (WPATH) and the Endocrine Society both endorse the use of gonadotropin releasing hormones (Gn-RH) to suppress puberty in young adolescents who have gender dysphoria. Both organizations state that the treatment is safe and fully reversible. In addition, they state that delaying pubertal onset can provide extra time for adolescents to explore the gender in which they choose to live. The associations further state that puberty suppression is necessary to prevent the development of primary and secondary sexual characteristics that can inhibit successful transitions into adulthood (WPATH, 2012; Endocrine Society, 2017). Of the two groups, WPATH offers clinical criteria an individual should meet to qualify for puberty suppression such as addressing psychological co-morbidities and assessing whether gender dysphoria has intensified (WPATH, 2012).

Neither organization explains that the majority of young adolescents who exhibit signs of gender dysphoria eventually desist and conform to their natal sex and that the puberty suppression can have side effects. Both organizations neglect to mention that using Gn-RH for gender dysphoria by altering the appearance is not an FDA-approved clinical indication. Furthermore, the research used to justify puberty suppression is low or very-low quality and little information is available on long-term effects (Hruz, 2019). Additionally, in his assessment, Quentin Van Meter explained that physical differences between central precocious puberty and natural onset puberty demonstrate that Gn-RH does not have permanent adverse effects for those treated for the former but can for the latter such as insufficient bone-mineral density and neural development (Van Meter, 2022). Also, as recently as May 17, 2022, during a U.S. Senate Committee on Appropriations hearing, Lawrence Tabak, acting director of the National Institutes of Health, responded to Senator Marco Rubio, acknowledging that no long-term studies are available evaluating the effects of puberty blockers when used for gender dysphoria (U.S. Senate Committee on Appropriations, 2022).

Currently, some studies provide weak support for this treatment but leave too many questions as to its effectiveness and medical necessity, especially considering how many children decide against transitioning. In addition, puberty blockers halt development of primary and secondary sexual characteristics and deny opportunities for adolescents to adapt and become comfortable with their natal sex. Instead, puberty blockers can serve as a potential “gateway drug” for cross-sex hormones by denying them the experience of physically maturing (Laidlaw et al, 2018).

A 2013 study by Steensma et al offers data on the percentage of children who opt not to transition after experiencing gender dysphoria. The authors follow 127 adolescents (mean age of 15 during the evaluation period) for four years who had been referred to a Dutch gender dysphoria clinic. Out of this cohort, 47 (37%; 23 boys and 24 girls) continued experiencing the condition and applied for sex reassignment treatment. The other 80 adolescents never returned to the clinic. Because this clinic was the only one that treated gender dysphoria in the Netherlands, Steensma et al assumed that those who did not return no longer desired transitioning. The study indicates one of the key predictors for persisting gender dysphoria was the age of first presentation. Older adolescents that started going to the clinic were more likely to persist, while younger adolescents tended not to follow through. Steensma et al provide further insight into other predicting factors, particularly on how each individual views his or her gender identity. The authors note that adolescents who “wished they were the other sex” were more likely to become desisters and that those who “believed that they were the other sex” persisted

and later sought sex reassignment treatment (Steensma et al, 2013). While the study focuses on factors that contribute to the condition's persistence or desistance, it raises the question as to whether puberty suppression is necessary when age plays such an important role regarding the decision to transition.

WPATH and the Endocrine Society state that the primary reason for initiating pubertal suppression is not to treat a physical condition but to improve the mental health of adolescents with gender dysphoria. However, available research does not yield definitive results that this method is effective at addressing a mental health issue. The "gold standard" for medical studies is the randomized-controlled trial (RCT). Because RCTs utilize large sample sizes, have blind testing groups (i.e, placebos), and use objective controls, they can offer concrete conclusions and shape the array of established treatments. In addition, RCTs require comparisons between cohort outcomes and ensure that participants are randomly assigned to each group. These measures further reduce the potential for bias and subjectivity (Hariton and Locascio, 2018).

Presently, no RCTs that evaluate puberty suppression as a method to treat gender dysphoria are available. Instead, the limited number of published studies on the topic utilize small sample sizes and subjective methods (Hruz, 2019). A 2015 article by Costa et al is one such example. The study asserts that "psychological support and puberty suppression were both associated with an improved global psychological functioning in gender dysphoric adolescents." To reach this conclusion, the authors selected 201 children diagnosed with the condition and divided them into two groups, one to receive psychological support only and the other to get puberty blockers in addition to psychological support. Costa et al did not create a third group that lacked a gender dysphoria diagnosis to serve as a control. To assess whether puberty suppression is an effective treatment, the authors administered two self-assessments (Utrect Gender Dysphoria Scale and Children's Global Assessment Scale)[6] to the groups at 6-month intervals during a 12-month period. Because the study relies heavily on self-assessments, the conclusions are likely biased and invalid. Another problem that is also present and common throughout articles supporting puberty suppression is the short-term period of the study. Costa et al's conclusions may not be the same if additional follow-ups occurred three or five years later (Costa et al, 2015). This further raises the question whether low-quality studies like Costa et al's should serve as the basis for clinical guidelines advising clinicians to prescribe drugs for off-label purposes.

Aside from questionable research, information regarding the full physical effects of puberty suppression is incomplete. In a 2020 consensus parameter prepared by Chen et al, 44 experts in neurodevelopment, gender development, and puberty/adolescence reached a conclusion stating that "the effects of pubertal suppression warrant further study." The basis for this was that the "full consequences (both beneficial and adverse) of suppressing endogenous puberty are not yet understood." The participating experts emphasized that the treatment's impact on neurodevelopment in adolescents remains unknown. Chen et al explain that puberty-related hormones play a role in brain development as documented in animal studies and that stopping these hormones also prevents neurodevelopment in addition to sexual maturation. The authors further raise the question whether normal brain development resumes as if it had not been interrupted when puberty suppression ceases. Because this

[6] Behavioral health practitioners use the Children's Global Assessment Scale (CGAS) to measure child functioning during the evaluation process to determine diagnoses. Available evidence indicates that the CGAS is not effective for evaluating children who experienced trauma and presented with mental health symptoms (Blake et al, 2006).

question remains unanswered, it casts doubt on the veracity of organizations' assertions that puberty suppression is "fully reversible" (Chen et al, 2020).

In addition to the unanswered questions and low-quality research, puberty suppression causes side effects, some of which have the potential to be permanent. According to a 2019 literature review by De Sanctis et al, most side effects associated with Gn-RH are mild, consisting mostly of irritation around injection sites. However, clinicians have linked the drug to long-term conditions such as polycystic ovarian syndrome, obesity, hypertension, and reduced bone mineral density. While reports of these events are low and the authors indicate that Gn-RH is safe for treating central precocious puberty (Note: De Sanctis et al do not consider gender dysphoria in their analysis), the review raises questions about whether off-label use to treat a psychological condition is worth the risks (De Sanctis et al, 2019).

Furthermore, De Sanctis et al cite studies noting increased obesity rates in girls who take Gn-RH but that more research is needed to gauge the consistency. Additionally, the authors note that evidence is strong regarding reduced bone mineral density during puberty suppression but indicate that the literature suggests it is reversible following treatment (De Sanctis et al, 2019). While research leans toward the reversibility of effects on bone mineral density, the quantity of studies available on this subject are limited. Also, no long-term research has been completed on how puberty suppression affects bone growth. This is significant because puberty is when bone mass accumulates the most (Kyriakou et al, 2020). One example of a complication involving bone growth and Gn-RH is slipped capital femoral epiphysis. This condition occurs when the head of the femur (i.e., thighbone) can slip out of the pelvis, which can eventually lead to osteonecrosis (i.e., bone death) of the femoral head. Although the complication is rare, its link to puberty suppression indicates that the "lack of adequate sex hormone exposure" could be a cause (De Sanctis et al, 2019).

The current literature on puberty suppression indicates that using it to treat gender dysphoria is off-label, poses potentially permanent side effects, and has questionable mental health benefits. The limited research and lack of FDA approval for that clinical indication prompt questions about whether medications with physically altering effects should be used to treat a problem that most adolescents who experience it will later overcome by conforming to their natal sex. Additional evidence is required to establish puberty suppression as a standard treatment for gender dysphoria.

Literature Review: Cross-Sex Hormones as a Treatment for Gender Dysphoria

Currently, the debate surrounding the use of cross-sex hormones to treat gender dysphoria revolves around their ability to improve mental health without causing irreversible effects. It is not about whether taking cross-sex hormones can alter someone's appearance. The evidence demonstrating the effectiveness of cross-sex hormones in achieving the secondary sexual characteristics of the opposite sex is abundant. Also, the overall scientific consensus concludes that individuals who take cross-sex hormones will reduce the primary sexual function of his or her natal sex organs. What researchers continue evaluating are the short and long-term effects on mental health, impacts on overall physical health, and how the changes affect the ability to detransition. Of these, benefits to mental health overshadow the other discussions. Prescribers of cross-sex hormones focus so heavily on behavioral health outcomes that they de-emphasize that these drugs cause permanent physical changes and side effects that can lead to premature death (Hruz, 2020). Some clinical guidelines such as WPATH's do not even indicate that some of the changes are irreversible.

Like puberty suppression, the Endocrine Society and WPATH provide guidance on administering cross-sex hormones to individuals with gender dysphoria. Both organizations state that this treatment should not be administered without a confirmed diagnosis of gender dysphoria and only after a full psychosocial assessment. In addition, behavioral health practitioners must ensure that any mental comorbidities are not affecting the individual's desire to transition. WPATH and the Endocrine Society further state that clinicians should administer hormone replacements such as testosterone and Estradiol (estrogen) in gradual phases, where the dose increases over several months. For trans-females, the organizations state that progesterone (anti-androgen) is also necessary to block the effects of naturally produced testosterone (WPATH, 2012; Endocrine Society, 2017). When taking cross-sex hormones, trans-males need increased doses for the first six months. After that, the testosterone's effects are the same on lower doses. Once started, individuals cannot stop taking hormones unless they desire to detransition (Unger, 2016).

Although the two groups provide similar guidance, they vary on statements that can have significant impact on long-term outcomes, particularly regarding age. According to WPATH's standards, 16 years is the general age for initiating cross-sex hormones, but the organization acknowledges that the treatment can occur for younger individuals depending on circumstances (WPATH, 2012). This differs from the Endocrine Society, which states no specific age for appropriateness and explains the disagreements in assigning a number. The group highlights that most adolescents have attained sufficient competence by age 16 but may not have developed adequate abilities to assess risk (Endocrine Society, 2017). This raises the question whether adolescents can make sound decisions regarding their long-term health. Additionally, the varying guidance raises an issue with WPATH not only using age 16 as a standard but also indicating that younger adolescents are capable of making that choice.

WPATH's guidance also does not stress the irreversible nature of cross-sex hormones, citing the treatment as "partially reversible" and not indicating which changes are permanent. Furthermore, parts of WPATH's information are misleading and directly conflict with guidance issued by clinics and other sources. One such example consists of WPATH stating that "hormone therapy *may* (emphasis added) lead to irreversible changes." This statement is misleading in light of existing research, which indicates that multiple physical changes are permanent. In addition, WPATH claims that certain effects of cross-

sex hormones such as clitoral enlargement can last one to two years when it is actually irreversible (UCSF, 2020). WPATH also does not explain the risks to male fertility, noting that lowered sperm count or sterility is "variable." The University of California at San Francisco (UCSF) provides starkly different information by stating that trans-females should expect to become sterile within a few months of starting cross-sex hormones. UCSF also advises trans-females to consult a sperm bank if they may want to father children after transitioning (WPATH, 2012; UCSF, 2020). Below is a chart that outlines the effects of cross-sex hormones and identifies which ones are reversible or permanent.

Physical Changes Effectuated by Cross-Sex Hormones	
Physical Changes in Trans-Males (Female-to-Male Transitions)	
Physical Change	**Reversible or Irreversible**
Oily Skin or Acne	Reversible
Facial and Body Hair Growth	Irreversible
Male-Pattern Baldness	Irreversible
Increased Muscle Mass	Reversible
Body Fat Redistribution	Reversible
Ceasing of Menstruation	Reversible
Enlarged Clitoris	Irreversible
Vaginal Atrophy	Reversible
Deepening of Voice	Irreversible
Physical Changes in Trans-Females (Male-to-Female Transitions)	
Body Fat Redistribution	Reversible
Decreased Muscle Mass	Reversible
Skin Softening or Decrease in Oiliness	Reversible
Lower Libido	Reversible
Fewer Spontaneous Erections	Reversible
Male Sexual Dysfunction	Possibly Irreversible
Breast Growth	Irreversible
Decrease in Testicular Size	Reversible
Decrease in Sperm Production or Infertility	Likely Irreversible
Slower Facial and Body Hair Growth	Reversible

Sources: UCSF, 2020; WPATH, 2012; Endocrine Society, 2017[7]

The above chart demonstrates that trans-males and trans-females experience different effects from cross-sex hormones that can cause myriad issues in later life. For example, trans-males who opt to detransition may face challenges related to permanent disfigurement (e.g., facial hair and deepened voices). Trans-females, on the other hand, may not endure the same issues pertaining to visible physical changes but might become despondent over being unable to reproduce. This can occur regardless of whether the transitioning individual is satisfied with sex reassignment. Given that the clinical guidelines do not provide uniform information on the permanent effects of cross-sex hormones, clinicians are unable to make sound recommendations to patients. This treatment can supposedly alleviate symptoms

[7] This chart consists of conclusions regarding physical changes made by three different clinical organizations. If one organization determined that a physical change was irreversible, that was sufficient to meet the criteria to be listed as "irreversible" in the chart.

of distress. However, cross-sex hormones' permanent effects also have the potential to cause psychological issues.

Arguments favoring cross-sex hormones assert that the desired physical changes can alleviate mental health issues in individuals with gender dysphoria but do not consider that hormones used in this manner, like puberty blockers, are off-label. While the FDA has approved estrogen and testosterone for specific clinical indications (e.g., hypogonadism), it has not cleared these drugs for treating gender dysphoria. Additionally, these arguments do not acknowledge that the U.S. Drug Enforcement Administration (DEA) lists testosterone as a Schedule III controlled substance, meaning that it has a high probability of abuse (DEA, 2022). Furthermore, evidence of psychological benefit from cross-sex hormones is low-quality and relies heavily on self-assessments taken from small sample groups (Hruz, 2020).

A 2019 study by Kuper et al seeks to demonstrate that adolescents desiring cross-sex hormones have elevated rates of depression, anxiety, and challenges with peer relationships. To make their findings, the authors provided questionnaires to 149 adolescents who presented at a gender clinic in Dallas, Texas and concluded that half of the sample group experienced increased psychological issues. One problem with the study is that it relies on parent or self-assessments such as the Youth-Self Report, Body-Image Scale, and the Child Behavior Checklist. While these assessments have strong reliability, the sample is cross-sectional, consisting of gender dysphoric individuals who presented for an initial visit at the clinic. Also, Kuper et al do not directly link these psychological symptoms to gender dysphoria but rather insinuate a strong connection. Without an analysis of the longitudinal histories of the participants, the study cannot demonstrate whether gender dysphoria was a direct cause of the psychological issues, which could possibly result from trauma, abuse, or family dysfunction. Kuper et al's study only presents weak correlation between adolescents who report symptoms of distress and gender dysphoria. While the authors do not claim that the participants' psychological problems caused the condition, they fail to explicitly state that no demonstrable relationship exists and explain that their findings are "broadly consistent with the previous literature" (Kuper et al, 2019).

Additionally, a more comprehensive literature review from 2019 by Nguyen et al evaluates the effect of cross-sex hormones on mental health outcomes. Although the authors argue that the evidence supports the treatment, they do note that available studies use "uncontrolled observational methods" and "rely on self-report." The review also asserts that "future research should focus on applying more robust study designs with large sample sizes, such as controlled prospective cohort studies using clinician-administered ratings and longitudinal designs with appropriately matched control groups." All of these are characteristics of RCTs. While Nguyen et al highlight flaws in the studies in their conclusion, they do not emphasize them in their analysis, opting to focus primarily on results. Another problem with the studies selected for the review is the short-term periods for evaluation. Out of 11 studies Nguyen et al discuss, only one tracks its participants for 24 months. The others only follow their cohorts for 6 or 12 months (Nguyen et al, 2019). Without long-term data to support assertions that cross-sex hormones substantially improve the mental health of individuals with gender dysphoria, the review cannot make definitive conclusions on the treatment's benefits.

Basing their stances on this low-quality evidence, clinical associations such as the American Academy of Pediatrics (AAP) and the American Psychology Association endorse the use of cross-sex hormones as treatments for gender dysphoria. In particular, the AAP discourages use of the term "transition" and

asserts that medical treatments used to obtain secondary characteristics of the opposite sex are "gender affirming." This decision mirrors the DSM-V's interpretation of gender being part of identity. The AAP further states that taking cross-sex hormones is an "affirmation and acceptance of who they (i.e., patient) have always been" (AAP, 2018). The American Psychological Association also takes a similar stance in its *Resolution on Gender Identity Change Efforts* by asserting that medical treatments such as puberty suppression, cross-sex hormones, and surgery improve mental health and quality of life and reinforce the notion that transitioning and seeking sex reassignment therapies do not constitute a psychological disorder (American Psychological Association, 2021). Stances like these can substantially influence practitioners and their treatment recommendations. Given that low-quality evidence serves as the basis for supportive positions, this raises questions about whether clinicians can make informed decisions for their patients that will promote the best outcomes.

James Cantor published a critique in 2020 of the AAP's endorsement of "gender affirming" treatments, arguing that the organization did not base its recommendations on established medical evidence. He asserts that the AAP's position is based on research that does not support intervention but rather supports "watchful waiting" because most transgender youths desist and identify as their natal sex during puberty. Cantor further argues that the AAP not only disregards evidence but also cites "gender affirming" interventions as the only effective method. To conclude, he states the organization is "advocating for something far in excess of mainstream practice and medical consensus" (Cantor, 2020).

Given those evidentiary problems, those who rely on the AAP's endorsement as a basis for "gender affirming" treatments are practicing eminence-based medicine as opposed to evidence-based medicine. Eminence-based medicine refers to clinical decisions made by relying on the opinions of prominent health organizations rather than relying on critical appraisals of scientific evidence (Nhi Le, 2016). While it is true that the AAP has more knowledge than a lay person and a degree of credibility in the medical community, the opinions of such organizations are not valid unless they are based on quality evidence.

Research on sex reassignment also does not adequately address the reasons for and prevalence of detransitioning. Although no definite numbers are available regarding the percentage of transgender people who decide to detransition, research indicates that roughly 8% decide to return to their natal sex. The reasons range from treatment side effects to more self-exploration that provided insight on individuals' gender dysphoria. In a 2020 study by Lisa Littman, 101 people who had detransitioned provided their basis for doing so. Out of the sample group, 96% had taken cross-sex hormones and 33% had sex reassignment surgery. The average age for transitioning was 22 years, and the mean duration for the transition was 4 years. This indicates that even allowing additional time beyond the recommended age of 16 years can still lead to regrets. The study also raises the question as to whether individuals who transitioned at 16 or younger wanted to detransition in greater numbers. The author further offers reasons why these individuals sought cross-sex hormones and surgery, which include having endured trauma (mental or sexual), homophobia (challenged to accept oneself as a homosexual), peer and media influences, and misogyny (applicable only to trans-males). To obtain the results, the participants responded to a survey that asked about their backgrounds (e.g., reasons for transitioning, mental health comorbidities), and motivations for detransitioning. Littman noted that half of the women (former trans-males) had a mental health disorder and/or had experienced trauma within a year of deciding to transition. Men (former trans-females) reported much lower numbers of behavioral health issues and trauma after de-transitioning. Additionally, 77% of men surveyed identified as the opposite gender prior to transition, whereas just 58% of women had (Littman, 2020).

Of the reasons cited for detransitioning, the majority (60%) noted that they became more comfortable with their natal sex. Other reasons included concerns over complications from the treatments, primarily cross-sex hormones, and lack of improved mental health. Other less-cited explanations include concerns about workplace discrimination and worsening physical health. The study also notes that approximately 36% of participants experienced worse mental health symptoms. Based on the findings, Littman concludes that more research is needed in tracking the transgender population to obtain accurate percentages of those who decide to detransition and that men and women reported varying reasons for deciding to transition and later return to their natal sex. The author notes that higher rates of trauma and peer group influences might have contributed to women's decisions, which Littman attributes partially to rapid onset gender dysphoria (Littman, 2020). What the study also indicates is that cross-sex hormones are not a validated treatment for gender dysphoria. Nearly all of the participants had taken them and decided against maintaining the physical changes. Given that the majority of surveyed detransitioners cited that they were comfortable with their biological sex, the study indicates that gender dysphoria is not necessarily a lifelong issue. This necessarily raises doubts about whether cross-hormones, which cause permanent physical damage, is justified.

In addition to the psychological factors, cross-sex hormones pose significant long-term health risks to transitioning individuals. Currently, little information is available given that researchers have not had adequate time to study the effects in this population. However, use of hormones for other conditions has yielded data on how these drugs can affect the body and the cardiovascular system in particular. Because of the high dosages required to achieve physical change and the need to continuously take the drugs, cross-sex hormones can potentially harm quality of life and reduce life expectancy for transitioning individuals. According to Dutra et al, trans-females are three times more likely to die from a cardiovascular event than the general population. In their 2019 literature review, Dutra et al examined the results of over 50 studies evaluating the effects of cross-sex hormones on not only transgender individuals but those with menopause and other endocrine disorders, all of which indicate that use of estrogen or testosterone can increase risks for cardiovascular disease. Throughout their review, Dutra et al cite examples of trans-females having higher triglyceride levels after 24 months of cross-sex hormones and how researchers halted a study on estrogen due to an increase in heart attacks among participants. Another article the authors reference indicates a higher risk for thromboembolisms (i.e., blood clots) in trans-females. For trans-males, Dutra et al explain that research shows significant increased risk for hypertension, high cholesterol, obesity, and heart attacks. One study noted that trans-males have a four times greater risk of heart attack compared to women identifying as their natal sex. Dutra et al conclude that most transgender individuals are younger than 50 and that more studies are needed as this population ages. They do note that available studies indicate that cross-sex hormones pose dangers to long-term cardiovascular health (Dutra et al, 2019).

In sum, the literature reveals that the evidence for cross-sex hormones as a treatment for gender dysphoria is weak and insufficient. Between the permanent effects, off-label use, and consequences to long-term health, cross-sex hormones are a risky option that does not promise a cure but does guarantee irreversible changes to both male and female bodies. Additionally, the inadequate studies serving as the basis for recommendations by clinical associations can lead to providers making poorly informed decisions for their patients. Research asserting that taking cross-sex hormones improves mental health is subjective and short-term. More studies that utilize large sample sizes and appropriate

methods is required before the medical profession should consider cross-sex hormones as one of gender dysphoria's standard treatments.

Literature Review: Sex Reassignment Surgery

The final phase of treatment for gender dysphoria is sex reassignment surgery. This method consists of multiple procedures to alter the appearance of the body to resemble an individual's desired gender. Some procedures apply to the genitals (genital procedures) while others affect facial features and vocal cords (non-genital procedures). While the surgery creates aesthetical aspects, it does not fully transform someone into the opposite biological sex. Transgender persons who undergo the procedures must continue taking cross-sex hormones to maintain secondary sexual characteristics. Additionally, all physical changes are irreversible, and the success rate of a surgery varies depending on the procedure and the population. For example, surgeries for trans-females have much better results than those for trans-males. Complications such as post-operative infections can also arise with the urinary tract system. However, sex reassignment surgery supposedly can provide drastic, if not complete, relief from gender dysphoria (Endocrine Society, 2017). The following is a list of procedures (both genital and non-genital) for trans-females and trans-males that create physical features of the desired sex.

Procedures for Trans-Females

- **Genital Surgeries:** These consist of penectomy (removal of the penis), orchiectomy (removal of the testicles), vaginoplasty (construction of a neo-vagina), clitoroplasty (construction of a clitoris), and vulvoplasty (construction of a vulva and labia). To perform, a surgeon begins by deconstructing the penis and removing the testicles. The penile shaft and glans are repurposed to serve as a neo-vagina and artificial clitoris (Note: These are not actual female genitalia but tissue constructed to resemble female anatomy). If the shaft tissue is insufficient, the surgeon may opt to use a portion of intestine to build a neo-vagina. The scrotum serves as material for fashioning a vulva and labia. In addition to constructing female genitalia, the surgeon reroutes the urethra to align with the neo-vagina. Genital surgeries for trans-females result in permanent sterility (Bizic et al, 2014).
- **Chest Surgery:** To attain full breasts, trans-females can undergo enlargement. The procedure is similar to breast augmentation for women where a surgeon places implants underneath breast tissue. Prior to surgery, trans-females need to take cross-sex hormones for roughly 24 months to increase breast size to get maximum benefit from the procedure (Endocrine Society, 2017).
- **Cosmetic and Voice Surgeries:** Designed to create feminine facial features, fat deposits, and vocal sounds, these procedures are secondary to genital procedures and intended to alter trans-females' appearances to better integrate into society as a member of the desired gender (WPATH, 2012).

Procedures for Trans-Males

- **Mastectomy:** This is the most performed sex reassignment surgery on trans-males because cross-sex hormones and chest-binding garments are often insufficient at diminishing breasts. To remove this secondary sexual characteristic, trans-males can undergo a mastectomy where a surgeon removes breast tissue subcutaneously (i.e., under the skin) and reconstructs the nipples to appear masculine. The procedure can result in significant scarring (Monstrey et al, 2011).
- **Genital Surgeries:** Unlike the procedures for trans-females, genital surgeries for trans-males are more complex and have lower success rates. Consisting of hysterectomy, oophorectomy

(removal of the ovaries), vaginectomy (removal of the vagina), phalloplasty (construction of a penis), and scrotoplasty (construction of prosthetic testicles), a team of surgeons must manufacture a penis using skin from the patient (taken from an appendage) while removing the vagina and creating an extended urethra. The functionality of the artificial penis can vary based on how extensive the construction was. Attaining erections requires additional surgery to implant a prosthesis, and the ability to urinate while standing is often not achieved. Genital procedures for trans-males result in irreversible sterility (Monstrey et al, 2011).

- **Cosmetic Surgeries:** Similar to trans-females, these procedures create masculine facial features, fat deposits, and artificial pectoral muscles. They aid trans-males with socially integrating as their desired gender. Surgery to deepen voices is also available but rarely performed (WPATH, 2012).

Because sex reassignment surgery is irreversible, the criteria for receiving these procedures is the strictest of all gender dysphoria treatments. WPATH and the Endocrine Society suggest rigorous reviews of patient history and prior use of other therapies before approving. Furthermore, the two organizations recommend that only adults (18 years old) undergo sex reassignment surgery.[8] WPATH and the Endocrine Society also recommend ensuring a strongly documented diagnosis of gender dysphoria, addressing all medical and mental health issues, and at least 12 months of cross-sex hormones for genital surgeries. Although the organizations agree on most criteria, they differ on whether hormones should be taken prior to mastectomies. WPATH asserts that hormones should not be a requirement, whereas the Endocrine Society advises up to 2 years of cross-sex hormones before undergoing the procedure (WPATH, 2012; Endocrine Society, 2017). What this indicates is that trans-males might undergo breast removal without having first pursued all options if their clinician adheres to WPATH's guidelines, which can lead to possible regret over irreversible effects.

As with cross-sex hormones, sex reassignment surgery's irreversible physical changes can potentially show marked mental health improvements and prevent suicidality in people diagnosed with gender dysphoria. In April 2022, the chair of the University of Florida's pediatric endocrinology department, Dr. Michael Haller, advocated for the benefits of "gender affirming" treatments (WUSF, 2020). However, the available evidence calls such statements into question. Recent research assessing both cross-sex hormones and sex reassignment surgery indicate that the effects on "long-term mental health are largely unknown." In studies regarding the benefits of surgery, the results have the same weaknesses as the research for the effectiveness of cross-sex hormones. These include small sample sizes, self-report surveys, and short evaluation periods, all of which are insufficient to justify recommendations for irreversible treatments (Bränström et al, 2020).

Two studies conducted in Sweden provide insight on the effectiveness of sex reassignment surgery in improving the behavioral health of transgender persons. Because Sweden has a nationalized health system that collects data on all residents, this country can serve as a resource to assess service utilization and inpatient admissions. Both studies, one by Dhejne et al from 2011 and another by Bränström et al published in 2020, assessed individuals who had received sex reassignment surgery and examined outcomes over several decades. Dhejne et al's findings indicate that sex reassignment

[8] Although practice guidelines indicate the minimum age to undergo sex reassignment surgery is 18, available evidence demonstrates that mastectomies have been performed on adolescent girls as young as 13 who experience "chest dysphoria" (Olson-Kennedy et al, 2018).

procedures do not reduce suicidality. The authors explained that individuals who underwent sex reassignment surgery were still more likely to attempt or commit suicide than those in the general population. This study is unique because it monitored the subjects over a long period of time. Dhejne et al note that the transgender persons tracked for the study did not show an elevated suicide risk until ten years after surgery (Dhejne et al, 2011). Given that a high proportion of research follows sex reassignment patients for much shorter timeframes, this evidence indicates that surgery might have little to no effect in preventing suicides in gender dysphoric individuals over the long run.

In addition to having an increased suicide risk, Dhejne et al discuss how individuals who underwent sex reassignment procedures also had higher mortality due to cardiovascular disease. The authors do not list the specific causes but establish the correlation. Given that cross-sex hormones can damage the heart, the increased risk could be related to the drugs and not the surgery. Furthermore, the study explains that the tracked population had higher rates of psychiatric inpatient admissions following sex reassignment. Dhejne et al established this by examining the rates of psychiatric hospitalizations in these individuals prior to surgery and noted higher utilization in the years following the procedures. These results are in comparison to the Swedish population at large. While the study contradicts other research emphasizing improvements in mental health issues, it has its limitations. For example, the sample size is small. Dhejne et al identified only 324 individuals who had undergone sex reassignment surgery between 1973 and 2003. In addition, the authors noted that while the tracked population had increased suicide risks when compared to individuals identifying as their natal sex, the rates could have been much higher if the procedures were not available (Dhejne et al 2011). What this study postulates is that sex reassignment surgery does not necessarily serve as a "cure" to the distress resulting from gender dysphoria and that ongoing behavioral health care may still be required even after a complete transition.

Bränström et al's study evaluating the Swedish population used a larger sample (1,018 individuals who had received sex reassignment surgery) but tracked them for just a ten-year period (2005 to 2015).[9] Unlike Dhejne et al, the authors did not track suicides and focused primarily on mood or anxiety disorder treatment utilization. Their results indicate that transgender persons who had undergone surgery utilized psychiatric outpatient services at lower rates and were prescribed medications for behavioral health issues at an annual decrease rate of 8%. Bränström et al also did not limit comparisons to Sweden's overall population and factored in transgender persons who take cross-sex hormones but have not elected to have surgery. Those results still presented a decrease in outpatient mental health services. However, Bränström et al note that individuals only on cross-sex hormones showed no significant reduction in that category, which calls into question claims regarding effectiveness of cross-sex hormones in ameliorating behavioral issues.

The Bränström et al study prompted numerous responses questioning its methodology. The study lacked a prospective cohort or RCT design, and it did not track all participants for a full ten-year period (Van Mol et al, 2020). These criticisms resulted in a retraction, asserting that Bränström et al's conclusions were "too strong" and that further analysis by the authors revealed that the new "results demonstrated no advantage of surgery in relation to subsequent mood or anxiety disorder-related

[9] Although Bränström et al claim to follow individuals for a ten-year period, peer reviews of the research revealed that this was not the case, noting the authors had varying periods of tracking, ranging from one to ten years (Van Mol et al, 2020).

health care visits or prescriptions or hospitalizations following suicide attempts in that comparison" (Kalin, 2020).

There are multiple explanations for why the Bränström et al study reached different results than the Dhejne et al study. For starters, Bränström et al tracked a larger sample group over a later period (2005 to 2015 as opposed to 1973 to 2003) during which gender dysphoria underwent a dramatic shift in definition. Also, Dhejne et al did not see elevated suicides until after ten years, raising the question as to whether sex reassignment surgery has temporary benefits on mental health rather than long-term or permanent benefits. Like the other Swedish study, Bränström et al's findings are a correlation and do not specifically state that the procedures cause reduced psychiatric service utilization (Bränström et al, 2020).

A 2014 study by Hess et al in Germany evaluated satisfaction with sex reassignment procedures by attempting to survey 254 trans-females on their quality of life, appearance, and functionality as women. Out of the participants selected, only 119 (47%) returned completed questionnaires, which Hess et al indicate is problematic because dissatisfied trans-females might not have wanted to provide input. The results from the collected responses noted that 65.7% of participants reported satisfaction with their lives following surgery and that 90.2% indicated that the procedures fulfilled their expectations for life as women. While these results led Hess et al to conclude that sex reassignment surgery generally benefits individuals with gender dysphoria, the information is limited and raises questions (Hess et al, 2014). Such questions include whether the participants had mental health issues before or after surgery and did their satisfaction wane over time. Hess et al only sent out one questionnaire and not several to ascertain consistency over multiple years. Questions like these raise doubts about the validity of the study. Although Hess et al's research is just one study, numerous others utilize the same subjective methods to reach their conclusions (Hruz, 2018).

In his assessment, Patrick Lappert contributes additional insight on the appropriate clinical indications for mastectomies, noting that removal of breast tissue is necessary following the diagnosis of breast cancer or as a prophylactic against that disease. He cites that this basis is verifiable through definitive laboratory testing and imaging, making it an objective diagnosis, whereas gender dysphoria has no such empirical methods to assess and depends heavily on the patient's perspective. Also, Lappert notes that trans-males who make such decisions are doing so on the idea that the procedure will reduce their dysphoria and suicide risk. However, they are making an irreversible choice based on anticipated outcomes supported only by weak evidence, and thus cannot provide informed consent (Lappert, 2022).

The literature is inconclusive on whether sex reassignment surgery can improve mental health for gender dysphoric individuals. Higher quality research is needed to validate this method as an effective treatment. This includes studies that obtain detailed participant histories (e.g., behavioral diagnoses) and track participants for longer periods of time. These are necessary to evaluate the full effects of treatments that cause irreversible physical changes. In addition, sex reassignment procedures can result in severe complications such as infections in trans-females and urethral blockage in trans-males. Health issues related to natal sex can also persist. For example, trans-males who undergo mastectomy can still develop breast cancer and should receive the same recommended screenings (Trum et al, 2015). Until more definitive evidence becomes available, sex reassignment surgery should not qualify as a standard treatment for gender dysphoria.

Literature Review: Quality of Available Evidence and Bioethical Questions

Quality of Available Evidence

Clinical organizations that have endorsed puberty suppression, cross-sex hormones, and sex reassignment surgery frequently state that these treatments have the potential to save lives by preventing suicide and suicidal ideation. The evidence, however, does not support these conclusions. James Cantor notes that actual suicides (defined as killing oneself) are low, occur at higher rates for men, and that interpretations of available research indicate a blurring of numbers between those with gender dysphoria and homosexuals (Cantor, 2022). Although information exists that contradicts certain arguments, media outlets continue to report stories emphasizing the "lifesaving" potential of sex reassignment treatment. A May 2022 story by NBC announced survey results under the headline "Almost half of LGBTQ youths 'seriously considered suicide in the past year'" (NBC, 2022). This is a significant claim that can have a sensational effect on patients and providers alike, but how strong is the evidence supporting it? Almost all of the data backing this assertion are based on surveys and cross-studies, which tend to yield low-quality results (Hruz, 2018). In addition, how many gender dysphoric individuals are seeing stories in the media and not questioning the narrative? Because research on the effectiveness of treatments is ongoing, a debate persists regarding their use in the adolescent and young-adult populations, and much of it is due to the low-quality studies serving as evidence.

In their assessment, Romina Brignardello-Petersen and Wojtek Wiercioch examined the quality of 61 articles published between 2020 and 2022 (Note: See Attachment A for the full study). They identified research on the effectiveness of puberty blockers, cross-sex hormones, and sex reassignment surgery and assigned a grade (high, moderate, low, or very low) in accordance with the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach. Out of the articles reviewed, all with a few exceptions received grades of low or very low quality when demonstrating outcomes regarding improvements in mental health and overall satisfaction with transitioning. For puberty blockers, Brignardello-Petersen and Wiercioch identified low quality evidence for alleviating gender dysphoria and very low quality for reducing suicidal ideation. The authors also had nearly identical findings for cross-sex hormones. However, they noted moderate quality evidence for the likelihood of cardiovascular side effects. Regarding surgery, Brignardello-Petersen and Wiercioch graded articles that examined overall satisfaction and complication rates. None of the studies received grades higher than low quality. These findings led the authors to conclude that "there is great uncertainty about the effects" of sex reassignment treatments and that the "evidence alone is not sufficient to support" using such treatments. Among the studies graded was one the U.S. Department of Health and Human Services cited in its information on "gender affirming" treatments. The authors noted this research had a "critical risk of bias" and was of low quality (Brignardello-Petersen and Wiercioch, 2022).

For his part, James Cantor provided a review of available literature, which addresses studies on etiology, desistance, effectiveness of puberty blockers and cross-sex hormones, suicidal behaviors, and clinical association and international guidelines. Throughout his analysis, Cantor cites weak evidence, poor methodologies (e.g., retrospective versus prospective studies), and lack of professional endorsements in research that indicates the benefits of sex reassignment treatment. Additionally, he notes that improvements in the behavioral health of adolescents who take cross-sex hormones can be attributed to the counseling they receive concurrently and that suicidality is not likely to result from gender

dysphoria but from co-occurring mental disorders. The reasoning behind the third point is based on the blending of suicide and suicidality, which are two distinct concepts. The former refers specifically to killing oneself, and the second regards ideation and threats in attempts to receive help. Cantor specifically notes that actual suicides are highly unlikely among gender dysphoric individuals, particularly trans-males. His other conclusions indicate that young children who experience gender identity issues will most likely desist by puberty, that multiple phenomena can cause the condition, and that Western European health services are not recommending medical intervention for minors. The basis for these statements is the paucity of high to moderate quality evidence on the effectiveness of sex reassignment treatments and numerous studies demonstrating desistance (Cantor, 2022).

Despite the need for stronger studies that provide definitive conclusions, many practitioners stand by the recommendations of the AAP, Endocrine Society, and WPATH. This is evident in a letter submitted to the *Tampa Bay Times*, which was a rebuttal to the Florida Department of Health's (DOH) guidance on treatment for gender dysphoria (Note: The guidance recommends against using puberty blockers, cross-sex hormones, or surgery for minors) (DOH, 2022). The authors, led by six professors at the University of Florida's College of Medicine, state that recommendations by clinical organizations are based on "careful deliberation and examination of the evidence by experts." However, evaluations of these studies show otherwise. Not only does the available research use cross-sectional methods such as surveys, but it provides insufficient evidence based on momentary snapshots regarding mental health benefits. These weak studies are the foundation for the clinical organizations' guidelines that the University of Florida professors tout as a gold standard. In addition, the letter's authors state that DOH's guidance is based on a "non-representative sample of small studies and reviews, editorials, opinion pieces, and commentary" (Tampa Bay Times, 2022). That statement misses the point when it comes to evidence demonstrating whether treatments with irreversible effects are beneficial because the burden of proof is on those advocating for this treatment, not on those acknowledging the need for further research. This raises the question concerning how much academic rigor these professors are applying to practice guidelines released by clinical organizations and whether they also apply the same level of rigor to novel treatments for other conditions (e.g., drugs, medical devices).

Another example of a lack of rigor is a 2019 article by Herman et al from the University of California at Los Angeles (UCLA) that evaluated responses to a 2015 national survey on transgender individuals and suicide. Unlike other studies, this one utilized a large cohort with 28,000 participants from across the U.S. responding. However, the researchers used no screening criteria and did not randomly select individuals. In addition, responses consisted entirely of self-reports with no supporting evidence to even prove a diagnosis of gender dysphoria. Although Herman et al conclude that the U.S. transgender population is at higher risk for suicidal behaviors, the authors' supporting evidence is subjective and serves as a weak basis. Additionally, the survey results do not establish gender dysphoria as a direct cause of suicide or suicidal ideation. The questions required participants to respond about their overall physical and mental health. Out of those that indicated "poor" health, 77.7% reported suicidal thoughts or attempts during the previous year, whereas just 29.1% of participants in "excellent" health had. These percentages indicate that causes beyond gender dysphoria could be affecting suicidal behaviors. Other reasons cited include rejection by family or religious organizations and discrimination. The authors also acknowledge that their findings are broad, not nationally representative, and should serve as a basis for pursuing future research (Herman et al, 2019).

Yet another example is a study published in 2022 by Olson et al tracks 300 young children that identify as transgender over a 5-year period, and asserts low probabilities for detransitioning, while supporting interventions such as puberty blockers. The authors found that children (median age of 8 years) who identified as a gender that differed from their natal sex were unlikely to desist at a rate of 94% and conclude that "transgender youth who socially transitioned at early ages" will continue "to identify that way." While this appears to contradict earlier studies that demonstrate most young adolescents who change gender identities return to their "assigned gender at birth," the authors note differences and limitations with the results. For example, Olson et al notes that they did not verify whether the participants met the DSM-V's diagnostic criteria for gender dysphoria and that the children's families supported the decisions to transition. Instead, the authors relied on a child's chosen pronouns to classify as transgender. Also, Olson et al acknowledged that roughly 66% of the sample was biologically male. This is particularly significant considering that the majority of transitioning adolescents in recent years were natal females. Another issue with the study includes the median age at the end of follow-up (13 years), which is when boys begin puberty. Furthermore, the authors cite that the participants received strong parental support regarding the transitions, which constitutes positive reinforcement (Olson et al, 2022). Other research demonstrates that such feedback on social transitioning from parents and peers can prevent desistance following pubertal onset (Zucker, 2019). Despite these limitations, the New York Times announced the study's publication under the headline "Few Transgender Children Change Their Minds After 5 Years" (New York Times, 2022). Such a title can add to the public's perception that gender dysphoria requires early medical intervention to address.

Bioethical Questions

The irreversible physical changes and potential side effects of sex reassignment treatment raise significant ethical questions. These questions concern multiple bioethical principles including patient autonomy, informed consent, and beneficence. In a 2019 article, Michael Laidlaw, Michelle Cretella, and Kevin Donovan argue that prescribing puberty blockers or cross-sex hormones on the basis that they will alleviate psychological symptoms should not be the standard of care for children with gender dysphoria. Additionally, the three authors assert that such treatments "constitute an unmonitored, experimental intervention in children without sufficient evidence of efficacy or safety." The primary ethical question Laidlaw, Cretella, and Donovan pose is whether pushing physical transitioning, particularly without parental consent, violates fully informed consent (Laidlaw et al, 2019).

In accordance with principles of bioethics, several factors must be present to obtain informed consent from a patient. These consist of being able to understand and comprehend the service and potential risks, receiving complete disclosure from the physician, and voluntarily providing consent. Bioethicists generally do not afford the ability of giving informed consent to children who lack the competence to make decisions that pose permanent consequences (Varkey, 2021). Laidlaw, Cretella, and Donovan reinforce this point regarding sex reassignment treatment when they state that "children and adolescents have neither the cognitive nor the emotional maturity to comprehend the consequences of receiving a treatment for which the end result is sterility and organs devoid of sexual function" (Laidlaw et al, 2019). This further raises the question whether clinicians who make such treatment recommendations are providing full disclosure about the irreversible effects and truly obtaining informed consent.

Another issue is the conflict between consumerism and the practitioner's ability to provide appropriate care. Consumerism refers to patients learning about treatments through media/marketing and requesting their health care provider to prescribe it, regardless of medical necessity. Considering that social media is rife with individuals promoting "gender affirmative" drugs and surgeries, children are making self-assessments based on feelings they may not understand and that can lead to deep regret in the future (Littman, 2018). This can contribute to patients applying pressure on their doctors to prescribe medications not proven safe or effective for the condition. Consumerism can also affect bioethical compliance because it constrains clinicians from using their full "knowledge and skills to benefit the patient," which is "tantamount to a form of patient abandonment and therefore is ethically indefensible" (Varkey, 2021).

In his assessment, G. Kevin Donovan explains the bioethical challenges related to sex reassignment treatment, emphasizing the lack of informed consent when administering these services. He asserts that gender dysphoria is largely a self-diagnosis practitioners cannot verify with empirical tests (e.g., labs and imaging) and that providing such treatments is experimental. Because of the lack of consent and off-label use of puberty blockers and cross-sex hormones, Donovan raises the question as to how "experienced and ethical physicians so mislead others or be so misled themselves?" He further attributes this phenomenon to societal and peer pressures that influence self-diagnosis and confirm decisions to transition. As a result, these pressures lead to individuals wanting puberty blockers, cross-sex hormones, and surgery. Donovan goes on to identify several news stories where embracing sex reassignment treatment is a "cult-like" behavior. To conclude, he links these factors back to the failure to obtain informed consent from transgender patients and how that violates basic bioethical principles (Donovan, 2022).

Coverage Policies of the U.S. and Western Europe

U.S. Federal Level Coverage Policies

Medicare: In 2016, the Centers for Medicare and Medicaid Services (CMS) published a decision memo announcing that Medicare Administrative Contractors (MACs) can evaluate sex reassignment surgery coverage on a "case-by-case" basis.[10] CMS specifically noted that the decision memo is not a National Coverage Determination and that "no national policy will be put in place for the Medicare program" (CMS, 2016). This memo was the result of CMS reviewing over 500 studies, reports, and articles to the validity of the procedures. Following its evaluation, CMS determined that "the quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding . . . small sample sizes, lack of validated assessment tools, and considerable (number of participants in the studies) lost to follow up." In 2017, CMS reinforced this position with a policy transmittal that repeated the 2016 memo's criteria (CMS, 2017).

The basis for Medicare's decision is that the "clinical evidence is inconclusive" and that "robust" studies are "needed to ensure that patients achieve improved health outcomes." In its review of available literature, CMS sought to answer whether there is "sufficient evidence to conclude that gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria." After evaluating 33 studies that met inclusion criteria, CMS's review concludes that "not enough high-quality evidence" is available "to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively." Additionally, out of the 33 studies, just 6 provided "useful information" on the procedures' effectiveness, revealing that their authors "assessed quality of life before and after surgery using validated (albeit non-specific) psychometric studies" that "did not demonstrate clinically significant changes or differences in psychometric test results" following sex reassignment surgery (CMS, 2016).

U.S. Department of Defense – Tricare: Tricare does not cover sex reassignment surgery, but it will cover psychological services such as counseling for individuals diagnosed with gender dysphoria and cross-sex hormones when medically necessary (Tricare, 2022).[11]

U.S. Department of Veterans Affairs: The U.S. Department of Veterans Affairs (VA) does not cover sex reassignment surgery, although it will reimburse for cross-sex hormones and pre- and post-operative care related to transitioning. Because the VA only provides services to veterans of the U.S. armed forces, it cannot offer sex reassignment treatment to children (VA, 2020).[12]

[10] The Centers for Medicare and Medicaid Services is part of the U.S. Department of Health and Human Services. Its primary functions are to administer the entire Medicare system and oversee federal compliance of state Medicaid programs. In addition, CMS sets reimbursement rates and coverage criteria for the Medicare program.
[11] Tricare is the insurance program that covers members of the U.S. armed forces and their families. This includes children of all ages.
[12] The U.S. Department of Veterans Affairs oversees the Veterans Health Administration (VHA), which consists of over 1,000 hospitals, clinics, and long-term care facilities. As the largest health care network in the U.S., the VHA provides services to veterans of the U.S. armed forces.

State-Level Coverage Policies

Florida: In April 2022, DOH issued guidance for the treatment of gender dysphoria, recommending that minors not receive puberty blockers, cross-sex hormones, or sex reassignment surgery. [13] The justification offered for recommending against these treatments is that available evidence is low-quality and that European countries also have similar guidelines. Accordingly, DOH provided the following guidelines:

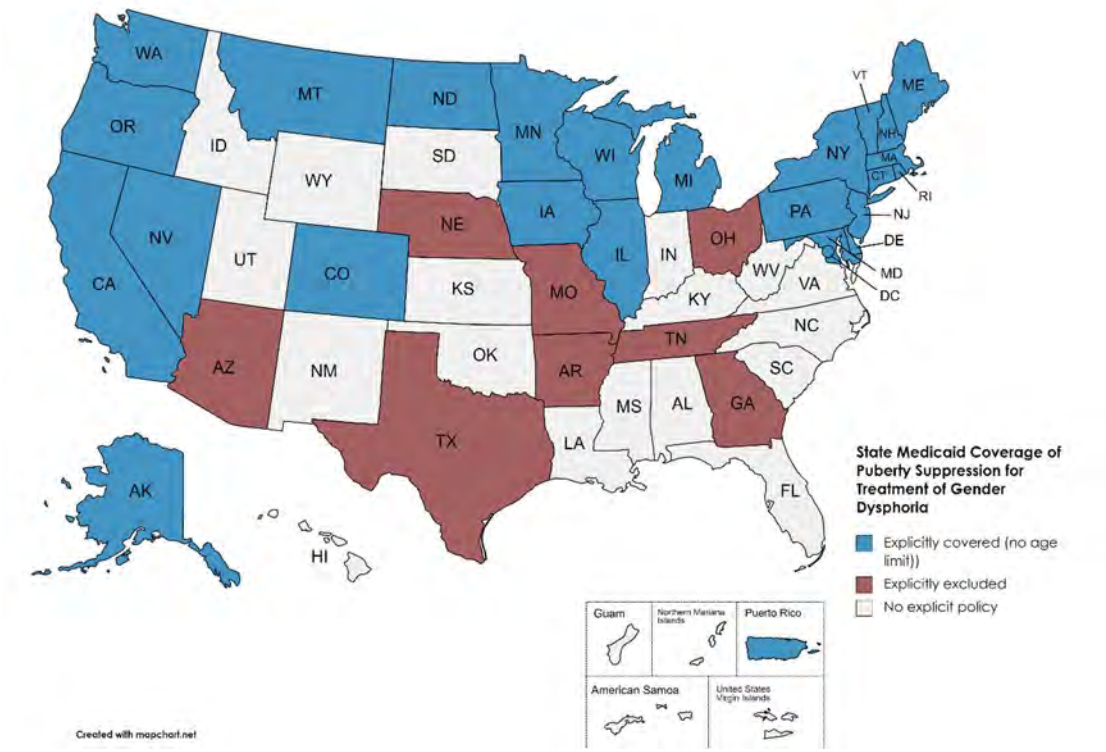
- "Social gender transition should not be a treatment option for children or adolescents."
- "Anyone under 18 should not be prescribed puberty blockers or hormone therapy."
- "Gender reassignment surgery should not be a treatment option for children or adolescents."
- "Children and adolescents should be provided social support by peers and family and seek counseling from a licensed provider."

In a separate fact sheet released simultaneously with the guidance, DOH further asserts that the evidence cited by the federal government cannot establish sex reassignment treatment's ability to improve mental health (DOH, 2022).

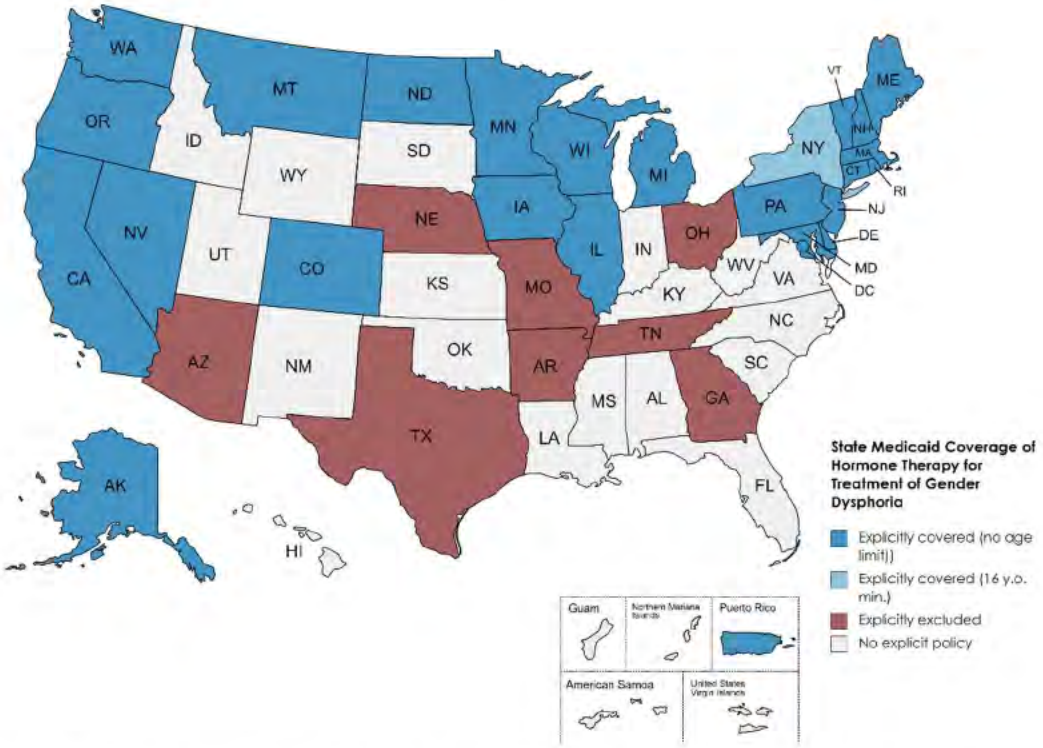
State Medicaid Programs: Because individual states differ in health services offered, Medicaid programs vary in their coverage of sex reassignment treatments. The following maps identify states that cover sex reassignment treatments, states that have no policy, and states that do not cover such treatments.

[13] Unlike the federal government, the State of Florida delegates responsibilities for Medicaid and health care services to five separate agencies (Agency for Health Care Administration, Department of Health, Department of Children and Families, Department of Elder Affairs, and Agency for Persons with Disabilities). Each agency has its own separate head (secretary or surgeon general), which reports directly to the Executive Office of the Governor. As Florida's public health agency, DOH oversees all county health departments, medical professional boards, and numerous health and welfare programs (e.g., Early Steps and Women, Infants, and Children). Because it oversees the boards, DOH has authority to release practice guidelines.

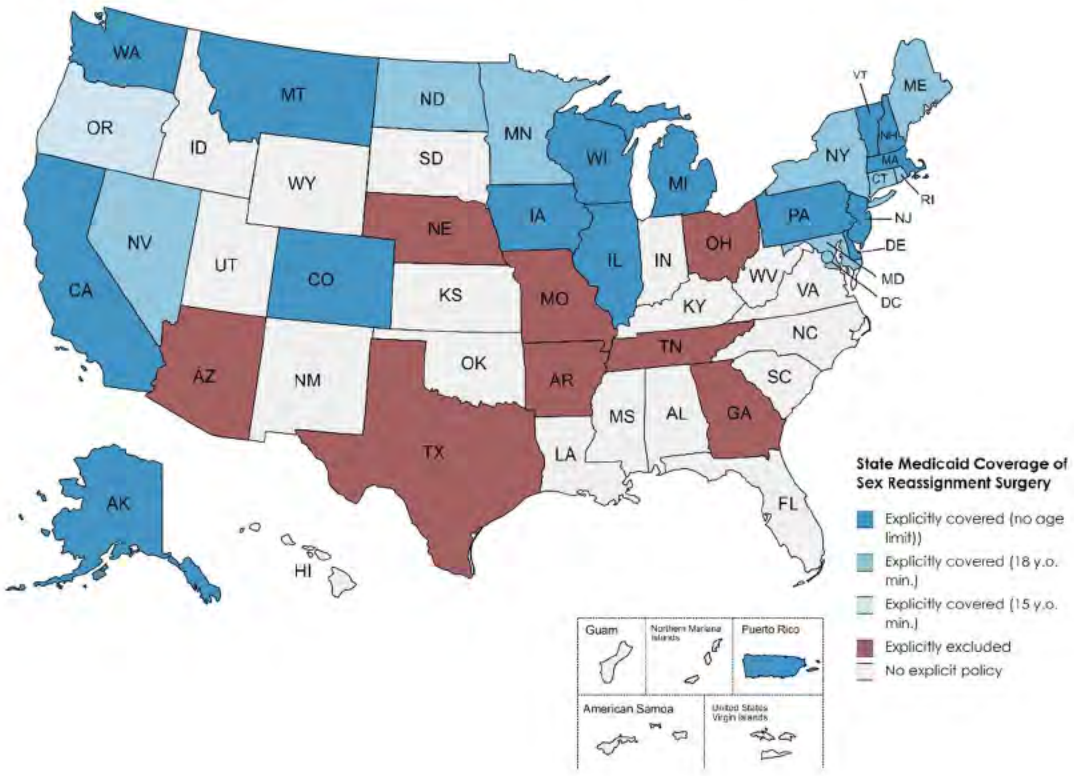
State Medicaid programs with coverage decisions regarding puberty blockers:



State Medicaid programs with coverage decisions regarding cross-sex hormones:



State Medicaid programs with coverage decisions regarding sex reassignment surgery:



Western Europe

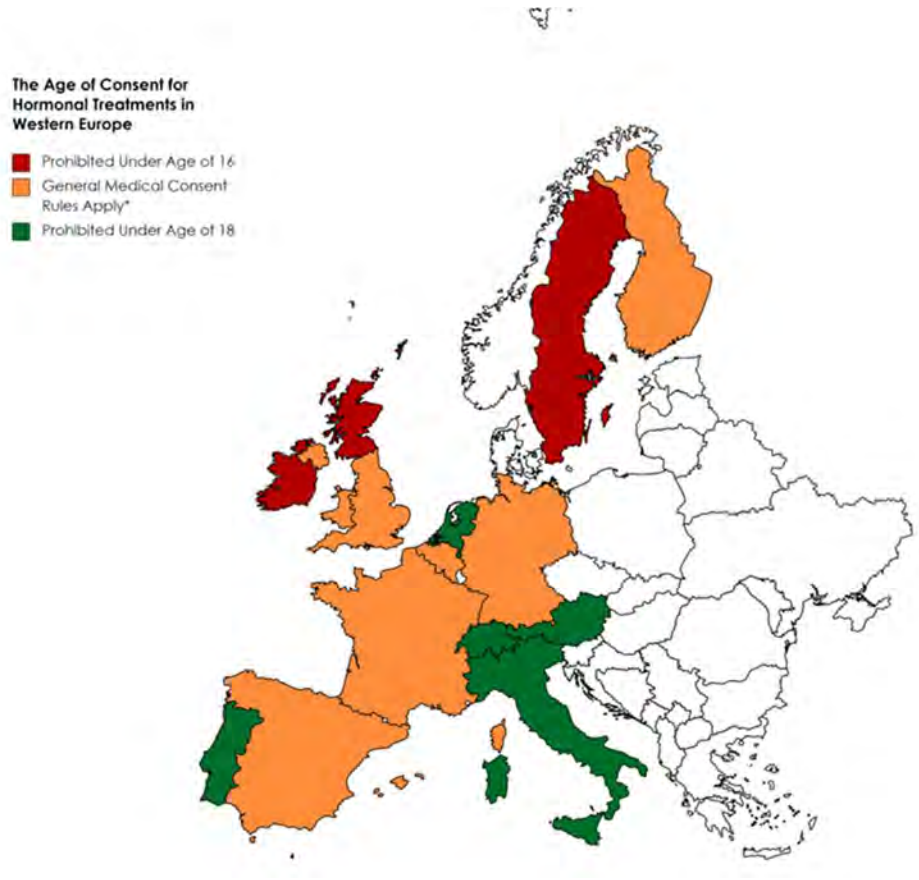
Scandinavian countries such as Sweden and Finland have released new guidelines on sex reassignment treatment for children. In 2022, the Swedish National Board of Health stated that "the risks of hormonal interventions for gender dysphoric youth outweigh the potential benefits." With the exception of youths who exhibited "classic" signs of gender identity issues, adolescents who present with the condition will receive behavioral health services and gender-exploratory therapy (Society for Evidence Based Gender Medicine, 2022).

In Finland, the Palveluvalikoima issued guidelines in 2020 stating that sex reassignment in minors "is an experimental practice" and that "no irreversible treatment should be initiated." The guidelines further assert that youths diagnosed with gender dysphoria often have co-occurring psychiatric disorders that must be stabilized prior to prescribing any cross-sex hormones or undergoing sex reassignment surgery (Palveluvalikoima, 2020).

The United Kingdom (U.K.) is also reassessing the use of irreversible treatments for gender dysphoria due the long-term effects on mental and physical health. In 2022, an independent interim report commissioned by the U.K.'s National Health Service (NHS) indicates that additional research and systematic changes are necessary to ensure the safe treatment of gender dysphoric youths. These include reinforcing the diagnosis process to assess all areas of physical and behavioral health, additional training for pediatric endocrinologists, and informing parents about the uncertainties regarding puberty blockers. The interim report is serving as a benchmark until the research is completed for final guidelines (The Cass Report, 2022).

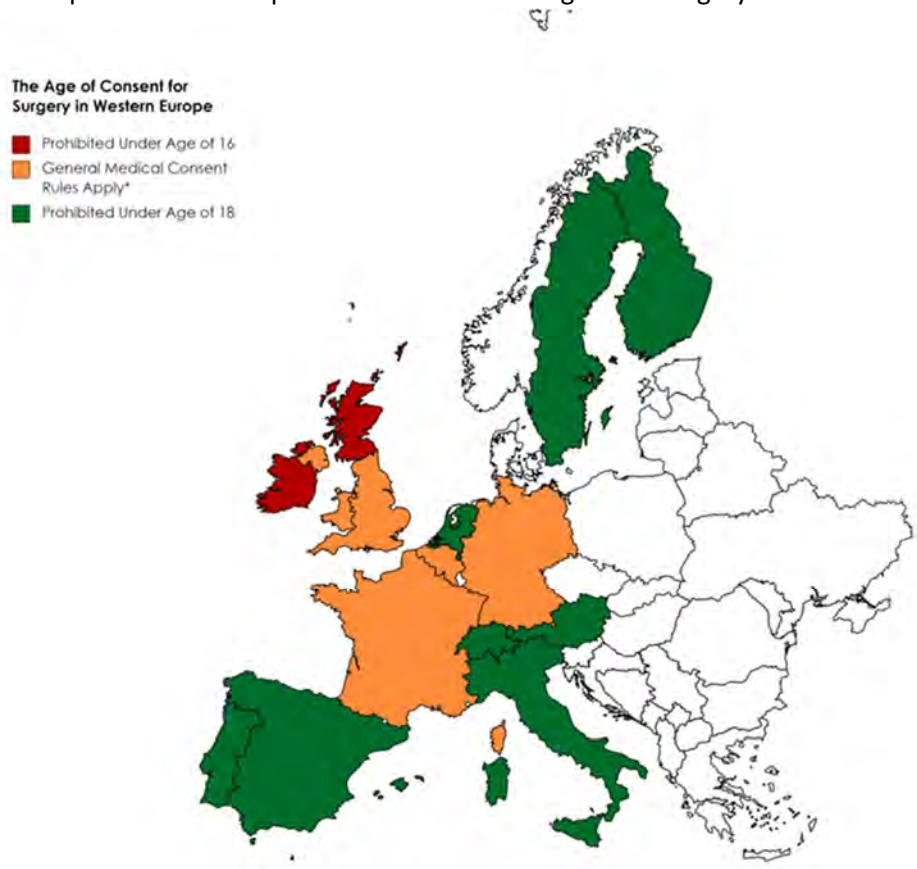
Like state Medicaid programs, health systems across Western Europe also vary in their coverage of sex reassignment treatment.

Western European nations' requirements for cross-sex hormones:



In this context, the age requirement for access to any medical treatment without consent of parents or of a public authority. This age may range from 16 to 18 years depending on each country's laws.

Western European nations' requirements for sex reassignment surgery:



In this context, the age requirement for access to any medical treatment without consent of parents or of a public authority. This age may range from 16 to 18 years depending on each country's laws.

Generally Accepted Professional Medical Standards Recommendation

This report does not recommend sex reassignment treatment as a health service that is consistent with generally accepted professional medical standards. Available evidence indicates that the services are not proven safe or effective treatments for gender dysphoria.

Rationale

The available medical literature provides insufficient evidence that sex reassignment through medical intervention is a safe and effective treatment for gender dysphoria. As this report demonstrates, the evidence favoring "gender affirming" treatments, including evidence regarding suicidality, is either low or very low quality:

- **Puberty Blockers:** Evidence does not prove that puberty blockers are safe for treatment of gender dysphoria. Evidence that they improve mental health and reduce suicidality is low or very low quality.
- **Cross-Sex Hormones:** Evidence suggesting that cross-sex hormones provide benefits to mental health and prevents suicidality is low or very low quality. Rather, evidence shows that cross-sex hormones cause multiple irreversible physical consequences as well as infertility.
- **Sex Reassignment Surgery:** Evidence of improvement in mental health and reduction in suicidality is low or very low quality. Sex reassignment surgery results in irreversible physical changes, including sterility.

While clinical organizations like the AAP endorse the above treatments, none of those organizations relies on high quality evidence. Their eminence in the medical community alone does not validate their views in the absence of quality, supporting evidence. To the contrary, the evidence shows that the above treatments pose irreversible consequences, exacerbate or fail to alleviate existing mental health conditions, and cause infertility or sterility. Given the current state of the evidence, the above treatments do not conform to GAPMS and are experimental and investigational.

✓ **Concur** ____ **Do not Concur**

Comments:

_____

_____

_____

_____ 6/2/22

Deputy Secretary for Medicaid (or designee) *Date*

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Attachments

Attachment A: Secretary for the Florida Agency for Health Care Administration's Letter to Deputy Secretary Thomas Wallace. 20 April 2022.

Attachment B: Complete text of Rule 59G-1.035, F.A.C.

Attachment C: Romina Brignardello-Petersen, DDS, MSc, PhD and Wojtek Wiercioch, MSc, PhD: *Effects of Gender Affirming Therapies in People with Gender Dysphoria: Evaluation of the Best Available Evidence*. 16 May 2022.

Attachment D: James Cantor, PhD: *Science of Gender Dysphoria and Transsexualism*. 17 May 2022.

Attachment E: Quentin Van Meter, MD: *Concerns about Affirmation of an Incongruent Gender in a Child or Adolescent*. 17 May 2022.

Attachment F: Patrick Lappert, MD: *Surgical Procedures and Gender Dysphoria*. 17 May 2022.

Attachment G: G. Kevin Donovan, MD: *Medical Experimentation without Informed Consent: An Ethicist's View of Transgender Treatment for Children*. 16 May 2022.

EXHIBIT F

July 8, 2022

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

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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 for gender dysphoria does not meet generally accepted medical standards and is experimental and investigational.[1]

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[*] 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.

[1] Division of Florida Medicaid, Agency for Health Care Administration, Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria, June 2022, at https://www.ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf ("June 2 Report").

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").[2] 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.[3]

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 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:

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[2] 48 Fl. Admin. Reg. 2461 (June 17, 2022).

[3] 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).

- 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.

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Analysis

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"[4] – 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.[5] These clinical guidelines are based on 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.[6] The original Endocrine Society guidelines were published in 2009 and updated in 2017.[7]

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.[8] 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

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[4] June 2 Report, p. 2.

[5] 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)").

[6] 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.

[7] Endocrine Society (2017), supra note 5.

[8] 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).

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.[9]

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, inexpert, 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."[10]

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)."[11] 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

[9] 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.

[10] June 2 Report, p. 2.

[11] Fl. Admin. Code Section 59G-1.035(4).

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.[12] 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.[13] That 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.[14] 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,[15] supports mental health providers practicing conversion therapy,[16] and describes childhood gender dysphoria as "confusion."[17] Troublingly, the van

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[12] 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).

[13] 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 22, 2022, at https://jamanetwork.com/journals/jama/pages/instructions-for-authors#SecConflictsofInterestandFinancialDisclosures

[14] Caruso, supra note 12.

[15] Den Trumbull, Defending Traditional Marriage, American College of Pediatricians (2013), https://acpeds.org/position-statements/defending-traditional-marriage. **Error! Hyperlink reference not valid.**See Jack Turban, The American College of Pediatricians is an Anti-LGBTQ Group, Psychology Today, May 8, 2017.

[16] 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.

[17] 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

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.[18] The van Meter attachment appears to be a re-use of paid testimony rather than an original product.[19]

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.[20] 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,[21] Troublingly, Cantor's appearance in that case seems to have been funded by the Alliance Defending Freedom ("ADF"), [22] a religious and political organization that opposes legal protections for transgender people and same-sex marriage[23] and defends the criminalization of sexual activity between partners of the same sex.[24] 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,[25] she has conducted research for the Society for Evidence-

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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

[18] 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.

[19] 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.

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

[21]The 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

[22] 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

[23] 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."

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

[25] 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.

Based Gender Medicine ("SEGM").[26] 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.[27]

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.[28] The judge found 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.[29] The judge gave no weight to Lappert's testimony about informed consent in that case, finding that it was unsupported by scientific evidence.[30] 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."[31]

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.*

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[26] 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."

[27] 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/.

[28] 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.

[29] Id.

[30] Id., pp. 29-30.

[31] Id., p. 31.

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.

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.[32] The other author (Wiercioch) is a junior researcher (a postdoctoral fellow) with no prior research or clinical experience in this field.[33]

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.[34] 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.

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

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

[34] 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.

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.[35] 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.

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.[36] 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.[37] 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 inexpert 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.*

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

[36] BPW document, Methods section, p. 2.

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

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.[38] 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.[39] 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 a*n 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. 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.[40]

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,

[38] BPW document, Introduction Section, p. 2.
[39] BPW document, Results Section, p. 1.
[40] 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.

the BPW analysis reaches the conclusion that there is little or no evidence for the benefits of medical care for gender dysphoria.[41]

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.[42] 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.

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.*[43]

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.

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[41] 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.

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

[43] Balshem et al., supra note 42, at 402 (emphasis added).

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.[44]

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.

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.[45] 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.[46]

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.[47] 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

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[44] Id.

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

[46] 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.")

[47] Endocrine Society (2017), supra note 5.

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.[48]

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.

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.[49] 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.[50]

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

[48] Id.

[49] 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.")

[50] 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.

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").[51] 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."[52] Concretely, many of the original treatment recommendations regarding statins are based on observational studies, not RCTs.[53] 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 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.[54] 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

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[51] 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).
[52] Id., Tables 3 and 4.
[53] Syed S. Mahmood, et al., The Framingham Heart Study and the Epidemiology of Cardiovascular Disease: a Historical Perspective, 383 Lancet 999-1008 (2014).
[54] 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).

empirical research.[55] 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.

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.[56] 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."[57] 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*

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[55] 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 Prace 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).

[56] 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)").

[57] Id.

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 studies.[59]

To take another example, the June 2 Report grossly misleads the reader in its discussion of a study by Chen et al. in 2020.[60] The report cherry-picks quotes from Chen et al. to the effect that "the effects of pubertal suppression warrant further study" and the "full consequences of suppressing endogenous puberty are not yet understood."[61]

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

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[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 27, at n. 43.

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

[61] June 2 Report, p. 15.

and well-tolerated in children and adolescents" and that most drug reactions were mild. [62] 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."[63] 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.[64] 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 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.[65] 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.[66]

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.[67]

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[62] 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).
[63] June 2 Report, p. 16.
[64] 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).
[65] June 2 Report, pp. 8, 14, 15, 19.
[66] 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").
[67] AAP Committee on Drugs (2014), supra note 66.

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.[68]

Off-label use is so common in pediatrics that off-label drugs are prescribed in 20% of patient visits.[69] 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.

A host of familiar examples provide illustrations of day-to-day, off-label use in pediatrics.[70] 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.

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[68] 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).

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

[70] 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.

Buproprion 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 ncluding sertraline and escitalopram) are off-label.[71] 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).[72]

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 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 transmasculine patients.

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."[73] 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.*[74] 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.

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[71] 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).

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

[73] June 2 Report, p. 14.

[74] Boulware et al., supra note 27, at 17-19.

The authoritative WPATH and Endocrine Society clinical practice guidelines contain measures to ensure that medical treatment is administered only when medically necessary.[75] 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.[76] 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.[77] 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 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."[78] 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

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[75] WPATH (2012) and Endocrine Society (2017), supra note 5.
[76] Id.
[77] 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).
[78] 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").

assault."[79] 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."[80]

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.[81]

Studies that actually focus on regret consistently find that transgender people only rarely regret their medical treatments.[82] 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).[83]

> 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,"[84] 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." [85]

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[79] Id.
[80] Id.
[81] Kristina R. Olson, et al., Gender Identity Five Years After Social Transition, Pediatrics (preprint, May 2022).
[82] 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).
[83] Id.
[84] June 2 Report, p. 12.
[85] Boulware et al., supra note 27, at 20-21 (internal citations omitted).

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.[86]

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.[87]

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.[88] 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 known 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

[86] Greta R. Bauer, et al., 243 J. Pediatrics 224-227 (2022).
[87] Sandy E. James, et al., The Report of the 2015 U.S. Transgender Survey, National Center for Transgender Equality (2015).
[88] 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).

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.[89]

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."[90] 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.

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. [91] 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.[92] 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

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[89] 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.

[90] June 2 Report, p. 6.

[91] 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).

[92] 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).

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.[93]

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 impact gender-affirming hormone therapy."[94] 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.[95] 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.[96] Indeed,

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[93] 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).
[94] Endocrine Society (2017), supra note 5.
[95] Lieke J. Vrouenraets, et al., Assessing Medical Decision-Making Competence in Transgender Youth, 148(6) Pediatrics e2020049643 (2021).
[96] 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-

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."[97]

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.*"[98]

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.[99] Costa's study ewas 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.[100] 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."[101] Put simply, Tordoff et al. clearly found

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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).

[97] 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.

[98] Cantor document, p. 13.

[99] Costa et al., supra note 56.

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

[101] Id.

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.[102] 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.

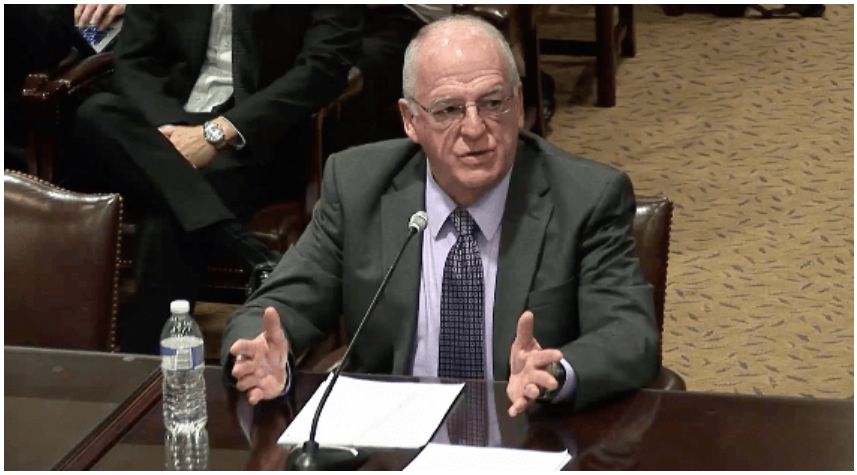
[102] Laura E. Kuper, et al., Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy, 145(4) Pediatrics e20193006 (2020).

EXHIBIT G

Civil Rights & Social Justice
Government & Politics
Health Care

A Texas judge ruled this doctor was not an expert. A Pennsylvania Republican invited him to testify on trans health care

By: Stephen Caruso - September 15, 2020 7:24 am



Dr. Quentin Van Meter testified at a March 12, 2020 House hearing on trans youth health issues. (Pa. House feed)

A physician testifying before a House panel Monday as part of a "fact-finding mission" on gender-affirming care was disqualified by a judge earlier this year as an expert on trans health care.

Dr. Quentin Van Meter, an Atlanta-based doctor and president of a conservative pediatric group, was one of three medical practitioners who testified before the Pennsylvania House Health Committee on the science behind gender dysphoria, or the feeling of being misaligned with the sex you were born with.

The first two Pennsylvania-based experts argued that gender-affirming care, including puberty-blocking drugs, were a safe way to help a young person grappling with their identity.

Then, lawmakers heard from Van Meter, who has previously called such treatment "medical experimentation based on wishful social theory," but in a February 2020 court ruling, was "discredited as an expert" on hormone treatment.

The ruling came in a Texas divorce case overseen by Judge Germaine Tanner of Harris County.

She found that Van Meter could not offer expert testimony on "the legal question of whether an adolescent transgender child should be administered puberty blockers and whether affirmation of an incongruent gender in a child is harmful or not," according to a court document acquired by the Capital-Star.

The case is now sealed, but Douglas Ray York, an attorney in the case, confirmed the document's authenticity to the Capital-Star.

The divorce case involved a child who was undergoing gender-affirming treatment. The mother wanted to end the treatment, the father did not.

York said that Van Meter's testimony was thrown out because he did not offer a fact-driven opinion on the impact of puberty blocking drugs.

"He says all transgender youth are delusional and need psychiatric help, and the court took that and said wait a minute, his opinion tended to be more agenda driven than scientific driven," York told the Capital-Star earlier this year.

He compared Van Meter's testimony to a "chocolate easter bunny. It looks great on the outside, but you penetrate it, it's hollow."

Van Meter spoke for just about 25 minutes Monday.

"No adolescent is capable of making a decision, with informed consent … of what that adolescent will feel like when they are an adult, and they are infertile, their genitalia [doesn't] work," Van Meter testified.

It was his second appearance before the House Health Committee this year. In March, he appeared at a nearly three-hour long hearing alongside Dr. Stephen Levine, a Case Western Reserve University professor who has also been skeptical of hormone treatment.

The hearings were organized by Rep. Paul Schemel, R-Franklin, chair of the subcommittee on health care, because Pennsylvania's CHIP program pays for gender-affirming care for children in low-income families.

The experts picked to support gender-affirming care were suggested by state Health Secretary Dr. Rachel Levine, who is a trans woman, Schemel said. She was originally supposed to testify herself, but had to cancel due to the COVID-19 pandemic.

Schemel added he was aware of the Texas judge's ruling, and disagreed with it.

"I think that the judge had actually not analyzed all of Dr. Van Meter's work," Schemel said, adding: "The only thing that would disqualify him in the eyes of some is that he has a divergent opinion."

Van Meter did not reply to a request for comment.

This isn't the only controversial stance Van Meter has taken. He also has advocated for conversion therapy, or trying to change someone's sexual orientation from homosexual to heterosexual. The practice is opposed by most mainstream medical groups, such as the American Psychiatric Association.

In neighboring Ohio, Van Meter is also being used as an expert in a lawsuit demanding that the state allow trans individuals to change their birth sex on their birth certificate, as reported by the Ohio Capital-Journal, a sibling site of the Capital-Star.

He also is the current president of the American College of Pediatricians. The Southern Poverty Law Center has also named the organization a hate group for "calling homosexual relationships promiscuous, a danger to children, unstable, and claiming that LGBTQ people experience 'shortened lifespans.'"

Speaking to the news site Christian Headlines in 2014, Van Meter said ACP was not religiously affiliated, but said members were "moral people who are like-minded, and want truth, and want what's best for children."

Studies show that LGBTQ, and in particular transgender teens, are more likely to contemplate and commit suicide.

For example, according to the Trevor Project, a national LGBTQ youth suicide prevention organization, 35 percent of LGBTQ people under 25 had attempted suicide, compared to 7 percent of cisgendered individuals in the same age range.

Speaking Monday, Van Meter downplayed those statistics, saying they were the result of a skewed sampl

"We are basically being blackmailed by the concept that these kids will kill themselves," without gender affirming care, Van Meter told the committee.

But Dr. Katharine Dalke, a psychiatrist focused on LGBTQ health at Penn State Hershey Medical Center, argued that the support and acceptance of their parents, as well as access to puberty blocking drugs could address the mental health concerns.

"The problems are not intrinsic to being transgender, but rather due to a combination of gender incongruence and social stigma," Dalke said.

The prescriptions do not "cause permanent changes in an adolescent's body. Instead, it pauses puberty, providing time to determine if a child's gender identity is long lasting. It also gives children and their families time to think about or plan for the psychological, medical, developmental, social and legal issues ahead," according to the Mayo Clinic.

The drugs also can minimize the need for costly medical operations down the line for people to transition to their preferred gender later in life, Dalke added.

Republican lawmakers peppered both Dalke and another witness, Nadia Dowshen of the Children's Hospital of Philadelphia, with questions about the earliest age they would prescribe hormone therapy or conduct any medical procedures.

Both Dalke and Dowshen said that teens between the aged of 14 and 16 would likely be the start date for any hormone use, and only after rounds of therapy and with the consent of parents. Surgical options wouldn't be considered until the gender non-conforming indvidual was an adult, they added.

Speaking after the meeting, Schemel said he did not have any policy goals in mind, and reminded lawmakers throughout the meeting that no votes were yet scheduled.

Van Meter did not recommend any specific policy Monday. But in his native Georgia, he did back at least one proposal: Making it a felony to provide hormone treatment to a minor.

EXHIBIT H

Child and Adolescent Mental Health

Child and Adolescent Mental Health27, No. 3, 2022, pp. 259 262 doi:10.1111/camh.12533

Commentary: The Signal and the Noise—questioning the benefits of puberty blockers for youth with gender dysphoria—a commentary on Rew et al. (2021)

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In less than a decade, there has been a sharp rise in the numbers of young people presenting with gender dysphoria (GD). Today, the majority are adolescents, many with post puberty adolescent onset transgender histories, and suffering from mental health and neurodevelopmental comorbidities (De Vries, 2020; Zucker, 2019). Furthermore, there is controversy and heated debate in the literature on this topic (Dubicka, 2021). This lack of scientific consensus highlights the need for any published literature on the topic of GD to be carefully evaluated.

In this commentary, we critically examine a systematic review of the evidence for puberty blockers for GD youth that was recently published in this journal (Rew, Young, Monge, & Bogucka, 2021). Our aim is to highlight problems with this review that compromise its findings and conclusions.

Brief description of Rew et al.'s (2021) study

Rew et al. described undertaking a "critical" and "systematic" literature review on the topic of puberty blockers for GD youth. They identified nine studies for review and, on the basis of these, concluded that puberty blockers have "few serious adverse outcomes," and "several potential positive ones." Rew et al.'s abstract highlighted two key conclusions: the "potentially life saving benefits" of puberty blockers; and a need for rigorous research. Their "implications," "conclusion," and "key practitioner message" sections appeared to claim that the literature supports the use of puberty blockers for the early puberty subgroup of GD youth.

Overview of our concerns

We agree with Rew et al.'s conclusion that more rigorous research is required in the area of management of GD in youth. However, in our view, their review suffers from methodological oversights, including the omission of relevant studies and suboptimal analysis of the quality of the included studies. As a result, the authors overstate the certainty of the potential positive outcomes and minimize the potential adverse outcomes of puberty blockers. Importantly, their statement, that a "positive outcome" of puberty blockers is "decreased suicidality in adulthood," is a misinterpretation of a single cross sectional study. This study's design was incapable of determining causation, and adult suicidality was not one of the measured outcomes (Turban, King, Carswell, & Keuroghlian, 2020).

Contrast Rew et al.'s (2021) conclusions with another recently completed systematic review of puberty blockers for GD youth, commissioned by England's NHS and conducted by The National Institute for Health and Care Excellence (NICE) (2020). The NICE review concluded that studies investigating the benefits or adverse effects of GnRH analogs (puberty blockers) were of "very low certainty using modified GRADE." They noted that any outcome differences that were found could have represented changes of "questionable clinical value," or, as the studies themselves were "not reliable," could have been "due to confounding, bias or chance." They suggest that if controlled studies are not possible, then reliable comparative studies are required.

These findings came just after NHS England suspended the use of puberty blockers for new patients under the age of 16, following the High Court's judgment that children so young could not consent to the unknown risks of these drugs. The Karolinska Institute in Sweden suspended the use of puberty blockers as treatment for GD youth outside of clinical trials following this review, citing multiple physical risks, including to bone development (Nainggolan, 2021). Finland also sharply curtailed the use of these drugs after their systematic review arrived at similar conclusions about the uncertain risk/benefit profile (COHERE, 2020).

We are concerned that Rew et al.'s review will mislead clinicians unfamiliar with the literature into prescribing puberty blockers to GD youth with confidence, when the only clinical stance supported by the evidence is that of extreme caution. This is also underscored by the fact that the research literature in this field is rapidly evolving. For example, a recently published study, that attempted to demonstrate the benefits of the Dutch puberty suppression protocol in the UK setting, failed to show any psychological benefit (Carmichael et al., 2021).

Limitations in study selection strategy

The review published by Rew et al. has important limitations that compromise its usefulness for clinical decision making. Rew et al. identified only 151 potentially eligible studies, while the NICE review found 525 studies. One possible explanation for this could be their limited study search strategy. Another possible explanation is that Rew et al. did not conduct a comprehensive search so that, in omitting one of the largest electronic databases EMBASE, they may have overlooked relevant evidence.

Notably, the final set of nine studies reviewed by Rew et al. is missing at least one key study on puberty blockers and psychosocial functioning (Costa et al., 2015), and two other studies examining the risks of puberty blockers on bone density (Joseph, Ting, & Butler, 2019; Klink, Caris, Heijboer, van Trotsenburg, & Rotteveel, 2015). It is unclear to us whether these studies were omitted due to the limited database search or whether the evaluators decided to exclude these studies, and if so for what reason. These three studies were all included in the NICE (2020) review. Although it has to be kept in mind that all the NICE reviewed studies' findings were assessed as "very low certainty," the Costa et al. study provided comparative evidence and found no significant difference in psychosocial functioning between a group of adolescents receiving puberty blockers plus psychosocial support, and a group receiving only psychosocial support, at eighteen months (the study end period) (Biggs, 2019). In addition, the Costa study was cited by the Finnish gender identity services in their policy change, which now recommends psychotherapy alone as first line treatment.

Failure to adequately assess certainty of the study findings

It is our contention that the reviewers did not adequately assess the certainty of the reviewed studies' findings. For example, they used the Joanna Briggs Institute checklist to assess Turban et al. (2020), the study from which their message that puberty blockers reduce adult suicidality and have "potentially life saving benefits" derives. This checklist can overemphasize whether studies report information and underemphasize the assessment of study validity. Below, we show how Rew et al. applied this tool to Turban et al. (2020), and the important study limitations it overlooked.

Was the exposure measured in a valid and reliable way? (Q3) Rew et al. answered "yes" to this question. We believe it should be "no." The exposure to puberty blockers was based on a self report, with 73% of those respondents, who answered yes, claiming they began to use puberty blockers after the age of 18. It was noted that the respondents likely confused puberty blockers with other hormonal interventions (Biggs, 2020; D'Angelo et al., 2020). Although Turban et al. attempted to reduce the effects of this confusion by excluding certain participants from the sample, no adequate correction was possible. This introduced a significant risk of bias.

Were confounding factors identified and strategies to deal with them stated? (Q5, Q6) Rew et al. answered "yes" to both questions. We believe the answer to the latter question should be "no." For example, while one key confounding factor prior mental health status was indeed correctly identified by Turban et al., no strategy was articulated to deal with it. When discussing their finding that puberty suppression is associated with lower lifetime suicidality, they acknowledged that "reverse causation cannot be ruled out: it is plausible that those without suicidal ideation had better mental health when seeking care and thus were more likely to be considered eligible for pubertal suppression" (Turban et al., 2020). This is one of the most serious limitations of the study, introducing a high risk of bias, and reducing the certainty of the findings.

In addition, while two questions ask about the subject selection criteria and whether the subjects and the setting were described in detail (Q1, Q2), these questions do not attempt to assess the impact of the sample composition. Affirmative ("yes") and "not applicable" answers to these questions, respectively, masked the fact that the study participants were not required to have a diagnosis of GD, and that the participant demographics were markedly different from the US population of transgender adults (D'Angelo et al., 2020), which negatively impacts the study's applicability/generalizability.

Rew et al. aggregated the answers to the checklist questions, with the Turban et al.'s study earning an 86% mark and a "good quality" rating. Even if we sideline the issue of any scoring inaccuracy, using such a simplistic scoring category is misleading since it implies that all questions are equally important, which is clearly not the case.

We also note, what appears to be, at least one error in Rew et al.'s assessment and reporting of study outcomes. In Table 2, they reported that Turban et al.'s positive outcome findings included decreased past month psychological distress, past month binge drinking, and lifetime illicit drug use. However, Turban et al.'s univariate analysis showed only one of these three outcomes, past month psychological distress, showed any significant difference, and this significance disappeared once demographic variables were controlled for in the multivariable analysis.

A more rigorous tool to assess Turban et al.'s study would be ROBINS I (The Risk of Bias of Non randomized Studies of Interventions) (Sterne et al., 2016). This tool focuses on confounding, selection bias, classification and deviations from intervention, measurement of outcome, missing data, and selective reporting, and the extent to which the study design minimized biases and yielded trustworthy results. Given this, applying the ROBINS I tool would find that the Turban et al.'s study is at a critical risk of bias.

Misleading statements regarding puberty blockers and suicidality

We are concerned that Rew et al.'s discussion of evidence about suicidality is unbalanced and misleading. Reading that puberty blockers had "positive outcomes [of] decreased suicidality in adulthood" will likely be understood as indicating causation. However, Turban et al. (2020), where this claim originates, noted that their study design did not allow for determination of causation, and "reverse causation" (individuals without suicidal ideation had better mental health and were more likely to be considered eligible for puberty blockers) was a plausible alternative explanation.

Further, there is a critical difference in meaning between "lifetime," and "adulthood." Not only does the

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latter erroneously imply a pre post effect (i.e., access to puberty blockers in childhood reduces suicidality in adults), which was not detectable in the study, but a measure of "adulthood suicidality," which Rew et al. claim was impacted, was never included in the original study (Turban et al., 2020).

There is also unclear use of the term suicidality, which exaggerates the implication of Turban et al.'s findings. Suicidality is a broad term, which is comprised of suicide attempts, plans, and ideation, and indeed this was the manner it was used by Turban et al. It is also important to note that Turban et al. made no assessment of com pleted suicides. Turban et al. assessed six areas of suici dality (including recent and lifetime suicide attempts, recent ideation with plans, recent and lifetime ideation) and found no association between puberty blockers and suicidality measures on five of the six areas. The only association was with "lifetime suicidal ideation." Of course, any suicidal ideation is concerning, but suicide attempts are generally considered of higher concern, in terms of suicide risk assessment, than suicidal ideation (Ryan & Oquendo, 2020).

Rew et al.'s inaccurate language further intensifies in the final sentence of their abstract, which described puberty blockers as "potentially life saving." This exag gerated claim is misleading, since there is no evidence to support it.

Absence of an appropriate process for making clinical recommendations

Finally, the authors appear to recommend the use of puberty blockers in the "key practitioner messages" box and in the "implications" section of their paper. Making recommendations requires not only evidence about ben efits and harms on all health outcomes that are impor tant for decision making (which this review provides in a suboptimal way), but also considerations about patients values and preferences, ethics, acceptability, resources, costs, etc. (Andrews et al., 2013). All these considera tions are balanced by making value judgments, which should be documented and reported explicitly and transparently. Rew et al. failed to do this, which, in our view, further undermines the credibility of their clinical practice recommendations.

Clinician reflections on the state of the GD literature

Rew et al.'s review illustrates a concerning trend, that we have observed in the GD literature, to overstate the evi dence underpinning clinical practice recommendations for youth with GD. New publications reference prior ones with increasing and unwarranted confidence, and with the risk of misleading clinicians regarding the state of evidence. There is also a marked asymmetry in outcomes reporting: findings of positive outcomes of medical inter ventions are trumpeted in abstracts, while their pro found limitations remain behind the paywall, thus, below the radar of busy clinicians.

Rew et al.'s paper demonstrates these types of issues. To start, the Turban et al.'s paper described a noncausal association between puberty blockers and "lifetime sui cidal ideation," carefully avoiding making a causal claim (although, arguably, implying it). Then, Rew et al., whose findings on suicidality are based solely on this Turban et al.' study, rewrite this finding to create the strong impression of causality that puberty blockers reduce adult suicidality and are "potentially life saving." Subse quently, a recent Commentary and Editorial in the Lan cet both directly state that puberty blockers reduce suicidality, and the latter adds the extraordinary claim that "removing these treatments is to deny life." The only reference provided for these claims is the Rew et al. (2021) paper (Baams, 2021; Lancet editorial, 2021).

This resembles the game of "Telephone," in which a message is whispered from person to person distorting the original meaning of the message. However, this is not a game, and these types of errors can cause harm. Clini cians relying on Rew et al.'s review are likely to misin form patients and families about the risk/benefit profile of puberty blockers. Can such patients really be consid ered as giving informed consent?

The clear signals emerging from the various reviews of the available evidence of the use of puberty blockers for GD youth are that there is very low certainty of the bene fits of puberty blockers, an unknown risk of harm and there is need for more rigorous research. The clinically prudent thing to do, if we aim to "first, do no harm," is proceed with extreme caution, especially given the rapidly rising case numbers and novel GD presenta tions. We must also, collectively, raise the bar on the quality of publications, in order to accurately educate clinicians and help patients make truly informed deci sions that may impact for the rest of their lives.

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Ethical information

No ethical approval was required for this commentary.

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EXHIBIT I

Notice of Proposed Rule

AGENCY FOR HEALTH CARE ADMINISTRATION
Medicaid
RULE NO.: RULE TITLE:
59G-1.050: General Medicaid Policy
PURPOSE AND EFFECT: The purpose of the amendment to Rule 59G-1.050, Florida Administrative Code, (F.A.C.), is to update covered Medicaid services.
SUMMARY: The rule specifies covered services and clarifies definitions.
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:
The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.
The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: A checklist was prepared by the Agency to determine the need for a SERC. Based on this information at the time of the analysis and pursuant to section 120.541, Florida Statutes, the rule will not require legislative ratification.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.
RULEMAKING AUTHORITY: 409.919, 409.961 FS.
LAW IMPLEMENTED: 409.902, 409.9025, 409.905, 409.906, 409.973 FS.
A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:
DATE AND TIME: July 8, 2022, from 3 p m. to 5 p m.
PLACE: Auditorium, Florida Department of Transportation, 605 Suwannee St, Tallahassee, FL 32399.
Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 48 hours before the workshop/meeting by contacting: Medicaid Policy. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: MedicaidRuleComments@ahca myflorida.com

THE FULL TEXT OF THE PROPOSED RULE IS:

59G-1.050 General Medicaid Policy.

(1) Purpose. This rule specifies requirements that apply to all providers rendering Florida Medicaid services to recipients.

(2) Billing the Recipient. Providers must inform a recipient of his or her responsibility to pay for services that are not covered by Florida Medicaid, and document in the recipient's file that the recipient was informed of his or her liability, prior to rendering each service.

(a) Providers may seek reimbursement from a recipient under the following circumstances:

1. The recipient is not eligible for Florida Medicaid on the date of service.

2. The service rendered is not covered by Florida Medicaid, if the provider seeks reimbursement from all patients for the specific service.

3. The provider verifies that the recipient has exceeded the Florida Medicaid coverage.

4. The recipient is enrolled in a Florida Medicaid managed care plan (plan) and is informed that:

a. The plan denies authorization for the service.

b. The treating provider is not in the plan's provider network (with the exception of emergency services).

(b) Providers may not seek reimbursement from recipients for missed appointments.

(c) Providers may not seek reimbursement from the recipient if the provider fails to bill Florida Medicaid correctly and in a timely manner. Providers who submit a claim to Florida Medicaid for reimbursement of a covered service whether the claim has been approved, partially approved, or denied, may not:

1. Seek reimbursement from the recipient, the recipient's relatives, or any person, or persons, acting as the recipient's designated representative.

2. File a lien against the recipient, the recipient's parent, legal guardian, or estate.

3. Apply money received from any non-Florida Medicaid source to charges related to a claim paid by Florida Medicaid (also known as "balance billing").

4. Turn a recipient's overdue account over to a collection agency, except in circumstances as specified in paragraph (2)(a), above.

(3) Cost of Doing Business. Florida Medicaid does not reimburse for time spent completing and submitting Florida Medicaid claims or time spent responding to an audit.

(4) Emergency Medicaid For Aliens. Florida Medicaid covers emergency services provided to aliens who meet all Florida Medicaid eligibility requirements except for citizenship or alien status, as follows:

(a) Eligibility is only authorized for the duration of the emergency.

(b) Florida Medicaid does not cover continuous or episodic services after the emergency has been alleviated.

(c) Providers must submit documentation establishing the emergency nature of the service with the claim for reimbursement. Exceptions are labor, delivery, and dialysis services, which are considered emergencies and are payable without documentation when the emergency indicator is entered on the claim form.

(5) Free Choice of Providers. Recipients may obtain services from any qualified Florida Medicaid provider that agrees to provide the services in accordance with Title 42, Code of Federal Regulations (CFR), section 431.51, except:

(a) Allowable restrictions specified in section 1915(a) of the Social Security Act.

(b) When the recipient is enrolled in a Florida Medicaid managed care program. Managed care plans may not restrict enrollee choice for a family planning provider and must cover family planning services regardless of whether the provider is in the managed care plan's provider network.

(6) Inmates of a Public Institution. Florida Medicaid does not cover services provided to individuals residing in public institutions as defined in 42 CFR 435.1009 and Section 409.9025, F.S. These individuals include those residing in correctional and holding facilities for prisoners who meet either of the following:

(a) Have been arrested or detained pending disposition of charges.

(b) Held under court order as material witnesses or juveniles.

(7) Gender Dysphoria

(a) Florida Medicaid does not cover the following services for the treatment of gender dysphoria:

1. Puberty blockers;

2. Hormones and hormone antagonists;

3. Sex reassignment surgeries; and

4. Any other procedures that alter primary or secondary sexual characteristics.

(b) For the purpose of determining medical necessity, including Early and Periodic Screening, Diagnosis, and Treatment (EPSDT), the services listed in subparagraph (7)(a) do not meet the definition of medical necessity in accordance with Rule 59G-1.010, F.A.C.

(~~7~~8) Out-of-State Services.

(a) Emergency. Florida Medicaid covers emergency services provided out-of-state without a referral, or authorization, when the recipient's health will be endangered if the care and services are postponed until returning to Florida.

(b) Non-Emergency. Florida Medicaid covers services performed out-of-state, in accordance with the service-specific coverage policy, when both of the following are met:

1. The recipient's primary care or specialist physician refers the recipient for services.

2. Services are prior authorized by the Florida Medicaid quality improvement organization in accordance with Florida Medicaid's Authorization Requirements Policy, as incorporated by reference in Rule 59G-1.053, F.A.C.

(c) Florida Medicaid does not cover services for recipients living out-of-state who are enrolled under the Title-IV-E Florida foster or adoption subsidy.

(~~8~~9) Payment in Full. Providers must accept payment from Florida Medicaid as payment in full, except for Florida Medicaid copayments and coinsurance. For information on copayment requirements and exemptions, refer to Florida Medicaid's General Policies on copayment and coinsurance.

(~~9~~10) Recipients or Providers that are Out of the Country. Florida Medicaid does not cover services provided to recipients when they are outside of the United States (U.S.), or for services rendered by providers who are not in the U.S.

(~~10~~11) Refusal of Services.

(a) Providers may not refuse to provide a covered Florida Medicaid service to a recipient solely because the recipient's eligibility does not display in the Florida Medicaid Management Information System, if the recipient has a valid temporary proof of eligibility from the Department of Children and Families, or proof of presumptive eligibility.

(b) Right to Refuse Services. Providers may limit the number of Florida Medicaid recipients the provider serves, and accept or reject recipients in accordance with the policies of the facility or practice, except as follows:

1. A hospital may not refuse to provide emergency services in accordance with the 1986 Emergency Medical Treatment and Active Labor Act.

2. Providers may not deny services to recipients based solely upon race, creed, color, national origin, disabling condition, or disability, in accordance with federal anti-discrimination laws.

(~~11~~12) Solicitation (Patient Brokering). Providers may not knowingly solicit, offer, pay, or receive any payment, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for furnishing, or arranging for the furnishing of, any item or service for which payment may be made, in whole or in part, under the Florida Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging for, or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Florida Medicaid program.

Rulemaking Authority 409.919, 409.961 FS. Law Implemented 409.902, 409.9025, 409.905, 409.906, 409.973 FS. History-New _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Cole Giering
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Simone Marstiller
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 16, 2022
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: June 3, 2022

EXHIBIT J

ENDOCRINE SOCIETY
Hormone Science to Health

July 8, 2022

Agency for Health Care Administration

Medicaid

MedicaidRuleComments@ahca.myflorida.com

RE: 59G-1.050: General Medicaid Policy

To Whom It May Concern:

The Endocrine Society strongly opposes the proposed rule, which would deny access to gender affirming care to the Florida Medicaid population. The Endocrine Society is the world's oldest and largest organization of scientists devoted to hormone research and physicians who care for people with hormone-related conditions. Many of our 18,000 members are recognized for their expertise in transgender medicine and research.

Our comments below are focused on responding to inaccurate and misleading statements about the Endocrine Society's clinical practice guidelines made in the report *Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria (GAPMS)* developed by Florida Medicaid in June 2022, which is used to justify the proposed rule.

Quality of Endocrine Society Clinical Practice Guidelines on Endocrine Treatment of Gender Dysphoric/Gender Incongruent Persons and the GRADE System

The Institute of Medicine (IOM) (now known as the National Academy of Medicine) defined clinical practice guidelines as "recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."[1] While guidelines are not standards of care that clinicians are legally

[1] Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, Board on Health Care Services, Institute of Medicine of the National Academies. Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E, eds. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press; 2011.

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bound to follow, they provide a framework for best practices, and deviations must be justified.[2]

Endocrine Society guidelines are developed using a robust and rigorous process that adheres to the highest standards of trustworthiness and transparency as defined by the IOM. The Endocrine Society follows the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methodology to develop its recommendations. GRADE is the most accepted and internationally recognized standard for guideline development. Of the over 100 international groups that endorse GRADE, other prominent organizations using this methodology include the U.S. Agency for Healthcare Research and Quality, the U.S. Centers for Disease Control and Prevention, England's National Institute for Health and Care Excellence, and the World Health Organization. GRADE is a transparent framework for summarizing evidence and provides a systematic approach for making clinical practice recommendations.

GRADE begins with the formulation of clinical questions followed by a systematic review of the evidence that supports those questions. This evidence is used to develop and support the clinical recommendations that form the basis of the guideline. A certainty of evidence assessment is made for the overall body of evidence for a particular question on a scale from very low, low, moderate, to high. While some of the recommendations in the Endocrine Society's guideline are based on low or very low certainty evidence, strong recommendations can be made for low and very low certainty evidence in the GRADE system in some circumstances (Life threatening situation; uncertain benefit, certain harm; potential equivalence, one option clearly less risky or less costly, high certainty in similar benefits, one option potentially more risky or costly; potential catastrophic harm.)[3] Additionally, the GRADE methodology does not account only for the certainty of the evidence when developing recommendations. Systematic reviews of the effects of an intervention provide essential, but not sufficient information for making informed decisions.[4] There are other factors that GRADE methodology requires guideline authors to account for including, most importantly, patient values and preferences, in making trade-offs between alternative courses of action.[5]

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[2] InformedHealth.org [Internet]. Cologne, Germany: Institute for Quality and Efficiency in Health Care (IQWiG); 2006-. What are clinical practice guidelines? 2016 Jun 15 [Updated 2016 Sep 8]. Available from: https://www ncbi.nlm nih.gov/books/NBK390308/

[3] Andrews J , Guyatt G , Oxman AD , et al . GRADE guidelines: 14. Going from evidence to recommendations: the significance and presentation of recommendations. J Clin Epidemiol 2013;66:719–25. doi:10.1016/j.jclinepi.2012.03.013 and Neumann I , Santesso N , Akl EA , et al . A guide for health professionals to interpret and use recommendations in guidelines developed with the GRADE approach. J Clin Epidemiol 2016;72:45–55.doi:10.1016/j.jclinepi.2015.11.017

[4] GRADE Working Group, 2022

[5] Alonso-Coello P , Schünemann HJ , Moberg J , et al . GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction. BMJ 2016;353:i2016.doi:10.1136/bmj.i201

Additionally, Endocrine Society guidelines are not developed in a vacuum. Guidelines take an average of 2-3 years to be developed through a multi-step drafting, comment, review, and approval process. This includes a public comment period and expert review period, and all comments are addressed by the guideline development panel prior to publication. Expert reviewers are subject to the same conflict of interest rules as panel members. There is ample opportunity for feedback and debate through this years-long development process.

Consequently, the Endocrine Society's guidelines represent a high-quality resource to be used for patient care based on medical evidence, author expertise, rigorous scientific review, and a transparent process. In contrast, GAPMS did not include endocrinologists with expertise in transgender medicine, misunderstands the use of the GRADE methodology and the notion of standard of care, and makes sweeping statements against gender affirming medical care that are not supported by evidence or references provided. Most disturbing, GAPMS does not acknowledge the data showing harm reduction and improvements in behavioral health issues, such as depression and anxiety, with gender affirming care.

Sufficiency of Evidence and Bar for Gender Affirming Care

The Endocrine Society and other medical and mental health organizations representing professionals who treat gender dysphoria/gender incongruence firmly believe there is sufficient evidence to support gender affirming care and to support that harm can occur if these people are not treated.[6] The statement in GAPMS that "low quality" studies provide insufficient evidence for gender affirming care demonstrates a failure to understand medical literature. The medical literature terminology is appropriately conservative. But "low-quality" studies are typical for much of medical care and much better than "expert opinion," also common for medical care.

The Endocrine Society believes Florida is imposing a bar for care that is too high, will result in harm to people with gender dysphoria/incongruence, and is not used for other patients. GAPMS suggests that because puberty blockers are used off-label they are experimental and not safe. The fact is many treatments used in medicine are used off-label. That just means that medication is used for a purpose other than that for which the pharmaceutical company did the paperwork. Such prescribing is common. That is part of the reason states license physicians, to make those prescribing decisions. FDA approval and randomized controlled trials are simply too stringent. Most medical care occurs appropriately without those in place.

[6] See, e.g., Brandt v. Rutledge, 551 F. Supp. 3d 882, 890 (E.E. ark. 2021) ("The consensus recommendation of medical organizations is that the only effective treatment for individuals at risk of or suffering from gender dysphoria is to provide gender-affirming care.")

Scientific Evidence Indicates the Effectiveness of Treating Gender Dysphoria According to the Guidelines

The results of multiple studies indicate that adolescents suffering from gender dysphoria who receive medical interventions as part of their gender-affirming care experience improvements in their overall well-being.[7] Eight studies have been published that investigated the use of puberty blockers in the care of adolescents suffering from gender dysphoria and six studies have been published that investigated the use of hormone therapy to treat adolescents suffering from gender dysphoria.[8] These studies find positive mental health outcomes for those adolescents who received puberty blockers or hormone therapy, including statistically significant reductions in anxiety, depression, and suicidal ideation.

For example, a 2020 study analyzed survey data from 89 transgender adults who had access to puberty blockers while adolescents and from more than 3,400 transgender adults who did not.[9] The study found that those who received puberty blocking hormone treatment had lower likelihood of lifetime suicidal ideation than those who wanted puberty blocking treatment but did not receive it, even after adjusting for demographic variables and level of family support.[10] Approximately nine in ten transgender adults who wanted puberty blocking treatment but did not receive it reported lifetime suicidal ideation.[11] Additionally, a

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[7] Simona Martin et al., Criminalization of Gender-Affirming Care—Interfering with Essential Treatment for Transgender Children and Case 2:22-cv-00184-LCB-SRW Document 91-1 Filed 05/04/22 Page 8 of 32
Viii Adolescents, 385 New Eng. J. Med. 579 (2021), https://www.nejm. org/doi/full/10.1056/NEJMp2106314

[8] See, e.g., Christal Achille, et al., Longitudinal impact of gender-affirming endocrine intervention on the mental health and well-being of transgender youths: preliminary results, 8 Int'l J. Pediatric Endocrinology 1-5 (2020), https://pubmed.ncbi.nlm.nih.gov/32368216; Luke R. Allen, et al., Well-being and suicidality among transgender youth after gender-affirming hormones, 7(3) Clinical Prac. Pediatric Psych. 302 (2019), https://psycnet.apa.org/record/2019-52280-009; Diego Lopez de Lara, et al., Psychosocial assessment in transgender adolescents, 93(1) Anales de Pediatria 41-48 (English ed. 2020), https://www.researchgate.net/publication/342652073; Annelou L.C. De Vries, et al., Young adult psychological outcome after puberty suppression and gender reassignment, 134(4) Pediatrics 696-704 (2014); Rittakerttu Kaltiala, et al., Adolescent development and psychosocial functioning after starting cross-sex hormones for gender dysphoria, 74(3) Nordic J. Psychiatry 213 (2020); Laura E. Kuper, et al., Body dissatisfaction and mental health outcomes of youth on gender-affirming hormone therapy, 145(4) Pediatrics e20193006(2020), https://pubmed.ncbi.nlm.nih.gov/32220906; Amy E. Green, et al., Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth, J. Adolescent Health (2021), https://www.jahonline.org/article/S1054-139X(21)00568-1/fulltext; Jack L. Turban, et al., Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults, J. Plos One (2022), https://journals.plos.org/plosone/article?id=10.1371/ journal.pone.0261039.

[9] See Jack L. Turban et al., Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145(2) Pediatrics e20191725 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC7073269.

[10] See id.

[11] See id.

longitudinal study of nearly 50 transgender adolescents found that suicidality was decreased by a statistically significant degree after receiving gender-affirming hormone treatment.[12] As another example, a prospective two-year follow-up study of adolescents with gender dysphoria published in 2011 found that treatment with puberty blockers was associated with decreased depression and improved overall functioning.[13] A six-year follow-up study of 55 individuals from the 2011 study found that subsequent treatment with hormone therapy followed by surgery in adulthood was associated with a statistically significant decrease in depression and anxiety.[14] "Remarkably, this study demonstrated that these transgender adolescents and young adults had a sense of well-being that was equivalent or superior to that seen in age matched controls from the general population."[15] As scientists and researchers, the Endocrine Society always welcomes more research, including on this crucial topic. However, the available data indicate that the gender-affirming treatments that would be denied by the proposed rule are effective for the treatment of gender dysphoria. For these reasons, the use of the gender-affirming medical interventions specified in the Endocrine Society's guidelines is supported by all mainstream pediatric organizations, representing thousands of physicians across multiple disciplines.[16]

Statements in GAPMS are Factually Inaccurate and Ignore the Recommendations of the Medical Community

GAPMS asserts that most adolescents who experience gender dysphoria will later overcome it by confirming to their natal sex. This assertion lacks scientific support. While some prepubertal children who experience gender dysphoria may go on to identify with their sex assigned at birth by the time they reach puberty, there are no studies to support the proposition that adolescents with gender dysphoria will come to identify with their sex assigned at birth, whether they receive treatment or not.[17] On the contrary, "[l]ongitudinal

[12] See Luke R. Allen et al., Well-being and suicidality among transgender youth after gender affirming hormones, 7(3) Clinical Prac. Pediatric Psych. 302 (2019), https://psycnet.apa.org/ record/2019-52280-009.

[13] See Annelou L.C. de Vries et al., Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study, 8(8) J. Sexual Medicine 2276 (2011), https://pubmed.ncbi.nlm.nih.gov/20646177.

[14] Annelou L.C. de Vries et al., Young adult psychological outcome after puberty suppression and gender reassignment, 134(4) Pediatrics 696 (2014), https://pubmed.ncbi.nlm.nih.gov/25201798.

[15] Stephen M. Rosenthal, Challenges in the care of transgender and gender-diverse youth: an endocrinologist's view, 17(10) Nature Rev. Endocrinology 581, 586 (Oct. 2021), https:// pubmed.ncbi.nlm.nih.gov/34376826.

[16] See, e.g., Brandt v. Rutledge, 551 F. Supp. 3d 882, 890 (E.D. Ark. 2021) ("The consensus recommendation of medical organizations is that the only effective treatment for individuals at risk of or suffering from gender dysphoria is to provide gender-affirming care.")

[17] See, e.g., Stewart L. Adelson, Practice parameter on gay, lesbian, or bisexual sexual orientation, gender non-conformity, and gender discordance in children and adolescents, 51 J. Am. Acad. of Child & Adolescent Psychiatry 957,

studies have indicated that the emergence or worsening of gender dysphoria with pubertal onset is associated with a very high likelihood of being a transgender adult."[18]

Further, GAPMS relies upon controversial research not recognized in the mainstream transgender medicine community. For example, it refers to a paper by Lisa Littman on Rapid Onset Gender Dysphoria (ROGD) – a condition that does not exist -- to justify not supporting gender affirming medical care for adolescents with gender dysphoria without noting the methodological concerns that have been raised regarding this paper, including the fact that only parents (recruited from anti-transgender websites) and none of the youth with gender dysphoria participated in the study, and that parents were not recruited from websites supportive of transgender youth. These methodological concerns prompted publication of a correction by the original author.

The Proposed Rule Would Irreparably Harm Many Adolescents with Gender Dysphoria by Denying Access to the Treatment They Need

The proposed rule would deny Medicaid beneficiaries with gender dysphoria access to medical interventions that alleviate suffering, are grounded in science, and are endorsed by the medical community. The medical treatments prohibited by the proposed rule can be a crucial part of treatment for people with gender dysphoria and necessary to preserve their health. As discussed above, research shows that people with gender dysphoria who receive puberty blockers and/or hormone therapy experience less depression, anxiety, and suicidal ideation. Several studies have found that hormone therapy is associated with reductions in the rate of suicide attempts and significant improvement in quality of life.[19] In light of this evidence supporting the connection between lack of access to gender-affirming care and lifetime suicide risk, banning such care can put patients' lives at risk.

The Endocrine Society is eager to work with Florida to address these concerns and would be happy to connect Florida Medicaid with our transgender medicine experts. If we can be of assistance or provide any additional information, please contact our Chief Policy Officer at mbecker@endocrine.org.

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964 (2020), https://pubmed.ncbi.nlm.nih.gov/ 22917211 ("In contrast, when gender variance with the desire to be the other sex is present in adolescence, this desire usually does persist through adulthood").

[18] Rosenthal, supra note 58 at 585.

[19] See M. Hassan Murad et al., Hormonal Therapy and Sex Reassignment: A Systematic Review and Meta-Analysis of Quality of Life and Psychosocial Outcomes, 72(2) Clinical Endocrinology 214 (Feb. 2010), https://onlinelibrary.wiley.com/doi/10.1111/j.1365-2265.2009.03625.x; see also Turban et al., Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, supra note 50.

Sincerely,

Ursula Kaiser

Ursula Kaiser, MD

President, Endocrine Society

EXHIBIT K

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

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July 7, 2022

Tom Wallace
Deputy Secretary for Medicaid
Florida Agency for Health Care Administration
2727 Mahan Drive
Mail Stop #8
Tallahassee, FL 32308

Dear Director Wallace,

The American Academy of Pediatrics (AAP), a nonprofit organization representing 67,000 pediatricians dedicated to the health, safety and well-being of all children and the Florida Chapter of American Academy of Pediatrics, Inc (FCAAP), a nonprofit organization representing more than 2,600 pediatricians committed to serving all children across the state, thank you for the opportunity to provide comments on the Florida Agency for Health Care Administration's proposed rule to prohibit gender-affirming care in the state's Medicaid program.

We write to express our grave concerns with the proposed rule. Denying evidence-based, medically necessary standards of care to transgender adolescents constitutes a broad and sweeping discriminatory action by the State of Florida and its Medicaid program.

Gender-affirming care is the widely accepted standard of care for treating transgender adolescents with gender dysphoria. Gender-affirming care is endorsed and recommended by the American Academy of Pediatrics;[1] the Florida Chapter of the American Academy of Pediatrics, Inc; [2] the American Medical Association;[3] the American College of Obstetricians and Gynecologists; [4] the American College of Physicians;[5] the American Psychiatric Association; [6] the American Psychological Association; [7] the American Academy of Family Physicians;[8] the American Academy of Child and Adolescent Psychiatry; [9] the Endocrine Society;[10] the Society for Adolescent Health and Medicine;[11] the Pediatric Endocrine Society;[12] the World Professional Association for Transgender Health (WPATH);[13] and many more members of the medical community.[14]

Gender-Affirming Care is the Standard of Care

Gender-affirming care is developmentally appropriate care that seeks to understand and appreciate a child's or adolescent's gender identity and experience through a safe and nonjudgmental partnership that includes general pediatricians, pediatric specialists, mental health providers, children and adolescents and their families.[15] While gender-affirming care is irrefutably the standard of care, it must, like all other areas of medicine, be individualized to meet the needs of each and every unique patient.

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[1] Rafferty J. Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents. Committee on Psychosocial Aspects of Child and Family Health, Committee on Adolescence and Section on Gay, Lesbian, Bisexual and Transgender Health and Wellness. *Pediatrics*. Oct 2018, 142 (4) e20182162

[2] Florida Chapter of the American Academy of Pediatrics, Inc. FCAAP Rejects New Florida Department of Health Guidelines on Gender-Affirming Care for Youth. 2022. Accessed on June 23, 2022. https://www.fcaap.org/posts/news/press-releases/florida-chapter-of-the-american-academy-of-pediatrics-rejects-new-florida-department-of-health-guidelines-on-gender-affirming-care-for-youth/

[3] American Medical Association. Health insurance coverage for gender-affirming care of transgender patients. 2019. Accessed on June 23, 2022. https://www.ama-assn.org/system/files/2019-03/transgender-coverage-issue-brief.pdf

[4] American College of Obstetricians and Gynecologists. Health care for transgender and gender diverse individuals. ACOG Committee Opinion No. 823. 2021. Accessed on June 23, 2022. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals

[5] Safer J, Tangpricha V. Care of the Transgender Patient. *Annals of Internal Medicine*. 2019 Jul 2;171(1):ITC1-ITC16.

[6] American Psychiatric Association. Position Statement on Treatment of Transgender (Trans) and Gender Diverse Youth. 2020. Accessed on June 23, 2022. https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Policies/Position-Transgender-Gender-Diverse-Youth.pdf

[7] American Psychological Association. Guidelines for Psychological Practice with Transgender and Gender Nonconforming People. *American Psychologist*, December 2015. Vol. 70, No. 9, 832–864

[8] American Academy of Family Physicians. Care for the Transgender and Gender Nonbinary Patient. 2020. Accessed on June 23, 2022. https://www.aafp.org/about/policies/all/transgender-nonbinary.html

[9] Adelson SL. Practice parameter on gay, lesbian, or bisexual sexual orientation, gender non-conformity, and gender discordance in children and adolescents. *Jrnl of the American Academy of Child & Adolescent Psychiatry*. 2020; 957-974

[10] Hembree W, Cohen-Kettenis P, Gooren L, Hannema S, Meyer W, Murad M, Rosenthal S, Safer J, Tangpricha V, T'Sjoen T. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*. 2017; 102(11): 3869–3903

[11] Barkley L, Kodjo C, West KJ, et al. Promoting Health Equality and Nondiscrimination for Transgender and Gender-Diverse Youth. *Jrnl of Adolescent Health*. 2020; 66 (6): 804-807

[12] Lopez X, Marinkovic M, Rosenthal SM, et al. Statement on gender-affirmative approach to care from the pediatric endocrine society special interest group on transgender health. *Current Opinion in Pediatric*. 2017; 29(4). 475-480.

[13] The World Professional Association for Transgender Health (WPATH). Standards of Care for the Health of Transsexual, Transgender and Gender Nonconforming People 2011. Accessed on June 25, 2022. https://www.wpath.org/media/cms/Documents/SOC v7/SOC V7_English2012.pdf

[14] Eknes-Tucker et al v Ivey et al. Brief amicus curiae American Academy of Pediatrics and Additional National and State Medical and Mental Health Organizations. 4 May 2022. https://downloads.aap.org/DOFA/%5b%5bAs-Filed%5d%5d2022.05.04EknesTuckerv.IveyMedicalOrgAmicusBrief.pdf

[15] Rafferty

WPATH and the Endocrine Society have developed well-researched and evidence-based standards of care and clinical guidelines for the care of children and adolescents with gender dysphoria. WPATH's Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7[16] and the Endocrine Society's Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline[17] (both are herein referenced as "standards of care") are in fact the gold standard, contrary to the State of Florida's assertion, among the medical community for caring for children and adolescents with gender dysphoria.

For a model of care to be considered the standard of care for a specific diagnosis, the care must be "treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals."[18] The State of Florida's attempt to argue that gender-affirming care is not the standard of care, as referenced in its Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria report[19] and its "Florida Fact-Checked" version of the[20] HHS Office of Population Affairs Guidance on gender-affirming care, is entirely inconsistent with the well-recognized and established definition of standard of care, and represents a purposeful mischaracterization of available evidence as well as the position of the medical community.

Instead of supporting the standard of care for transgender adolescents, the state is seeking to rely only on "watchful waiting." This outdated model is based on long-refuted binary notions of gender and assumes without evidence that gender identity becomes fixed at a certain age[21] and will result in direct harm to gender dysphoric children and adolescents who are denied access to well-evidenced multidisciplinary care.[22] Notably, "watchful waiting" is based on studies with flawed methodology, validity concerns, and limited follow-up of transgender adolescents.[23] Thus, "watchful waiting" is not recommended by any major medical association in the United States.

Gender Dysphoria

Gender dysphoria is a formal diagnosis under *The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) in which there is a pronounced incongruence between someone's gender identity or expression and sex assigned at birth.[24] For the diagnosis, the patient must exhibit 2 of the following for at least 6 months:

- A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)

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[16] WPATH

[17] Hembree et al

[18] National Institute for Health, National Cancer Institute. Definition of Standard of Care. Accessed June 21, 2022. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/standard-of-care

[19] Florida Agency for Health Care Administration (ACHA), Division of Florida Medicaid. *Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria (GAPMS)*. 2022. Accessed on June 22, 2022. https://ahca.myflorida.com/LetKidsBeKids/docs/AHCA_GAPMS_June_2022_Report.pdf

[20] Florida Agency for Health Care Administration (ACHA). *Florida Fact-Checked*. 2022. Accessed on June 22, 2022. https://ahca.myflorida.com/LetKidsBeKids/docs/FLFactCheck.pdf

[21] Ibid

[22] Rafferty

[23] Ibid

[24] American Psychiatric Association. A Guide for Working with Transgender and Gender Nonconforming Patients, Gender Dysphoria Diagnosis. Accessed on June 26, 2022. https://www.psychiatry.org/psychiatrists/cultural-competency/education/transgender-and-gender-nonconforming-patients/gender-dysphoria-diagnosis

- A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
- A strong desire for the primary and/or secondary sex characteristics of the other gender
- A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
- A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)
- A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)[25]

In an apparent attempt to undermine the validity of the diagnosis of gender dysphoria, the state, under "Etiology of Gender Dysphoria,"[26] implies that mental and physical health conditions are the primary cause of gender dysphoria and that psychological support is all that is needed to provide care for gender dysphoric youth. However, the preponderance of the evidence indicates that gender dysphoria is indeed a primary diagnosis in which mental health issues are often exacerbated by lack of access to appropriate gender affirming care.[27] The state disqualifies its own arguments by stating: "At the moment, none of these studies provides a definitive cause and offer only correlations and weakly supported hypotheses. In addition, evidence favoring a biological explanation is highly speculative."[28] To be clear, there is no evidence that mental or physical health conditions cause gender dysphoria. As such, mischaracterizing the diagnosis in an effort to prohibit gender-affirming care is disingenuous at best and would result in direct harm to transgender children and adolescents.

Included in the state's document is the suggestion that mental health care should be the first line of care for youth diagnosed with gender dysphoria. On this, we agree. In fact, the evidence-based standards of care for gender-dysphoria, as referenced above, recommend mental health evaluation and care as the first step for affected children and adolescents.[29] Indeed, research demonstrates that transgender children and adolescents experience stigma and discrimination, which adversely affects their mental health.[30] Children and adolescents diagnosed with gender dysphoria often have to hide their gender identities to avoid bullying and harassment and face greater risks of homelessness, physical violence in the home and in the community, and substance use.[31] However, the state conflates the association of mental health diagnoses, trauma, and attachment issues with causality for gender dysphoria in an effort to discredit the primary diagnosis. In reality, the mental health issues faced by those with gender dysphoria are often the *direct result of* a lack of access to care or not being supported in their gender identity.[32]

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[25] Ibid
[26] Florida ACHA GAPMS
[27] Rafferty
[28] Florida ACHA GAPMS
[29] WPATH; Hembree et al
[30] Rafferty
[31] Ibid
[32] Ibid

In further attempting to undermine the well-established diagnosis of gender dysphoria, the state seeks to incorporate the concept of "rapid onset gender dysphoria."[33] The manuscript from which the term "rapid onset gender dysphoria" originates has been widely criticized.[34] An expert review emphasized the following issues:

- "This study of parent observations and interpretations serves to develop the hypotheses that rapid-onset gender dysphoria is a phenomenon and that social influences, parent-child conflict, and maladaptive coping mechanisms may be contributing factors for some individuals. Rapid-onset gender dysphoria (ROGD) is not a formal mental health diagnosis at this time. This report did not collect data from the adolescents and young adults (AYAs) or clinicians and therefore does not validate the phenomenon. Additional research that includes AYAs, along with consensus among experts in the field, will be needed to determine if what is described here as rapid-onset gender dysphoria (ROGD) will become a formal diagnosis. Furthermore, the use of the term, rapid-onset gender dysphoria should be used cautiously by clinicians and parents to describe youth who appear to fall into this category. The term should not be used in a way to imply that it explains the experiences of all gender dysphoric youth nor should it be used to stigmatize vulnerable individuals."[35]
- "…the study design of this research falls under descriptive research: as such, it did not assign an exposure, there were no comparison groups, and the study's output was hypothesis-generating rather than hypothesis-testing."[36]

The Coalition for the Advancement & Application of Psychological Science, which includes the American Psychiatric Association, the American Psychological Association, the Society for a Science of Clinical Psychology, the Society of Clinical Child and Adolescent Psychology, the Society of Pediatric Psychology, and many more international, national, and state psychological and psychiatric associations, published a position statement on the concept of rapid onset gender dysphoria, stating:

- …it has not been subjected to rigorous peer-review processes that are standard for clinical science. Further, there is no evidence that ROGD aligns with the lived experiences of transgender children and adolescents.
- Research on gender identity development in children and adolescents continues to evolve and these advances will likely influence diagnosis and empirically-based standards of care, as well as the legislative landscape impacting trans people's access to care and legal protections. The available research is clear that transgender people are subjected to marginalization, stigmatization, and minority stress, which have significant detrimental effects on health and well-being. Terms, such as ROGD, that further stigmatize and limit access to gender-affirming and evidence-based care violate the principles upon which CAAPS was founded and public trust in clinical science.[37]

Mental Health Care

Under the evidence-based standards of care, mental health care is indeed the first step in the care of children and adolescents diagnosed with gender dysphoria. The evidence-based standards of care recommend that a child or adolescent diagnosed with gender dysphoria be seen and evaluated by a qualified mental health professional trained in child and adolescent developmental psychopathology, competent in diagnosing and

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[33] ACHA GAPMS

[34] Littman L. Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. *PLoS ONE* 2019; 14(3): e0214157

[35] Ibid

[36] Ibid

[37] Coalition for the Advancement and Application of Psychological Science (CAAPS). CAAPS Position Statement on Rapid Onset Gender Dysphoria (ROGD). Accessed June 24, 2022. https://www.caaps.co/rogd-statement

treating the ordinary problems of children and adolescents and meeting the same competency requirements as mental health professionals working with adults.[38] Under the evidence-based standards of care, a qualified mental health professional has a responsibility to:[39]

- Directly assess gender dysphoria in children and adolescents (see general guidelines for assessment, below).
- Provide family counseling and supportive psychotherapy to assist children and adolescents with exploring their gender identity, alleviating distress related to their gender dysphoria, and ameliorating any other psychosocial difficulties.
- Assess and treat any coexisting mental health concerns of children or adolescents (or refer to another mental health professional for treatment). Such concerns should be addressed as part of the overall treatment plan.
- Refer adolescents for additional physical interventions (such as puberty-suppressing hormones) to alleviate gender dysphoria. The referral should include documentation of an assessment of gender dysphoria and mental health, the adolescent's eligibility for physical interventions (outlined below), the mental health professional's relevant expertise, and any other information pertinent to the youth's health and referral for specific treatments.
- Educate and advocate on behalf of gender dysphoric children, adolescents, and their families in their community (e.g., day care centers, schools, camps, other organizations). This is particularly important in light of evidence that children and adolescents who do not conform to socially prescribed gender norms may experience harassment in school (Grossman, D'Augelli, & Salter, 2006 Grossman, D'Augelli, Howell, & Hubbard, 2006); Sausa, 2005), putting them at risk for social isolation, depression, and other negative sequelae (Nuttbrock et al., 2010).
- Provide children, youth, and their families with information and referral for peer support such as support groups for parents of gender-nonconforming and transgender children (Gold & MacNish, 2011; Pleak, 1999; Rosenberg, 2002).[40]

The evidence-based standards of care clearly recommend that mental health providers who care for children and adolescents with gender dysphoria diagnose and treat any other mental health conditions the child or adolescent is experiencing. Thus, the state's implication that mental health providers are not addressing existing mental health concerns prior to beginning gender-affirming medical care is wholly inaccurate. Prior to puberty, mental health professionals, pediatricians, and other health care providers "work together to destigmatize gender variance, promote the child's self-worth, facilitate access to care, educate families, and advocate for safer community spaces where children are free to develop and explore their gender" without medical interventions.[41]

Medical Care

The state begins its literature review on gender dysphoria and puberty suppression by attempting to argue that a majority of children and adolescents will cease showing signs of gender dysphoria and conform to their sex assigned at birth. Herein lies a distinction between prepubertal children and adolescents that the state fails to consider, or outright ignores.

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[38] WPATH
[39] Ibid
[40] WPATH
[41] Rafferty

In its "Florida Fact-Checked" version of the HHS Gender Affirming Care document, the state notes that "most *children* identifying as transgender will detransition following the onset of puberty."[42] Additionally, in the ACHA GAPMS report, the state makes a similar argument, including "neither organization explains that a majority of young *adolescents* who exhibit signs of gender dysphoria eventually desist and conform to their natal sex and that puberty suppression can have side effects."[43] By definition, a child is defined as "a young person especially between infancy and puberty,"[44] while adolescence is defined as "the period of life when a child develops into an adult: the period from puberty to maturity terminating legally at the age of majority."[45]The key difference between children and adolescents being the onset of puberty. By referencing "children" it is "Florida Fact- Checked" document[46] and "young adolescents"[47] in the ACHA GAPMS report, the state erroneously conflates the 2 terms. However, the definitions of these terms are different and cannot be used interchangeably.

Furthermore, the state relies on a study that "offers data on the percentage of children who opt not to transition after experiencing gender dysphoria."[48] Similar claims made in other states that have attempted to ban gender-affirming care have been thoroughly debunked by a recent expert review from faculty from Yale University and the University of Texas Southwestern. The report from Yale examined in detail the misrepresentation of the Steensma et al study, explaining that:

- "...the Steensma study was not designed to (and the lead author has acknowledged) does not provide a basis for calculating what percentage of prepubertal children diagnosed with gender dysphoria persist with that diagnosis into adolescence. Rather, the Steensma study was designed only to study the characteristics of those who persisted.[60] Among other limitations, in Steensma (2013), former patients who opted to not participate in the study (either refused to participate or did not respond to an offer to participate) were categorized as "desisters," i.e., patients whose gender dysphoria resolved without transition or treatment. Patients can fail to respond to a study request for many reasons, including having moved away, receiving treatment elsewhere, or being uninterested in participating in a study. Thus, SEGM misuses the Steensma data by counting nonresponding patients as having "desisted" in experiencing gender dysphoria.[61] Indeed, in published correspondence, Steensma emphasizes that the 2013 study should not be used to calculate the percentages of "persisters" and "desisters."[62] The misrepresentation of Steensma on the SEGM website constitutes a major violation of the scientific method and the accepted conventions of research."[49]

Some prepubertal children's diagnosis of gender dysphoria will indeed not continue in adolescence, and as such, **there are no recommended medical interventions for prepubertal children**. For prepubertal children,

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[42] ACHA GAPMS; Florida Fact-Checked
[43] Florida ACHA GAPMS
[44]Merriam-Webster. Definition of child, 2022. Accessed on June 25, 2022. https://www.merriam-webster.com/dictionary/child
[45] Merriam-Webster. Definition of adolescence, 2022. Accessed on June 25, 2022. https://www.merriam-webster.com/dictionary/adolescence
[46] Florida Fact-Checked
[47] Florida ACHA GAPMS
[48] Ibid
[49] Boulware SD, Kamody R, Kuper L, McNamara M, Olezeski C, Szilaygi N, and Alstott A. 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. Accessed on June 27, 2022. https://medicine.yale.edu/childstudy/policy-and-social-innovation/lgbtq-youth/report%20on%20the%20science%20of%20gender-affirming%20care%20final%20april%2028%202022_437080_54636_v2.pdf

gender exploration is a natural part of child development.[50] However, for children diagnosed with gender dysphoria persisting at the onset of puberty (adolescence), research demonstrates that gender dysphoria will continue.[51;52] Under gender-affirming care, adolescents diagnosed with gender dysphoria, after careful and exhaustive mental health evaluation and care[53], may progress to gender-affirming medical care under the evidence-based standards of care.

Pubertal Blockers

Under the evidence-based standards of care, gender-affirming medical care is a highly individualized model of care. Prior to beginning gonadotrophin-releasing hormone agonists (GnRH, herein referred to as puberty blockers) as a component of a multidisciplinary approach to caring for adolescents diagnosed with gender dysphoria, adolescents must meet stringent criteria under the evidence-based standards of care from WPATH, including:

- The adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed);
- Gender dysphoria emerged or worsened with the onset of puberty;
- Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment.
- The adolescent has given informed consent and, particularly when the adolescent has not reached the age of medical consent, the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process. Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment."[54]

The Endocrine Society lays out additional criteria that must be met prior to undergoing puberty blockers as a component of gender-affirming medical care:

- (the adolescent) has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility,
- (the adolescent) has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
- And a pediatric endocrinologist or other clinician experienced in pubertal assessment
    - agrees with the indication for GnRH agonist treatment,
    - has confirmed that puberty has started in the adolescent (Tanner stage ≥G2/B2),
    - has confirmed that there are no medical contraindications to GnRH agonist treatment.[55]

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[50] Rafferty
[51] WPATH
[52] Boulware et al
[53] WPATH
[54] Ibid
[55] Hembree et al

In the ACHA GAPMS report and the "Florida Fact- Checked" document, the state asserts that there is no credible evidence demonstrating puberty blockers benefit adolescents diagnosed with gender dysphoria. However, the state either unknowingly or willingly ignores the body of evidence that supports this practice.[56] Medication to suppress puberty has been used to treat precocious puberty for decades.[57] The identical therapeutics are also used in adolescents diagnosed with gender-dysphoria and perhaps more importantly represent a very reasonable balance of risk and benefit when considering the totality of the available data and clinical experience. The pubertal blocker phase of gender-affirming care importantly allows the patient to delay the development of secondary sex characteristics.[58] By pausing the progression of secondary sex characteristics, adolescents are provided time to explore their gender identity, access and/or continue mental health support, and assess and define their treatment goals, in conjunction with their families.[59]

Contrary to the state's assertion that the evidence supporting use of puberty blockers is "weak," a large body of evidence supports their use in adolescents diagnosed with gender dysphoria.[60] For example, recent research examined 272 adolescents who were referred to a gender clinic, but had not yet began undergoing gender-affirming medical care, including puberty blockers, and 178 adolescents who had already began receiving gender-affirming care using puberty blockers with 651 cisgender adolescents.[61] The researchers found that adolescents with gender dysphoria had worse psychological health compared with their cisgender adolescent peers and that after receiving puberty blockers as part of gender-affirming care, the adolescents with gender dysphoria had similar or better psychological health than their cisgender peers.[62] Another recent study found that transgender adults who wanted and were able to access puberty blockers as adolescents were less likely to have lifetime suicidal ideation compared to transgender adults who were not able to access puberty suppression medication as adolescents.[63] In a 2-year follow-up study, researchers found that the use of puberty blockers led to improvements in overall functioning and decreased instances of depression.[64]

The state further asserts that "puberty suppression causes side effects, some of which have the potential to be permanent."[65] However, experts point out that "recent studies suggest that puberty-blocking medication has negligible or small effects on bone development in adolescents, and any negative effects are temporary and reversible. The most recent studies show that puberty-blocking drug therapy either has no effect on bone mineral density (BMD), a proxy measure of bone strength, or is associated with a very small decrease."[66]

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[56] Eknes-Tucker et al v Ivey et al. Brief amicus curiae American Academy of Pediatrics and Additional National and State Medical and Mental Health Organizations. 4 May 2022. https://downloads.aap.org/DOFA/%5b%5bAs-Filed%5d%5d2022.05.04EknesTuckerv.IveyMedicalOrgAmicusBrief.pdf; Rafferty; Boulware et al

[57] Guaraldi F, Beccuti G, Gori D, and Ghizzoni L. MANAGEMENT OF ENDOCRINE DISEASE: Long-term outcomes of the treatment of central precocious puberty. *European Journal of Endocrinology*. 174(3); 79-87

[58] Rafferty

[59] Rafferty

[60] Eknes-Tucker et al v Ivey et al. Brief amicus curiae American Academy of Pediatrics and Additional National and State Medical and Mental Health Organizations. 4 May 2022. https://downloads.aap.org/DOFA/%5b%5bAs-Filed%5d%5d2022.05.04EknesTuckerv.IveyMedicalOrgAmicusBrief.pdf; Rafferty; Boulware et al

[61] van der Miesen, AI, Steensma, TD, de Vries, AL, Bos, H, & Popma, A. (2020). Psychological functioning in transgender adolescents before and after gender-affirmative care compared with cisgender general population peers. *Journal of Adolescent Health*. 66(6), 699-704

[62] Ibid

[63] Turban JL, King D, Carswell JM, Keuroghlian AS. Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. *Pediatrics*. Feb 2020;145(2) doi:10.1542/peds.2019-1725

[64] De Vries ALC, Steensma TD, Doreleijers TAH, Cohen-Kettenis, PT. Puberty suppression in adolescents with gender identity disorder: a prospective follow-up study. *J Sex Med*. 2011 Aug;8(8):2276-83

[65] Florida ACHA GAPMS

[66] Boulware et al

Overall, the studies that have examined the use of puberty blockers, as a component of gender-affirming care, demonstrate that the use of these medications is evidence-based and provides for an appropriate risk/benefit ratio for adolescents diagnosed with gender dysphoria.[67]

In addition, the state fixates on the argument that puberty blockers are used off-label, not approved by the Federal Drug Administration (FDA), and that no randomized clinical trials (RCT) have been completed on the use of puberty blockers to treat gender dysphoria. These arguments lack any basis. First, in pediatric medicine, "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."[68] The use of off-label medication in pediatric medicine is supported by clinical evidence and data.[69] In suggesting that puberty blockers cannot be used to treat gender dysphoria simply because they have not been approved by the FDA for such purposes, the state fails to understand the relationship between the FDA and the practice of medicine:

- Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a marketed product in this manner when the intent is the "practice of medicine" does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB). However, the institution at which the product will be used may, under its own authority, require IRB review or other institutional oversight.[70]

The use of off-label medication in pediatric medicine is not experimental, nor does it constitute anything other than the practice of evidence-based medicine. Off-label medication use for pediatric patients is commonplace and there is no basis to prohibit puberty blockers because of their off-label use in pediatrics.[71]

The state's argument that puberty blockers have not undergone RCTs and therefore should be disqualified for use treating adolescents diagnosed with gender dysphoria is also severely flawed. As explained by Armand H. Antommaria, MD, PhD, FAAP, HEC-C, Director of the Ethics Center, the Lee Ault Carter Chair of Pediatric Ethics, and an Attending Physician in the Division of Hospital Medicine at Cincinnati Children's Hospital Medical Center:

- …it may, at times, be unethical to conduct randomized trials. For randomized trials to be ethical, clinical equipoise must exist; there must be uncertainty about whether the efficacy of the intervention or the control is greater. Otherwise, it would be unethical to knowingly expose trial participants to an inferior intervention or control. Trials must also be feasible; it would also be unethical to expose

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[67] Ibid

[68] Neville, KA, Frattarelli DAC, Galinkin JL, Green TP, et al; American Academy of Pediatrics Committee on Drugs. Off-Label Use of Drugs in Children. *Pediatrics*. 2014; 133(3)563-567

[69] Ibid

[70] US Food and Drug Administration. "Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices. 2020. Accessed on June 27, 2022. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices

[71] Allen HC, Garbe CM, Lees J, et al. Off-Label Medication use in Children, More Common than We Think: A Systematic Review of the Literature. *J Okla State Med Assoc*. 2018 Oct; 111(8): 776–783

> individuals to the risks of trial participation without the benefit of the trial generating generalizable knowledge. A randomized trial that is unlikely to find enough people to participate because they believe they might be randomized to an inferior intervention would be unethical because it could not produce generalizable knowledge due to an inadequate sample size.[72]

Furthermore, a group of leading bioethicists echo Dr Antommaria's explanation: "Randomized control trials also are only ethical when there is clinical "equipoise," which means they are only appropriate when there is genuine uncertainty about whether the intervention will be more effective than the control."[73] There is no uncertainty about the use of puberty blockers to treat adolescents diagnosed with gender dysphoria -- the evidence fully supports this intervention as a component of gender-affirming care. Studies other than RCTs are, in fact, utilized regularly in the practice of medicine and are preferable in some instances.[74]

Gender-Affirming Hormone Therapy

As a component of gender-affirming care, adolescents who have received extensive mental health care and puberty blockers may progress to hormone therapy. As with every component of gender-affirming care, the use of hormone therapy is a highly individualized decision, and any decisions are made in concert with the adolescent, their family, and mental health and medical care providers. Under the evidence-based standards of care for receiving hormone therapy, the following criteria must be met:

- A qualified MHP (mental health professional) has confirmed:
  - the persistence of gender dysphoria,
  - any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start sex hormone treatment,
  - the adolescent has sufficient mental capacity (which most adolescents have by age 16 years) to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to this (partly) irreversible treatment,
- And the adolescent:
  - has been informed of the (irreversible) effects and side effects of treatment (including potential loss of fertility and options to preserve fertility),
  - has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
- And a pediatric endocrinologist or other clinician experienced in pubertal induction:
  - agrees with the indication for sex hormone treatment,
  - has confirmed that there are no medical contraindications to sex hormone treatment.[75]

The state remarks in its Fact-Checked document that it is "misleading" to state that hormone therapy is partially reversible.[76] This is purposefully misleading. The evidence-based standards of care acknowledge that

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[72] Eknes-Tucker et al v Ivey et al. Declaration of Dr Armand H. Matheny Antommaria. 15 June 2021 https://www.aclu.org/legal-document/brandt-et-al-v-rutledge-et-al-declaration-dr-armand-h-matheny-antommaria.

[73] Eknes-Tucker et al v Ivey et al. Brief amicus curiae Biomedical Ethics and Public Health Scholars. 19 January 2022 https://www.aclu.org/legal-document/brandt-et-al-v-rutledge-et-al-amicus-brief-bioethicists

[74] Eknes-Tucker et al v Ivey et al. Declaration of Dr Armand H. Matheny Antommaria

[75] Hembree et al

[76] Florida Fact-Checked

some forms of hormone therapy are reversible and that some are not reversible.[77] Initiating hormone therapy is not a decision that is made lightly and there are stringent criteria that must be met, as referenced above. Furthermore, experts at Yale University explain that hormone therapy has a wide range of uses in adolescents:

- Estrogen and testosterone are often used off-label to treat adolescents with intersex conditions. Common hormonal medications used off-label include norethindrone, a progesterone analogue used off-label for the treatment of heavy menstrual bleeding in those with polycystic ovarian syndrome, bleeding disorder, and anovulatory bleeding of early puberty. It is also used to treat endometriosis, which is a painful inflammatory condition. Many forms of combined hormonal contraception, as well as a testosterone-blocking medication (spironolactone), are used off-label to treat acne. Other examples include clonidine, a blood pressure medication used off-label for the treatment of ADHD, migraine headaches, disorders of behavioral regulation, and insomnia; and propranolol, a blood pressure medication used off-label for the treatment of performance anxiety.[78]

As referenced in the preceding paragraph, the off-label use of hormone therapy for adolescents diagnosed with gender dysphoria "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."[79] Decision-making to initiate this form of gender-affirming care takes place at the clinical level, using the evidence-based standards of care and the best available evidence. By attempting to argue that hormone therapy is somehow more dangerous to adolescents with gender dysphoria than to cisgender adolescents undergoing to same treatment for a different medical condition, the state makes it abundantly clear that this is not about the health and well-being of adolescents; it is rather a misguided attempt to discriminate against adolescents with gender dysphoria.

In the GAPMS report, the state cites a study by Dutra et al that "examined the results of over 50 studies evaluating the effects of cross-sex hormones on not only transgender individuals but those with menopause and other endocrine disorders, all of which indicate that the use of estrogen or testosterone can increase risks for cardiovascular disease."[80] To use this as a basis for the state's argument to prohibit gender-affirming care for adolescents diagnosed with gender dysphoria would mean that the state would need to prohibit the use of hormone therapy in Florida's population at large. Additionally, in making this argument the state fails to consider the intent of hormone therapy -- to align one's body with one's gender identity. The experts at Yale University also clarify this misrepresentation or misunderstanding:

- The medical result is that transgender individuals move toward the typical medical profile of their identified gender. And so transgender women, like cisgender women, have lower risks of cardiovascular disease than cisgender men.[111] Transgender women, like cisgender women, have a slightly higher risk of venous thromboembolism than cisgender men. In fact, transgender women have a lower risk of venous thromboembolism than cisgender women, and the overall risk is extremely low (less than 1%) for all transgender individuals, both women and men.[112] The risk of venous thromboembolism in transgender women and non-pregnant cisgender women is less than the risk in pregnancy, which is the highest estrogenic physiologic state known.
- It is also critical to note that the medical impact of gender-affirming treatment is generally the same in transgender people as in cisgender people who take the same hormone medications. For example, physicians commonly prescribe hormonal contraceptives containing ethinyl estradiol (a synthetic

[77] WPATH
[78] Boulware et al
[79] Neville et al
[80] Florida ACHA GAPMS

estrogen) to adolescents for reasons including birth control, management of irregular or painful menstrual periods, and acne. In other words, similar doses of exogenous sex hormones are commonly administered to cisgender individuals for a host of reasons and are well tolerated.[81]

Research shows that hormone therapy, as a component of gender-affirming care, is beneficial to caring for adolescents diagnosed with gender dysphoria. A recent study in the Journal of Adolescent Health examined data from transgender or nonbinary adolescents and young adults between 13-24 and found that the provision of hormone therapy in those under 18 resulted in lower levels of depression and suicide attempts compared to adolescents who were unable to access hormone therapy.[82] Another recent study demonstrated that the provision of puberty blockers and hormone therapy reduced depression and suicidality over the course of 1 year.[83]

Additionally, the evidence cited in the evidence-based standards of care reinforces the sound basis for the provision of hormone therapy in adolescents diagnosed with gender dysphoria. Under the evidence-based standards of care, there are specific criteria for gender-affirming surgical interventions.[84] The state's focus on gender-affirming surgery and its attempt to classify it as common is a blatant misrepresentation intended to politicize the issue and cast doubt on the evidence-based standards of care.

Risks

Unlike the state's assertion on its "Florida Fact-Checked" document that "no reliable evidence shows that gender dysphoria significantly increases the risk of suicide," there is in fact evidence to support this.[85] In a study of more than 1,000 transgender adolescents, transgender adolescents had higher odds of all suicide outcomes compared to cisgender adolescents, and were at greater risk for suicidal ideations and attempts compared to their cisgender peers.[86] Additionally, in the first large scale (N = 120,670) study examining the relationship between transgender adolescents and suicide, the authors found that between 30-51% of transgender adolescents reported engaging in suicidal behavior, compared to between 10-18% of their cisgender peers.[87]

As noted in the earlier section on mental health, adolescents with gender dysphoria face increased bullying, discrimination, harassment, and a lack of social acceptance.[88] To add to these daily, ongoing issues, adolescents with gender dysphoria are at greater risk for suicide and other mental health conditions. Curiously, the State of Florida appears to agree that transgender adolescents (and other LGBTQ adolescents) face more serious mental health concerns than their cisgender peers, as it maintains a web site, Youth Suicide Prevention under the FL Department of Health, explaining the protective factors and risks associated with suicide in

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[81] Boulware et al

[82] Green AE, DeChants JP, Price MN, Davis, CK. Association of Gender-Affirming Hormone Therapy With Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth. *Jrnl of Adol Health*. 2021: 70(4) P643-649

[83] Tordoff, DM, Wanta, JW, Collin, A, Stephney, C, Inwards-Breland, DJ, Ahrens, K. (2022) Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care. *JAMA Network Open*, 5(2), e220978

[84] WPATH, Hembree et al

[85] Turban J. The Evidence for Trans Youth Gender-Affirming Medical care. Psychology Today. January 24, 2022. Accessed on June 27, 2022. https://www.psychologytoday.com/us/blog/political-minds/202201/the-evidence-trans-youth-gender-affirming-medical-care

[86] Thoma BC, Salk RH, Choukas-Bradley , et al. Suicidality Disparities Between Transgender and Cisgender Adolescents. *Pediatrics*. 2019; 144(5)

[87] Toomey RB, Syvertsen AK, Shramko M. Transgender Adolescent Suicide Behavior. *Pediatrics*. 2018; 142(4)

[88] Rafferty

adolescents (the state refers to this population as teens).[89] In identifying these protective factors and risks associated with suicide in adolescents, the state readily admits that "It is important to know that some youths experience an increased amount of risk. Youths are those who identify as LGBTQ, American Indian/Alaska Native, youth in the child welfare and juvenile justice systems or military service members can have higher incidence of suicidal behavior."[90] The state cannot have it both ways; it cannot argue that gender dysphoria doesn't increase the risk of suicide, as noted it its "Florida Fact-Checked" document[91] (ignoring the evidence that patently refutes this argument), and then readily acknowledge via its youth suicide prevention web site that transgender adolescents are at increased risk of suicide.

As referenced in an earlier section of this comment letter, access to and the provision of puberty blockers and hormone therapy as part of gender-affirming care works and is the gold standard according to the medical community to alleviate mental health conditions and risks associated with gender dysphoria in adolescents.[92]

Medicaid is a Critical Source of Health Care for Children, including Transgender Adolescents

Medicaid is a vital source of health insurance for children (for data reporting purposes below, the term "children" is inclusive of "adolescents") in Florida and across the United States. Nationally, children make up the single largest group of enrollees in Medicaid and the Children's Health Insurance Program (CHIP); more than 40 million—or 53% of all US children—rely on Medicaid and CHIP coverage, including with special health care needs and those from low-income families.[93] In Florida, over 2.8 million children were enrolled in Medicaid or CHIP as of February 2022.[94] Medicaid also provides comprehensive prenatal care, enabling millions of healthy pregnancies and births, thereby helping millions of children obtain a healthy start. In states that have expanded Medicaid coverage to low-income adults, this coverage not only provides many documented benefits to those adults,[95] but also has added benefits for children and adolescents, including an increased likelihood that they are covered, improved access to needed care, improved financial security for the family, higher preventive care use, and other benefits.[96; 97]

The direct benefits of Medicaid coverage for children and adolescents are many. In addition to improved access to care and health outcomes, those with Medicaid coverage miss less school, do better in school, are more likely to graduate and attend college, become healthier adults, earn higher wages, and pay more in taxes.[98]

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[89] Florida Department of Health. Youth Suicide Prevention. June 16, 2022. Accessed on June 28, 2022. https://www.floridahealth.gov/programs-and-services/prevention/suicide-prevention/youth.html

[90] Florida Department of Health. Youth Suicide Prevention

[91] Florida Fact-Checked

[92] Tordoff et al

[93] AAP analysis of data submitted by states to CMS released through the Medicaid and the Children's Health Insurance Program (CHIP) Performance Indicator Projects

[94] The Centers for Medicare and Medicaid Services (CMS). February 2022 Medicaid & CHIP Enrollment Data Highlights. Accessed June 29, 2022. https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html

[95] Guth M, Garfield R, Rudowitz R. The Effects of Medicaid Expansion under the ACA: Studies from January 2014 to January 2020. March 17, 2020. Accessed June 28, 2022. https://www.kff.org/medicaid/report/the-effects-of-medicaid-expansion-under-the-aca-updated-findings-from-a-literature-review/

[96] Searing A, Corcoran A, Alker J. Report Finds Medicaid Expansion Associated with Lower Child Uninsured Rates. Georgetown Center for Children and Families. February 17, 2021. Accessed June 27, 2022. https://ccf.georgetown.edu/2021/02/17/report-finds-medicaid-expansion-associated-with-lower-child-uninsured-rates/

[97] Schubel J. Expanding Medicaid for Parents Improves Coverage and Health for Both Parents and Children. Center for Budget and Policy Priorities. June 14, 2021. Accessed June 27, 2022. https://www.cbpp.org/research/health/expanding-medicaid-for-parents-improves-coverage-and-health-for-both-parents-and

[98] Wagnerman, K, Chester A, Alker J. Medicaid Is a Smart Investment

Together with CHIP, Medicaid has been instrumental in driving down the rate of uninsurance among children, which stands at 5.7% nationally and 7.6% in Florida (2019).[99]
Medicaid is not a benefit exclusive to cisgendered individuals. Indeed, Medicaid is of vital importance to transgender individuals, as it is estimated that almost 1/3 of all transgender persons will fall below the poverty line, more than twice the rate of the general population.[100] Both cisgender and transgender individuals enrolled in Medicaid rely on the program to cover their necessary medical care. However, the State of Florida, in promulgating this rule, is discriminating against Medicaid's transgender enrollees by seeking to arbitrarily ban a whole category of treatments which is exclusively utilized by transgender individuals.

Unlike many private health insurance plans, Medicaid guarantees that benefits for children are designed specifically for them. The Early and Periodic Screening, Diagnosis and Treatment (EPSDT) provision of federal Medicaid law is a cornerstone Medicaid protection and the definitive gold standard of pediatric health care benefits. EPSDT guarantees that all Medicaid-eligible children are screened to assess and identify health issues early and ensures the provision of medically necessary health services to address those identified health conditions.[101] EPSDT is designed to attend to a broad range of child health needs, including preventive care; physical and mental health; oral, hearing and vision care; habilitative care; and social and emotional development. EPSDT ensures that the medically necessary health care needs of the individual child determine what services and treatments Medicaid ultimately covers for that child. Such decisions of medical necessity are based on the expertise of the pediatrician or other treating clinician, who, through years of education, clinical training, and practice, takes into consideration the widely accepted evidence-based standards of care for the condition being treated.

This regulation as proposed would usurp this process of expert clinical decision-making made in the context of the physician-patient relationship; instead, it seeks to codify a discriminatory ban on widely accepted evidence-based standards of care for transgender adolescents and other individuals. As described in detail above, these standards of care are evidence-based and recommended by the medical community. Presented under the guise of an alternative care standard, this proposed prohibition on specific treatments for gender dysphoria not only ignores the prevailing consensus of numerous medical organizations, but also seeks to jettison the role of the treating clinician in determining medically necessary care for an individual. In every way, this proposed ban is a discriminatory gutting of the practice of medicine for transgender adolescents and other individuals, seeking to stifle the physician-patient relationship and replace it with the state's entirely ideological interest in ending gender affirming care in Florida's Medicaid program. In so doing, this proposed rule ignores the health and well-being of children, adolescents, and other individuals in Florida, both now and in the future, who could benefit from these treatments, and places their health interests as secondary to that of the state. This proposed rule counters medical consensus, discriminates against transgender adolescents, obstructs the physician-patient relationship, subverts Medicaid's EPSDT protection that places medical judgment central to coverage determinations, and, if finalized as proposed, would leave transgender adolescents and other individuals enrolled in Florida Medicaid with nowhere to turn for their much-needed health care.

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in Children. Georgetown Center for Children and Families. March 2017. Accessed June 27, 2022. https://ccf.georgetown.edu/wp-content/uploads/2017/03/MedicaidSmartInvestment.pdf

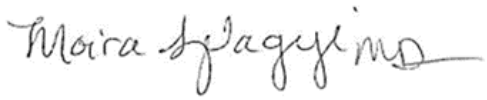
[99] US Census Bureau. American Community Survey. Accessed June 27, 2022. https://www.census.gov/data/tables/time-series/demo/health-insurance/historical-series/hic.html

[100] National Center for Transgender Equality. The Report of the 2015 Transgender Survey. December 2016. Accessed June 27, 2022. https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf

[101] The Centers for Medicare and Medicaid Services (CMS). Early and Periodic Screening, Diagnostic and Treatment. Accessed June 27, 2022. https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html

The consequences of such actions are likely to be many. As detailed throughout this letter, the mental and physical health and well-being of transgender children and adolescents often rely on their abilities to access much needed mental and physical health care—care that is in keeping with the widely recognized evidence-based standards of care for gender dysphoria. In proposing this rule, Florida ignores broad consensus among the medical community as to what those evidence-based standards of care are, and instead seeks, for its own discriminatory reasons, to impose alternate standards and an outright ban of specific treatments for transgender adolescents in the state's Medicaid program. As pediatricians who care for the health and well-being of all children in Florida and across the United States, we call for the Florida Medicaid program to return to the evidence-based standards of care widely accepted among the medical community, and for this discriminatory ban to be rescinded. Only by doing so will the health and well-being of transgender children and adolescents in Florida be preserved.

Sincerely,



Moira Szilaygi, MD, PhD, FAAP
President, American Academy of Pediatrics

Lisa Gwynn, DO, MBA, MSPH, FAAP
President, Florida Chapter of the American Academy of Pediatrics, Inc

EXHIBIT L

July 8, 2022

VIA E-MAIL AND WEBSITE

Simone Marstiller, 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 Marstiller 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.

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[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]

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[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

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[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

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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 inexpert 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

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[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

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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

[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 marriage[32] 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

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[30]The 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

[31] 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

[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]

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[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 inexpert 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 inexpert 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

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[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

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[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] Balshem 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

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[53] Balshem 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 2020[60] and a study by DeSanctis et al. in 2019.[61] The Appendix discusses these examples at

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[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 Prace 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]

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[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*

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[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

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[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

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[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); 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).

[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,

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[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).