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

PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION
AND INCORPORATED MEMORANDUM OF LAW

Pursuant to Federal Rule of Civil Procedure 65, Plaintiffs hereby move for an order preliminarily enjoining the enforcement of Fla. Admin. Code R. 59G-1.050(7), Fla. Admin. Code.

1. On August 21, 2022, Defendant Florida Agency for Healthcare Administration ("AHCA") adopted Fla. Admin. Code R. 59G-1.050(7) (the "Challenged Exclusion") prohibiting Medicaid coverage for medically necessary treatments for gender dysphoria. Defendants continue to cover those same services to treat other conditions.

2. Plaintiffs are transgender Medicaid beneficiaries diagnosed with gender dysphoria who have received medically necessary treatment for their gender dysphoria diagnoses for years, which Medicaid has covered. Because of the

Challenged Exclusion, however, Medicaid coverage for this treatment is no longer available to them, resulting in the denial of access to necessary medical care, grave threats to their health and wellbeing, and other dire consequences.

3. Plaintiffs are likely to succeed on the merits. The Challenged Exclusion targets only transgender persons and violates the Equal Protection Clause (ECF 1, at 74-77) and Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116 (ECF 1, at 77-79), by discriminating against transgender Medicaid beneficiaries on the basis of sex, gender identity, nonconformity with sex stereotypes, and transgender status.[1]

4. Without the requested preliminary injunctive relief, Plaintiffs and other transgender Medicaid beneficiaries will be subjected to immediate and irreparable harms, including the further loss of access to medically necessary care.

5. Plaintiffs have already suffered and will continue to face irreparable harm, and have no adequate remedy at law.

6. The balance of equities and the public interest favor Plaintiffs because Plaintiffs' irreparable injuries far outweigh any burden on Defendants that might result from non-enforcement of the Challenged Exclusion during the pendency of this case. Governmental entities have no legitimate interest in enforcing unconstitutional policies.

[1] Although Plaintiffs' Complaint includes claims under the federal Medicaid Act, Plaintiffs do not seek preliminary injunctive relief under those claims.

7. A preliminary injunction will maintain the status quo and preserve transgender beneficiaries' longstanding access to Medicaid coverage for the treatment of their gender dysphoria, including Plaintiffs, until a decision on the merits is rendered.

8. Plaintiffs request that the Court waive the requirement of bond in Fed. R. Civ. P. 65(c). *See BellSouth Tellecomm., Inc. v. MCIMetro Access Transmission Srvcs., LLC*, 425 F.3d 964, 971 (11th Cir. 2005). Public interest litigation is a recognized exception to the bond requirement, especially where, as here, the bond would injure the civil and constitutional rights of Plaintiffs and the relief sought would not pose a hardship to Defendants. *See Univ. Books & Videos, Inc. v. Metro. Dade Cnty.*, 33 F.Supp.2d 1364, 1374 (S.D. Fla. 1999).

WHEREFORE, Plaintiffs respectfully request an order preliminarily enjoining Defendants from enforcing Fla. Admin. Code R. 59G-1.050(7).

REQUEST FOR ORAL ARGUMENT

Pursuant to Local Rule 7.1(K), Plaintiffs respectfully request oral argument on this motion, estimating up to three hours for a non-evidentiary hearing.

MEMORANDUM OF LAW IN SUPPORT OF MOTION

I. INTRODUCTION

Defendants target transgender Medicaid beneficiaries, including Plaintiffs August Dekker, Brit Rothstein, Susan Doe,[2] and K.F., by excluding from Medicaid coverage the medically necessary treatments for their gender dysphoria. On August 21, 2022, after covering such care for years, Defendant the Florida Agency for Health Care Administration ("AHCA") adopted Fla. Admin. Code R. 59G-1.050(7) (the "Challenged Exclusion"), prohibiting Medicaid coverage of services necessary for the treatment of gender dysphoria. Defendants continue to cover the same services to treat other conditions.

Simply stated, the Challenged Exclusion targets only transgender persons and, accordingly, it violates the Fourteenth Amendment's Equal Protection Clause and Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116.

There is nothing experimental about the medical treatment (known as gender-affirming care) for gender dysphoria. To the contrary, gender-affirming care is supported by scientific evidence and recognized as safe, effective, and medically necessary.

Defendants' abrupt deviation from the status quo has caused and will continue

[2] By separate motion, Plaintiff Susan Doe, a minor, and her parents and next friends John Doe and Jane Doe, are requesting to proceed under pseudonyms.

to cause irreparable harm to Plaintiffs, who will no longer be able to access medically necessary care, endangering their health and wellbeing.

There is no rational basis, let alone the exceedingly persuasive justification or compelling interest, necessary for the implementation of the Challenged Exclusion. Plaintiffs seek to preserve the status quo wherein transgender Medicaid beneficiaries receive coverage for medically necessary treatments for their gender dysphoria, and respectfully request this Court grant Plaintiffs' Motion for a Preliminary Injunction.

II. STATEMENT OF FACTS

A. The Medically Necessary Treatment of Gender Dysphoria

Gender identity is a person's internal sense of their sex. (*See* Decl. of J. Olson-Kennedy, M.D., M.S., ¶18 ("Olson-Kennedy"); Decl. of D. Karasic, M.D., ¶22 ("Karasic").) Gender identity is innate, immutable, has significant biological underpinnings, and it cannot be altered. (Olson-Kennedy, ¶¶18, 23, 25, 33; Karasic, ¶22.) Every person has a gender identity, and it does not always align with their sex assigned at birth. (Olson-Kennedy, ¶18; Karasic, ¶22.)

A person's sex assigned at birth is generally based on a visual assessment of external genitalia. (Olson-Kennedy, ¶21; Karasic, ¶21.) People who have a gender identity that aligns with their sex assigned at birth are cisgender, while people who have a gender identity that does not align with their sex assigned at birth are transgender. (Olson-Kennedy, ¶20; Decl. of L. Schechter, M.D. ¶21 ("Schechter").)

A transgender boy or man was assigned a female sex at birth but has a male gender identity. A transgender girl or woman was assigned a male sex at birth but has a female gender identity. The incongruence between a transgender person's gender identity and their sex assigned at birth can result in clinically significant distress, referred to as gender dysphoria. (Karasic, ¶23; Schechter, ¶22.)

Gender dysphoria is a serious medical condition, the diagnosis of which is codified in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition* ("DSM-5"). (Olson-Kennedy, ¶26; Karasic, ¶23; Schechter, ¶22.) It is also recognized as "gender incongruence" in the *International Classification of Diseases* (World Health Org., 11th rev.). (Olson-Kennedy, ¶27; Schechter, ¶22.)

Gender dysphoria, if left untreated, may result in debilitating anxiety, severe depression, self-harm, and even suicidality. (Olson-Kennedy, ¶96; Karasic, ¶25; Schechter, ¶22.) The longer a person goes without appropriate treatment for gender dysphoria, the greater the risk of severe harm to their health and wellbeing. (Olson-Kennedy, ¶113; Karasic, ¶89.)

Treatment for gender dysphoria is provided pursuant to well-established guidelines, developed through decades of research and clinical practice. (Olson-Kennedy, ¶¶29-30; Decl. of A. Antommaria, M.D., Ph.D. ¶40 ("Antommaria").) Like all medical care, treatment for gender dysphoria is individualized and based on

patient needs. (Olson-Kennedy, ¶38; Schechter, ¶73.) For more than four decades, medical organizations have studied and created evidence-based standards for the treatment of gender dysphoria. The World Professional Association for Transgender Health ("WPATH") and the Endocrine Society have published guidelines for treating gender dysphoria.[3] (Olson-Kennedy, ¶¶29-30, 70; Schechter, ¶¶25-28; Karasic, ¶¶26-31, 36.) Major medical organizations have endorsed these guidelines. (Olson-Kennedy, ¶¶29, 112; Karasic, ¶¶31, 59, 86.)

Treatment seeks to eliminate the distress of gender dysphoria by aligning a patient's body and presentation with their gender identity. (Schechter, ¶26; Karasic, ¶¶33, 58.) Gender-affirming care may include counseling, hormone therapy, surgery, and other medically necessary treatments. (Olson-Kennedy, ¶38; Karasic, ¶¶26, 38-42; Schechter, ¶26.) The precise treatments are determined by the health care team in collaboration with the patient, and, if the patient is an adolescent, with the patient's parents or guardians. (Olson-Kennedy, ¶38.)

The guidelines differ depending on whether the patient is an adolescent who has started puberty or an adult. (Olson-Kennedy, ¶38.) Neither WPATH nor the

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[3] Endocrine Society, *Endocrine Treatment of Gender Dysphoric/ Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline* (September 2017), *available at* https://www.endocrine.org/clinical-practice-guidelines/gender-dysphoria-gender-incongruence; World Prof'l Ass'n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People (7th ver. 2012), https://www.wpath.org/publications/soc.

Endocrine Society recommend any medical, pharmaceutical, or surgical interventions before puberty. (*Id.*; Antommaria, ¶48.)

For adolescents with gender dysphoria who experience severe distress with the onset of puberty, puberty-delaying medication may be indicated. (Olson-Kennedy, ¶¶38-39; Karasic, ¶39.) Medical treatments for adolescents are provided in consultation with qualified mental health professionals. (Olson-Kennedy, ¶38; Karasic, ¶39.) Puberty-delaying medications pause endogenous puberty, limiting the influence of endogenous hormones on the body. (Olson-Kennedy, ¶40.) Such interventions afford the adolescent time to better understand their gender identity while delaying the development of secondary sex characteristics. (*Id.*)

Treatment with puberty-delaying medications is reversible, meaning that if an adolescent discontinues the treatment, puberty will resume. (*Id.*, ¶¶40-41, 102; Karasic, ¶39.) Treatment with puberty-delaying medication can drastically minimize gender dysphoria during adolescence and later in adulthood, and in some cases may eliminate the need for future surgery. (Olson-Kennedy, ¶40.)

For some adolescents with gender dysphoria, initiating puberty consistent with their gender identity through hormone therapy may be medically necessary. (Olson-Kennedy, ¶¶38, 43; Antommaria, ¶40; Karasic, ¶40.) For adults, hormone therapy may also be medically necessary. (Olson-Kennedy, ¶¶38, 43; Antommaria, ¶40; Karasic, ¶40.) Hormone therapy is provided only when medically indicated.

(Olson-Kennedy, ¶43; Karasic, ¶40.) As with all medical care, no treatment is provided without discussing the risks and benefits of the treatment and informed consent. (Olson-Kennedy, ¶43; Antommaria ¶¶46-48.)

Gender-affirming surgeries are means for transgender adult individuals to align their body with their gender identity. (Olson-Kennedy, ¶¶44-45; Karasic, ¶41; Schechter, ¶26.) Though not all transgender people require gender-affirming surgery, such care is necessary when medically indicated. (Schechter, ¶26.)

Every major medical association in the country agrees that gender-affirming care is safe, effective, and medically necessary treatment for gender dysphoria that improves the health and wellbeing of transgender people. (Olson-Kennedy, ¶112; Schechter, ¶28.) The consequences of untreated gender dysphoria are serious, including irreversible and harmful physical changes and irreparable mental harm, and can lead to higher levels of stigmatization, discrimination, and victimization. (Olson-Kennedy, ¶¶73, 96; Karasic, ¶58.)

B. The Lead Up to the Challenged Exclusion

Florida participates in the federal Medicaid program. Defendant AHCA is the "single state agency" responsible for implementing the program. § 409.963, Fla. Stat. It oversees the promulgation of all Medicaid coverage policies, including the Challenged Exclusion. § 409.919, Fla. Stat.

On April 20, 2022, Florida's Department of Health ("FDOH"), issued a set

of guidelines titled "Treatment of Gender Dysphoria for Children and Adults" (hereinafter "FDOH Guidelines").[4] The FDOH Guidelines indicated that children should not be permitted to undergo a social transition, no one under 18 should be prescribed puberty-delaying medication or hormone therapy, and gender-affirming surgery should not be a treatment option for children or adolescents. The FDOH Guidelines directly contradicted guidance from the U.S. Department of Health and Human Services noting that access to "gender affirming care is crucial to overall health and well-being,"[5] as well as established experts in the treatment of gender dysphoria.

More than 300 Florida health care professionals who care for transgender youth published a letter denouncing the FDOH Guidelines for citing "a selective and non-representative sample of small studies and reviews, editorials, opinion pieces and commentary" which contradict existing guidelines for treating gender dysphoria.[6]

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[4] *See* Fla. Dep't Health, *Treatment of Gender Dysphoria for Children and Adults* (April 20, 2022), Altman Ex. A.

Unless otherwise noted, all Exhibits cited herein are attached to the Declaration of Jennifer Altman filed concurrently.

[5] *See Gender-Affirming Care and Young People*, U.S. Dep't of Health & Human Servs. (March 2022), Altman Ex. B.

[6] Brittany S. Bruggeman, *We 300 Florida health care professionals say the state gets transgender guidance wrong*, TAMPA BAY TIMES (Apr. 27, 2022), Altman Ex. C, at 3.

Still, Secretary Marstiller requested that AHCA determine if the treatments addressed in the FDOH Guidelines "are consistent with generally accepted professional medical standards and not experimental or investigational."[7]

On June 2, 2022, Defendants published their report, "Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria"[8] (hereinafter "GAPMS Memo"),[9] which was rife with errors and misrepresentations. The GAPMS Memo wrongly concluded that gender-affirming medical treatments "do not conform to [generally accepted professional medical standards] and are experimental and investigational."[10] The GAPMS Memo cited to, and relied upon, five non-peer-reviewed, unpublished "assessments" that Defendants commissioned solely to support their conclusion.

According to a report from a team of medical and legal experts, the GAPMS Memo was "so thoroughly flawed and biased that it deserves no scientific weight."[11]

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[7] Letter from Secretary Marstiller to Deputy Secretary Wallace (April 20, 2022), Altman Ex. D.

[8] The GAPMS process purports to be an independent determination based on "reliable scientific evidence published in peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations' recommendations." Fla. Admin. Code R. 59G-1.035.

[9] *See* Altman Ex. E.

[10] *See* Altman Ex. E, at 3.

[11] *A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria* (July 8, 2022), Altman Ex. F, at 2.

Some of those flaws are worth mentioning. *First*, the GAPMS Memo relies solely on unpublished papers that have not been peer-reviewed or scrutinized as is standard in the scientific community. *Second*, the GAPMS Memo does not identify these so-called "expert" authors' qualifications, the process through which they were selected, or why their outlier opinions are more credible than well-established guidelines and the opinions of major medical associations. *Third*, the GAPMS Memo relies on unscientific evidence, *e.g.*, blogs and articles. *Fourth*, no author of the "assessments" provided statements regarding their funding and conflicts of interest, violating a strong norm in scientific writing. *Fifth*, the GAPMS Memo ignored the standard of care for gender dysphoria supported by major professional medical associations and societies. And finally, each author of the commissioned "assessments" has been shown to have indicia of unreliability or bias:

- A Texas court barred Dr. Quentin Van Meter from providing expert testimony regarding medical treatment for gender dysphoria;[12]
- Dr. James Cantor's opinion regarding gender-affirming care was given little weight by a federal judge due to his lack of experience in this field;[13]

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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 on the now-sealed case), Altman Ex. G.

[13] *Eknes-Tucker v. Marshall*, Case No. 2:22-CV-184, 2022 WL 1521889, at *5 (M.D. Ala. May 13, 2022).

- Dr. Romina Brignardello-Petersen conducts research for a group that opposes gender-affirming care, although she indicated in her assessment that she had no research interests in medical care for transgender youth;[14]
- A federal judge disqualified Dr. Patrick Lappert from testifying regarding aspects of gender-affirming care, citing the lack of scientific support for his opinions and "evidence that calls Dr. Lappert's bias and reliability into serious question."[15]

With the GAPMS Memo as foundation, on June 17, 2022, Defendants published a Notice of Proposed Rule seeking to amend Florida Administrative Code 59G-1.050 to prohibit Medicaid from covering "services for the treatment of gender dysphoria."[16] The Proposed Rule went beyond the FDOH Guidelines by seeking to prohibit Medicaid coverage for all transgender beneficiaries. AHCA accepted written comments from the public about the Proposed Rule, and on July 8, 2022, held a public hearing.

Thousands of written comments were submitted in opposition to the Proposed

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[14] 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), Altman Ex. H.

[15] *Kadel v. Folwell*, Case No. 1:19-CV-272, 2022 WL 3226731, *9 (M.D.N.C. Aug. 10, 2022).

[16] AHCA, Notice of Proposed Rule (June 17, 2022), Altman Ex. I.

Rule, including comments from the Endocrine Society,[17] the American Academy of Pediatrics,[18] and a team of legal and medical experts from various academic institutions.[19] Together, these comments made it clear that: (1) the Proposed Rule would cause unnecessary harm and suffering; (2) the GAPMS Memo was significantly flawed and contrary to established standards of care; and (3) the Proposed Rule was illegal.

Notwithstanding these comments, Defendants filed to adopt the Proposed Rule a mere three weeks after the close of the comment period. The final version was identical to the Proposed Rule, and went into effect on August 21, 2022.

The timing of the GAPMS Memo and adoption of the Challenged Exclusion underscores its biased nature, as it came amidst a wave of actions by Florida's government clawing back the rights of transgender persons. (*See* ECF 1, at 40-42.)

C. The Challenged Exclusion

The Challenged Exclusion impermissibly targets solely those Florida Medicaid beneficiaries diagnosed with gender dysphoria, *i.e.*, those who are transgender, for unequal health care coverage. The Challenged Exclusion

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[17] *Letter from the Endocrine Society to the AHCA* (July 8, 2022), Altman Ex. J.

[18] *Letter from the American Academy of Pediatrics et al. to AHCA Deputy Secretary Tom Wallace* (July 7, 2022), Altman Ex. K.

[19] *Letter from Anne L. Alstott et al. to AHCA Secretary Marstiller* (July 8, 2022), Altman Ex. L.

categorically excludes Medicaid coverage of treatment for gender dysphoria, specifically: (i) "puberty blockers;"[20] (ii) "hormones and hormone antagonists;" (iii) "sex reassignment surgeries;" and (iv) "[a]ny other procedures that alter primary or secondary sexual characteristics." Rule 59G-1.050(7), Fla. Admin. Code. The Challenged Exclusion provides that these services "do not meet the definition of medical necessity in accordance with Rule 59G-1.010, F.A.C." *Id.*

Defendants continue to cover these services when used to treat other medical conditions.

D. Plaintiffs' Need for Medical Care

1. <u>Plaintiff August Dekker</u>

Plaintiff August Dekker is a 28-year-old transgender man with rheumatoid arthritis who qualifies for Florida Medicaid coverage. (Decl. of A. Dekker, ¶¶3-5 ("Dekker").)

As early as age 5, August began experiencing symptoms of gender dysphoria, which continued into adulthood. (*Id.*, ¶8.) In 2017, August received a formal diagnosis of gender dysphoria. (*Id.*, ¶12.) August then began hormone therapy at the recommendation of his medical providers, which he continues to receive today. (*Id.*, ¶¶13, 15.) He received masculinizing chest surgery in April 2022. (*Id.*, ¶16.) All of August's gender-affirming care to date has been covered by Medicaid as

[20] We will refer to these medications as "puberty-delaying medication."

medically necessary. (*Id.*, ¶17.)

August continues to need hormone therapy to treat his gender dysphoria. (*Id.*, ¶26.) The gender-affirming care August has received allows him to live without the symptoms of gender dysphoria in his day-to-day life. (*Id.*, ¶¶18-19.) Under the Challenged Exclusion, Medicaid will no longer cover this care, and because August cannot afford to pay out-of-pocket for it, he will lose access to hormone therapy, which will cause him to undergo physical changes that will cause him psychological distress and increase his risk of discrimination and violence. (*Id.*, ¶¶23, 26-27.)

2. <u>Plaintiff Brit Rothstein</u>

Plaintiff Brit Rothstein is a 20-year-old transgender man attending college. Brit has been enrolled in Medicaid since he was a child. (Decl. of B. Rothstein, ¶4 ("Rothstein").) Brit has been aware of his gender identity since the third grade. (*Id.* ¶¶7, 8.) Brit's gender dysphoria intensified over time, and he sought therapy for his dysphoria in seventh grade. (*Id.* ¶9.)

At age 14 in July 2016, Brit received a formal diagnosis of gender dysphoria. (*Id.*, ¶11.) At age 17, Brit began receiving medically necessary hormone therapy. (*Id.*, ¶12.) And, in May 2022, after many years of debilitating dysphoria, a surgeon recommended that Brit undergo masculinizing chest surgery to align Brit's appearance with his gender identity. (*Id.*, ¶¶15-17.)

Brit receives health insurance coverage through Medicaid, which has covered

all his gender-affirming care. (*Id.*, ¶¶4, 12.) Moreover, Brit has received Medicaid approval for his chest surgery, which is scheduled for December 2022. (*Id.*, ¶¶17-18.)

Because of the Challenged Exclusion, Brit will not be able to have this medically-necessary procedure, despite Medicaid already approving it. (*Id.*, ¶17.) Now, Brit is without the ability to pay for his medications or his upcoming surgery. (*Id.*, ¶¶19-20.) The Challenged Exclusion will cause Brit to continue to suffer intense gender dysphoria related to his chest, and subject him to increased risk of discrimination, harassment, and violence. (*Id.*, ¶21.)

3. <u>Plaintiff Susan Doe</u>

Plaintiff Susan Doe is 12-year-old transgender adolescent girl. Jane and John Doe are Susan's parents. (Decl. of J. Doe ("Doe"), ¶¶2-3.) They adopted Susan out of medical foster care when she was two years old, which entitles her to Medicaid coverage until age 18. (*Id.*, ¶9.)

Susan first realized she was a girl at age 3. (*Id.*, ¶10.) The summer before starting second grade, Susan told her parents clearly: "I need to be a girl." (Id., ¶13.) Thereafter, her therapist diagnosed her with gender dysphoria. (*Id.*, 13.)

In July 2020, after Susan began puberty, her endocrinologist prescribed her puberty-delaying medication (Lupron) as medically necessary treatment for her gender dysphoria. (*Id.*, ¶19.) Florida Medicaid covered this medication that

prevents Susan from developing secondary sex characteristics consistent with her sex-assigned birth. (*Id.*) Susan's endocrinologist expects that she will be ready to start cross-sex hormone therapy in a year or two. (*Id.*, ¶21.)

Susan is due to have her next Lupron injection on October 3, 2022. (*Id.*, ¶24.) Because of the Challenged Exclusion, Medicaid will no longer cover it; her parents will have no choice but to try to pay for the treatment out-of-pocket. Based on their research, the retail price for a single Lupron injection is roughly $11,000, a prohibitively high cost for a family of four living on a single income. (*Id.*, ¶29.)

Should Susan have to stop taking Lupron and go through endogenous puberty, she would be devastated. She has been living as a girl in every aspect of her life since 2017. (*Id.*, ¶26.) Without Lupron, Susan's mental health will suffer as endogenous puberty would be torture for her. (*Id.*) It will also be devastating for her parents to watch her suffer. (*Id.*)

4. <u>Plaintiff K.F.</u>

Plaintiff K.F. is a 12-year-old transgender boy who receives Medicaid coverage due to his family's income. (Decl. of J. Ladue, ¶8 ("Ladue").) From a very young age, K.F. knew that his sex assigned at birth did not match his gender identity. (*Id.*, ¶¶9-10.) When K.F. came out, his parents arranged for him to see mental health professionals and later pediatric endocrinologists. (*Id.*, ¶¶13, 16.)

In August 2020, before K.F.'s move to Florida, he received puberty-delaying medication, covered by Massachusetts' Medicaid program. (*Id.*, ¶6.) Upon moving to Florida, K.F. established care with Florida-based specialists, and he received his second puberty-delaying implant in April 2022, which Florida Medicaid covered. (*Id.*, ¶¶19-20.)

Presently, K.F.'s bloodwork demonstrates that K.F. may need to switch to a medication that is more effective at suppressing his puberty. (*Id.* ¶21.) The alternative medication would cost $3,000-3,600 every three months. (*Id.* ¶23.) Moreover, K.F.'s treating specialists have indicated that within the next year K.F. will need to begin hormone therapy. (*Id.* ¶24.) Whatever course K.F.'s treatment takes, his family will be unable to afford it because of the Challenged Exclusion. (*Id.* ¶30.)

Gender-affirming care created a "night and day" change in K.F. His persistent anxiety and issues functioning at school significantly improved, and he is now "thriving." (*Id.*, ¶25.) Without access to this care through Medicaid, K.F.'s mental health will suffer tremendously. (*Id.*, ¶28.)

III. ARGUMENT

The purpose of a preliminary injunction is to preserve the status quo and thus prevent irreparable harm until the respective rights of the parties can be ascertained during a trial on the merits. *Powers v. Sec., Fla. Dep't of Corrections*, 691

Fed.App'x 581, 583 (11th Cir. 2017). To prevail, a plaintiff must demonstrate: (1) a substantial likelihood of success on the merits; (2) irreparable injury; (3) the harms will likely outweigh any harm that defendant will suffer as a result of an injunction; and (4) that preliminary relief will not disserve the public interest. *Scott v. Roberts*, 612 F.3d 1279, 1290 (11th Cir. 2010). "[A]ll of the well-pleaded allegations of [the] complaint and uncontroverted affidavits filed in support of the motion for a preliminary injunction are taken as true." *Elrod v. Burns*, 427 U.S. 347, 350 n.1 (1976).

A. Plaintiffs Are Likely to Succeed on the Merits.

Plaintiffs are likely to succeed on the merits of their claims that the Challenged Exclusion violates the Equal Protection Clause and Section 1557 of the Affordable Care Act.

1. Plaintiffs Are Likely to Succeed On the Merits of their Equal Protection Claim.

The Equal Protection Clause provides that no state may "deny to any person within its jurisdiction the equal protection of the laws." U.S. Const. amend. XIV, § 1. Accordingly, Defendants Marstiller and AHCA must "treat all persons similarly situated alike or, conversely, [must] avoid all classifications that are 'arbitrary or irrational' and that reflect a 'bare desire to harm a politically unpopular group.'" *Glenn v. Brumby*, 663 F.3d 1312, 1315 (11th Cir. 2011) (quoting *City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 446-47 (1985)).

Discrimination based on sex is subject to heightened scrutiny. *See United States v. Virginia*, 518 U.S. 515, 533 (1996) ("*VMI*"); *Glenn*, 663 F.3d at 1319. And, both the Supreme Court and the Eleventh Circuit have made clear that discrimination because a person is transgender is discrimination based on sex. *See Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1741 (2020); *Glenn*, 663 F.3d at 1317.

On its face, the Challenged Exclusion – which explicitly precludes Medicaid coverage for "services for the treatment of *gender* dysphoria," including "*[s]ex* reassignment surgeries" and any "procedures that alter primary or secondary *sexual* characteristics" – constitutes sex-based discrimination. Courts considering similar categorical coverage exclusions have held as much. *See Kadel*, 2022 WL 3226731, at *19; *Fain v. Crouch*, 2022 WL 3051015, at *8 (S.D.W. Va. Aug. 2, 2022); *Fletcher v. Alaska*, 443 F.Supp.3d 1024, 1027, 1030 (D. Alaska 2020); *Flack v. Wisconsin Dep't of Health Servs.*, 395 F.Supp.3d 1001, 1019-22 (W.D. Wis. 2019); *Boyden v. Conlin*, 341 F.Supp.3d 979, 1002-03 (W.D. Wis. 2018). *Cf. Brandt by & through Brandt v. Rutledge*, 2022 WL 3652745, at *2 (8th Cir. Aug. 25, 2022) (finding a state law banning gender-affirming care for minors discriminates on the basis of sex).

The Challenged Exclusion cannot withstand heightened scrutiny.

i. Because the Challenged Exclusion Discriminates Based on Sex, Including Transgender Status, It Triggers Heightened Scrutiny.

"[I]t is impossible to discriminate against a person for being . . . transgender without discriminating against that individual based on sex." *Bostock*, 140 S. Ct. at 1741. Taking adverse action against "a transgender person who was identified as a male at birth but who now identifies as a female," while not taking such action against "an otherwise identical [person] who was identified as female at birth," "intentionally penalizes" the transgender person. *Id*. at 1741-42; *see also Glenn*, 663 F.3d at 1317 (holding "discrimination against a transgender person because of her gender-nonconformity is sex discrimination, whether it's being described as being on the basis of sex or gender").

That is precisely what the Challenged Exclusion does. For example, "[a] minor born as a male may be prescribed testosterone … but a minor born as a female is not permitted to seek the same medical treatment." *Brandt*, 2022 WL 3652745, at *2; *see also Kadel*, 2022 WL 3226731, at *19 ("The Plan expressly limits members to coverage for treatments that align their physiology with their biological sex and prohibits coverage for treatments that 'change or modify' physiology to conflict with assigned sex."); *Fletcher*, 443 F.Supp.3d at 1030. In other words, "sex plays an unmistakable and impermissible role" in the Challenged Exclusion, which "intentionally penalizes a person … for traits or actions that it tolerates" in another

individual simply because of sex assigned at birth. *See Bostock*, 140 S. Ct. at 1741–42; *see also Boyden*, 341 F.Supp.3d at 995 (discrimination in coverage based on one's birth-assigned sex is a "straightforward" case of sex discrimination).

As *Boyden* explained, excluding coverage for gender-affirming care "entrenches" the sex-stereotyped "belief that transgender individuals must preserve the genitalia and other physical attributes of their [sex assigned at birth] sex over not just personal preference, but specific medical and psychological recommendations to the contrary." 341 F.Supp.3d at 997; *see also Flack*, 328 F.Supp.3d at 951. "This is textbook sex discrimination." *Kadel*, 2022 WL 3226731, at *19. And courts throughout the country have found similar discrimination against transgender people to be rooted in impermissible sex stereotyping. *See, e.g.*, *Kadel v. Folwell*, 446 F.Supp.3d 1, 14 (M.D.N.C. 2020) (exclusion "tethers Plaintiffs to sex stereotypes which, as a matter of medical necessity, they seek to reject"); *Toomey v. Arizona*, 2019 WL 7172144, at *6 (D. Ariz. Dec. 23, 2019).

Furthermore, discrimination "on the basis that an individual was going to, had, or was in the process of changing their sex … is still discrimination based on sex." *Flack.*, 328 F.Supp.3d at 949 (emphasis added). The same is true here because the Challenged Exclusion expressly prohibits coverage for "the treatment of *gender* dysphoria," including "[*s*]*ex reassignment* surgeries" and any "procedures that *alter* primary or secondary *sexual* characteristics[.]" Fla. Admin. Code R. 59G-1.050(7).

In addition to sex-based discrimination, discrimination based on transgender status is separately entitled to, at least, heightened scrutiny. *See Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 607 (4th Cir. 2020), as amended (Aug. 28, 2020); *see also Karnoski v. Trump*, 926 F.3d 1180, 1200 (9th Cir. 2019). In identifying whether a classification is suspect or quasi-suspect, courts consider whether: (a) the class has historically been "subjected to discrimination," *Bowen v. Gilliard*, 483 U.S. 587, 602 (1987); (b) the class's defining characteristic "bears [any] relation to ability to perform or contribute to society," *City of Cleburne*, 473 U.S. at 440-41; (c) the class exhibits "obvious, immutable, or distinguishing characteristics that define them as a discrete group," *Gilliard*, 483 U.S. at 602; and (d) the class is "a minority or politically powerless." *Id*.

All indicia are present for transgender people. "[T]ransgender people as a class have historically been subject to discrimination or differentiation; … they have a defining characteristic that frequently bears no relation to an ability to perform or contribute to society; … as a class they exhibit immutable or distinguishing characteristics that define them as a discrete group; and … as a class, they are a minority with relatively little political power." *Evancho v. Pine-Richland Sch. Dist.*, 237 F.Supp.3d 267, 288 (W.D. Pa. 2017). Numerous courts have reached the same conclusion. *See, e.g.*, *Grimm*, 972 F.3d at 607; *Karnoski*, 926 F.3d at 1200; *Flack*, 328 F.Supp.3d at 951–53; *M.A.B. v. Bd. of Educ. of Talbot Cnty.*, 286 F.Supp.3d

704, 718–22 (D. Md. 2018); *Norsworthy v. Beard*, 87 F.Supp.3d, 1104, 1119 (N.D. Cal. 2015).

ii. The Challenged Exclusion Cannot Survive Heightened Scrutiny.

Defendants' discriminatory rule targeting Plaintiffs and other transgender Medicaid beneficiaries demands meaningful review. Arguably, it is subject to the onerous strict scrutiny standard, wherein Defendants must show that the Challenged Exclusion is narrowly tailored to advance a compelling state interest. *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 227 (1995). Even under the heightened scrutiny required for all sex-based classifications, Defendants carry the heavy burden of showing that the Challenged Exclusion is substantially related to an important government interest, and that they had an "exceedingly persuasive" justification for it. *Glenn*, 663 F.3d at 1321; *see also, e.g.*, *VMI*, 518 U.S. at 533. Under both standards, the "burden of justification is demanding and [] rests entirely on the State," and constitutionality is judged based on the "the actual state purposes, not rationalizations for actions in fact differently grounded." *VMI*, 518 U.S. at 533, 535-36.

Here, the Challenged Exclusion cannot meet either standard. To the extent that Defendants contend the Challenged Exclusion is justified because gender-affirming care is allegedly "experimental" and "investigational," that conclusion is contradicted by the evidence. (Antommaria, ¶52; Schechter, ¶¶48-50; Karasic,

¶¶67-72.) The Court cannot simply accept the assertions of the GAPMS memo that gender-affirming medical treatments are "experimental" and "investigational" [21] because "[t]he Court retains an independent constitutional duty to review factual findings where constitutional rights are at stake." *Gonzales* v. *Carhart*, 550 U.S. 124, 165 (2007).

AHCA cannot carry its burden to justify the Challenged Exclusion based on purported concerns about the quality of the evidence concerning treatment. AHCA's purported concern directly conflicts with the views of the mainstream medical community. (Antommaria, ¶¶22-24, 29, 52; Olson-Kennedy, ¶¶88, 112; Schechter, ¶74.) While the GAPMS Memo baldly asserts that this well-established treatment is "experimental,"[22] the medical and scientific landscape shows the opposite. Thus, AHCA cannot carry its burden to show a substantial relationship between the Challenged Exclusion and a purported interest in excluding coverage for experimental or investigational treatments.

The GAPMS Memo relies on a claimed absence of long-term longitudinal studies and randomized clinical trials assessing safety and efficacy of gender-affirming care.[23] These kinds of studies are not the only type of studies upon which

[21] Altman Ex. E, at 3.

[22] Altman Ex. E, at 3.

[23] Altman Ex. E, at 15.

the medical profession relies on to determine the safety and efficacy of treatments. (Antommaria, ¶¶29-44; Olson-Kennedy, ¶¶75-81.) In the context of pediatric medicine, the body of research is less likely to use randomized trials than is clinical research for adults, and, at times, it is unethical to conduct such randomized trials.[24] (Antommaria, ¶¶35-37; Olson-Kennedy, ¶¶73-74.) For similar reasons, researchers rarely use randomized clinical trials for surgical treatments. (Schechter, ¶55.) Thus, if AHCA were to exclude from Medicaid coverage all treatment unsupported by randomized clinical trials, it would have to exclude much of pediatric medicine and many surgical procedures.

If limiting Medicaid coverage to treatments supported by certain kinds of medical research, such as randomized clinical trials, somehow advanced a government interest in individual patients' well-being, then AHCA would have to require that standard to be met for all treatments, but it does not. *See Eisenstadt*, 405 U.S. at 452. AHCA cannot provide any rational explanation—much less an "exceedingly persuasive" one—to justify subjecting only gender-affirming care to this unique burden. *VMI*, 518 U.S. at 533.

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[24] Requiring use of randomized trials to justify a medical intervention would be unethical because it would require doctors to disregard substantial evidence demonstrating the safety and efficacy of medical treatments and deny patients treatments that are known to provide relief for their medical conditions. Moreover, even if this demand were legitimate, an exclusion of coverage for treatment would prohibit any additional research, thereby undermining any purported desire for further study.

The only purportedly scientific or medical bases Defendants relied upon in promulgating the Challenged Exclusion were five non-peer reviewed, unpublished "assessments" that Defendants themselves commissioned to support their predetermined outcome. (*see* Section II.B, *supra)*. The "assessments" authors have either been barred from testifying in court as to the treatment of gender dysphoria, have had their credibility called into "serious question" by a federal court, and otherwise lack any expertise in the treatment of gender dysphoria. (*see* Section II.B, *supra)*. Defendants cannot establish any reputable scientific or medical support for the Challenged Exclusion, let alone an "exceedingly persuasive" justification, *VMI*, 518 U.S. at 531, or one "narrowly tailored to a compelling state interest." *Adarand*, 515 U.S. at 235.

The Challenged Exclusion cannot even withstand deferential "rational basis" review. Under rational basis, the classification must be rationally related to a legitimate state interest. *City of Cleburne*, 473 U.S. at 440. States must "avoid all classifications that are arbitrary or irrational and those that reflect a bare … desire to harm a politically unpopular group." *Glenn*, 663 F.3d at 1315 (cleaned up). Here, Defendants have chosen to exclusively single out transgender Medicaid beneficiaries for exclusion of coverage. The Challenged Exclusion targets only transgender beneficiaries and their medical care alone for unequal treatment. *See Kadel*, 2022 WL 3226731, at *20 ("Discrimination against individuals suffering

from gender dysphoria is also discrimination based on sex and transgender status."); *Toomey*, 2019 WL 7172144, at *6 (noting exclusion "singles out transgender individuals for different treatment" because "transgender individuals are the only people who would ever seek gender reassignment surgery").[25]

Defendants' reliance on discredited, biased, and unreliable "experts" in promulgating the Challenged Exclusion demonstrates Defendants' true intent was to

[25] This is not a situation where Defendants are able to rely on *Geduldig v. Aiello*, 417 U.S. 484 (1974). *First*, the Challenged Exclusion explicitly classifies based on sex as it prohibits coverage for "services to treat *gender* dysphoria," ," including "*[s]ex* reassignment surgeries" and any "procedures that alter primary or secondary *sexual* characteristics." *See Fletcher*, 443 F.Supp.3d at 1027, 1030; *see also Whitaker v. Kenosha Unified Sch. Dist. No.1 Bd. of Educ.*, 858 F.3d 1034, 1051 (7th Cir. 2017). Every person to whom the Challenged Exclusion applies is therefore discriminated against because of sex. "[O]ne cannot explain gender dysphoria 'without referencing sex' or a synonym." *Kadel*, 2022 WL 3226731, at *20. *Second*, *Geduldig* only held that an exclusion of pregnancy from a disability benefits program with no showing of "pretext" is not per se "discrimination against the members of one sex." 417 U.S. at 496 n.20. But "[s]ome activities may be such an irrational object of disfavor that, if they are targeted, and if they also happen to be engaged in exclusively or predominantly by a particular class of people, an intent to disfavor that class can readily be presumed." *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993). Here, the Exclusion was designed to categorically exclude gender-affirming care from coverage —care "which is only sought by transgender individuals." *Brandt v. Rutledge*, 2021 WL 3292057, at *2 (E.D. Ark. Aug. 2, 2021). That is precisely what *Geduldig* and *Bray* prohibit: a pretextual classification designed to effectuate discrimination. *Third*, the centrality of gender transition to transgender identity distinguishes this case from *Geduldig*. Unlike the pregnancy exclusion in *Geduldig*, the Exclusion here is based on a characteristic that defines membership in the excluded group. Pregnancy is not the defining characteristic of a woman. Living in accord with one's gender identity rather than birth-assigned sex is the defining characteristic of a transgender person. *See, e.g.*, *Glenn*, 663 F.3d at 1316.

harm transgender people, not further any legitimate state interest. (Antommaria, ¶¶49-52.) As such, the Challenged Exclusion violates the Equal Protection Clause.

2. <u>The Challenged Exclusion Violates the ACA's Section 1557.</u>

Section 1557 of the Affordable Care Act provides that:

> [A]n individual shall not ... be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, ...

42 U.S.C. § 18116(a). An "important component of the ACA's effort to ensure the prompt and effective provision of health care to all individuals . . . is the statute's express anti-discrimination mandate" in Section 1557. *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 485 F.Supp.3d 1, 11 (D.D.C. 2020), *appeal dismissed*, No. 20-5331, 2021 WL 5537747 (D.C. Cir. Nov. 19, 2021). "To state a claim under this provision, a plaintiff is required to show that he or she (1) was a member of a protected class, (2) qualified for the benefit or program at issue, (3) suffered an adverse action, and (4) the adverse action gave rise to an inference of discrimination." *Griffin v. Gen. Elec. Co.*, 752 F. App'x 947, 949 (11th Cir. 2019).

Here, Section 1557 unquestionably applies to AHCA. Indeed, courts have routinely applied Section 1557 to state-administered Medicaid programs. *See, e.g.*, *Fain*, 2022 WL 3051015 at *8; *Flack*, 328 F.Supp.3d at 949; *Cruz v. Zucker*, 195 F.Supp.3d 554, 571 (S.D.N.Y. 2016).

Plaintiffs clearly satisfy the second and third elements of a Section 1557

claim. *See Griffin*, 752 Fed.App'x at 949. Each plaintiff is enrolled in Medicaid and received coverage for medically necessary gender-affirming services. Due to the Challenged Exclusion, however, Plaintiffs suffered an "adverse action."

As to the first element, Section 1557 incorporates Title IX to prohibit discrimination based on sex in healthcare. *See Kadel*, 2022 WL 3226731, at *29. And for the reasons explained above, *see* Section III.A.1, *supra*, Plaintiffs and other transgender Medicaid beneficiaries have been subjected to discrimination in the provision of health services based on sex. *See, e.g.*, *Fain*, 2022 WL 3051015, at *11.[26]

Finally, as to the fourth element, Defendants promulgated the Challenged Exclusion with discriminatory intent to achieve a discriminatory effect. The Challenged Exclusion bans coverage of medically necessary care for the treatment of gender dysphoria, which only transgender persons experience. (Olson-Kennedy, ¶24.) *See also Kadel*, 2022 WL 3226731, at *20. Defendants lack any legitimate justification for the Challenged Exclusion, which was premised solely on prejudice towards transgender persons.

The Challenged Exclusion therefore constitutes impermissible sex

[26] Courts often construe the anti-discrimination provisions in Title IX in the same manner as in Title VII. *See, e.g.*, *Franklin v. Gwinnett Cnty. Pub. Sch.*, 503 U.S. 60 (1992). The Supreme Court discrimination has held that discrimination based on transgender status constitutes sex under Title VII. *Bostock*, 140 S. Ct. at 1743.

discrimination under Section 1557.

B. The Challenged Exclusion Will Cause Immediate Irreparable Harm to Plaintiffs.

The denial of medically necessary care, including coverage thereof, constitutes irreparable harm for which there is no other adequate legal remedy. *See Brandt*, 2022 WL 3652745, at *4 (affirming conclusion that "Plaintiffs will suffer irreparable harm" by being "denied access to hormone treatment"); *Planned Parenthood S. Atl. v. Baker*, 941 F.3d 687, 707 (4th Cir. 2019); *Eknes-Tucker v. Marshall*, 2022 WL 1521889, at *12 (concluding "Plaintiffs will suffer irreparable harm absent injunctive relief" because "without transitioning medications, [] Plaintiffs will suffer severe medical harm, including anxiety, depression, eating disorders, substance abuse, self-harm, and suicidality"); *Flack*, 328 F.Supp.3d at 942-46 (finding likelihood of irreparable harm to transgender Medicaid beneficiaries denied coverage for gender dysphoria treatments); *Edmunds v. Levine*, 417 F.Supp.2d 1323, 1342 (S.D. Fla. 2006) ("The denial of medical benefits, and resultant loss of essential medical services, constitutes an irreparable harm to these individuals."); *Karnoski*, WL 6311305, at *9 ("[M]onetary damages proposed by Defendants will not … cure the medical harms caused by the denial of timely health care.").[27]

[27] *See also Mitson v. Coler*, 670 F.Supp. 1568, 1577 (S.D. Fla.1987); *Newton–Nations v. Rogers*, 316 F.Supp.2d 883, 888 (D. Ariz. 2004); *cf. Washington v.*

Without access to gender-affirming care, transgender Medicaid beneficiaries, like Plaintiffs, will suffer severe harms to their health and wellbeing, including anxiety, depression, and suicidality, on top of the aggravation of their gender dysphoria. (Olson-Kennedy, ¶113 ("The denial of gender-affirming care, on the other hand, is harmful to transgender people. It exacerbates their dysphoria and may cause anxiety, depression, and suicidality, among other harms."); Karasic, ¶58 ("The denial of medically indicated care to transgender people not only results in the prolonging of their gender dysphoria, but causes additional distress and poses other health risks, such as depression, posttraumatic stress disorder, and suicidality."); Schechter, ¶22.) Plaintiffs have noted their distress and fear over these certain consequences. (Dekker, ¶¶25-28; Rothstein, ¶¶15-16, 18-19, 21; Doe, ¶¶25-26; Ladue, ¶¶25, 28.)

In addition, without access to the medically necessary treatments for their gender dysphoria, transgender Medicaid beneficiaries will be forced to undergo physical changes that will cause them great distress and aggravate their gender dysphoria. (*E.g.*, Dekker, ¶26.) For some, like Plaintiffs Susan Doe and K.F., they will be forced to "undergo endogenous puberty—a process that cannot be reversed." *Brandt*, 2022 WL 3652745, at *4. (Doe, ¶¶25-26; Ladue, ¶28.)

DeBeaugrine, 658 F.Supp.2d 1332, 1339 (N.D. Fla. 2009) ("Withholding benefits essential to a disabled person's ability to remain in the community rather than in an institution rather obviously would constitute irreparable harm.").

The Challenged Exclusion also sends to transgender people a discriminatory message: That they are not worthy of protection and their health care needs may be disregarded. This governmental message on its own has and will continue to result in significant distress, hopelessness, anxiety, and stigma for transgender people like Plaintiffs. (*E.g.*, Dekker, ¶27; Rothstein, ¶22; Doe, ¶33; Ladue, ¶35.) Structural forms of stigma like the Challenged Exclusion harm the health of transgender people and are associated with minority stress. (Karasic, ¶58.)

The Challenged Exclusion imposes a combination of psychological and physical hardships. These hardships make it impossible for Plaintiffs to live and be accurately perceived, increasing the risk that Plaintiffs face discrimination, harassment, and violence. A preliminary injunction is the only way to prevent these irreparable harms from continuing.

C. Injuries to Plaintiffs Sharply Outweigh Any Damage to the State.

When the state is a party, the "balance of harms" and "public interest" factors of the preliminary injunction test merge such that the harm caused to the state in the "balance of harms" prong is the same as the public interest. *Swain v. Junior*, 958 F.3d 1081, 1091 (11th Cir. 2020); *Eknes-Tucker*, 2022 WL 1521889, at *13. However, "neither the government nor the public has any legitimate interest in enforcing an unconstitutional" policy. *Otto v. City of Boca Raton*, 981 F.3d 854, 870 (11th Cir. 2020); *see also Austin v. Univ. of Fla. Bd. of Trustees*, 2022 WL 195612,

at *26 (N.D. Fla. Jan. 21, 2022) ("[T]he public and the State have no interest in enforcing a likely unconstitutional policy.").

As a threshold matter, the Challenged Exclusion violates the Equal Protection Clause. *See* Section III.A.1, *supra*. Issuing a preliminary injunction in this case will unquestionably serve the public interest by preserving Plaintiffs' constitutional rights.

By the same token, a preliminary injunction will enforce the Affordable Care Act's sex-discrimination prohibition. *See Schmitt v. Kaiser Found. Health Plan of Wash.*, 965 F.3d 945, 955 (9th Cir. 2020) ("Section 1557 is an affirmative obligation not to discriminate in the provision of health care."). Defendants promulgated the Challenged Exclusion with the intent of discriminating against transgender beneficiaries, in clear violation of Section 1557. *See* Section III.A.2, *supra*. Such discrimination should not be enforceable while this case is pending.

In light of the harm caused to Plaintiffs, as well as the benefits to the public interest, the Court should grant the preliminary injunction. *See Eknes-Tucker*, 2022 WL 1521889, at *13 (finding that the imminent threat of harm caused by restrictions on transgender care, including "severe physical and/or psychological harm," outweighs any harm the State will suffer from the injunction); *Flack*, 328 F.Supp.3d at 954-55 (finding that harm caused by the state Medicaid policy denying coverage for transgender surgeries is outweighed by any harm to the State).

D. An Injunction Will Preserve the Status Quo.

"The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981). "Preservation of the status quo enables the court to render a meaningful decision on the merits." *United States v. Lambert*, 695 F.2d 536, 540 (11th Cir. 1983). Injunctions meant to prohibit enforcement of a new law or policy preserve the status quo. *See Hecox v. Little*, 479 F.Supp.3d 930, 972 (D. Id. 2020); *see also Austin*, 2022 WL 195612, at *26 ("Plaintiffs seek to restore the status quo that existed before Defendants implemented the subject policy. Thus, as the policy causes Plaintiffs irreparable injury, Plaintiffs move for a return to the last uncontested status quo between the parties.") (cleaned up).

For years before the Challenged Exclusion, the Florida Medicaid program covered transgender Medicaid beneficiaries' treatments for gender dysphoria. Plaintiff Susan Doe and K.F. have been receiving coverage for over two years. (Doe, ¶19; Ladue, ¶17.) Plaintiff Brit Rothstein has been receiving coverage for 3 years. (Rothstein, ¶12.) Finally, Plaintiff August Dekker has been receiving coverage for over four years. (Dekker, ¶13.) Only now have Defendants altered coverage for Plaintiffs and other transgender beneficiaries. The only parties altering the status quo are the Defendants. This Motion thus fulfills the purpose of all preliminary injunctions and preserves Plaintiffs' longstanding access to coverage until a decision

on the merits is rendered. *See Brandt v. Rutledge*, 4:21-cv-00450, Dkt. No. 59, at 68 (E.D. Ark. July 26, 2021) (emphasizing that the "status quo for a very long time has been that there's been no ban"), *subsequent written order affirmed by Brandt*, 2022 WL 3652745.

E. Request for Relief from Requirement to Post Bond.

Plaintiffs request an exemption from the requirements of Fed. R. Civ. P. 65(c). "[T]he amount of security required by [Rule 65(c)] is a matter within the discretion of the trial court…[and] the court may elect to require no security at all." *BellSouth Tellecomm., Inc. v. MCIMetro Access Transmission Srvcs., LLC*, 425 F.3d 964, 971 (11th Cir. 2005). Waiving the bond requirement is particularly appropriate in public interest litigation, where plaintiffs are primarily low-income and allege the infringement of a civil and constitutional rights. *See id*; *Washington v. DeBeaugrine*, 658 F. Supp. 2d 1332, 1339 (N.D. Fla. 2009). Courts that have ordered a preliminary injunction of a state Medicaid regulation have consistently ruled that the plaintiffs need not post a bond. *Flack*, 328 F.Supp.3d at 955; *cf. Eknes-Tucker*, 2022 WL 1521889, at *13.

IV. CONCLUSION

For the reasons stated above, Plaintiffs respectfully request that this Court preliminarily enjoin the enforcement of the Challenged Exclusion.

Respectfully submitted this 12th day of September 2022.

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** Application for admission pro hac vice forthcoming.*

CERTIFICATE OF WORD COUNT

According to Microsoft Word, the word-processing system used to prepare this Motion and Memorandum, there are 487 total words contained within the Motion, and there are 7,617 words contained within the Memorandum of Law.

/s/ Jennifer Altman
Jennifer Altman

CERTIFICATE OF SATISFACTION OF ATTORNEY-CONFERENCE REQUIREMENT

Pursuant to Local Rule 7.1(B), counsel for the Plaintiffs conferred with counsel for the Defendants on September 7 and September 9, 2022. Counsel for Defendants indicated that Defendants oppose the relief sought.

CERTIFICATE OF SERVICE

I hereby certify that, on September 12, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system. Counsel for Defendants had indicated that Defendants would accept service of this motion via email. I certify that I served by email the foregoing on the following non-CM/ECF participant:

Simone Marstiller, Secretary
Agency for Health Care Administration
c/o Andrew T. Sheeran
Deputy General Counsel
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/s/ Jennifer Altman
Jennifer Altman

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

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EXHIBIT A

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

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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.

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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

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

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EXHIBIT C

Tampa Bay Times

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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.

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

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

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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.

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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

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care of transgender youth "requires a full, diligent understanding of the scientific 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.

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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.

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

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

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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

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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.

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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

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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

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EXHIBIT D

RON DESANTIS
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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

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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]

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[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:

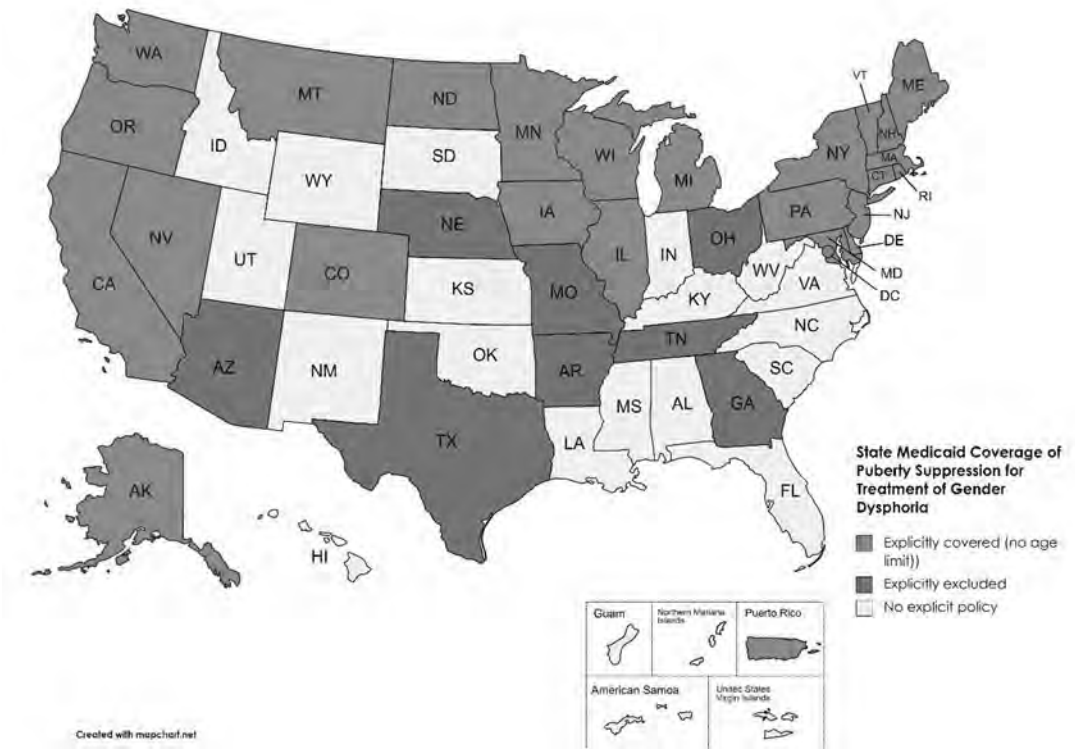
- "Social gender transition should not be a treatment option for children or adolescents."
- "Anyone under 18 should not be prescribed puberty blockers or hormone therapy."
- "Gender reassignment surgery should not be a treatment option for children or adolescents."
- "Children and adolescents should 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).

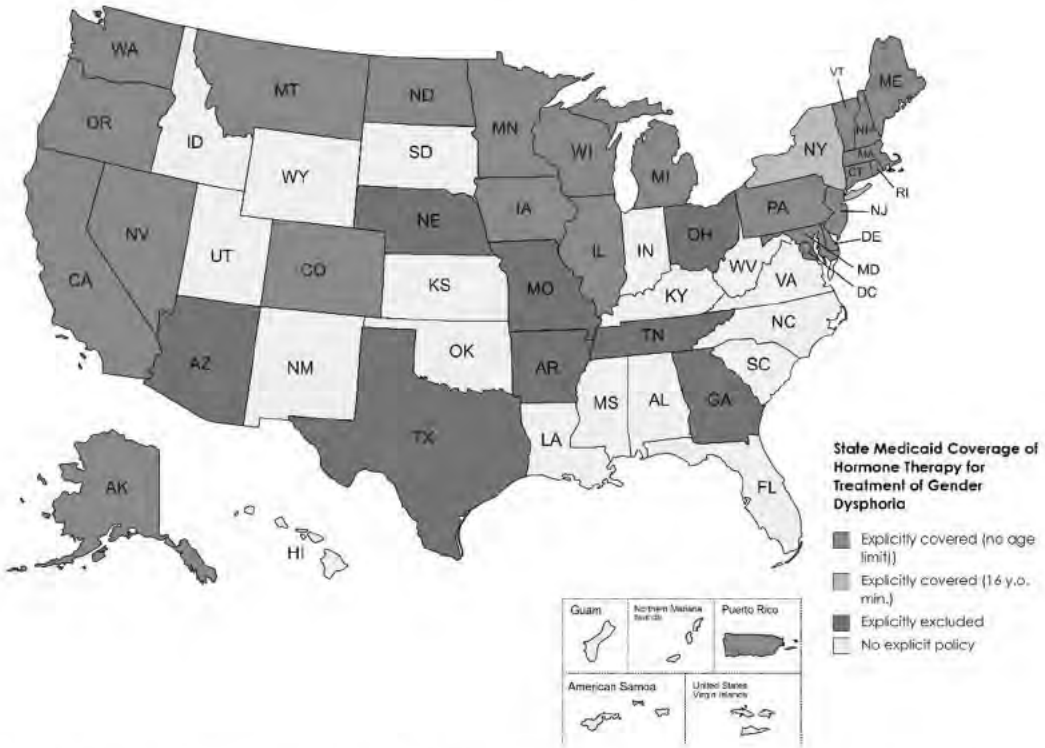
State Medicaid Programs: Because individual states differ in health services offered, Medicaid programs vary in their coverage of sex reassignment treatments. The following maps identify states that cover sex reassignment treatments, states that have no policy, and states that do not cover such treatments.

[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.

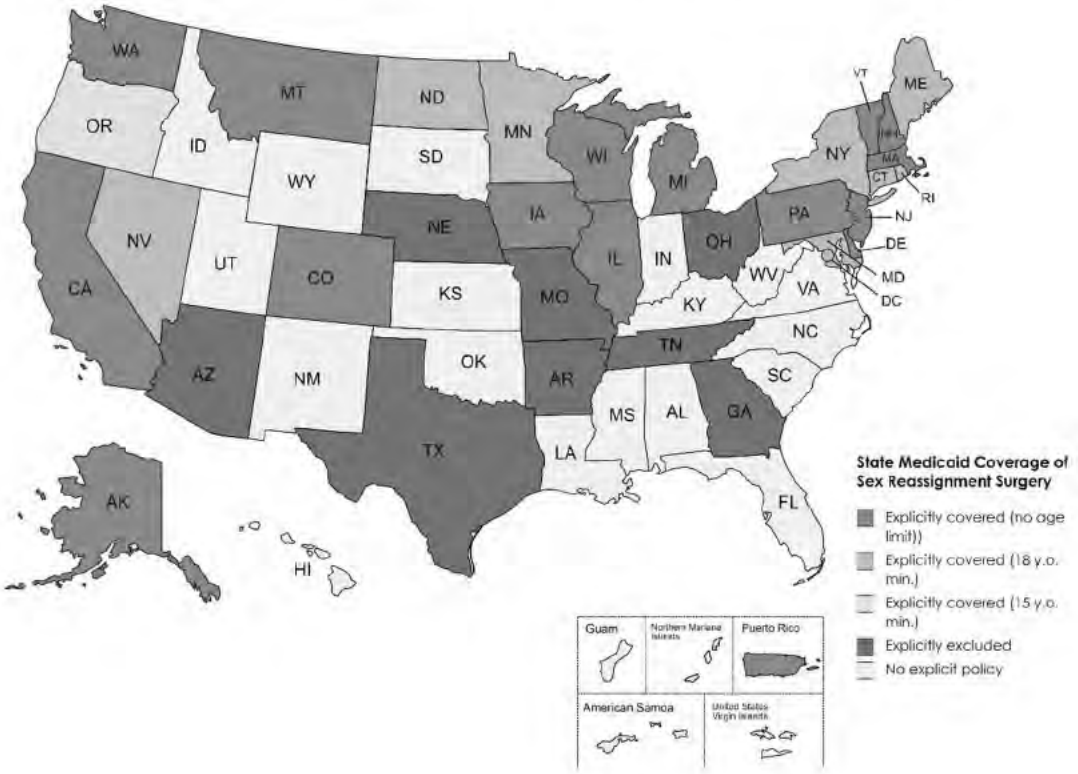
State Medicaid programs with coverage decisions regarding puberty blockers:



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



State Medicaid programs with coverage decisions regarding sex reassignment surgery:



Western Europe

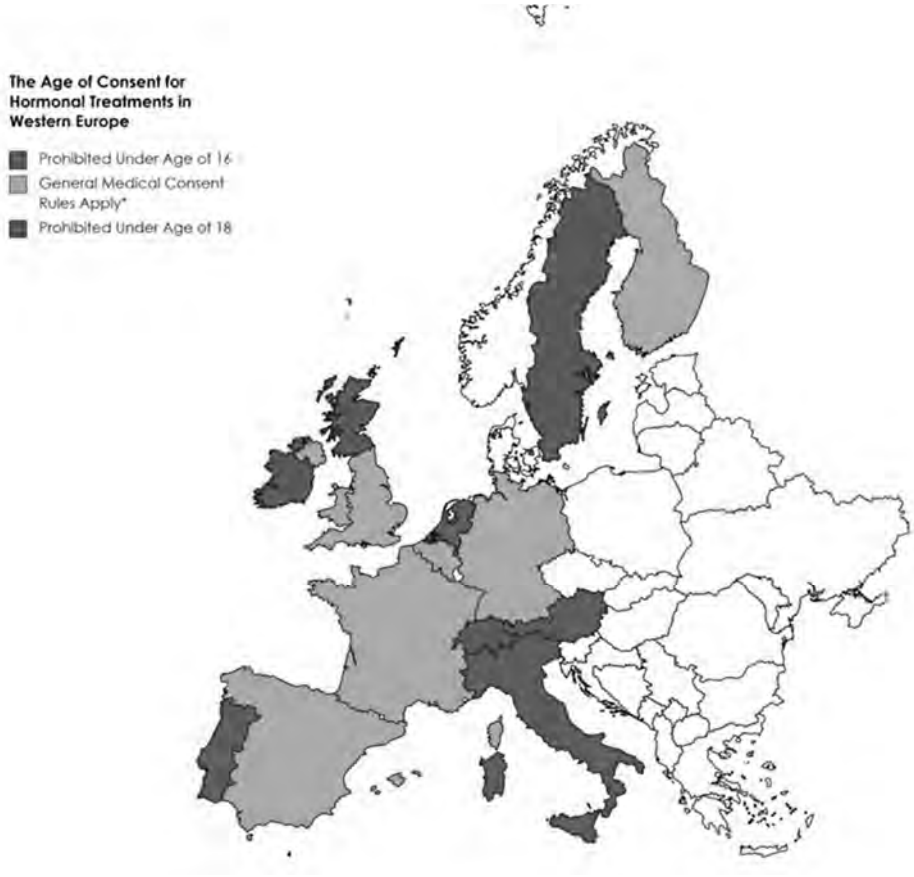
Scandinavian countries such as Sweden and Finland have released new guidelines on sex reassignment treatment for children. In 2022, the Swedish National Board of Health stated that "the risks of hormonal interventions for gender dysphoric youth outweigh the potential benefits." With the exception of 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:

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Deputy Secretary for Medicaid (or designee)

6/2/22
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:

[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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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. _____ *6*

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. _____ 6

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. __ 9

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. _____ *15*

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. _____ 15

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. _____ 16

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. _____ 19

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. __ 21

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. _____ 21

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. _ 23

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. _____ 25

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. _____ 27

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

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[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,

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[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

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[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

[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.

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EXHIBIT H

Child and Adolescent Mental Health

*Child and Adolescent Mental Health*27, 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 dys phoria (GD). Today, the majority are adolescents, many with post puberty adolescent onset transgender histo ries, and suffering from mental health and neurodevel opmental 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 pub lished literature on the topic of GD to be carefully evalu ated.

In this commentary, we critically examine a system atic 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 high light problems with this review that compromise its find ings and conclusions.

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

Rew et al. described undertaking a "critical" and "sys tematic" literature review on the topic of puberty block ers for GD youth. They identified nine studies for review and, on the basis of these, concluded that puberty block ers 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 pub erty 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 rel evant 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 min imize the potential adverse outcomes of puberty block ers. 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 block ers 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 cer tainty using modified GRADE." They noted that any out come 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 sus pended 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 sys tematic 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 evolv ing. For example, a recently published study, that attempted to demonstrate the benefits of the Dutch pub erty suppression protocol in the UK setting, failed to show any psychological benefit (Carmichael et al., 2021).

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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 completed suicides. Turban et al. assessed six areas of suicidality (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 exaggerated 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 benefits and harms on all health outcomes that are important 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 considerations 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 evidence 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 interventions are trumpeted in abstracts, while their profound 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 suicidal 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." Subsequently, a recent Commentary and Editorial in the Lancet 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. Clinicians relying on Rew et al.'s review are likely to misinform patients and families about the risk/benefit profile of puberty blockers. Can such patients really be considered 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 benefits 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 presentations. We must also, collectively, raise the bar on the quality of publications, in order to accurately educate clinicians and help patients make truly informed decisions 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

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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 Medicin*e. 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,

Anne L. Alstott

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

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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).

IN 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

EXPERT DECLARATION OF DR. JOHANNA OLSON-KENNEDY, M.D., M.S.

I, Johanna Olson-Kennedy, M.D., M.S., hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I have been asked by Plaintiffs' counsel to provide my expert opinion on gender identity; the treatment and diagnosis of gender dysphoria; the Florida Medicaid Generally Accepted Professional Medical Standards (GAPMS) Determination on the Treatment of Gender Dysphoria published by Florida's Agency for Health Care Administration (AHCA) in June 2022, along with its attachments; and Fla. Admin. Code. R. 59G-1.050(7) which prohibits Medicaid coverage of puberty blockers, hormone and hormone antagonists, "sex

reassignment" surgeries, and any other procedures that alter primary or secondary sexual characteristics.

3. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

I. BACKGROUND AND QUALIFICATIONS

4. I received my Doctor of Medicine (M.D.) degree from the Chicago Medical School in 1997. In 2000, I completed my residency in pediatrics at the Children's Hospital of Orange County, California, and from 2000 to 2003, I was a Fellow in adolescent medicine at the Children's Hospital of Los Angeles.

5. I have been a licensed physician in California since 2000 and am Double Board Certified by the American Board of Pediatrics in Pediatrics and in Adolescent Medicine. I specialize in the care of transgender youth and gender diverse children, and am currently the Medical Director of the Center for Transyouth Health and Development, in the Division of Adolescent Medicine at the Children's Hospital in Los Angeles, California. The Center is the largest clinic in the United States for transgender youth and provides gender diverse youth with both medical and mental health services, including consultation for families with gender diverse children and routine use of medications to suppress puberty in peri-pubertal youth (i.e., youth at the onset of puberty), gender-affirming hormone use for

masculinization and feminization, as well as surgical referrals. Under my direction, the Center conducts rigorous research aimed at understanding the experience of gender diversity and gender dysphoria from childhood through early adulthood.

6. Over the course of my work with this population during the past 16 years, I have provided services for approximately 1000 young people and their families, and currently have an active panel of around 650 patients of varying ages, up to 25 years old.

7. I have been awarded research grants to examine the impact of early interventions including puberty-delaying medication (commonly known as puberty blockers) and gender-affirming hormones on the physiological and psychosocial development of gender diverse and transgender youth. I have lectured extensively, across the United States and internationally on the treatment and care of gender diverse children and transgender adolescents, the subjects including pubertal suppression, gender-affirming hormone therapy, transitioning teens and the adolescent experience, age considerations in administering hormones, and the needs, risks, and outcomes of hormonal treatments. I have published numerous articles and chapters, both peer reviewed, and non-peer reviewed, on transgender health-related issues.

8. I am currently the principal investigator on a multisite National Institutes of Health grant to continue, for an additional 5 years, an ongoing study examining the impact of gender-affirming medical care for transgender youth on physiologic and psychological health and well-being. The first five years have already been completed. This is the first study of its kind in the US to determine longitudinal outcomes among this population of vulnerable youth. The study to date has yielded approximately 26 manuscripts.

9. I am an Associate Professor at the Keck School of Medicine at the University of Southern California and attending physician at Children's Hospital of Los Angeles. I have been a member of the World Professional Association for Transgender Health (WPATH) since 2010, and a Board Member of the US Professional Association for Transgender Health (USPATH) since 2017. I was recently appointed to the Executive Board of the USPATH. I am also a member of the Society for Adolescent Health and Medicine and the American Academy of Pediatrics. In addition I am a member of the LGBT Special Interest Group of the Society for Adolescent Health and Development.

10. I am the 2014 Recognition Awardee for the Southern California Regional Chapter of the Society for Adolescent Health and Medicine.

11. In 2019, I was invited by the University of Bristol as a Benjamin Meaker visiting professor, the purpose of which is to bring distinguished researchers from overseas to Bristol in order to enhance the research activity of the university.

12. In preparing this report, I have relied on my training and years of research and clinical experience, as set out in my curriculum vitae, and on the materials listed therein. A true and accurate copy of my curriculum vitae is attached hereto as **Exhibit A**. It documents my education, training, research, and years of experience in this field and includes a list of publications.

13. I have also reviewed the materials listed in the attached bibliography (**Exhibit B**). The sources cited therein are authoritative, scientific peer-reviewed publications. I generally rely on these materials when I provide expert testimony, and they include the documents specifically cited as supportive examples in particular sections of this declaration.

14. In addition, I have reviewed the Florida Medicaid Generally Accepted Professional Medical Standards (GAPMS) Determination on the Treatment of Gender Dysphoria published by Florida's Agency for Health Care Administration (AHCA) in June 2022, along with its attachments, including the "assessments" of Dr. Romina Brignardello-Petersen and Dr. Wojtek Wiercioch (Attachment C), Dr. James Cantor (Attachment D), Dr. Quentin Van Meter (Attachment E), Dr. Patrick

Lappert (Attachment F), and Dr. G. Kevin Donovan (Attachment G) (hereinafter, "GAPMS Memo"); and Fla. Admin. Code. R. 59G-1.050(7) which prohibits Medicaid coverage of puberty blockers, hormone and hormone antagonists, "sex reassignment" surgeries, and any other procedures that alter primary or secondary sexual characteristics. I may rely on these documents, as well as those cited in curriculum vitae and the attached bibliography, as additional support for my opinions.

15. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject. I reserve the right to revise and supplement the opinions expressed in this report or the bases for them if any new information becomes available in the future, including as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

Prior Testimony

16. In the last four years, I have testified as an expert at trial or by deposition in the following cases: *Fain v. Crouch*, No. 3:20-cv-00740 (S.D. W.Va.); *Kadel v. Folwell*, Case No. 1:19-cv-00272-LCB-LPA (M.D.N.C.); *In the interest of JA.D.Y. and JU.D.Y., Children*, Case No. DF-15-09887 (255th Jud. District Ct.,

Dallas Cty., Tex.); and *Paul E. v. Courtney F.*, No. FC2010-051045 (Superior Ct., Maricopa Cty., Ariz.).

Compensation

17. I am being compensated for my work on this matter at a rate of $200.00 per hour for preparation of declarations and expert reports, as well as any pre-deposition and/or pre-trial preparation and any deposition testimony or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

II. EXPERT OPINIONS

A. Gender Identity

18. The term gender identity was originally coined in 1964 by American psychiatrist Robert J. Stoller, a noted psychoanalyst who studied sexual orientation, gender identity, and differences in sexual development. Gender identity is a distinct characteristic and is defined as one's internal sense of being male or female (or rarely, both or neither). It has a strong biological basis. Every person has a gender identity.

19. The concept of gender identity is contemporaneously understood both colloquially and within the domain of science and medicine to denote someone's gender. It is a concept well-understood and accepted in medicine and science.

Indeed, gender identity information is commonly collected and reported on within the context of scientific research. (Clayton, et al., 2016).

20. The term cisgender refers to a person whose gender identity matches their sex assigned at birth. The term transgender refers to a person whose gender identity does not match their sex assigned at birth.

21. Historically, "gender" was equated with a person's sex assigned at birth, which refers to the sex assigned to a person when they are born, generally based on external genitalia. However, a more contemporary understanding of gender shows that one's gender identity may differ from one's sex assigned at birth.

22. While both gender identity and sex are often assumed and treated as binary and oppositional, they are more accurately experienced as along a spectrum. For example, there are multiple sex characteristics, such as genitalia, chromosomal makeup, hormones, and variations in brain structure and function. For some of these characteristics there is significant variance as reflected by the dozens of intersex mechanisms and varying gender identities. Additionally, not all sex characteristics, including gender identity, are always in alignment. Accordingly, the Endocrine Society Guidelines state that, "As these may not be in line with each other (e.g., a person with XY chromosomes may have female-appearing genitalia), the terms biological sex and biological male or female are imprecise and should be avoided."

23. As early as 1966 it has been understood that gender identity cannot be changed. Efforts to do so have been shown to be unsuccessful and harmful.

24. "Conversion" or "reparative" therapy refers to the practice of attempting to change an individual's sexual orientation and attractions from members of the same sex to those of the opposite sex. A similar model of therapy for individuals with a transgender identity or experience has historically been an approach promoted by some individuals, notwithstanding its ineffectiveness and harmful effects. Accordingly, 20 states and the District of Columbia have banned reparative therapy for youth, and major medical organizations have issued statements deeming the practice to be unethical.

25. A Williams Institute report published in 2018 estimates that just under 700,000 LGBT individuals in the United States have undergone "conversion therapy" at some point in their lifetime, about half of those during adolescence. Because some psychiatrists and sexologists working in the 1960's and 70's perpetuated the idea that being transgender was likely the result of a pathological early childhood experience, many professionals and lay community members continue to believe that gender is malleable. Tactics have ranged from simple redirection, thought pattern alteration or hypnosis to aversion techniques including induction of vomiting, nausea, paralysis or electric shocks, have been employed in

order to change the expression, behavior, and assertion of one's authentic gender. (Mallory, et al., 2019). However, multiple studies show that gender identity has a strong biological basis and cannot be changed. As such, reparative therapy is both ineffective and harmful for transgender and gender diverse youth.

B. <u>Gender Dysphoria and its Treatment</u>

26. Gender Dysphoria (GD) is a serious medical condition characterized by distress due to a mismatch between assigned birth sex and a person's internal sense of their gender. GD was formerly categorized as Gender Identity Disorder (GID) but the condition was renamed in May 2013, with the release of the American Psychiatric Association (APA)'s fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-V). In announcing this change, the APA explained that in addition to the name change, the criteria for the diagnosis were revised "to better characterize the experiences of affected children, adolescents, and adults." The APA further stressed that "gender nonconformity is not in itself a mental disorder. The critical element of gender dysphoria is the presence of clinically significant distress associated with the condition."

27. On May 25, 2019, the World Health Assembly approved International Classification of Diseases (ICD) version 11 that had been published by the World Health Organization in 2018. In this newest version of the ICD, all trans-related

diagnostic codes were removed from the chapter "Mental and Behavioral Disorders," and the code "Gender incongruence" was included in a new chapter "Conditions related to sexual health." These codes replaced the outdated "Gender Identity Disorder of childhood" (F64.2), "Gender Identity Disorder not otherwise specified" (F64.9), "transsexualism" (F64.0), and "Dual-role transvestism" (F64.1), which perpetuated the idea that patients seeking and undergoing medical interventions for a medical condition are mentally ill. (Suess Schwend, 2020).

28. For a person to be diagnosed with GD, there must be a marked difference between the individual's expressed/experienced gender and the gender others would assign to the individual, present for at least six months. In children, the desire to be of the other gender must be present and verbalized.[1] The condition must cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

29. The World Professional Association of Transgender Health (WPATH) has clear recommendations for the health of transsexual, transgender, and gender non-conforming people in what is now the Standards of Care version 7 (SOC 7). The SOC are based on the best available science and expert professional consensus. They

[1] Notably, the DSM-IV included a separate diagnosis for GID in children, which required the child to display a number of behaviors stereotypical of the non-natal gender. That diagnosis, and its list of behavioral requirements, have been deleted from the DSM-V and replaced by updated and more precise diagnostic criteria.

are currently under revision to create an updated version 8. The WPATH SOC have been endorsed and cited as authoritative by most major medical associations in the United States, including the American Medical Association, the American Psychiatric Association, the American Psychological Association, the Endocrine Society, the Pediatric Endocrine Society, the American College of Physicians, and the American Academy of Family Physicians, among others.

30. The UCSF Center for Excellence in Transgender Care as well as the Endocrine Society have both published comprehensive guidelines for the care of transgender and non-binary individuals that are largely consistent with the WPATH SOC.

31. The GAPMS Memo and some its attached "assessments" discuss a number of approaches to care, though they fail to properly describe them and to discuss their limitations.

32. One of the approaches discussed by Dr. Van Meter is "reparative" or "corrective" therapy. *See* Attachment E to GAPMS Memo, at 6 ("Van Meter"). As discussed above, this so-called "therapy" has proven to be ineffective and harmful, and has been deemed to be unethical.

33. **"Redirection"** – Under this approach, advocated by people like Dr. Van Meter, a mental health therapist would encourage caregivers to use positive

reinforcement to try to "redirect" children toward behavior that is more typical of their birth-designated sex or less gender specific. Underlying this approach is the assumption that a child's gender identity is malleable through social interventions. The goal of redirection is thus to eliminate gender-diverse desires and expressions over time, and to try to prevent the transgender child from being transgender. This approach is not recommended because negative reinforcement (e.g., shaming the child for gender diverse expression) has substantial negative mental and social health consequences. (Turban and Ehrensaft, 2018; Ehrensaft, 2017). It also ignores that gender identity is innate and cannot be changed.

34. **Wait-and-see** – The wait-and-see approach (also called watchful waiting) involves waiting to see if the child's gender identity will change as the child gets older. This approach typically recommends that caregivers prohibit a prepubertal social transition, but may allow cross-gender play and clothing within the home or support both masculine and feminine activities as the child explores their interests in other social settings. The wait-and-see approach assumes that gender is binary and becomes fixed at a certain age; it pathologizes gender diversity and fluidity. It is distinguished from following the child's lead, an affirming approach that allows the child to present in the gender role that feels correct and moves at a pace that is largely directed by the child. This approach ignores evidence

that young children thrive when given permission to live in the gender that is most authentic to them and are at risk for symptomatic behaviors if prevented from doing so. (Ehrensaft, 2017).

35. **Affirmation** - The affirmative approach considers no gender identity outcome: transgender, cisgender, or otherwise, to be preferable. (Turban and Ehrensaft, 2018). It permits a child to explore gender development and self-definition within a safe setting. A fundamental concept of this approach is that gender diversity is not a mental illness. The gender-affirmative model is defined as a method of therapeutic care that includes allowing children to speak for themselves about their self-experienced gender identity and expressions and providing support for them to evolve into their authentic gender selves, no matter at what age. Under this model, a child's self-report is embedded within a collaborative model with the child as subject and the collaborative team including the child, parents, and professionals. Support is not characterized by "encouraging" children or youth to be transgender or not, but rather by allowing children who express a desire to undergo a social transition (which may include changing names, pronouns, clothing, hairstyles, etc.) to do so. **For children who have not yet reached puberty, medical intervention is unnecessary and unwarranted.** After the onset of puberty medical

interventions such as puberty blockers, and later hormones and surgery, may be appropriate.

36. While some argue that gender affirmation leads a child or adolescent down a path of inevitable transgender identity, no such evidence exists, either in the scientific or the clinical setting. To the contrary, studies show that gender identification does not meaningfully differ before and after social transition. (Rae, et al., 2019).

37. Under both the "wait and see" and affirmative care models, as understood in the scientific literature, medical care is recommended following the onset of puberty. (Ehrensaft, 2017).

38. The most effective treatment for adolescents and adults with GD, in terms of both their mental and medical health, contemplates an individualized approach. Medical and surgical treatment interventions are determined by the care team (usually a medical and mental health professional) in collaboration with the patient, and the patient's family, if the patient is a minor. These medical decisions are made by the care team in conjunction with the patient and, if the patient is a minor, the patient's family, and consider the patient's social situation, the level of gender dysphoria, developmental stage, existing medical conditions, and other relevant factors. Sometimes treatment begins with puberty delaying medications

(also referred to as puberty blockers), later followed by gender-affirming hormones. Most youth, and certainly all adults, accessing treatment are already well into or have completed puberty. Gender-affirming genital surgeries are generally sought after hormone treatment and, as described below, whether they are recommended varies based on whether the patient is an adolescent or adult, as well as other factors.

39. *Puberty blockers:* The beginning signs of puberty in transgender youth (the development of breast buds in assigned birth females and increased testicular volume in assigned birth males) is often a painful and sometimes traumatic experience that brings increased body dysphoria and the potential development of a host of comorbidities including depression, anxiety, substance abuse, self-harming behaviors, social isolation, high-risk sexual behaviors, and increased suicidality. Puberty suppression, which involves the administration of gonadotrophin-releasing hormone analogues (GnRHa), essentially pauses puberty, thereby allowing the young person the opportunity to explore gender without having to experience the anxiety and distress associated with developing the undesired secondary sexual characteristics. In addition, for parents/guardians who are uneducated about gender diversity and/or who have only recently become aware of their child's transgender identity, puberty blockers provide additional time and opportunity to integrate this new information into their own experience and to develop skills to support their

child. Puberty suppression also has the benefit of potentially rendering obsolete some gender-affirming surgeries down the line, such as male chest reconstruction, tracheal shave, facial feminization, and vocal cord alteration, which otherwise would be required to correct the initial "incorrect" puberty.

40. Puberty suppression has been used safely for decades in children with other medical conditions, including precocious puberty, and is a reversible intervention. (Mul, et al., 2008). If the medication is discontinued, the young person continues their endogenous puberty. The "Dutch protocol," developed from a study conducted in the Netherlands and published in 2006, calls for the commencement of puberty blockers for appropriately diagnosed and assessed gender dysphoric youth as early as 12 years of age. (de Vries, et al., 2014). Both the Endocrine Society and the WPATH's SOC, however, recommend initiation of puberty suppression at the earliest stages of puberty (usually, Tanner 2) (assuming someone has engaged in services before or around this time), regardless of chronological age, in order to avoid the stress and trauma associated with developing secondary sex characteristics of the natal sex.

41. A growing body of evidence demonstrates the positive impact of pubertal suppression in youth with GD on psychological functioning including a decrease in behavioral and emotional problems, a decrease in depressive symptoms,

and improvement in general functioning. (Turban, et al., 2020; de Vries, et al., 2014, Costa et al 2015).

42. Puberty blockers, thus, afford youth the opportunity to undergo a single, congruent pubertal process and avoid many of the surgical interventions previously necessary for assimilation into an authentic gender role. It is a simple reversible intervention that has the capacity to improve health outcomes and save lives. Over the course of my work in the past sixteen years with gender diverse and transgender youth, I have prescribed hormone suppression for over 250 patients. All of those patients have benefitted from putting their endogenous puberty process on pause, even the small handful who discontinued GnRH analogues and went through their endogenous puberty. Many of these young people were able to matriculate back into school environments, begin appropriate peer relationships, and participate meaningfully in therapy and family functions. Children who had contemplated or attempted suicide or self-harm (including cutting and burning) associated with monthly menstruation or the anxiety about their voice dropping were offered respite from those dark places of despair. GnRH analogues for puberty suppression are, in my opinion, a sentinel event in the history of transgender medicine, and have changed the landscape almost as much as the development of synthetic hormones.

43. *Gender-affirming hormones:* Cross-gender or gender-affirming hormone therapy involves administering steroids of the experienced sex (i.e., their gender identity) (estrogen for transfeminine individuals and testosterone for transmasculine individuals). The purpose of this treatment is to attain the appropriate masculinization or feminization of the transgender person to achieve a gender phenotype that matches as closely as possible to their gender identity. Gender-affirming hormone therapy is a partially reversible treatment in that some of the effects produced by the hormones are reversible (e.g., changes in body fat composition, decrease in facial and body hair) while others are irreversible (e.g., deepening of the voice, breast tissue development). Eligibility and medical necessity should be determined case-by-case, based on an assessment of the youth's unique cognitive and emotional maturation and ability to provide a knowing and informed consent. The decision would be made only after a careful review with the youth and parents/guardians of the potential risks and benefits of hormone therapy. The youth's primary care provider, therapist, or another experienced mental health professional can help document and confirm the patient's history of gender dysphoria, the medical necessity of the intervention, and the youth's readiness to transition medically.

44. *Gender-affirming surgeries:* Some transgender individuals need surgical interventions to help bring their phenotype into alignment with their gender. Surgical interventions may include vaginoplasty, tracheal shave, liposuction, breast implants, and orchiectomy for transfeminine individuals and chest reconstruction, hysterectomy, oophorectomy, salpingectomy, construction of a neoscrotum, and metoidioplasty or phalloplasty for transmasculine individuals.

45. The current WPATH SOC recommend that genital surgery – i.e., surgery which will render the individual sterile – not be carried out until the individual reaches the legal age of majority to give consent for medical procedures, while acknowledging that care is individualized. In addition, the Standards recommend that the other surgical interventions (e.g., chest surgery for transgender males and breast augmentation for transgender females) may occur earlier than the legal age of consent, preferably after ample time living in the desired gender role and after one year of hormone therapy. The SOC, however, further recognize that these are individual determinations and that "different approaches may be more suitable, depending on an adolescent's specific clinical situation and goals for gender identity expression."

46. Gender-affirming medical interventions are considered medically necessary and are recognized as such by many major professional organizations. The denial of this care results in negative health consequences.

47. There are those (see GAPMS Memo at 12-13) who would make the argument that the recent uptick in youth presenting for services related to GD is the result of "social contagion." But if social contagion theory applied to gender and gender identity, there would be zero transgender people, because of the consistent exposure to an overwhelming majority of cisgender people. The social contagion argument that is posited by some confuses the relationship between one's recognition of their gender and their exposure to gender related information and community, particularly with regard to internet activity, asserting that youth are declaring themselves to be transgender or gender diverse because they were exposed to this online, or they have multiple friends who are also experiencing GD. Adolescent development includes finding like groups of peers, which extends to finding friend groups who are also gender diverse. Finally, attributing GD to "social contagion" is a simplistic perspective that discounts that the process of doing something about one's gender dysphoria is complex and difficult and involves parental consent for minors.

48. There is no scientific evidence that one develops gender dysphoria from being exposed to people with GD. To the contrary, most evidence shows that gender identity has a biological basis (Korpaisarn, et al., 2019; Saraswat, et al., 2015) and is affixed by early childhood (Slaby, et al., 1975).

C. Critiques of the GAPMS Memo and the Attached "Assessments"

49. The GAPMS Memo and the attached assessments contain a number of inaccurate assertions or misrepresentations, in addition to those noted above.

Misunderstandings and Misrepresentations of Desistance

50. The GAPMS Memo falsely states 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." (GAPMS Memo at 14). This is a blatant misrepresentation of the scientific literature. The studies pertaining to desistance upon which the GAPMS Memo relies pertain to *pre-pubertal* youth, not adolescents. In fact, contrary to the GAPMS Memo's assertion, studies show that if gender dysphoria is present in adolescence, it usually persists (DeVries, et al., 2011).

51. To be sure, there are a significant number of *pre-pubertal* children who demonstrate an interest or preference for clothing, toys, and games that are stereotypically of interest to members of the "other" gender. Some of these children

are transgender and some are not. It is the study of such *pre-pubertal* children that has created confusion about the persistence of gender dysphoria into adolescence and adulthood. Specifically, the *pre-pubertal* children who were the subject of research endeavors in the late 20th century included both children who are transgender and children who are not, i.e., those that would have met current criteria for a diagnosis of "Gender Dysphoria in Children" and those who would be considered "sub-threshold" for this diagnosis.

52. At the time of these studies, the diagnosis of "Gender Dysphoria in Children" did not exist and therefore the study subjects did not need to meet criteria B, which is "the presence of clinically significant distress associated with the condition." In addition, the criteria for the then-used "gender identity disorder in children" diagnosis did not require a child to have "a strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender)," which the current "Gender Dysphoria in Children" diagnosis requires.

53. Thus, given the broader criteria used at the time, it is unsurprising that some of the research undertaken toward the end of the 20th century demonstrated that most children who exhibited gender-nonconforming behavior did not go on to have a transgender identity in adolescence. Yet, notwithstanding its inapplicability

and faulty underpinnings, this "evidence" has been used to argue against gender affirmation for children and adolescents.

54. What is more, these arguments about desistance in *pre-pubertal* children are wholly irrelevant to the question of coverage and provision of medical care as treatment for GD. That is because research to date shows that if transgender identification persists into adolescence, then desistance is incredibly rare, and no medical or surgical treatments are recommended for *pre-pubertal* children.

55. Additionally, no studies have ever demonstrated that gender affirmation in childhood "leads to" a child being transgender who otherwise might not have been. Studies have demonstrated that the majority of youth whose GD and cross-gender identity continue to be present, or those whose GD emerges in adolescence, are highly unlikely to identify and live as cisgender individuals. Youth with GD, particularly those who are unaffirmed and denied care, are at high risk for depression, anxiety, isolation, self-harm and suicidality at the onset of puberty-related changes that feel wrong to them.

The Myth of Social Contagion and Rapid-Onset Gender Dysphoria (ROGD)

56. The GAPMS memo asserts that gender-affirming care should not be provided because the causes of GD are uncertain. It suggests that "exposure to 'social and peer contagion'" accounts for the rise in numbers of adolescents who

identify as transgender, pointing to research that has identified so-called "rapid-onset gender dysphoria" (ROGD). (GAPMS Memo at 12-13; see also Cantor ¶ 48-49). However, ROGD is not a diagnosis recognized by any medical or scientific institution, and there is no scientific evidence in support of it.

57. The concept of ROGD originated from a single article authored by Lisa Littman (Littman, 2018), a researcher who had no experience in the field of gender medicine, transgender issues, or gender dysphoria, prior to the publication of her article.

58. Littman's article was heavily criticized for its flawed methodology, potential for bias, and overrepresentation of its findings (see, e.g., Brandelli Costa, 2019; Restar, 2019). For example, Littman's study was based solely on "parent observations and interpretations." But parental reports are not necessarily a reliable basis for understanding a particular youth's experience with their gender, let alone whether the youth has gender dysphoria (see, e.g., Kennedy, 2022; Brandelli Costa, 2019). Moreover, most of the parents who participated in the study were recruited from websites targeted to parents likely to question their child's gender self-identification and the current best health care approaches. In addition, the study also failed to collect data from the adolescents and young adults (AYAs) or clinicians,

which would have been necessary in order to come up with and validate ROGD as a new phenomenon.

59. Following the numerous critiques of the Littman study, the journal that published the study retracted it, ordered a post-publication review, and republished the article with a correction notice (Littman, 2019), along with an apology (Heber, 2019).

60. The correction notice acknowledged, among other things, that:

a. "there is some information about the AYAs that the parents would not have access to and the answers might reflect parent perspectives" and that "consideration of what information parents may or may not have access to is an important element of the findings";

b. "the study's output was hypothesis-generating rather than hypothesis-testing";

c. "three of the sites that posted recruitment information expressed cautious or negative views about medical and surgical interventions for gender dysphoric adolescents and young adults and cautious or negative views about categorizing gender dysphoric youth as transgender"; and

d. "There is expected variation in how objective parents can be about their own children" and that the "descriptive study was not designed to explore or measure the objectivity of participants."

61. Thus, the correction notice ultimately acknowledged that the study "does not validate the phenomenon" of ROGD and that the term ROGD "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." In the end, aside from the correction notice, the journal that published the study issued an apology "for oversights that occurred during the original assessment of the study" (Heber, 2019).

62. What is more, since the publication of the Littman article, new studies have been published that dispel the notion of ROGD or that social contagion contributes to the development of gender dysphoria (Bauer, et al., 2022; Turban, et al., 2022). To date, no study has been published that validates or proves the hypothesis of ROGD presented by the Littman study. Indeed, Lisa Littman herself said at the GenSpect 2021 Conference that ROGD was not a new phenomenon, but rather a re-naming of late onset GD.

63. The GAPMS Memo, Dr. Cantor, and Dr. Van Meter incorrectly allege that an increase in numbers of youth presenting for care related to GD provides

support for the social contagion theory. (See GAPMS Memo at 12-13; Van Meter at 9-10). For one, varying estimates of prevalence are the result of inconsistent measures of transgender populations. Some studies have assessed the fraction of a population which had received the DSM-IV diagnosis of GID or the ICD 10 diagnosis of transsexualism, both of which were limited to clinical populations who sought a binary transition (male-to-female or female-to-male). For example, the prevalence reported in DSM-5 (0.005–0.014% for birth-assigned males; 0.002–0.003% for birth-assigned females) are based on people who received a diagnosis of GID or transsexualism and were seeking hormone treatment and surgery from gender specialty clinics, and, therefore, do not reflect the prevalence of all individuals with gender dysphoria or who identify as transgender. Other studies have reported on those who self-identified as transgender or gender incongruent and found that measuring self-identity yields much higher numbers. In 2016, data from the Center for Disease Control's Behavioral Risk Factor Surveillance System suggested that 0.6% of U.S. adults identify as transgender, double the estimate utilizing data from the previous decade. (Byne, et al., 2018). Ultimately, there is nothing surprising about the fact that more transgender people have begun identifying themselves to others as societal stigma has started to abate, and nothing about that lends support to the "social contagion" theory.

Dr. Cantor's False Assertion of Transition-on-Demand

64. In his "assessment," Dr. Cantor, a psychologist with no clinical experience in treating gender dysphoria in minors and no experience monitoring patients receiving drug treatments for gender dysphoria, states that "transition-on-demand" increases the probability of unnecessary transition and unnecessary medical risks. (Cantor ¶ 21).

65. His claim is wholly divorced from the reality of care for transgender people. First, like all health care, gender-affirming care for every transgender person is individualized. There simply is no one specific route.

66. Second, Dr. Cantor inaccurately assumes that every transgender person wants and receives rapid access to services. For most transgender individuals seeking care, nothing about their process has been rapid, even when they are young. Most individuals with gender dysphoria have engaged in a long, arduous and private process of understanding their gender to be different from the one assumed at birth. Dr. Cantor gives no credibility to transgender patients regarding their right to bodily autonomy nor their capacity to make sound and informed decisions.

67. Finally, Dr. Cantor is wrong to assert that affirmation "increases the probability of unnecessary transition and unnecessary medical risks." (Cantor ¶ 21). There is no evidence to support the notion that affirmation of gender in pre-pubertal

children, or at any age, leads to transition. Medical interventions are not recommended and are not appropriate for pre-pubertal children. If one's gender could be impacted by the role of rearing, there would be few transgender people who transition in adulthood, as most were reared in the gender role that corresponded with their sex assigned at birth. It is not logical to think that while we have been epically failing at convincing transgender people to be cisgender that we would be able to make someone who is cisgender into someone who is transgender, a directionality that may correspond with higher rates of discrimination, harassment, and even violence. There is no data to support any such notion that children who are socially transitioned in a pre-pubertal time period who then go on to embrace their assumed gender at birth are damaged. I know several such young people who are healthy and happy.

The Quality of the Evidence and Lack of Randomized Controlled Trials

68. The care of transgender individuals has a long history. As with all medical care, there is a range of quality in the existing data regarding the treatment of gender dysphoria (see UCSF Guidelines), and there is certainly a need for additional studies of a longitudinal nature. But again, that is true with most medical care.

69. Between 1963 and 1979, over 20 university-based gender identity clinics opened in the United States. These clinics provided interdisciplinary care that included psychiatrists and other mental health professionals and played an important role in the provision of medical services to transgender people and in promoting research to improve their care. The majority of these clinics closed following a 1981 decision of the U.S. Department of Health and Human Services (HHS) that labeled sex reassignment surgery as experimental, in large part due to advocacy by Dr. Paul McHugh.[2] That decision was overturned by HHS in 2014 in a determination that concluded that the 1981 decision was "unreasonable and contrary to contemporary science and medical standards of care." (Byne, et al., 2018).

70. Over the last four decades: research has continued to occur in the United States and internationally; WPATH (formerly the Henry Benjamin International Gender Dysphoria Association) published the first iteration of the Standards of Care in 1979, which is now in its 7th version and for which the 8th version is in development; the DSM and ICD stopped classifying transgender identification as a mental disorder; the American Psychological Association and Endocrine Society, as well as other medical organizations, adopted clinical guidelines consistent with the WPATH Standards of Care; and dozens of

[2] In this way, Dr. McHugh actively attempted to suppress the research that he complains is lacking in this field of care.

interdisciplinary gender clinics associated with research institutions and teaching hospitals have been providing gender-affirming care for transgender youth and adults across the United States.

71. Drs. Brignardello-Petersen and Wiercioch repeatedly refer to an apparent lack of data comparing treated vs. untreated individuals with gender dysphoria. Their report continually places emphasis on data that they rated as "low certainty" based on GRADE criteria. These observations about the data do not mean that gender-affirming care is experimental or investigational.

72. One of the intrinsic elements of rating the quality of evidence is the study design. Randomized controlled trials (RCTs) are considered the highest quality in the grading of evidence. Many of the research studies on gender-affirming care get a "low quality" grade due to the lack of RCTs.

73. But it is well-established that utilizing an untreated control group is unethical in this context – gender-affirming medical interventions have been used for decades, resulting in a vast amount of clinical knowledge about their efficacy. That said, we have a large de facto group of untreated individuals with gender dysphoria who experience significant psychiatric symptoms because of widespread barriers to access to care.

74. Clinicians who are competent in the care of transgender individuals practice according to a "first do no harm" ethic which understands that doing nothing is not a neutral option for those with gender dysphoria. Multiple studies have demonstrated the safety of gender-affirming hormones, and a growing body of evidence does the same with regards to the safety of GnRH analogues. (Kuper, et al., 2020; Chew, et al., 2018; Colton-Meier, et al., 2011). The same is true with regards to surgery. (Marano, et al., 2021; Olson-Kennedy, et al., 2018; Murad, et al., 2010; Smith, et al., 2005; Pfafflin & Junge, 1998).

75. In addition, RCTs are ill-suited to studying the effects of gender-affirming interventions on psychological wellbeing and quality of life of trans people. Adequate masking, adherence, and generalizability are severely impeded in trans care, thereby negating the superior scientific value of RCTs.

76. Gender-affirming interventions have physiologically evident effects, making it impossible to mask RCTs. The purpose of puberty blockers, hormone therapy, and transition-related surgeries is to inhibit or produce visible bodily changes.

77. In an RCT, adolescents who are on puberty blockers would notice that their endogenous pubertal development had stopped, whereas those not on puberty blockers will notice that they had not. Hormonal suppression is achieved around four

weeks after treatment is initiated, but it may take multiple months before participants notice that pubertal development has ceased.

78. Similarly, transgender people given hormone therapy would notice bodily changes from taking estrogen or testosterone, whereas trans people in the control arm would notice no such changes. The onset of visible effects from hormone therapy varies from person-to-person. The first changes typically appear between one and six months of initiation, whereas other desired changes may not begin for up to a year.

79. Although it may take some time before participants are able to ascertain which treatment arm they were allocated to due to the delayed effect of puberty blockers and the progressive effect of and hormone therapy, large-scale unmasking is inevitable. Because the physiological changes are the primary purpose of gender-affirming care, meaningful effects on psychological wellbeing and quality of life are not expected until unmasking occurs. As such, while RCTs can be utilized to examine the effects of gender-affirming care on physiology, using RCTs to measure the effect of gender-affirming care on psychological wellbeing and quality of life would be inappropriate.

80. Unmasking an RCT of gender-affirming care would lead to non-compliance, cross-over, and response bias in the control arm of the study.

Transgender people with gender dysphoria who pursue gender-affirming care are typically insistent and persistent in seeking the interventions. They are not ambivalent as to whether they are assigned to the intervention or control arm of the study. Upon realizing that they are in the control arm due to physiological effects or lack thereof, a large proportion of the study participants would likely withdraw from the study or pursue alternative sources of gender-affirming interventions.

81. Withdrawing from the study and noncompliance with the study protocol is most likely among people who have alternative means of securing gender-affirming care and who experience more severe bodily gender dysphoria, raising grave concerns of systematic bias. Gender-affirming interventions can be obtained from parents, peers, illicit or unauthorized sources, other providers within or outside of the health care system, and through medication-sharing with participants from the active arm of the study. Some of these options are associated with elevated safety risks, giving rise to additional ethical concerns about the use of RCTs. Intentional withdrawal with the goal of forcing the study to end is also possible. Resentment towards researchers for not allowing all participants to receive gender-affirming interventions may also increase the risk of response bias compared to observational studies, and the experimental design may motivate youths to engage

in self-harm or suicidal behavior to influence the study results, aggravating scientific and ethical concerns.

82. Given that withdrawal rates could be high enough for studies to be terminated before they are concluded, RCTs may prove impossible to conduct altogether. The likelihood of withdrawal, non-adherence, and response bias in the context of trans care undermines RCTs' ability to detect true associations and avoid specious associations between the intervention and the outcomes.

83. Many disciplines and areas of research rely on observational studies because RCTs are considered impracticable or unethical. This is especially common when studying the mental health outcomes of physiologically evident interventions due to the impossibility of masking, and when studying the outcomes of highly desired interventions due to the risks of de-randomization. Psychological and psychosocial interventions are most commonly studied using observational methodologies, and many research questions remain unstudied with RCTs.

84. Thus, while the GAPMS Memo correctly notes that "[p]resently, no RCTs that evaluate puberty suppression as a method to treat gender dysphoria are available," the lack of RCTs is easily understood considering the above observations about RCTs in this context. (See GAPMS Memo at 15). And, the GAPMS Memo fails to mention is that "[d]espite GnRH analogue treatment being used in precocious

puberty for more than 20 years, there are no randomized controlled trials to evaluate the effect of GnRHa on a final height compared with untreated controls." (Mul, et al., 2008).

85. In addition, the GAPMS Memo's focus on RCTs reveals AHCA's fundamental misunderstanding of "evidence-based medicine." (GAPMS Memo at 9).

86. Evidence-based medicine, which originated in the second half of the 19th Century, means the conscientious, explicit, judicious, and reasonable use of current best evidence in making decisions about the care of individual patients. Since its inception, evidence-based medicine has included an element of clinician expertise. Indeed, the modern understanding of evidence-based medicine is a systematic approach to clinical problem solving which allows the integration of the best available research evidence with *clinical expertise and patient values*. (Masic, et al., 2018).

87. Contemporaneous evidence-based medicine is defined by the *integration of clinical knowledge and skills* with the best critically-appraised-evidence available *as well as patient values and preferences in order to make a clinical decision*. The research literature is continually growing as new discoveries unravel.

88. The GAPMS Memo assigns no value to clinician expertise, experience, and skill, nor to the desires of the individual seeking services. In fact, the GAPMS Memo repeatedly and broadly asserts that recommendations for treatment of GD by well-established professional associations do not rely on evidence-based medicine, but rather on the recommendations outlined by WPATH, the Endocrine Society or others. But these two organizations not only examine best available evidence, but the guidelines and standards of care are updated by clinicians and scientists at the top of the field.

The Use of "Off-Label" Medications

89. Both the GAPMS Memo and Dr. Van Meter repeatedly express concern that the U.S. Food and Drug Administration (FDA) has not approved puberty blockers or hormone therapy for the treatment of gender dysphoria. (See, e.g., GAPMS Memo at 8, 19; Van Meter at 8). Indeed, Dr. Van Meter asserts that the mere use of these medications "off-label" amounts to "uncontrolled, non-consentable experimentation on children." (Van Meter at 8). These concerns are misleading and false.

90. The use of "off-label" medications is extremely common across all fields in medicine and there are many medications that are used "off-label" in the pediatric population. Most of the therapies prescribed to children are on an off-label

or unlicensed basis. (Allen, et al., 2018). Common medications that are used "off-label" in pediatrics include antibiotics, antihistamines, and antidepressants. That is because the majority of drugs prescribed have not been tested in children and safety and efficacy of children's medicines are frequently supported by low quality evidence. This is explained by the lack of clinical research in this population, caused by ethical, scientific, and technical issues, as well as commercial priorities.

91. "From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient." (FDA, 2018). Indeed, for over 40 years, the FDA has informed the medical community that "once a [drug] product has been approved …, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling." (FDA, 1994). Accordingly, the American Academy of Pediatrics has stated that "off-label use of medications is neither experimentation nor research." (Fratarelli, et al., 2014). Thus, "[t]he administration of an approved drug for a use that is not approved by the FDA is not considered research and does not warrant special consent or review if it is deemed to be in the individual patient's best interests."

Concerns about the Diagnosis of Gender Dysphoria and the Use of Self-Reports

92. The GAPMS Memo and Dr. Cantor criticize that the diagnosis of gender dysphoria is based, at least in part, on a patient's self-report. (GAPMS Memo at 19, 24, 28; Cantor ¶¶ 42, 49). This critique demonstrates a fundamental misunderstanding of how gender-affirming care is provided.

93. While we have continued to attain a greater understanding about the etiology of gender incongruence, patients do not self-diagnose, as Dr. Cantor suggests. (Cantor ¶¶ 42, 49). However, it is not unusual or extraordinary in medicine for a provider to consider patients' reports of their symptoms as part of the medical assessment. Much like the diagnosis of many clinical conditions, providers rely on self-report to ascertain accurate diagnoses. Consider the diagnosis of chronic fatigue. The diagnostic criteria for this diagnosis include the following: fatigue so severe that it interferes with the ability to engage in pre-illness activities; of new or definite onset (not lifelong); not substantially alleviated by rest; worsened by physical, mental or emotional exertion. Like gender dysphoria, these diagnostic criteria are a subjective telling of an individual's personal experience. It is incumbent upon providers of gender-affirming care to acquire skills that help them ascertain many details about their patient's gender experience including but not limited to the history, developmental trajectory, and expectations regarding treatment options.

94. The provision of gender-affirming care occurs in multi-disciplinary settings, and indeed, the WPATH SOC recommend such an approach. (Chen, et al., 2016; Coleman, et al., 2012). The multiple health providers involved, from various fields, are well trained to conduct clinical interviews and to assess a patient's report to determine whether they meet the diagnostic criteria for GD.

Particular Concerns about the Use of Puberty Delaying Medications

95. The GAPMS Memo and Dr. Cantor allege that the provision of puberty delaying medications for the treatment of gender dysphoria are not effective. This is not true.

96. A substantial body of evidence shows that gender-affirming medical interventions improve mental health outcomes for transgender persons with gender dysphoria, who, without treatment, experience higher levels of depression, anxiety, and suicidality. While each of these studies—as with all studies in medicine—has strengths and limitations, and no one study design can answer all questions regarding an intervention. Taken together, these studies indicate that gender-affirming medical care improves mental health for adolescents who require such care.

97. Keeping this in mind, peer-reviewed cross-sectional and longitudinal studies have found that pubertal suppression is associated with a range of improved mental health outcomes for transgender adolescents, including statistically

significant improvements in internalizing psychopathology (*e.g.*, anxiety and depression), externalizing psychopathology (*e.g.*, disruptive behaviors), global functioning, and suicidality. (e.g., Tordoff, et al., 2022; Turban, et al., 2020; van der Miesen, et al., 2020; Achille, et al., 2020; de Vries, et al., 2014; de Vries, et al., 2011).

98. For example, in the realm of cross-sectional studies, Turban et al. *Pediatrics* 2020 found that, after controlling for a range of other variables, those who accessed pubertal suppression had lower odds of lifetime suicidal ideation than those who desired but were unable to access this intervention during adolescence. A similar study by van der Miesen et al. in the *Journal of Adolescent Health* compared 272 adolescents who had not yet received pubertal suppression with 178 adolescents who had been treated with pubertal suppression. Those who had received pubertal suppression had statistically significant lower "internalizing psychopathology" scores (a measure of anxiety and depression). Longitudinal studies have yielded similar results; for example, de Vries et al. in the *Journal of Sexual Medicine* found statistically significant improvements in symptoms of depression and general functioning following pubertal suppression for adolescents with gender dysphoria.

99. The GAPMS Memo, as well as the "assessments" by Dr. Brignardello-Petersen and Dr. Wiercioch and by Dr. Cantor, emphasize the possible risks and side

effects associated with the provision of gender-affirming care. Every single medication, however, has potential negative side effects, in addition to the possibility of new side effects that have not been historically documented. This is one of the reasons that evidence-based medicine relies heavily on experienced clinicians to exercise their expertise and judgement.

100. The risks associated with the provision of GnRH analogues are comparable when used for transgender and non-transgender patients alike. For example, many of the side effects and risks associated with the provision of GnRH analogues have been well-studied with regards to the use of these medications for the treatment of central precocious puberty (CPP) (Eugster, 2019).

101. Given than puberty blockers are reversible, permanent sterility is not a side effect. There is no data to support that patients who have been treated with blockers for central precocious puberty are "sterilized" following its use. To the contrary, information regarding long-term outcomes of patients treated with GnRH analogues with respect to gonadal function are reassuring. In fact, some studies have shown that assigned males had normal sperm function following treatment and cisgender women treated as children did not need assisted reproductive techniques.

102. In addition, while during the course of treatment with pubertal delaying medication, there is some loss in bone density, which is a side effect that we discuss

with all patients and their families, studies show that with removal of the blocking agent or addition of gender affirming hormone therapy, bone mineral density begins to improve (Vlot, et al., 2017; Klink, et al., 2015). Studies regarding the use of GnRH analogues for the treatment of CPP document that following cessation of therapy with puberty delaying medications bone mineral accrual appears to be within the normal range compared with population norms (Eugster, 2019). Indeed, patients treated with pubertal suppression for CPP are on pubertal blockades without affirming hormones for longer periods of time than patients treated with puberty blockers for the treatment of gender dysphoria and the same risks are present.

Particular Concerns about the Use of Cross-Sex Hormones

103. The claim that treating gender dysphoria with medically supervised and recommended hormone treatment is particularly risky or causes serious mental health effects is not supported by data.

104. Peer-reviewed research studies have found improved mental health outcomes following gender-affirming hormone treatment (*e.g.*, estrogen or testosterone) for individuals with gender dysphoria, including adolescents (see, e.g., Achille, et al., 2020; de Lara, et al., 2020; Grannis, et al., 2021; de Lara, et al., 2020; Allen, et al., 2019). These include statistically significant improvements in internalizing psychopathology (*e.g.*, anxiety and depression), general well-being,

and suicidality. For example, Allen et al. followed a cohort of 47 adolescents with gender dysphoria, and found statistically significant improvements in general well-being and suicidality, as measured by the National Institutes of Health "Ask Suicide Screening Questions" instrument.

105. The use of hormones for the treatment of gender dysphoria, like all medical treatment, can cause side effects, but all mental health and mood-related effects are better managed in the population of gender dysphoric patients who are under ongoing supervision and treatment by mental health providers. By contrast, other diagnoses do not require the ongoing support of mental health providers while on these treatments. In fact, this treatment monitoring in persons with gender dysphoria would actually be considered a safer protocol than those used for individuals receiving hormone therapy to treat other diagnoses.

106. What is more, the side effects and risks associated with these treatments are not unique to transgender individuals placed on these therapies.

107. Fertility preservation is offered to all transgender patients prior to the initiation of gender affirming hormones. However, data shows that treatment with testosterone is not sterilizing (Yaish, 2021). And many transgender men become pregnant on their own.

108. It is also important to note that when these risks are reported, they are rare risks. They are also the risks associated with these hormones whether they are endogenous or exogenous. While starting a transgender individual with gender dysphoria on these medications can raise their risk, their risk profile remains similar to their cisgender counterparts. Many times, the lipid profiles, hematologic profiles, and findings are equivalent to that of the gender these individuals identify with, as opposed to that of their sex they were born.

109. Overall, as a physician that treats many conditions, treatment for gender dysphoria is in no way the riskiest or potentially harmful. Insulin, if used inappropriately, can cause death. Some endocrine patients may require pituitary surgeries or adrenal tumor removals. The postoperative management of these individuals is crucial to their care and avoidance of severe complications that could result in mortality.

The Misconceived Notion that Psychotherapy Alone Is Sufficient for the Treatment of Gender Dysphoria

110. Dr. Cantor describes several studies and claims that because the study subjects who were recipients of both gender-affirming hormones or puberty blockers, on the one hand, and psychotherapy, on the other hand, demonstrated improvements in mental health, that the medical interventions could not be differentiated as responsible for the improvement. (Cantor ¶¶ 40-41).

111. Historically the psychotherapy professional world advocated for a "therapy only" model to address gender dysphoria. As early as the 1920's and 1930's it became evident to the preeminent scholars in the field that gender dysphoria (named something else at that time) was refractory to psychotherapy. As noted in 1966 in Harry Benjamin's The Transsexual Phenomenon, "Allegedly, transsexualism, although basically a psychiatric condition, is paradoxically resistant to psychiatric help." In this statement, Harry Benjamin acknowledges that psychiatric intervention cannot alter people's gender, nor does it lead to a diminishing of the distress that arises from gender incongruence. There has been an abundance of opportunity to demonstrate unequivocally that gender dysphoria is best treated with psychotherapy alone, and yet it never has been. To suggest this is now an appropriate approach simply because transgender people are coming out at younger ages is illogical.

III. CONCLUSION

112. Gender-affirming medical and surgical care is effective, beneficial, and necessary for transgender people suffering with gender dysphoria, including transgender youth after the onset of puberty. It is well documented and studied, through years of clinical experience, observational scientific studies, and even some

longitudinal studies. It is also the accepted standard of care by all major medical organizations in the United States.

113. The denial of gender-affirming care, on the other hand, is harmful to transgender people. It exacerbates their dysphoria and may cause anxiety, depression, and suicidality, among other harms.

114. The GAPMS memo is misguided and informed by individuals with no experience or knowledge base regarding the provision of gender-affirming care, not to mention well-documented biases against transgender people and/or the provision of gender-affirming care. The report leans heavily on manuscripts that are not contemporaneous with our modern understanding of gender identity and gender dysphoria, demonstrated by outdated and incorrect terminology.

115. While data may be described as weak due to the lack of randomized controlled trials, many disciplines and areas of research rely on observational studies because RCTs are considered impracticable or unethical. This is especially common when studying the mental health outcomes of physiologically evident interventions due to the impossibility of masking, and when studying the outcomes of highly desired interventions due to the risks of de-randomization. Psychological and psychosocial interventions are most commonly studied using observational methodologies, and many research questions remain unstudied with RCTs.

116. Finally, the reports completely overlook bodily autonomy. Given the repeated conflation of children and adolescents, it is not surprising that the "assessments" relied upon by the GAPMS Memo and the GAPMS Memo itself view adolescents as too immature to understand their own gender. However, many studies have demonstrated that cisgender children as young as age 2 know their gender. Denying medical care to adolescent youth with gender dysphoria is an act of acquiescence to the fear of what is not understood.

117. I do not disagree that, as with every field of medicine, there is more to learn in the field of transgender youth care. That is why I became an investigator. However, there is room to provide gender-affirming medical interventions in a thoughtful manner that extrapolates from relevant fields of science and medicine, existing data and clinical expertise while simultaneously carrying out necessary investigations.

118. The denial of much needed care only serves to harm transgender people.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and corrected.

Executed this 11th day of September 2022.

Johanna Olson-Kennedy, M.D., M.S.

EXHIBIT A

Curriculum Vitae

CURRICULUM VITAE
JOHANNA OLSON-KENNEDY MS, MD
AUGUST 30, 2022

PERSONAL INFORMATION:

Work
5000 Sunset Blvd. 4th Floor Los Angeles, CA 90027
Phone: 323-361-3128
Fax: 323-953-8116
Work Email: jolson@chla.usc.edu

EDUCATION AND PROFESSIONAL APPOINTMENTS

EDUCATION:

Year	*Degree, Field, Institution, City*
1992	BA, Mammalian Physiology, UC San Diego, San Diego
1993	MS, Animal Physiology, The Chicago Medical School, Chicago
1997	MD, Medical Doctor, The Chicago Medical Shool, Chicago
2015	MS, Clinical and Biomedical Investigations in Translational Science, USC, Los Angeles

POST-GRADUATE TRAINING:

Year-Year	*Training Type, Field, Mentor, Department, Institution, City*
1997 - 1998	Internship, Pediatrics, Children's Hospital Orange County, Orange
1998 - 2000	Residency, Pediatrics, Antonio Arrieta, Children's Hosptial Orange County, Orange
2000 - 2003	Fellowship, Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles
2012 - 2015	Master's Degree, Clinical and Biomedical Investigations in Translational Science, USC

ACADEMIC APPOINTMENTS:

Year-Year	*Appointment*	*Department, Institution, City, Country*
2006 - 2016	Assistant Professor of Clinical Pediatrics	Division of Adolescent Medicine, Children's Hospital Los Angeles/USC Keck School of Medicine, Los Angeles, USA
2016 - Present	Associate Professor of Clinical Pediatrics	Division of Adolescent Medicine, Children's Hospital Los Angeles/USC Keck School of Medicine, Los Angeles, USA

CLINICAL/ADMINISTRATIVE APPOINTMENTS:

2008 - 2012	Fellowship Director	Division of Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles, USA
2012 - present	Medical Director	The Center for Transyouth Health and Development, Division of Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles, USA

2021 - present	Clinical consultant	Santa Barbara Neighborhood Clinics

LICENSURE, CERTIFICATIONS

LICENSURE:

Year	*License number, State, Status*
2000	A-67352, California, Active

BOARD CERTIFICATION OR ELIGIBILITY:

Year	*Board, State, Status*
2001, 2009, 2015	Pediatrics, California, active

SPECIALTY CERTIFICATION:

Year	*Specialty Certification, Status*
2003, 2013	Adolescent Medicine, California, active

HONORS, AWARDS:

Year	*Description*	*Awarding agency, address, city*
2009	Health Care Advocacy Champion	Democratic Advocates for Disability Issues, Los Angeles
2010	Clinical Research Academic Career Development Award	Saban Research Center TSRI Program: Community Health Outcomes and Intervention, Los Angeles
2012	Extraordinary Service Award	Equality California, 202 W 1st St., Suite 3-0130, Los Angeles
2013	Top Doctor	Castle Connolly
2014	Anne Marie Staas Ally Award	Stonewall Democratic Club; 1049 Havenhurst Drive #325, West Hollywood
2014	Top Doctor	Castle Connolly
2014	Recognition Award for Outstanding, Compassionate and Innovative Service	SoCal Society for Adolescent Health and Medicine Regional Chapter, Los Angeles
2015	The Champion Award	The Division of Adolescent Medicine; CHAMPION FUND 5000 Sunset Blvd. Los Angeles
2016	America's Most Honored Professional's – Top 10%	America's Most Honored Professional's
2016	Regional Top Doctor	Castle Connolly
2017	Exceptional Women in Medicine	Castle Connolly
2017	Regional Top Doctor	Castle Connolly
2017	America's Most Honored Professional's – Top 5%	America's Most Honored Professional's
2018	Regional Top Doctor	Castle Connolly
2019	Benjamin Meaker Visiting Professorship	University of Bristol, Bristol UK
2019	Regional Top Doctor	Castle Connolly
2019	L.A's Top Docs	Los Angeles Magazine
2019	Top Docs	Pasadena Health
2019	America's Most Honored Professional's – Top 1%	America's Most Honored Professional's
2020	Regional Top Doctor	Castle Connolly
2020	Southern California Top Doc	Castle Connolly

2020	Southern California Top Doctors	
2020	L.A's Top Docs	Los Angeles Magazine
2020	America's Most Honored Professional's – Top 1%	America's Most Honored
2021	Southern California Top Doc	Castle Connolly
2021	America's Most Honored Doctors – Top 1%	America's Most Honored
2021	Top Doctors	Castle Connolly
2022	America's Most Honored Doctors – Top 1%	America's Most Honored
2022	Top Doctors	Castle Connolly

TEACHING

DIDACTIC TEACHING:

Keck School of Medicine at USC

Year-Year	*Course Name*	*Units/Hrs*	*Role*
2019	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth	One hour	Curriculum development and delivery
2020, 2021, 2022	Approach to the Care of Gender Non-conforming Children and Transgender Youth	One hour	Curriculum development and delivery

CalState Fullerton

Year-Year	*Course Name*	*Units/Hrs*	*Role*
2017	Gender Nonconforming and Transgender Youth	One hour	Curriculum development and delivery

UNDERGRADUATE, GRADUATE AND MEDICAL STUDENT (OR OTHER) MENTORSHIP:

Year-Year	*Trainee Name*	*Trainee Type*	*Dissertation/Thesis/Project Title*
2015 - 2016	David Lyons	MD	Transgender Youth Clinical Clerkship
2016 - 2019	Jonathan Warus	MD	Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts
2019 - 2021	Laer Streeter	MD	Comparison of Histrelin Implants
2020 - Present	Richard Mateo Mora	MD	Fertility Preservation Among Transgender Women
2022	Avery Everhart	PhD	Incomplete Data & Insufficient Methods: Transgender Population Health Research in the US

GRADUATE STUDENT THESIS, EXAM AND DISSERTATION COMMITTEES:

Year-Year	*Trainee Name*	*Committee Type*	*Student Department*
2022	Avery Everhart	Dissertation	Social Work

POSTGRADUATE MENTORSHIP:

Year-Year	*Trainee Name*	*If past trainee, current position and location*
2012-2013	Lisa Simons, MD	Clinical Instructor – Lurie Children's Hospital
2013	Shelley Aggarwal, MD	Clinical Instructor – Stanford University School of Medicine
2014	Julie Spencer, MD	Adolescent Medicine Provider Kaiser Hospital
2014-2015	Michael Haymer, MD	Program Director, Psychiatry Department UCLA
2015-2017	Patrick Shepherd, MD	CHLA Endocrinology Fellow
2015-2018	Jonathan Warus, MD	Faculty, CHLA/USC Keck School of Medicine
2015-2020	Shannon Dunlap, PhD	Postdoctoral Scholar - Research Associate, University of Southern California, Suzanne Dworak-Peck School of Social Work
2020-Present	Marianela Gomez-Rincon, MD	Adolescent Medicine Fellow
2020-Present	Jonathan Warus, MD	CHLA, Assistant Professor of Clinical Pediatrics
2022	Emmett Henderson, PhD, MS	USC Suzanne Dworak-Peck School of Social Work Senior mentor K99; USC

MENTORSHIP OF FACULTY:

Year-Year	*Mentee Name*	*Mentee Department*
2021 - present	Jonathan Warus, MD	Division of Adolescent Medicine, CHLA
2022	Brigid Conn, PhD	Clinical Psychologist, CHLA

SERVICE

DEPARTMENT SERVICE:

Year-Year	*Position, Committee*	*Organization/Institution*
2010-2015	Secretary, The CHAMPION Fund Executive Board	The Division of Adolescent Medicine, Children's Hospital Los Angeles

HOSPITAL OR MEDICAL GROUP SERVICE:

Year-Year	*Position, Committee*	*Organization/Institution*
2021 - present	Committee Member	SOGI work group, CHLA

PROFESSIONAL SERVICE:

Year-Year	*Position, Committee*	*Organization/Institution*
2012-present	Member, LGBT Special Interest Group	Society for Adolescent Health and Medicine
2022	Secretary, Executive Board of Directors	US Professional Association of Transgender Health

CONSULTANTSHIPS AND ADVISORY BOARDS:

Year	*Position, Board*	*Organization/Hospital/School, Institution*
2010-2017	Member, Advisory Board	Transyouth Family Allies
2017-present	Member, National Medical Committee	Planned Parenthood
2017 - Present	Board Member	US Professional Association of Transgender Health
2021	Expert Panelist	Robert Wood Johnson Foundation - National Commission on Data Transformation for Health Equity
2021	Member, Advisory Board	The National LGBTQIA+ Health Education Center

PROFESSIONAL SOCIETY MEMBERSHIPS:

Year- Year	*Society*
2003 - present	Society for Adolescent Health and Medicine
2005 - present	American Academy of Pediatrics
2006 - 2011	Los Angeles Pediatric Society (Past president 2010)
2010 - present	Professional Association for Transgender Health
2014 - present	Society for Pediatric Research
2017 - present	US Professional Association for Transgender Health

MAJOR LEADERSHIP POSITIONS: (E.G., DEAN, CHAIR, INSTITUTE DIRECTOR, HOSPITAL ADMINISTRATION, ETC.)

<u>RESEARCH AND SCHOLARSHIP</u>

EDITORSHIPS AND EDITORIAL BOARDS:

Year-Year	*Position*	*Journal/Board Name*
2015 - present	Associate Editor	Journal of Transgender Health

MANUSCRIPT REVIEW:

Year-Year	*Journal*
2014 - present	Pediatrics
2014 - present	Journal of Adolescent Health
2014 - present	LGBT Health
2014 - present	International Journal of Transgenderism
2015 - present	Journal of Transgender Health
2018 - present	Clinical Child Psychology and Psychiatry
2018 - present	Journal of Sexual Medicine
2018 - present	Journal of Transgender Health
2021 - present	JAMA Peds

GRANT REVIEWS:

Year	*Description*	*Awarding agency, City, State, Country*
2017	Cognition and Perception Study Section	National Institutes of Health, Bethesda, Maryland, USA
2017	Neurological, Aging and Musculoskeletal Epidemiology Study Section	National Institutes of Health, Bethesda, Maryland, USA
2018	Social Psychology, Personality and Interpersonal Processes Study Section	National Institutes of Health, Bethesda, Maryland, USA
2018	Neurological, Aging and Musculoskeletal Epidemiology Study Section	National Institutes of Health, Bethesda, Maryland, USA
2019	Special Emphasis Panel Review of Research Conference (R13) Grants	National Institutes of Health, Bethesda, Maryland, USA
2019	The Einstein Foundation Award for Promoting Quality in Research	Einstein Foundation, Berlin
2020	Biobehavioral and Behavioral Sciences Study Section	National Institutes of Health, Bethesda, Maryland, USA
2021	Social Psychology, Personality and Interpersonal Processes Study Section	National Institutes of Health, Bethesda, Maryland, USA

MAJOR AREAS OF RESEARCH INTEREST

Research Areas
1. Transgender and non-binary children, adolescents and young adults
2. HIV medication adherence

GRANT SUPPORT - CURRENT:

Grant No. (PI)2R01HD082554-06A1 (Olson-Kennedy)	*Dates of Award: 2021-2026*
Agency: NICHD	*Percent Effort 25%*
Title: The Impact of Early Medical Treatment in Transgender Youth	
Description: This is the continuations of a multicenter study, the first of its kind in the U.S. to evaluate the long-term outcomes of medical treatment for transgender youth. This study will provide essential, evidence-based information on the physiological and psychosocial impact, as well as safety, of hormone blockers and cross-sex hormones use in this population.	
Role: Principle Investigator	
*Total Direct Costs: $*4,918,586	

Grant No. 1R01HD097122-01 (Hidalgo)	*Dates of Award: 2019-2024*
Agency: NICHD	*Percent Effort 2.5%*
Title: A Longitudinal Study of Gender Nonconformity in Prepubescent Children	
Description: The purpose of this study is to establish a national cohort of prepubertal transgender/gender nonconforming (TGNC) children (and their parents), and longitudinally observe this cohort to expand the body of empirical knowledge pertaining to gender development and cognition in TGNC children, their mental health symptomology and functioning over time, and how family-initiated social gender transition may predict or alleviate mental health symptoms and/or diagnoses.	
Role: Site PI	
Total Direct Costs: $2,884,950	

GRANT SUPPORT - PAST:

Grant No. (PI) 1RO1HD082554-01A1	*Dates of Award: 2015-2020*
Agency: NICHD	*Percent Effort 45%*
Title: The Impact of Early Medical Treatment in Transgender Youth	
Description: This is a multicenter study, the first of its kind in the U.S. to evaluate the long-term outcomes of medical treatment for transgender youth. This study will provide essential, evidence-based information on the physiological and psychosocial impact, as well as safety, of hormone blockers and cross-sex hormones use in this population.	
Role: Principle Investigator	
*Total Direct Costs: $*4,631,970	
Grant No. (COI) R01AI128796-01	Dates of Award: 2/24/17-1/31/18
Agency: NIAID	Percent Effort: 5%
Title: Maturation, Infectibility and Trauma Contributes to HIV Susceptibility in Adolescents	
Description: This proposal explores the overarching hypothesis that fluctuations in sex steroid levels and mucosal trauma (sexual activity) are key determinants of mucosal immune activation and epithelial integrity, and that microbial communities are central to these processes. We will pursue this hypothesis by examining longitudinal changes in the anogenital microbiome as well as protein expression at these mucosal sites during sexual maturation (cisgender youth) and in hormonally-controlled sexual maturation (transgender youth). Associations between sex steroid levels, microbial community composition, mucosal trauma, and vaginal proteins will be determined and modeled.	
Role: Co-Investigator	
Total Direct Costs: $44,816	

Grant No. (PI) U01HD040463	*Dates of Award* 2006 – 2016
Agency: NIH/NICHD	*Percent Effort: 10%*
Title: Adolescent Medicine Trials Network for HIV/AIDS	
Description: Adolescent Medicine Trials Network for HIV/AIDS	
Role: Co-Investigator	
Total Direct Costs: 2,225,674	

Grant No. (PI) SC CTSI 8KL2TR000131	*Dates of Award: 2012-2014*
Agency: KL2 Mentored Career Research Development Program of the Center for Education, Training and Career Development	*Percent Effort: 37.5%*
Title: The Impact of Hormone Blockers on the Physiologic and Psychosocial Development of Gender Non-Conforming Peri-Pubertal Youth	
Description: This study aimed to understand the impact of puberty blocking medications on mental health and physiolgic parameters in peri-pubertal transgender youth.	
Role: Principal Investigator	
Total Direct Costs: 191,525	

Invited Lectures, Symposia, keynote addresses

Date	***Type***	***Title, Location***
2014	Invited Lecture	Transgender Youth; Needs, Risks, Outcomes and the Role of the System, Including Permanency and Inclusion for Our Youth, Administrative Office of the Courts, Center for Families and Children, San Diego, California
2015	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Lopez Family Foundation Special Lecture for Puerto Rico and Panama, Lopez Family Foundation, Children's Hospital Los Angeles, Los Angeles, California
2015	Symposium	Transgender Youth – An Overview of Medical and Mental Health Needs of Gender Non-Conforming Children and Transgender Adolescents, Public Child Welfare Training Academy, Academy for Professional Excellence at San Diego State University School of Social Work, San Diego, California
2015	Invited Lecture	Meeting the Needs of Transgender Adolescents; 1st Annual Southern California LGBT Health Symposium; USC/UCLA, Los Angeles, California
2015	Symposium	Transgender Youth; An Overview of Medical and Mental Health Needs of Gender Non-conforming Children and Transgender Adolescents; GetReal California's Initiative; "Integrating Sexual Orientation, Gender Identity, and Expression (SOGIE) into California's Child Welfare System," Oakland, California
2016	Invited Symposium	Caring for Gender Nonconforming and Transgender Youth; Idyllwild, California
2016	Educational symposium	Gender 101: A Primer; Vista Mar, California
2016	Invited Lecture	Caring for Gender Non-conforming Children and Teens in the New Millennium - A Multidisciplinary Team Approach, California Association of Marriage and Family Therapists, Los Angeles, California
2016	Invited Lecture	Caring for Gender Nonconforming Children and Transgender Youth, California Psychological Association, Continuing Education Institute, Irvine, California
2016	Invited Lecture	Health Issues Related to Transgender Youth; LA City Health Commission, Los Angeles, California
2016	Invited Lecture	Caring for Gender Nonconforming and Transgender Youth, Medical Directors 12th Annual Update on Reproductive Health and Medical Leadership, Planned Parenthood, Steamboat Springs, Colorado
2016	Invited Lecture	Caring For Transgender Teens, UCLA Meet the Professor, Los Angeles, CA
2017	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Santa Barbara, CA
2017	Invited Lecture	Healthcare for TGNC Youth, Expanding Competency for LGBT Youth in the System, Washington DC
2017	Invited Lecture	Gender Non-conforming and Transgender Children and Youth; Center for Early Education, West Hollywood, CA
2017	Invited Lecture	Rethinking Gender, University of Massachusetts, Annual Convocation Welcome Luncheon, Worcester, MA

2017	Invited Lecture	Gender Non-Conforming Children and Transgender Youth, Board of Behavioral Sciences, Orange, CA
2017	Invited Lecture	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth, Santa Monica Rape Treatment Center, Santa Monica, CA
2017	Invited Lecture	Transgender Youth Care in the New Millennium, USC Law and Global Health Initiative, Los Angeles, CA
2018	Invited Lecture	Supporting Gender Diverse and Transgender Youth: A Deeper Look at Gender Dysphoria, Studio City, CA
2018	Invited Lecture	Working with Trans and Gender Non-Conforming Youth, Children's Hospital Orange County, CA
2018	Invited Lecture	Caring for gender Non-conforming and Transgender Youth and Young Adults, Ascend Residential, Encino CA
2018	Invited Lecture	Caring for gender Non-conforming and Transgender Youth and Young Adults, California State University Northridge, Northridge, CA
2018	Invited Lecture	Gender Dysphoria; School Nurse Organization of Idaho Annual Conference, Idaho
2018	Invited Lecture	Gender and What You Should Know, Archer School for Girls, Brentwood, CA
2018	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Oceanside, CA
2018	Invited Lecture	Gender Dysphoria: Beyond the Diagnosis, Advance LA, Los Angeles, CA
2018	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Andrology Society of America Clinical Symposium, Portland, OR
2018	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Los Angeles, CA
2018	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Center for Early Education, Los Angeles, CA
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Cal State Los Angeles, California
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Claremont Colleges, California
2019	Symposium	TransYouth Care; Flagstaff, AZ
2019	Invited Lecture	Transgender and Gender Non-conforming Youth, Ascend Residential Treatment, Utah
2019	Invited Lecture	Gender Diverse and Transgender Youth; What Pediatricians Should Know, Common Problems in Pediatrics Conference, Utah AAP, Utah
2019	Invited Lecture	Gender Diverse and Transgender Youth; What Pediatricians Should Know, Common Problems in Pediatrics Conference, Utah AAP, Utah
2019	Invited Lecture	Caring for Gender Diverse and Transgender Youth, Grand Rounds, UCLA Olive View, CA
2019	Invited Lecture	Caring for Gender Diverse and Transgender Youth, Grand Rounds, Good Samaritan, CA
2019	Invited Lecture	Puberty Suppression in Youth with Gender Dysphoria, Fenway Trans Health Program, Boston
2019	Invited Lecture	Recognizing the Needs of Transgender Youth, California Department of Corrections and Rehabilitation, Ventura, CA
2019	Invited Lecture	Gender Dysphoria; Beyond the Diagnosis, Gender Education Demystification Symposium, GA

2019	Invited Lecture	Caring for Gender Nonconforming and Transgender Youth, Los Angeles Superior Court/Los Angeles Bar Association Training, CA
2019	Invited Lecture	Supporting Gender Diverse and Transgender Youth; A Deeper Look at Gender Dysphoria, Oakwood School, CA
2020	Symposium	Trans Youth Care, Chico Transgender Week, Virtual Presentation
2020	Invited Lecture	Gender Nonconforming and Transgender Youth, Novartis, Virtual Presentation
2020	Invited Lecture	Advanced Hormones; More than Just T and E, CHLA, Virtual Presentation
2020	Invited Lecture	Video Telehealth and Transgender Youth, Telehealth Best Practices for the Trans Community, The Central Texas Transgender Health Coalition, Virtual Presentation
2020	Invited Lecture	Gear Talk, Transforming Families, Virtual Lecture
2020	Invited Lecture	Tips for Parenting a Trans or Gender Diverse Youth, Models of Pride, Virtual Presentation
2020	Invited Lecture	Caring for Gender Diverse and Transgender Youth, LGBTQ+ Clinical Academy, Palo Alto University, Virtual presentation
2020	Invited Lecture	USC Medical School, Los Angeles, CA
2020	Invited Lecture	Medical Interventions for transgender youth, Cal State Los Angeles, Los Angeles
2020	Plenary Session	Understanding Issues Involving Gender Non-Conforming and Transgender Individuals Coming to a Courtroom Near You, Mid-Winter Workshop for Judges of the Ninth Circuit, Palm Springs, CA
2021	Invited Lecture	Gender Affirmation through a Social Justice Lens; Center for Gender Equity in Medicine and Science (GEMS) at Keck School of Medicine, Los Angeles
2021	Invited Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Providence Medical Group – South Bay Pediatrics (Torrance, San Pedro, Redondo Beach), virtual lecture
2021	Invited Lecture	Caring for Gender Diverse and Transgender Youth. SLO Acceptance, Cal Poly, Virtual Presentation
2022	Invited Lecture	Transgender and Non-binary children and youth, Board of Behavioral Sciences
2022	Invited Lecture	Gender Affirmation through a Social Justice Lens; University of Arizona Health Sciences LGBTQ+ Symposium & Health Fair
2022	Invited Lecture	Gender Dysphoria in Children, Adolescents and Young Adults, MedLambda and PsychSIG Keck USC School of Medicine, Virtual Lecture
2022	Invited Lecture	Caring for Transgender and Gender Nonconforming Youth, Presbyterian Healthcare Services, New Mexico, Virtual lecture
2022	Invited Lecture	Transgender and Non-Binary Youth, Rogers Behavioral Health, Virtual Lecture

Invited Grand Rounds, CME Lectures

Date	***Type***	***Title, Location***
2014	Grand Rounds	Caring for Gender Non-conforming Children and Teens in the New Millennium - A Multidisciplinary Team Approach; Seattle Children's Hospital, Seattle, Washington

2014	CME lecture	Transgender Youth; An Overview of Medical and Mental Health Needs of Gender Non-conforming Children and Transgender Adolescents; Eisenhower Medical Center Transgender Health Symposium, Palm Springs, California
2014	Grand Rounds	Toddlers to Teens: Comprehensive Health Care for the Transgender Child, Cultural Psychiatry Lecture Series, University of Iowa Carver College of Medicine, Iowa City, Iowa
2014	Grand Rounds	Caring for Gender Non-conforming Children and Teens in the New Millennium; A Multidisciplinary Team Approach, Children's Hospital Los Angeles, Los Angeles, California
2014	CME lecture	Difficult Cases, Gender Spectrum Family Conference, Gender Spectrum, Moraga, California
2014	CME lecture	Difficult Cases, Gender Spectrum Family Conference, Gender Spectrum, Moraga, California
2014	CME lecture	Cross-sex Hormones for Teenagers, How Young is Too Young? Philadelphia Trans Health Conference, Philadelphia, Pennsylvania
2014	CME lecture	Pediatric Update, Philadelphia Trans Health Conference, Philadelphia, Pennsylvania
2015	Grand Rounds	Caring for Gender Nonconforming and Transgender Youth, Stanford Division of Adolescent Medicine, Palo Alto, CA
2015	CME Educational Lecture	The Transgender Experience, St. Joseph's Providence, Burbank, CA
2015	CME Educational Lecture	Update on the Transgender Patient for the PCP, St. Joseph's Providence, Burbank, CA
2015	CME Educational Lecture	Caring for Gender Non-Conforming Children and Transgender Teens, Providence Tarzana, CA
2015	Grand Rounds	Caring for Gender Nonconforming and Transgender Youth, University of Southern California, Los Angeles, California
2015	Grand Rounds	Puberty Blockers and Cross Sex Hormones, Pediatric Endocrinology, Children's Hospital Los Angeles, Los Angeles, California
2015	CME lecture	Youth and Hormones, 2015 Gender Expansion Conference, University of Montana, Missoula Montana
2015	CME lecture	Transyouth Healthcare, 2015 Gender Expansion Conference, University of Montana, Missoula Montana
2015	CME lecture	Supporting Transgender Youth, Southern Oregon University Student Health and Wellness Center Workshop, Southern Oregon University, Ashland, Oregon
2015	PCS Grand Rounds	Caring for Gender Nonconforming Children and Transgender Youth, Children's Hospital Los Angeles, Los Angeles, California
2015	CME lecture	Medical Care for Gender Non-Conforming Children, Transgender Adolescents and Young Adults in the New Millennium, Continuing Medical Education of Southern Oregon, Medford, Oregon
2015	Grand Rounds	Medical Care for Gender Non-Conforming Children and Transgender Youth, Olive View Medical Center-UCLA, Sylmar, California
2015	Grand Rounds	Caring for Gender Non-conforming Children and Transgender Teens, Harbor-UCLA Department of Pediatrics, Torrance, California

2015	CME lecture	Caring for Gender Non-conforming Children and Teens in the New Millennium, Healthcare Partners Pediatric Town Hall Meeting, Healthcare Partners CME, Glendale, California
2016	Pediatric Grand Rounds	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth; Children's Hospital Los Angeles, Los Angeles, California
2016	Endocrine Grand Rounds	Approach to Care of Gender Non-Conforming Children and Transgender Adolescents; Cedars Sinai Hospital, Los Angeles, California
2016	Pediatric Grand Rounds	Care of Gender Non-Conforming Children and Transgender Adolescents in the New Millennium, Stanford Lucille Packard Children's Hospital, Palo Alto, California
2016	Pediatric Update	Caring for Gender Variant Children and Adolescents, St. Louis, Missouri
2016	Grand Rounds	Care of Gender Non-Conforming Children and Transgender Adolescents in the New Millennium, St. Jude's Grand Rounds, Memphis, Tennessee
2016	CME Educational Lecture	Transgender and Gender Non-Conforming Youth: Innovative Approaches to Care in 2016; Integrating Substance Use, Mental Health, and Primary Care Services: Courageous and Compassionate Care, Los Angeles, California
2016	CME; professional conference	Caring for Gender Non-conforming Children and Teens in the New Millennium - A Multidisciplinary Team Approach, Arizona Psychiatric Society, Tempe, Arizona
2016	CME/Educational Symposium	Caring for Gender Nonconforming and Transgender Youth, San Diego, California
2016	CME/CEU Educational Training	Medical Interventions for Transgender Youth and Young Adults, San Diego State University, San Diego, California
2016	Grand Rounds	Caring for Gender Nonconforming Children and Transgender Youth, Mt. Sinai Hospital, Pediatric Grand Rounds George J. Ginandes Lecture, New York, New York
2016	CME Educational Lecture	The Transgender Experience, Providence Tarzana, CA
2017	CME Educational Seminar	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, San Diego, CA
2017	CME Educational Seminar	The Care of Gender Non-Conforming children and Transgender Youth; Orange County Health Care Agency, Orange County, CA
2017	CME Educational Lecture	Rethinking Gender, Adolescent Grand Rounds, Children's Hospital Los Angeles, Los Angeles, CA
2017	CME Educational Lecture	Gender Non-Conforming Children and Transgender Youth, Pasadena CA
2017	CME Educational Lecture	Gender Non-Conforming and Transgender Children and Adolescents, Developmental Pediatrics continuing education lecture, Children's Hospital Los Angeles, CA

2017	CME Educational Lecture	Care of Gender Non-Conforming Children and Transgender Adolescents, Lopez Family Foundation Educational Lecture, Los Angeles, CA
2017	CME Educational Lecture	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth, USC Keck School of Medicine Reproductive Health, Los Angeles, CA
2017	CME Educational Seminar	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, San Diego, CA
2018	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Glendale Unified School District, CA
2018	CME Educational Lecture	Caring for Gender Non-Conforming Children and Transgender Youth, CME by the Sea, CA
2018	CME Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Austin, TX
2018	CME Educational Lecture	Approach to the Care of Gender Non-Conforming Children and Transgender Youth, Desert Oasis Healthcare, Palm Desert, CA
2018	CME Workshop	Mental and Medical Healthcare for Transgender Adolescents, California Association of Marriage and Family Therapists, Garden Grove, CA
2018	CME Educational Lecture	Approach to the Care of Gender Non-Conforming Children and Transgender Youth, Keck School of Medicine, Los Angeles, CA
2018	Grand Rounds	Caring for Gender Non-Conforming Children and Transgender Adolescents, Primary Children's Hospital, Salt Lake City, UT
2018	CME Educational Lecture	Caring for Transgender Youth, Chico Trans Week, Chico, CA
2018	CME Educational Lecture	Rethinking Gender, UCSD Medical School, San Diego, CA
2018	CME Educational Lecture	Rethinking Gender, UCLA Medical School, Los Angeles, CA
2019	Symposium	Recognizing the Needs of Transgender Youth, California Department of Corrections and Rehabilitation, Stockton, CA
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Cal State Los Angeles, California
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Claremont Colleges, California
2019	CME Lecture	Gender Diverse and Transgender Youth, Harbor UCLA Medical Center Grand Rounds, Torrance, CA
2019	CME Lecture	Gender Dysphoria – Beyond the Diagnosis, Gender Odyssey San Diego, San Diego, CA
2019	Grand Rounds	Transgender Youth; What's New in 2019?, Children's Hospital Los Angeles, CA

2019	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Children's Hospital Orange County, CA
2019	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Stanislaus County Behavioral Health and Recovery Services, CA
2019	CME Eduational Lecture	Rethinking Gender, Olive View Medical Center Grand Rounds, CA
2020	CME Lecture	Gender Affirmation Through a Social Justice Lens, SAHM Conference, Virtual Presentation
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, AAP Conference, Virtual Lecture
2020	CME Lecture	Conversations with LGBTQ youth; the role of the pediatrician, AAP Conference, Virtual Lecture
2020	Grand Rounds	Creating Affirming Environments for Trans and Gender Diverse Patients, USC OB/Gyn Grand Rounds, Virtual Presentation
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Resident Lecture, CHLA
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Facey Medical Group, Los Angeles, CA
2020	Plenary Lecture	Reframing Gender Dysphoria, LEAH Conference, Los Angeles, CA
2020	CME Lecture	Gender Affirming Care for Pre and Peri-pubertal Trans and Gender Diverse Youth, LEAH Conference, Los Angeles, CA
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Division of Endocrinology, USC, Los Angeles, CA
2021	CME Lecture	Transitioning: From Invalidation and Trauma to Gender Affirming Care; Department of Anesthesiology at CHLA
2021	CME Lecture	Transitioning from Invalidation and Trauma to Gender Affirming Care; ACCM Grand Rounds, Children's Hospital Los Angeles, Virtual presentation
2021	CME Symposium	TransYouth Care; Transfamily Support San Diego, Virtual Symposium
2021	Symposium	TransYouth Care for Parents; Santa Clara, CA
2022	CME Lecture	Gender affirming medical interventions; An Evolving landscape, Critical Issues in Child and Adolescent Mental Health Conference, San Diego, California
2022	CME Symposium	TransYouth Care for Mental Health Providers; Santa Clara, CA
2022	CME Symposium	TransYouth Care; Transfamily Support San Diego, Virtual Symposium

International Lectures

Date	***Type***	***Title, Location***

2013	Keynote	Caring for Gender Non-conforming Children and Adolescents in the New Millennium, Vancouver, Canada
2016	CME; professional conference	Social Transitions in Pre-pubertal Children; What do we know? World Professional Association of Transgender Health, Amsterdam, The Netherlands
2016	CME; professional conference	Beyond Male and Female; Approach to Youth with Non-Binary Gender Identities, World Professional Association of Transgender Health, Amsterdam, The Netherlands
2016	CME; professional conference	Workgroup on Gender Nonconforming/Transgender Youth: Biopsychosocial Outcomes and Development of Gender Identity, World Professional Association of Transgedner Health, Amsterdam, The Netherlands
2017	Invited Lecture	Gender Dysphoria, Beyond the Diagnosis, Pink Competency, Oslo Norway
2017	Invited Lecture	Caring for Gender Non-Conforming Children and Transgender Adolescents: A United States Perspective, Pink Competency, Oslo Norway
2017	Invited Lecture	Caring for Gender Non-conforming and Transgender youth and Young Adults, Diverse Families Forum: The Importance of Family Support in The Trans And LGBT Children, Organized by COPRED and The International Association Of Families For Diversity (FDS), Mexico City, Mexico
2018	Invited Lecture	Chest Reconstruction and Chest Dysphoria in Transmasculine Adolescents and Young Adults: Comparison of Nonsurgical and Postsurgical Cohorts, Buenos Aires, Argentina
2018	Invited Lecture	Transgender Youth and Gender Affirming Hormones; A 6-8 year follow-up, Buenos Aires, Argentina
2018	Invited Lecture	Transyouth Care – An NIH Multisite Study About the Impact of Early Medical Treatment in Transgender Youth in the US, Buenos Aires, Argentina
2018	Invited Lecture	Uso de Hormonas Reaffirmantes de Genero en Adolescentes Transgenero, Trans Amor Congreso Nacional de Transexualidad Juvenil y Infantos, Monterey, Mexico
2018	Invited Lecture	Bloquedores de la Pubertad, Trans Amor Congreso Nacional de Transexualidad Juvenil y Infantos, Monterey, Mexico
2018	CME Educational Lecture	Puberty Blockers and Gender Affirming Hormones for Transgender Youth: What Do We Know, and What Have We Learned, Pediatric Academic Societies, Toronto, Canada
2018	Keynote	Transgender Youth Care, SickKids, Toronto, Canada
2019	Invited Lecture	Hormonas que Affirman el Genero pasa Juventud y Adultos Menores Trans, Transformando Desde el Amor y Las Familias, Colombia
2019	Invited Lecture	Infancia Trans y da Genero Diverso, Transformando Desde el Amor y Las Familias, Colombia
2019	Invited Lecture	Transgender Youth: Medical and Mental Health Needs, Bristol, United Kingdom
2019	Invited Lecture	Rethinking Gender, University of Bristol, United Kingdom

2019	CME; professional conference	Male Chest Reconstruction and Chest Dysphoria in Transmasculine Adolescents and Young Adults, European Professional Association of Transgender Health, Rome Italy
2019	CME; professional conference	Transgender Youth and Gender Affirming Hormones; 5-7 Year Follow Up, European Professional Association of Transgender Health, Rome Italy
2019	CME Educational Lecture	Gender Dysphoria; Beyond the Diagnosis, European Professional Association of Transgender Health, Rome Italy
2021	CME; professional conference	Advances and Challenges in the Care of Transgender/Gender Diverse Youth; USPATH Conference, Virtual presentation
2022	Plenary Session	The Landscape of Gender Affirming Care for Youth in the US, AusPATH, Virtual

Keynote/Plenary Presentations

Date	***Type***	***Title, Location***
2015	Keynote	The Future of Trans Care in the New Millennium, Gender Infinity Conference, Houston, Texas
2016	Plenary Session	Caring for Trans Youth and Gender Non-Conforming Children, Transgender Spectrum Conference, St. Louis, Missouri
2018	Keynote	Future Directions, USPATH, Washington DC
2019	Keynote	Gender Dysphoria; A Deeper Dive Beyond the Diagnosis, Inaugural LGBTQ summit, Santa Clara CA
2022	Keynote	Gender Affirmation Through a Social Justice Lens, Indiana University School of Medicine

PUBLICATIONS:

*** INDICATES TRAINEES**
**** INDICATE YOURSELF AS CO-FIRST OR CO-CORRESPONDING OR SENIOR AUTHORS**

REFEREED JOURNAL ARTICLES:

1. Belzer M, Sanchez K, **Olson J**, Jacobs AM, Tucker D. Advance supply of emergency contraception: a randomized trial in adolescent mothers. J Pediatr Adolesc Gynecol. 2005 Oct;18(5):347-54. PubMed PMID: 16202939.

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3. **Olson J**,** Forbes C, Belzer M. Management of the transgender adolescent. Arch Pediatr Adolesc Med. 2011 Feb;165(2):171-6. doi: 10.1001/archpediatrics.2010.275. Review. PubMed PMID: 21300658.

4. Simons L*, Schrager SM, Clark LF, Belzer M, **Olson J**.** Parental support and mental health among transgender adolescents. J Adolesc Health. 2013 Dec;53(6):791-3. DOI: 10.1016/j.jadohealth.2013.07.019. Epub 2013 Sep 4. PubMed PMID: 24012067; PubMed Central PMCID: PMC3838484.

5. Belzer ME, Naar-King S, **Olson J**, Sarr M, Thornton S, Kahana SY, Gaur AH, Clark LF; Adolescent Medicine Trials Network for HIV/AIDS Interventions. The use of cell phone support for non-adherent HIV-infected youth and young adults: an initial randomized and controlled intervention trial. AIDS Behav. 2014 Apr;18(4):686-96. doi: 10.1007/s10461-013-0661-3. PubMed PMID: 24271347; PubMed Central PMCID: PMC3962719.

6. **Olson J****, Garofalo R. The peripubertal gender-dysphoric child: puberty suppression and treatment paradigms. Pediatr Ann. 2014 Jun;43(6):e132-7. doi: 10.3928/00904481-20140522-08. PMID: 24972421.

7. **Olson J****, Schrager SM, Clark LF, Dunlap SL, Belzer M. Subcutaneous Testosterone: An Effective Delivery Mechanism for Masculinizing Young Transgender Men. LGBT Health. 2014 Sep;1(3):165-7. doi: 10.1089/lgbt.2014.0018. Epub 2014 Jun 26. PMID: 26789709.

8. Schrager SM, **Olson J,** Beharry M*, Belzer M, Goldsich K*, Desai M, Clark LF. Young men and the morning after: a missed opportunity for emergency contraception provision? J Fam Plann Reprod Health Care. 2015 Jan;41(1):33-7. doi: 10.1136/jfprhc-2013-100617. Epub 2014 Jan 24. PubMed PMID: 24465024.

9. Belzer M, Kolmodin MacDonell K, Clark L, Huang J, **Olson J**, Kahana S, Naar S, Sarr M, Thornton S. Acceptability and Feasibility of a Cell Phone Support Intervention for Youth Living with HIV with Nonadherence to Antiretroviral Therapy, AIDS Patient Care and STDs, Vol. 29, No. 6, June 2015: 338-345. doi: 10.1089/apc.2014.0282;

10. Klein DA, Ellzy JA, **Olson J****. Care of a Transgender Adolescent. Am Fam Physician. 2015 Jul 15;92(2):142-8. PMID: 26176373.

11. **Olson J****, Schrager SM, Belzer M, Simons LK*, Clark LF. Baseline Physiologic and Psychosocial Characteristics of Transgender Youth Seeking Care for Gender Dysphoria. J Adolesc Health. 2015 Oct;57(4):374-80. doi: 10.1016/j.jadohealth.2015.04.027. Epub 2015 Jul 21. PMID: 26208863; PMCID: PMC5033041.

12. **Olson-Kennedy J**,** Cohen-Kettenis PT, Kreukels BP, Meyer-Bahlburg HF, Garofalo R, Meyer W, Rosenthal SM. Research priorities for gender nonconforming/transgender youth: gender identity development and biopsychosocial outcomes. Curr Opin Endocrinol Diabetes Obes. 2016 Apr;23(2):172-9. doi: 10.1097/MED.0000000000000236. PMID: 26825472; PMCID: PMC4807860.

13. **Olson-Kennedy J**,** Okonta V, Clark LF, Belzer M. Physiologic Response to Gender-Affirming Hormones Among Transgender Youth. J Adolesc Health. 2018 Apr;62(4):397-401. doi: 10.1016/j.jadohealth.2017.08.005. Epub 2017 Oct 19. PMID: 29056436; PMCID: PMC7050572.

14. **Olson-Kennedy J****, Warus J*, Okonta V, Belzer M, Clark LF. Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. JAMA Pediatr. 2018 May 1;172(5):431-436. doi: 10.1001/jamapediatrics.2017.5440. PMID: 29507933; PMCID: PMC5875384.

15. Sayegh CS, MacDonell KK, Clark LF, Dowshen NL, Naar S, **Olson-Kennedy J**, van den Berg JJ, Xu J, Belzer M. The Impact of Cell Phone Support on Psychosocial Outcomes for Youth Living with HIV Nonadherent to Antiretroviral Therapy. AIDS Behav. 2018 Oct;22(10):3357-3362. doi: 10.1007/s10461-018-2192-4. PMID: 29948339; PMCID: PMC6530981.

16. Pang KC, Notini L, McDougall R, Gillam L, Savulescu J, Wilkinson D, Clark BA, **Olson-Kennedy J**, Telfer MM, Lantos JD. Long-term Puberty Suppression for a Nonbinary Teenager. Pediatrics. 2020 Feb;145(2):e20191606. doi: 10.1542/peds.2019-1606. PMID: 31974217.

17. **Olson-Kennedy J****, Chan YM, Garofalo R, et al. Impact of Early Medical Treatment for Transgender Youth: Protocol for the Longitudinal, Observational Trans Youth Care Study. JMIR Res Protoc. 2019;8(7):e14434. Published 2019 Jul 9. doi:10.2196/14434

18. Rider, G. N., Berg, D., Pardo, S. T., **Olson-Kennedy, J**., Sharp, C., Tran, K. M., Calvetti, S., & Keo-Meier, C. L. (2019). Using the Child Behavior Checklist (CBCL) with transgender/gender nonconforming children and adolescents. *Clinical Practice in Pediatric Psychology, 7*(3), 291–301. https://doi.org/10.1037/cpp0000296

19. **Olson-Kennedy J****, Chan YM, Rosenthal S, Hidalgo MA, Chen D, Clark L, Ehrensaft D, Tishelman A, Garofalo R. Creating the Trans Youth Research Network: A Collaborative Research Endeavor. Transgend Health. 2019 Nov 1;4(1):304-312. doi: 10.1089/trgh.2019.0024. PMID: 31701011; PMCID: PMC6830532.

20. Lee JY, Finlayson C, **Olson-Kennedy J**, Garofalo R, Chan YM, Glidden DV, Rosenthal SM. Low Bone Mineral Density in Early Pubertal Transgender/Gender Diverse Youth: Findings from the Trans Youth Care Study. Journal of the Endocrine Society. 2020 September 1;4(9):bvaa065. PubMed PMID: 32832823; PubMed Central PMCID: PMC7433770; DOI: 10.1210/jendso/bvaa065

21. Millington K, Schulmeister C, Finlayson C, Grabert R, **Olson-Kennedy J**, Garofalo R, Rosenthal SM, Chan YM. Physiological and Metabolic Characteristics of a Cohort of Transgender and Gender-Diverse Youth in the United States. J Adolesc Health. 2020 Sep;67(3):376-383. doi: 10.1016/j.jadohealth.2020.03.028. Epub 2020 May 14. PMID: 32417098; PMCID: PMC7483238.

22. Pang KC, Notini L, McDougall R, Gillam L, Savulescu J, Wilkinson D, Clark BA, **Olson-Kennedy J**, Telfer MM, Lantos JD. Long-term Puberty Suppression for a Nonbinary Teenager. Pediatrics. 2020 Feb;145(2):e20191606. doi: 10.1542/peds.2019-1606. PMID: 31974217.

23. **Olson-Kennedy J**,** Streeter LH*, Garofalo R, Chan YM, Rosenthal SM. Histrelin Implants for Suppression of Puberty in Youth with Gender Dysphoria: A Comparison of 50 mcg/Day (Vantas) and 65 mcg/Day (SupprelinLA). Transgender health. 2021 February;6(1):36-42. PubMed PMID: 33644320; PubMed Central PMCID: PMC7906230; DOI:10.1089/trgh.2020.0055.

24. Millington K, Finlayson C, **Olson-Kennedy J**, Garofalo R, Rosenthal SM, Chan YM. Association of High-Density Lipoprotein Cholesterol With Sex Steroid Treatment in Transgender and Gender-Diverse Youth. JAMA pediatrics. 2021 May 1;175(5):520-521. PubMed PMID: 33587098; PubMed Central PMCID: PMC7885095; DOI: 10.1001/jamapediatrics.2020.5620.

25. Chen D, Abrams M, Clark L, Ehrensaft D, Tishelman AC, Chan YM, Garofalo R, **Olson-Kennedy J**, Rosenthal SM, Hidalgo MA. Psychosocial Characteristics of Transgender Youth Seeking Gender-Affirming Medical Treatment: Baseline Findings from the Trans Youth Care Study. The Journal of adolescent health: official publication of the Society for Adolescent Medicine. 2021 June;68(6):1104-1111. PubMed PMID: 32839079; PubMed Central PMCID: PMC7897328; DOI: 10.1016/j.jadohealth.2020.07.033.

26. Julian JM, Salvetti B, Held JI, Murray PM, Lara-Rojas L, **Olson-Kennedy J****. The Impact of Chest Binding in Transgender and Gender Diverse Youth and Young Adults. J Adolesc Health. 2021 Jun;68(6):1129-1134. doi: 10.1016/j.jadohealth.2020.09.029. Epub 2020 Oct 27. PMID: 33121901.c

27. Millington, K., Barrera, E., Daga, A., Mann, N., **Olson-Kennedy, J**., Garofalo, R., Rosenthal, S. M., & Chan, Y. M. (Accepted/In press). The effect of gender-affirming hormone treatment on serum creatinine in transgender and gender-diverse youth: implications for estimating GFR. *Pediatric Nephrology*. https://doi.org/10.1007/s00467-022-05445-0

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2. Forcier M, **Olson J****, Transgender and Gender Nonconforming Youth, AM:STARs Hot Topics in Adolescent Health: Adolescent Medicine State of the Art Reviews, 25(2), August 2014 American Academy of Pediatrics Section on Adolescent Health

3. **Olson J**,** Transgender Youth and Young Adults. In: Neinstein's Adolescent and Young Adult Health Care: A Practical Guide, 6th edition, Lippincott Williams and Wilkins, 2015

4. **Olson-Kennedy J****. Mental Health Disparities Among Transgender Youth: Rethinking the Role of Professionals. JAMA Pediatr. 2016 May 1;170(5):423-4. doi: 10.1001/jamapediatrics.2016.0155. PMID: 26998945.

5. Clark BA, Virani A, Ehrensaft D, **Olson-Kennedy J**. Resisting the Post-Truth Era: Maintaining a Commitment to Science and Social Justice in Bioethics. Am J Bioeth. 2019 Jul;19(7):W1-W3. doi: 10.1080/15265161.2019.1618951. PMID: 31237512.

6. **Olson-Kennedy J**.** The Care of Gender Non-Conforming and Transgender Youth. Lavin N, Manual of Endocrinology and Metabolism, 5th Edition, Wolters Kluwer, 2019

7. **Olson-Kennedy J****. When the Human Toll of Conversion Therapy Is Not Enough. JAMA Pediatr. 2022 May 1;176(5):450-451. doi: 10.1001/jamapediatrics.2022.0049. PMID: 35254396.

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1. **Olson, J**.** Lesbian, gay, bisexual, transgender, queer youth and the internet- a virtual closet or cornucopia? – California Pediatrician, Jan 2011

2. Hildago MA, Ehrensaft D, Tishelman AC, Clark LF, Garofalo R, Rosenthal SM, Spack NP, **Olson J**.** The gender affirmative model: What we know and what we aim to learn. *Human Development*, 2013, 3: 285-290. Edited manuscript; senior author
3. **Olson-Kennedy, J****, 2018. "Hot Topics and Fresh Paradigms in Gender, Diversity, and Care", AM:STARs: LGBTQ Youth: Enhancing Care For Gender and Sexual Minorities, American Academy of Pediatrics Section on Adolescent Health
4. **Olson J****, Forcier M, Overview of the management of gender nonconformity in children and adolescents, In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA Role: co-first authored manuscript – drafting and editing.
5. Forcier M, **Olson J****, Overview of gender development and clinical presentation of gender nonconformity in children and adolescents, In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Role: co-first authored manuscript – drafting and editing.

ABSTRACTS AND PRESENTATIONS:

1. Beharry M*, **Olson J**,** Men and the Morning After, poster presented at the Society for Adolescent Health and Medicine, Toronto, 2010.

2. **Olson J**,** Clark L, Schrager S, Simons L, Belzer M**,** Baseline Characteristics Of Transgender Youth Naïve To Cross Sex Hormone Therapy, J Adol Health, February 2013 (Vol. 52, Issue 2, Supplement 1, Pages S35-S36, DOI: 10.1016/j.jadohealth.2012.10.086)

3. **Olson J**, Transgender Youth; An Overview of Medical and Mental Health Needs of Gender Non-conforming Children and Transgender Adolescents, Models of Pride, Los Angeles LGBT Center's LifeWorks, Los Angeles, CA, 2014

4. **Olson J**, Transitioning Teens and the Adolescent Experience, Gender Spectrum Family Conference, Gender Spectrum, Moraga, CA, 2014

5. **Olson J**, Outside of the Gender Binary: Defining and Caring for Non-Binary Identified Youth, Gender Spectrum Family Conference, Gender Spectrum, Moraga, CA, 2014

6. **Olson J**, Medical Care of Transgender Adolescents, Cross sex Hormones, Gender Infinity Conference, Houston, TX, 2014

7. **Olson J**, Cross Sex Hormone Therapy for Transgender Teens, Southern Comfort Conference, Atlanta, GA, 2014

8. **Olson J**, Puberty Suppression, Southern Comfort Conference, Atlanta, GA, 2014

9. **Olson J**, Medical Treatment of Gender Nonconforming and Transgender Youth, Chico Trans* Week, Stonewall Alliance & Chico California Association of Marriage and Family Therapists, Chico, CA

10. **Olson J**, Transgender Youth 101, Stonewall LGBT Health Symposium, Los Angeles, CA, 2014

11. **Olson J**, Gender Non-conforming Children and Transgender Adolescents, EDGY Conference, Los Angeles, CA, 2015

12. **Olson J**, Gender Non-conforming Children and Transgender Teens, Chico Trans Week, Stonewall Alliance Center of Chico, Chico, CA, 2015

13. **Olson J**, Cross-sex Hormones for Transgender Youth, Transgender Health and Education Alliance Family Conference, Atlanta, Georgia, 2015

14. **Olson J**, Puberty Suppression in Gender Non-conforming Children, Gender Odyssey Conference, Gender Odyssey, Seattle, WA, 2014

15. **Olson J**, Cross sex Hormones, Gender Odyssey Conference, Gender Odyssey, Seattle, WA, 2014

16. **Olson J**, Just a Boy, Just a Girl, Gender Spectrum, Gender Spectrum Professional Conference, Moraga, California, 2015

17. **Olson J**, Transition for Teens and Young Adults, Gender Infinity Provider and Advocacy Day, Gender Infinity Conference, Houston, TX, 2015

18. **Olson J**, Puberty Blockers and Hormone Therapy, Gender Infinity Conference, Houston, TX, 2015

19. **Olson J**, Just a Boy, Just a Girl; Gender Odyssey Conference, Seattle, WA, 2015

20. **Olson J**, Puberty Blockers and Cross Sex Hormones, Gender Odyssey Conference, Seattle, WA, 2015

21. **Olson J**, Outside of the Binary, Gender Odyssey Conference, Seattle, WA, 2015

22. **Olson J**, Outside of the Gender Binary: Defining and Caring for Non-Binary Identified Youth, Gender Spectrum, Gender Spectrum Family Conference, Moraga, CA, 2015

23. **Olson, J**, Caring for Youth with Gender Dysphoria, Pediatric Academic Societies Annual Meeting, Pediatric Academic Societies, San Diego, California, 2015

24. **Olson-Kennedy J,** Parents of Trans and Gender Fluid Youth, Models of Pride, Los Angeles, CA, 2016

25. **Olson-Kennedy J,** Caring for Gender Nonconforming and Transgender Youth, Intersections in Queer Health, SoCal LGBT Health Conference, Irvine, CA, 2016

26. **Olson-Kennedy J,** Outside of the Binary; Care for Non-Binary Adolescents and Young Adults, US Professional Association of Transgender Health, Los Angeles, CA, 2016

27. **Olson-Kennedy J,** Gender Nonconforming Children and Adolescents, AAP National Conference, San Francisco, California, 2016

28. **Olson-Kennedy J,** Masculinizing Hormone Therapy, Gender Infinity, Houston Texas, 2016

29. **Olson-Kennedy J,** Just a Boy, Just a Girl, Houston, Gender Infinity, Houston Texas, 2016

30. **Olson-Kennedy J,** Puberty Blockers, Houston, Gender Infinity, Houston Texas, 2016

31. **Olson-Kennedy J,** Gender Affirming Hormone Therapy for Adolescents and Young Adults, Gender Infinity, Houston Texas, 2016

32. **Olson-Kennedy J,** Feminizing Hormone Therapy, Gender Infinity, Houston Texas, 2016

33. **Olson-Kennedy J,** Models of Care & Legal Issues Related to Consent, Gender Infinity, Houston Texas, 2016

34. **Olson-Kennedy J,** Defining and Caring for Non-binary Identified Youth, Gender Infinity, Houston Texas, 2016

35. **Olson-Kennedy J,** Beyond Male and Female; Approach to Youth with Non-Binary Gender Identities; Gender Spectrum, Moraga, California, 2016

36. **Olson-Kennedy J,** Meier, C, TYFA Research: Demographics of a US sample of Two Cohorts of Gender Non-conforming Children, Gender Odyssey, Seattle, WA 2016

37. **Olson-Kennedy J,** Gender Affirming Hormones; Gender Odyssey, Seattle, WA 2016

38. **Olson-Kennedy J,** Beyond Male and Female; Approach to Youth with Non-Binary Gender Identities; Gender Odyssey, Seattle, WA, 2016

39. **Olson-Kennedy J,** Puberty Suppression; What When and How?; Gender Odyssey, Seattle, WA, 2016

40. **Olson-Kennedy J,** Care of Gender Nonconforming Children and Adolescents, Southeastern Transgender Health Summit, Asheville, North Carolina, 2016

41. **Olson-Kennedy J,** Puberty Suppression in the United States; practice models, lessons learned, and unanswered questions, US Professional Association of Transgender Health, Los Angeles, CA 2017

42. **Olson-Kennedy J,** Puberty Suppression in the United States; practice models, lessons learned, and unanswered questions, US Professional Association of Transgender Health, Los Angeles, CA 2017

43. **Olson-Kennedy J,** "Just a Boy, Just a Girl" Gender Infinity, Houston TX 2017

44. **Olson-Kennedy J,** Chest Dysphoria – The Impact of Male Chest Reconstruction, Gender Infinity, Houston TX 2017

45. **Olson-Kennedy J,** Outside of the Binary; Care for Non-Binary Adolescents and Young Adults, Gender Infinity, Houston TX 2017

46. **Olson-Kennedy J,** Puberty Blockers; What, When and How, Gender Infinity, Houston TX 2017

47. **Olson-Kennedy J,** Gender Non-Conforming Children and Transgender Youth; Integrated Care Conference, Los Angeles, CA, 2017

48. **Olson-Kennedy J,** Gender Non-Conforming and Transgender Children and Adolescents; A Multidisciplinary Approach, California Psychiatric Association Annual Conference, Yosemite, CA, 2017

49. **Olson-Kennedy J,** Gender Dysphoria; Beyond the Diagnosis, Models of Pride, Los Angeles, CA

50. **Olson-Kennedy J,** Puberty Delay and Cross Hormones for Trans* Youth, Models of Pride, Los Angeles, CA

51. **Olson-Kennedy J,** Masculinizing Hormones, Central Texas Transgender Health Conference, Austin, TX, 2017

52. **Olson-Kennedy J,** Children, Youth, Families and Hormone Blockers, Central Texas Transgender Health Conference, Austin, TX, 2017

53. **Olson-Kennedy J,** "Just a Boy, Just a Girl" Gender Infinity, Houston TX, 2017

54. **Olson-Kennedy J,** Chest Dysphoria – The Impact of Male Chest Reconstruction, Gender Odyssey Professional Symposium, Seattle, WA, 2017

55. **Olson-Kennedy J,** Puberty Delay and Cross Hormones for Transyouth, Gender Odyssey Professional Symposium, Seattle, WA, 2017

56. **Olson-Kennedy J**, Olson-Kennedy A, Just a Girl, Just a Boy, Gender Odyssey Professional Symposium, Pasadena, CA, 2017

57. **Olson-Kennedy J**, Puberty Blockers and Cross Sex Hormones, Gender Odyssey, Pasadena, CA, 2017

58. **Olson-Kennedy J**, Olson-Kennedy A, Gender Dysphoria, Gender Spectrum Family Conference, Moraga, CA, 2017

59. **Olson-Kennedy J**, Rethinking Gender, Chico TransGNC Week, Chico, CA, 2017

60. **Olson-Kennedy J**, Caring for Gender Non-Conforming and Transgender Youth, Chico TransGNC Week, Chico, CA, 2017

61. **Olson-Kennedy J**, Puberty Suppression in the United States; practice models, lessons learned, and unanswered questions, US Professional Association of Transgender Health, Los Angeles, CA, 2017

62. **Olson-Kennedy J**, The Impact of Male Chest Reconstruction on Chest Dysphoria in Transmasculine Adolescents and Young Men; A Preliminary Study, US Professional Association of Transgender Health, Los Angeles, CA, 2017

63. **Olson-Kennedy J**, Outside of the Binary; Care for Non-Binary Adolescents and Young Adults, US Professional Association of Transgender Health, Los Angeles, CA, 2017

64. **Olson-Kennedy J**, Olson-Kennedy A, Gender Dysphoria: Beyond the Diagnosis, Center for Juvenile Justice Reform Supporting the Well-Being of LGBTQ Youth Certificate Program, Washington DC, 2018

65. **Olson-Kennedy J**, Olson-Kennedy A, Gender Dysphoria; Beyond the Diagnosis; Midwest LGBTQ Health Symposium, Chicago, IL, 2018

66. **Olson-Kennedy J**, Puberty Suppression and Gender Affirming Hormones, Gender Fest, Las Vegas, NV, 2018

67. **Olson-Kennedy J**, Gender Dysphoria; Beyond the Diagnosis, Gender Odyssey Family Conference, Seattle WA, 2018

68. **Olson-Kennedy J**, Gender Affirming Hormone Therapy for Transmasculine Adolescents and Young Adults, Gender Infinity, Houston, TX, 2018

69. **Olson-Kennedy J**, Outside of the Binary; Care for Non-Binary Adolescents and Young Adults, Gender Infinity, Houston, TX, 2018

70. **Olson-Kennedy J**, Chest Dysphoria and the Impact of Chest Reconstruction, Gender Infinity, Houston, TX, 2018

71. **Olson-Kennedy J**, Olson-Kennedy A, Landon S, Just a Girl, Just a Boy, Gender Infinity, Houston, TX, 2018

72. **Olson-Kennedy J**, Hormones 201: More than Testosterone and Estrogen, Gender Odyssey Professional Symposium, WA, 2018

73. **Olson-Kennedy J**, Puberty Suppression: What, When, and How, Gender Odyssey Family Conference, Seattle WA, 2018

74. **Olson-Kennedy J**, Gender Google; Gender Odyssey Family Conference, Seattle WA, 2018

75. **Olson-Kennedy J**, Male Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults, Gender Odyssey Professional Symposium, WA, 2018

76. **Olson-Kennedy J**, Mosser S, Chest Surgery, Gender Spectrum, Moraga, CA 2018

77. **Olson-Kennedy J**, Olson-Kennedy A, Understanding Gender Dysphoria, Gender Spectrum, Moraga, CA 2018

78. **Olson-Kennedy J**, Puberty Suppression and Gender Affirming Hormones, Gender Odyssey, Los Angeles, CA, 2018

79. **Olson-Kennedy J**, Olson-Kennedy A, Gender Dysphoria – Beyond the Diagnosis, Gender Odyssey, Los Angeles, CA, 2018

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82. **Olson-Kennedy J**, Providing 360 degree transgender hormone therapy: beyond the protocols, Medical Directors Council (MeDC) 14th Annual Clinical Update in Reproductive Health and Medical Leadership, Snowbird, Utah, 2018

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85. **Olson-Kennedy J**, Hormones 201 – Beyond T and E, Gender Odyssey San Diego, San Diego, CA, 2019

86. **Olson-Kennedy J**, Olson-Kennedy A, Landon S, Just a Boy, Just a Girl, Gender Odyssey San Diego, San Diego, CA, 2019

87. **Olson-Kennedy J**, Gender Dysphoria; A Deeper Dive Beyond the Diagnosis, Advance LA Conference, California

88. **Olson-Kennedy J**, Histrelin Implants for Suppression of Puberty in Youth with Gender Dysphoria: a Comparison of 50 mcg/day (Vantas) and 65 mcg/day (SupprelinLA), WPATH Conference, Virtual Presentation, 2020

89. **Olson-Kennedy J**, Chest Reconstruction and Chest Dysphoria in Transmasculine Adolescents and Young Adults, Comparison of Post-surgical and Non-surgical Cohorts, WPATH Conference, Virtual Presentation, 2020

90. **Olson-Kennedy J**, Olson-Kennedy A, Gender Dysphoria: Beyond the Diagnosis, Center for Juvenile Justice Reform Supporting the Well-Being of LGBTQ Youth Certificate Program, Virtual Presentation, 2020

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EXHIBIT B

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IN 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

EXPERT DECLARATION OF DAN H. KARASIC, M.D.

I, Dan H. Karasic, M.D., hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I am over the age of 18. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

I. BACKGROUND AND QUALIFICATIONS

A. Qualifications

3. The information provided regarding my professional background, experiences, publications, and presentations are detailed in my curriculum vitae ("CV"). A true and correct copy of my most up-to-date CV is attached as **Exhibit A**.

4. I am a Professor Emeritus of Psychiatry at the University of California – San Francisco (UCSF) Weill Institute for Neurosciences. I have been on faculty at UCSF since 1991. I have also had a telepsychiatry private practice since 2020.

5. I received my Doctor of Medicine (M.D.) degree from the Yale Medical School in 1987. In 1991, I completed my residency in psychiatry at the University of California – Los Angeles (UCLA) Neuropsychiatric Institute, and from 1990 to 1991, I was a postdoctoral fellow in a training program in mental health services for persons living with AIDS at UCLA.

6. For over 30 years, I have worked with patients with gender dysphoria. I am a Distinguished Life Fellow of the American Psychiatric Association and currently the chair of the American Psychiatric Association Workgroup on Gender Dysphoria, as well as the sole author of the chapter on transgender care in the American Psychiatric Press's Clinical Manual of Cultural Psychiatry, Second Edition.

7. Over the past 30 years, I have provided care for thousands of transgender patients. For 17 years, I was the psychiatrist for the Dimensions Clinic for transgender youth in San Francisco.

8. I previously sat on the Board of Directors of the World Professional Association for Transgender Health (WPATH) and am a co-author of WPATH's *Standards of Care for the Health of Transsexual, Transgender, and Gender*

Nonconforming People, Version 7, which are the internationally accepted guidelines designed to promote the health and welfare of transgender, transsexual, and gender variant persons. I remain active in the work of WPATH. For the upcoming WPATH Standards of Care, Version 8, I am the lead author on the Mental Health chapter.

9. As a member of the WPATH Global Education Initiative, I helped develop a specialty certification program in transgender health and helped train over 2,000 health providers. At UCSF, I developed protocols and outcome measures for the Transgender Surgery Program at the UCSF Medical Center. I also served on the Medical Advisory Board for the UCSF Center of Excellence for Transgender Care and co-wrote the mental health section of the original *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People* and the revision in 2016.

10. I have also worked with the San Francisco Department of Public Health, having helped develop and implement their program for the care of transgender patients and for mental health assessments for gender-affirming surgery. I served on the City and County of San Francisco Human Rights Commission's LGBT Advisory Committee, and I have been an expert consultant for California state agencies and on multiple occasions for the United Nations Development Programme on international issues in transgender care.

11. I have held numerous clinical positions concurrent to my clinical professorship at UCSF. Among these, I served as an attending psychiatrist for San Francisco General Hospital's consultation-liaison service for AIDS care, as an outpatient psychiatrist for HIV-AIDS patients at UCSF, as a psychiatrist for the Transgender Life Care Program and the Dimensions Clinic at Castro Mission Health Center, and the founder and co-lead of the UCSF Alliance Health Project's Transgender Team. In these clinical roles, I specialized in the evaluation and treatment of transgender, gender dysphoric, and HIV-positive patients. I also regularly provide consultation on challenging cases to psychologists and other psychotherapists working with transgender and gender dysphoric patients. I have been a consultant in transgender care to the California Department of State Hospitals and am currently a consultant for the California Department of Corrections and Rehabilitation on the care of incarcerated transgender people.

12. As part of my psychiatric practice treating individuals diagnosed with gender dysphoria and who receive other medical and surgical treatment for that condition, as well as a co-author of the WPATH Standards of Care and UCSF's *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People*, I am and must be familiar with additional aspects of medical care for the diagnosis of gender dysphoria, beyond mental health treatment, assessment, and diagnosis.

13. In addition to this work, I have done research on the treatment of depression. I have authored many articles and book chapters and edited the book *Sexual and Gender Diagnoses of the Diagnostic and Statistical Manual (DSM): A Reevaluation*.

14. Since 2018, I have performed over 100 independent medical reviews for the State of California to determine the medical necessity of transgender care in appeals of denial of insurance coverage.

B. Compensation

15. I am being compensated for my work on this matter at a rate of $400.00 per hour for preparation of declarations and expert reports. I will be compensated $3,200.00 per day for any deposition testimony or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

C. Previous Testimony

16. Over the past four years, I have given expert testimony at trial or by deposition in the following cases: *C.P. v. Blue Cross Blue Shield of Illinois*, No. 3:20-cv-06145-RJB (W.D. Wash.); *Kadel v. Folwell*, No. 1:19-cv-00272 (M.D.N.C.); *Fain v. Crouch*, 3:20-cv-00740 (S.D.W. Va.); and *Brandt v. Rutledge*, No. 4:21-cv-00450 (E.D. Ark.). To the best of my recollection, I have not given expert testimony at a trial or at a deposition in any other case during this period.

II. BASIS FOR OPINIONS

17. In preparing this report, I have relied on my training and years of research and clinical experience, as set out in my curriculum vitae, and on the materials listed therein, as documented in my curriculum vitae, which is attached hereto as **Exhibit A**.

18. I have also reviewed the materials listed in the bibliography attached hereto as **Exhibit B**. The sources cited therein include authoritative, scientific peer-reviewed publications. They include the documents specifically cited as supportive examples in particular sections of this report.

19. Additionally, I have reviewed Florida's Administrative Rule governing the determination of generally accepted professional medical standards under Florida Medicaid coverage (Fla. Admin. Code R. 59G-1.035); the Florida Medicaid Generally Accepted Professional Medical Standards (GAPMS) Determination on the Treatment of Gender Dysphoria published by Florida's Agency for Health Care Administration (AHCA) in June 2022, along with its attachments, including the reports of Dr. Romina Brignardello-Petersen and Dr. Wojtek Wiercioch (Attachment C), Dr. James Cantor (Attachment D), Dr. Quentin Van Meter (Attachment E), Dr. Patrick Lappert (Attachment F), and Dr. G. Kevin Donovan (Attachment G) (hereinafter, "GAPMS Memo"); and Fla. Admin. Code. R. 59G-1.050(7) which prohibits Medicaid coverage of puberty-delaying medications (commonly referred

to as "puberty blockers"), hormone and hormone antagonists, "sex reassignment" surgeries, and any other procedures that alter primary or secondary sexual characteristics, on the basis that the services do not meet Florida's definition of "medical necessity" for purposes of its Medicaid program.

20. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject. I reserve the right to revise and supplement the opinions expressed in this report or the bases for them if any new information becomes available in the future, including as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

III. EXPERT OPINIONS

A. Gender Identity

21. Sex assigned at birth refers to the sex assigned to a person at the time of their birth, typically based on the appearance of external genital characteristics. While the terms "male sex" and "female sex" are sometimes used in reference to a person's genitals, chromosomes, and hormones, the reality is that sex is complicated and multifactorial. Aside from external genital characteristics, chromosomes, and endogenous hormones, other factors related to sex include gonads, gender identity, and variations in brain structure and function. Because these factors may not always be in alignment as typically male or typically female, "the terms biological sex and

biological male or female are imprecise and should be avoided." (Hembree, et al., 2017).

22. Gender identity is "a person's deeply felt, inherent sense of being a girl, woman, or female; a man, or male; a blend of male or female; or an alternative gender" (American Psychological Association, 2015, at 834). Gender identity does not always align with sex assigned at birth. Gender identity, which has biological bases, is not a product of external influence and not subject to voluntary change. As documented by multiple leading medical authorities, efforts to change a person's gender identity are ineffective, can cause harm, and are unethical. (American Psychological Association, 2021, Byne, et al., 2018, Coleman, et al., 2012).

B. Gender Dysphoria

23. The term "gender dysphoria" is distress related to the incongruence between one's gender identity and attributes related to one's sex assigned at birth.

24. The diagnosis of Gender Dysphoria in the Diagnostic and Statistical Manual Fifth Edition (DSM-5), released in 2013, involves two major diagnostic criteria for adolescents and adults:

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by at least two of the following (one of which must be Criterion A1):

1. A marked incongruence between one's experienced/expressed gender and primary or secondary sex characteristics.
2. 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.
3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
6. 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).

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

25. Given that gender dysphoria can cause such distress, many transgender individuals face depression, anxiety, and higher rates of suicidality than cisgender people. This is noted both in adults and adolescents. However, gender dysphoria is

a condition that is highly amenable to treatment, and the prevailing treatment for it is highly effective. The aforementioned risks decline when transgender individuals are supported and live according to their gender identity. And with access to medically indicated care, transgender people can experience significant and potentially complete relief from their symptoms of gender dysphoria. Not only is this documented in scientific literature and published data, but I witness this each time I see my patients being supported by their community, family, school, and medical providers.

C. Evidence-Based Guidelines for Treatment of Gender Dysphoria

26. The World Professional Association of Transgender Health (WPATH) has issued *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* ("WPATH SOC") since 1979. The current version is WPATH SOC 7, with WPATH SOC 8 due out in 2022. WPATH SOC 7 provides guidelines for multidisciplinary care of transgender individuals and describes criteria for medical interventions to treat gender dysphoria, including hormone treatment and surgery when medically indicated.

27. WPATH SOC 7 also states, "Treatment aimed at trying to change a person's gender identity and expression … is no longer considered ethical," because it is known to be ineffective and can cause harm to patients.

28. A clinical practice guideline from the Endocrine Society (the Endocrine Society Guideline) provides similar protocols for the medically necessary treatment of gender dysphoria. (Hembree, et al., 2017).

29. Guidelines from other organizations, including those developed by the UCSF Center of Excellence for Transgender Care, also list similar protocols for the medically necessary treatment of gender dysphoria.

30. Each of these guidelines are evidence-based and supported by scientific research and literature, as well as extensive clinical experience.

31. The protocols and policies set forth by the WPATH Standards of Care and the Endocrine Society Guidelines are endorsed and cited as authoritative by the major professional medical and mental health associations in the United States, including the American Medical Association, the American Academy of Pediatrics, the American Psychiatric Association, the American Psychological Association, the American College of Obstetrics and Gynecology, the American College of Physicians, and the World Medical Association, among others.

32. To be sure, being transgender is widely accepted as a variation in human development and is not considered a mental illness. People who are transgender have no impairment in their ability to be productive, contributing members of society simply because of their transgender status.

a. The American Psychiatric Association's DSM 5 states: Gender dysphoria "is more descriptive than the previous DSM-IV term 'gender identity disorder' and focuses on dysphoria as the clinical problem, not identity per se." (APA, 2013).

b. WPATH SOC 7 states: "Being transsexual, transgender, or gender-nonconforming is a matter of diversity, not pathology…. Thus, transsexual, transgender, and gender-nonconforming individuals are not inherently disordered. Rather, the distress of gender dysphoria, when present, is the concern that might be diagnosable and for which various treatment options are available."

c. The American Psychological Association states: "Whereas diversity in gender identity and expression is part of the human experience and transgender and gender nonbinary identities and expressions are healthy, incongruence between one's sex and gender is neither pathological nor a mental health disorder." (American Psychological Association, 2021).

d. The World Health Organization states: "Gender incongruence has thus broadly been moved out of the 'Mental and behavioural disorders' chapter and into the new 'Conditions related to sexual health' chapter. This reflects evidence that trans-related and gender diverse identities

are not conditions of mental ill health, and classifying them as such can cause enormous stigma." (WHO Europe).

33. Thus, the overarching goal of treatment is to eliminate the distress of gender dysphoria by aligning an individual patient's body and presentation with their internal sense of self. The denial of medically indicated care to transgender people not only results in the prolonging of their gender dysphoria, but causes additional distress and poses other health risks, such as depression, posttraumatic stress disorder, and suicidality. In other words, lack of access to gender-affirming care directly contributes to poorer mental health outcomes for transgender people. (Owen-Smith, et al., 2018).

34. For patients for whom gender-affirming medical care is indicated, no alternative treatments have been demonstrated to be effective. The American Psychological Association states that gender identity change efforts provide no benefit and instead do harm. (American Psychological Association, 2021).

35. Accordingly, major medical organizations, such as the American Medical Association, American Psychiatric Association, the Endocrine Society, American College of Obstetricians and Gynecologists, and American Academy of Family Physicians oppose the denial of this medically necessary care and support public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician. (American Medical Association, 2021;

American Psychiatric Association, 2018; Endocrine Society, 2012; American College of Obstetricians and Gynecologists, 2021; American Academy of Family Physicians, 2020).

D. Treatment of Gender Dysphoria

36. The WPATH SOC 7 and the Endocrine Society Guidelines establish authoritative protocols for the treatment of gender dysphoria.

37. In accordance with the WPATH SOC 7 and the Endocrine Society Guidelines, medical interventions to treat gender dysphoria may include treatment with pubertal suppression and/or hormones, and treatment with surgery.

38. No medical or surgical treatment for gender dysphoria is provided to pre-pubertal children.

39. Once a patient enters puberty, treatment options include pubertal suppression therapy and gender-affirming hormones. Pubertal blocking involves methods of temporarily suppressing endogenous puberty to alleviate gender dysphoria and give the patient more time to work with their mental health providers to assess treatment needs. These blockers are reversible medications and once stopped, a patient immediately returns to the stage of pubertal development that had begun when the treatment was initiated.

40. If a patient is assessed to have a medical need for hormone therapy, gender-affirming hormone therapy involves administering steroids of the

experienced sex (i.e., their gender identity), such as testosterone in transgender male individuals and estrogen in transgender female individuals, to treat gender dysphoria later in puberty. The purpose of this treatment is to attain the appropriate masculinization or feminization of the transgender person to achieve a gender phenotype that matches as closely as possible to their gender identity. For adolescents, this treatment allows patients to have pubertal changes and development consistent with their gender identity. Gender-affirming hormone therapy is a partially reversible treatment in that some of the effects produced by the hormones are reversible (e.g., changes in body fat composition, decrease in facial and body hair) while others are irreversible (e.g., deepening of the voice, decreased testicular mass).

41. Some transgender individuals need surgical interventions to help bring their phenotype into alignment with their gender. Surgical interventions may include, *inter alia*, vaginoplasty and orchiectomy for transgender female individuals, and chest reconstruction and hysterectomy for transgender male individuals.

42. For transgender male adolescents, chest surgery may be provided prior to age 18 if medically indicated.

43. The treatment protocols for gender dysphoria are comparable to those for other mental health and medical conditions. Indeed, these or similar procedures are provided for cisgender people with other diagnoses.

E. Gender-Affirming Medical and Surgical Care Is Safe and Effective.

44. Gender-affirming medical and surgical interventions in accordance with the WPATH SOC 7 and Endocrine Society Guidelines are widely recognized in the medical community as safe, effective, and medically necessary for many transgender people with gender dysphoria. (See American Academy of Pediatrics, 2018; the American Medical Association, 2021; the Endocrine Society, 2020, the Pediatric Endocrine Society, 2021; the American Psychiatric Association, 2018; the American Psychological Association, 2021; the American Congress of Obstetricians and Gynecologists, 2021; the American Academy of Family Physicians, 2020; WPATH, 2012).

45. There is substantial evidence that gender-affirming medical and surgical care is effective in treating gender dysphoria. This evidence includes scientific studies assessing mental health outcomes for transgender people who are treated with these interventions, including adolescents, and decades of clinical experience.

46. The research and studies supporting the necessity, safety, and effectiveness of medical and surgical care for gender dysphoria are the same type of evidence-based data that the medical community routinely relies upon when treating other medical conditions.

47. Medical treatment for gender dysphoria has been studied for over half a century, and there is substantial evidence that it improves quality of life and measures of mental health. (Aldridge et al., 2020; Almazan, et al., 2021; Baker et al., 2021; Murad, et al., 2010; Nobili et al., 2018; Pfafflin & Junge, 1998; T'Sjoen et al. 2019; van de Grift et al., 2017; White Hughto and Reisner, 2016; Wierckx et al., 2014).

48. A systematic review of 20 studies showed improved quality of life, decreased depression, and decreased anxiety with hormonal treatment in transgender people. (Baker, et al., 2021). Another systematic review showed improvement in mental health and quality of life measures in transgender people with hormonal treatment (White Hughto and Reisner, 2016). In the United Kingdom, one study demonstrated that depression and anxiety were substantially reduced over 18 months of gender-affirming hormonal treatment. (Aldridge, et al., 2020). In a secondary analysis of data from the US Transgender Survey, having had genital surgery was associated with decreased psychological distress and suicidal ideation. (Almazan, et al., 2021). In transgender patients followed 4-6 years after surgery, satisfaction was very high (over 90%) and regret was low. (van de Grift et al., 2018). The Cornell "What We Know" systematic review of 55 studies from 1991-2017 strongly supported that gender-affirming hormone and surgical treatment improved the well-being of transgender individuals. (What We Know, 2018).

49. The studies on gender-affirming medical care for treatment of dysphoria are consistent with decades of clinical experience of mental health providers across the U.S. and around the world. At professional conferences and other settings in which I interact with colleagues, clinicians report that gender-affirming medical care, for those for whom it is indicated, provides great clinical benefit. In my 30 years of clinical experience treating gender dysphoric patients, I have seen the benefits of gender-affirming medical care on my patients' health and well-being. I have seen many patients show improvements in mental health, as well as in performance in school, in social functioning with peers, and in family relationships when they experience relief from gender dysphoria with gender-affirming medical care.

50. Accordingly, treatments for gender dysphoria are not considered elective or cosmetic. Indeed, as WPATH (2016) states, "The medical procedures attendant to gender-affirming/confirming surgeries are not 'cosmetic' or 'elective' or 'for the mere convenience of the patient.' These reconstructive procedures are not optional in any meaningful sense, but are understood to be medically necessary for the treatment of the diagnosed condition. In some cases, such surgery is the only effective treatment for the condition, and for some people genital surgery is essential and life-saving."

51. As part of the treatment process for gender dysphoria, patients provide informed consent to their care. In addition, a treating doctor will not offer gender-affirming medical treatments unless they have concluded after weighing the risks and benefits of care that treatment is appropriate. The risks and benefits of care are discussed with the transgender patient, who must assent. This process is no different than the informed consent process for other treatments. However, for gender-affirming medical care, there is the additional safeguard of the assessment by a mental health professional, who, in addition to diagnosing gender dysphoria, also assesses capacity to consent and reviews the risks and benefits of treatment with the patient.

52. Regret among those who are treated with gender-affirming medical care is rare. For example, in one study in the Netherlands, none of the youth who received puberty-delaying treatment, hormones, and surgery, and were followed over an 8-year period expressed regret. (DeVries, 2014.) Zucker, et al., (2010), summarizing key studies on regret for adolescents referred for surgery when they reached the age of majority in the Netherlands, states, "there was virtually no evidence of regret, suggesting that the intervention was effective."

53. A study of 209 gender-affirming mastectomies in transmasculine adolescents aged 12-17, performed at Kaiser Permanente Northern California from 2013 to 2020, showed a regret rate of 1%. (Tang, et al 2022).

54. Regret rates for gender-affirming surgery in adults are also very low. A pooled review across multiple studies of 7,928 patients receiving gender-affirming surgery showed a regret rate of 1%. (Bustos, et al., 2021). Over 50 years of gender-affirming surgery in Sweden, the regret rate, as measured by legal gender change reversal, was 2%. (Dhejne, et al., 2014). These are very low regret rates for surgery. For example, 47% of women expressed at least some regret after reconstructive breast surgery following mastectomy for breast cancer. (Sheehan, et al., 2008).

55. For all the reasons above, I am aware of no basis in medicine or science for categorical exclusion of coverage for gender-affirming care.

56. One misperception is that hormone therapy is experimental because it is not FDA-approved for the specific application of treating Gender Dysphoria. Medications very commonly are prescribed for off-label uses. All gender-affirming hormone treatments are approved for treatment of other conditions and have been used to treat those conditions, as well as for gender-affirming care, for many years, supporting their safety and efficacy. The U.S. Department of Health and Human Services Agency for Healthcare Research and Quality states, "[Off-label prescribing] is legal and common. In fact, one in five prescriptions written today are for off-label use."[1]

[1] See https://www.ahrq.gov/patients-consumers/patient-involvement/off-label-drug-usage.html.

57. Finally, the cost of providing coverage for gender-affirming care is generally very low. To begin, transgender people constitute a small percentage of the overall population, approximately 0.5%. (Crissman, et. al., 2017). Furthermore, the fraction of the population receiving clinical care for Gender Dysphoria is much smaller, well under one in a thousand patients (Zhang, et al., 2020). As a result, one study estimated an average cost of $0.016 cents per member per month to provide gender-affirming care. (Padula, et al., 2016). A study by Herman (2013) similarly found low costs to providing health coverage for gender-affirming care. Additionally, when a form of treatment is covered for cisgender people under an insurance plan, it is generally not disproportionately costly to cover the same treatment for transgender people simply because it is provided to treat gender dysphoria.

F. Harms of Denying Gender-Affirming Care

58. The overarching goal of treatment is to eliminate the distress of gender dysphoria by aligning an individual patient's body and presentation with their internal sense of self. The denial of medically indicated care to transgender people not only results in the prolonging of their gender dysphoria, but causes additional distress and poses other health risks, such as depression, posttraumatic stress disorder, and suicidality. The prevalence of these mental health conditions is also thought to be a consequence of minority stress, the chronic stress from coping with

societal stigma and discrimination because of one's identity, including gender identity and gender expression. (American Medical Association, 2019). In other words, lack of access to gender-affirming care directly contributes to poorer mental health outcomes for transgender people. (Owen-Smith, et al., 2018).

59. Accordingly, major medical organizations, such as the American Medical Association, American Psychiatric Association, and American College of Obstetricians and Gynecologists, oppose the denial of this medically necessary care and support public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician. (American Medical Association, 2019).

60. Denial of this appropriate care for transgender adolescents is also opposed by mainstream organizations responsible for the care of youth, including the American Academy of Pediatrics, the American Academy of Child and Adolescent Psychiatry, and the Pediatric Endocrine Society.

61. Familial and social support and the provision of gender-affirming medical treatment have been associated with dramatically less suicidal ideation in transgender people. (Bauer, et al., 2015). Provision of puberty blockers and gender-affirming hormones for transgender youth likewise decreases suicidality (Tordoff, et al., 2022; Turban, et al., 2020; Green, et al., 2022), Allen, et al., 2019). The American Academy of Child and Adolescent Psychiatry states, "Research consistently

demonstrates that gender diverse youth who are supported to live and/or explore the gender role that is consistent with their gender identity have better mental health outcomes than those who are not." (AACAP, 2019).

62. In a University of Washington study of 104 transgender and nonbinary youth, treatment with puberty blockers or hormones was associated with 60% less moderate to severe depression and 73% less suicidal ideation over 12 months, compared to youth not treated. (Tordoff, et al. 2022).

63. In a University of Texas Southwestern study, treatment with gender-affirming hormones in transgender youth was associated with a substantial reduction in body dissatisfaction, as well as improvement on measures of depression and anxiety. (Kuper, et al., 2020).

64. In a University of Southern California and Children's Hospital Los Angeles study of 136 transgender male youth, the half that had received chest masculinizing surgery had far less gender dysphoria than those who had not yet had surgery. (Olson et al, 2018).

65. In a University of Pennsylvania and University of Rochester study, transgender male youth aged 13-21 suffered substantial emotional distress and functional impairment from dysphoria related to their chest. Chest dysphoria resolved with surgery. Youth reported improvement functionally and in quality of life (Mehringer et al 2021).

66. In the past 10 years, there has been a reversal in longstanding coverage policies that had excluded reimbursement of gender-affirming care for transgender people. There are many more clinics providing care to transgender youth and adults in academic medical centers than a decade ago, because funding is now available. This change is allowing clinical researchers to expand the body of research in the United States, as well as increasing access to care.

G. The GAPMS Memo and AHCA's Decision to Prohibit Medicaid Coverage of Gender-Affirming Care

67. According to criteria of the Florida Administrative Code 59G-1.035, the Agency for Health Care Administration (AHCA) makes coverage determinations based on "Generally accepted professional medical standards—standards based on reliable scientific evidence published in peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations' recommendations." It is my understanding that AHCA purports to have used the standards set forth in this rule to reach the conclusion set forth in its June 2022 GAPMS Memo that gender-affirming care, including puberty blockers, hormone replacement therapy, and gender-affirming surgery does not meet generally accepted professional medical standards and, is therefore, experimental and investigational.

68. To craft the GAPMS Memo (which served as the basis for AHCA's decision to ban gender-affirming care in accordance with Fla. Admin. Code R. 59G-1.050(7)), AHCA enlisted Drs. Romina Brignardello-Petersen and Wojtek

Wiercioch. Dr. Brignardello-Petersen is a dentist who is an assistant professor in the Department of Health Research Methods, Evidence, and Impact at McMaster University in Canada. Dr. Wiercioch is a post-doctoral research fellow in the same department as Dr. Brignardello-Petersen. Both authors report no academic interests in the care of people with gender dysphoria.

69. Drs. Brignardello-Petersen and Wiercioch performed a manual search of websites that includes only one non-governmental organization site: the Society for Evidence-Based Gender Medicine (SEGM). The fact that SEGM was chosen instead of much larger and more established organizations representing the mainstream of care, e.g., the American Psychological Association, the American Medical Association, or the American Psychiatric Association, raises a concern for bias, as SEGM is a small group founded recently specifically in opposition to gender-affirming care.

70. To support the conclusions provided to AHCA, Drs. Brignardello-Petersen and Wiercioch preferentially relied on studies that only included participants under age 25. Drs. Brignardello-Petersen and Wiercioch do not provide a basis to support their selection of only these studies, or of leaving out a multitude of other studies that include participants that are over age 25. In my experience working with people on Medicaid, those who seek gender-affirming surgery are mostly over 25. Thus, reliance on studies related only to those under age 25 does not

accurately capture the full body of scientific evidence pertaining to this form of care. This is especially important given that the GAPMS memo concludes that gender-affirming care is not a generally accepted professional medical standard for individuals at any age.

71. Drs. Brignardello-Petersen and Wiercioch relied on an overview of selected systematic reviews of studies of transgender care, with quality of evidence ranked by GRADE criteria. GRADE criteria assigns low quality scores to studies not performed by randomized, blinded clinical trials. However, randomly selecting people to receive or not receive gender-affirming medical or surgical interventions is impossible, for practical and ethical reasons. Notably, many treatments for other conditions are in widely accepted use without having been studied through randomized, controlled clinical trials. Many drugs for cancer and hematologic disorders have been FDA approved without a randomized controlled trial (Hatswell, et al., 2016). Many other drugs have been FDA approved with randomized controlled trials for one indication, but are commonly used for another condition or in a different population than the one for which it was approved (Wittich, et. al., 2012).

72. People have been receiving gender-affirming medical and surgical treatment for well over half a century, with very low regret rates (Dhejne, et al 2014), and there is substantial research and clinical experience that supports gender-affirming care as treatment for gender dysphoria. The scientific evidence "published

in peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations" led the American Medical Association, the American Academy of Pediatrics, the American Psychiatric Association, the American Psychological Association, and other mainstream medical organizations to conclude that the provision of gender-affirming medical and surgical interventions falls within generally accepted professional medical standards.

73. Another person enlisted to provide an opinion to AHCA in drafting its GAPMS memo is James Cantor, PhD, a forensic psychologist in Toronto, Canada. Dr. Cantor's report indicates that his work at the University of Toronto from 1998 to 2018 was limited to its adult forensic program, that is, Dr. Cantor worked with people with paraphilias,[2] and in particular with pedophiles. Dr. Cantor is well known for this work, but not for his work with transgender people. In testimony in *Eknes-Tucker v. Marshall*, Dr. Cantor stated that he had not personally diagnosed any child or adolescent with gender dysphoria, and that he had personally never treated any child or adolescent for gender dysphoria.

[2] Paraphilias are persistent and recurrent sexual interests, urges, fantasies, or behaviors of marked intensity involving objects, activities, or even situations that are atypical in nature. Being transgender is not a paraphilic disorder.

74. Dr. Cantor agrees that transgender adults "adjust well to life as the opposite sex" if they are otherwise mentally healthy. Dr. Cantor is also correct to report that regret rates are low.

75. Dr. Cantor focuses on desistance rates of prepubertal children brought into clinics in Toronto and Amsterdam. However, given that these prior longitudinal studies included gender nonconforming children who were not transgender due to the broad criteria for the since-abandoned "gender identity disorder in children" diagnosis, or who did not qualify even for the gender identity disorder in children diagnosis, these studies shed little light into questions of persistence and desistance of gender dysphoria in pre-pubertal children. In fact, a more recent study, which is the only large American prospective study that has been published in the past 35 years, showed much lower desistance rates (Olson, et al., 2022). Specifically, only 2.5% of the youth studied identified with their sex assigned at birth.[3]

76. In any event, longitudinal studies show that gender dysphoria in adolescence usually persists (DeVries, et al., 2011). And no medical treatment, let alone irreversible medical and surgical interventions, is used prior to puberty. Even in the clinics with higher desistance rates for *pre-pubertal* children upon which Dr.

[3] Of these, youth with cisgender identities were more common among youth whose initial social transition occurred before age 6 years; their retransitions often occurred before age 10 years. And, again, no medical treatment is recommended for any transgender person prior to the onset of puberty.

Cantor relies, puberty blockers and hormones were used when gender dysphoria persisted after the onset of puberty. In sum, the desistance statistics of *pre-pubertal* children do not inform the decision whether or not to initiate these treatments in adolescents and adults.

77. The WPATH Standards of Care and the American Psychiatric Association each recommend that transgender people who also suffer from depression, anxiety, and other mental health symptoms should seek out treatment for these symptoms. However, in most cases, having a history of mental illness should not prevent people from receiving gender-affirming medical and surgical treatment. (Coleman, et al., 2012; Byne, et al., 2018).

78. Dr. Cantor uses the term "affirmation on demand" as a straw man. The WPATH Standards of Care require a comprehensive mental health assessment for patients who are minors, and clinical assessments are also required for adults. (Coleman, et al., 2012).

79. Dr. Cantor cites a Finnish study as evidence for his conclusion that adolescents should not be prescribed gender-affirming hormones because they are supposedly not effective in the treatment of gender dysphoria. (Kaltiala, et al, 2020). However, in that study, after starting hormones, the need for treatment for depression dropped from 54% of the youth to 15%; the need for treatment for anxiety dropped

from 48% of the youth to 15%; and the need for treatment for suicidality/self-harm dropped from 35% to 4%. All of these were statistically highly significant changes.

80. Dr. Cantor states that the study by Kuper, et al. 2020 did not show benefit from treatment. This statement is misleading at best. The article concludes, "Youth reported large improvements in body dissatisfaction ($P < .001$), small to moderate improvements in self-report of depressive symptoms ($P < .001$), and small improvements in total anxiety symptoms ($P < .01$)." Dr. Cantor further states that the study by Achille et al. does not show that those studied benefitted from endocrine treatment. Again, Cantor's characterization of this study's conclusion is misleading. The results of the paper actually show that, "Mean depression scores and suicidal ideation decreased over time while mean quality of life scores improved over time. When controlling for psychiatric medications and engagement in counseling, regression analysis suggested improvement with endocrine intervention. This reached significance in male-to-female participants."

81. In reviewing the international health care consensus regarding gender-affirming care, Dr. Cantor refers to an interim report on care of transgender youth in the United Kingdom's National Health System which is currently being compiled by Dr. Hilary Cass. The interim report states that the final report will synthesize published evidence with expert opinion and stakeholder input. Notably, the interim report recommends increasing the number of health providers, shortening wait times,

and increasing the number of centers across the country providing care to transgender youth.

82. Swedish and Finnish national health authorities, which Dr. Cantor also references, have recommended caution and more research but have not banned care for transgender youth. In these countries, gender-affirming care for adults and for youth who qualify is fully paid for by the national health system of each country.

83. There remains strong international support for the continued provision of gender-affirming medical and surgical care. Experts from the around the world have collaborated on the new WPATH Standards of Care Version 8. I am chapter lead of the Mental Health chapter of this version, and the authors of that chapter include psychiatrists who are leaders of transgender health programs in Belgium, Sweden, and Turkey. There is broad agreement in philosophy of care, including support for gender-affirming care and opposition to conversion therapy.

84. The ethics of providing transgender care are discussed by one expert, Dr. G. Kevin Donovan. Dr. Donovan ignores the larger ethical question raised by Florida's actions to terminate Medicaid coverage of gender-affirming care for those who were previously approved for that same coverage. Florida's actions amount to forced detransition. As Dr. Donovan states, the principles of ethical care include autonomy, beneficence, and justice. There has been little research on those forced to detransition, but abruptly terminating Medicaid coverage for low-income and

disabled Floridians will force these Medicaid recipients and their health providers into detransition, an experiment to which they did not consent. Autonomy, beneficence, and justice are entirely ignored in this experiment, with no respect for the autonomy of the individual to decide their course, no concern for "do no harm" or maximizing benefits and minimizing harm, and no justice—fairness in distribution of risks and benefits—as the poor and those with disabilities will be forced into this detransition experiment while those with resources will be spared.

85. I have only had a few patients over the years who have been forced to detransition, because of incarceration or institutionalization, or other circumstances, and results have been uniformly disastrous, with suicide and self-harm attempts, depression, and deterioration of functioning. Some of my patients forced to detransition were receiving intensive mental health care at the time, on psychiatric wards. But no amount of psychotherapy could counter the deleterious effects of forced detransition and the withholding of needed gender-affirming medical and surgical care.

IV. CONCLUSION

86. The categorical exclusion of coverage for gender-affirming medical care adopted by Florida's Agency for Health Care Administration, which bars coverage for medical treatments for gender dysphoria, is contrary to widely accepted medical protocols for the treatment of transgender people with gender dysphoria that

are recognized by major medical and mental health professional associations in the United States.

87. The accepted protocols for the treatment of transgender people with gender dysphoria provide for mental health assessments, including of co-occurring conditions; criteria for eligibility for each treatment; and an informed consent process before medical interventions are initiated.

88. Decades of medical research and clinical experience have demonstrated that the medical treatments AHCA has barred from Medicaid coverage are safe, effective, and medically necessary to relieve gender dysphoria for transgender people. AHCA's conclusion otherwise is not supported by medical evidence or consensus.

89. Denying gender-affirming medical care to transgender people for whom it is medically indicated puts them at risk of significant harm to their health and wellbeing, including heightened risk of depression and suicidality.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 10th day of September 2022.

Dan H. Karasic, M.D.

EXHIBIT A

Curriculum Vitae

University of California, San Francisco

CURRICULUM VITAE

Name: Dan H. Karasic, MD

Position: Professor Emeritus
Psychiatry
School of Medicine

Voice: 415-935-1511
Fax: 888-232-9336

EDUCATION

1978 - 1982	Occidental College, Los Angeles	A.B.; Summa Cum Laude	Biology
1982 - 1987	Yale University School of Medicine	M.D.	Medicine
1987 - 1988	University of California, Los Angeles	Intern	Medicine, Psychiatry, and Neurology
1988 - 1991	University of California, Los Angeles; Neuropsychiatric Institute	Resident	Psychiatry
1990 - 1991	University of California, Los Angeles; Department of Sociology	Postdoctoral Fellow	Training Program in Mental Health Services for Persons with AIDS

LICENSES, CERTIFICATION

1990	Medical Licensure, California, License Number G65105
1990	Drug Enforcement Administration Registration Number BK1765354
1993	American Board of Psychiatry and Neurology, Board Certified in Psychiatry

PRINCIPAL POSITIONS HELD

1991 - 1993	University of California, San Francisco	Health Sciences Psychiatry Clincial Instructor
1993 - 1999	University of California, San Francisco	Health Sciences Psychiatry Assistant Clinical Professor
1999 - 2005	University of California, San Francisco	Health Sciences Psychiatry

		Associate Clinical Professor	
2005 - present	University of California, San Francisco	Health Sciences Psychiatry Clinical Professor	

OTHER POSITIONS HELD CONCURRENTLY

1980 - 1980	Associated Western Universities / U.S. Department of Energy	Honors Undergraduate Research Fellow	UCLA Medicine
1981 - 1981	University of California, Los Angeles; American Heart Association, California Affiliate	Summer Student Research Fellow	UCLA Medicine
1986 - 1987	Yale University School of Medicine; American Heart Association, Connecticut Affiliate	Medical Student Research Fellow	Psychiatry
1990 - 1991	University of California, Los Angeles Postdoctoral	Sociology Fellow	
1991 - 2001	SFGH Consultation-Liaison Service; AIDS Care	Attending Psychiatrist	Psychiatry
1991 - 2001	AIDS Consultation-Liaison Medical Student Elective	Course Director	Psychiatry
1991 - present	UCSF Positive Health Program at San Francisco General Hospital (Ward 86)	HIV/AIDS Outpatient Psychiatrist	Psychiatry
1991 - present	UCSF AHP (AIDS Health Project/Alliance Health Project)	HIV/AIDS Outpatient Psychiatrist	Psychiatry
1994 - 2002	St. Mary's Medical Center CARE Unit. The CARE Unit specializes in the care of patients with AIDS dementia.	Consultant	Psychiatry
2001 - 2010	Depression and Antiretroviral Adherence Study (The H.O.M.E. study: Health Outcomes of Mood Enhancement)	Clinical Director	Psychiatry and Medicine
2003 - 2020	Transgender Life Care Program and Clinic, Castro Mission Health Center	Psychiatrist Dimensions Clinic	Dimensions
2013 - 2020	UCSF Alliance Health Project, Co-lead, Transgender Team	Co-Lead and Psychiatrist	Psychiatry

HONORS AND AWARDS

1981	Phi Beta Kappa Honor Society	Phi Beta Kappa
1990	NIMH Postdoctoral Fellowship in Mental Health Services for People with	National Institute of Mental Health

	AIDS (1990-1991)	
2001	Lesbian Gay Bisexual Transgender Leadership Award, LGBT Task Force of the Cultural Competence and Diversity Program	SFGH Department of Psychiatry
2006	Distinguished Fellow	American Psychiatric Association
2012	Chancellor's Award for Leadership in LGBT Health	UCSF

KEYWORDS/AREAS OF INTEREST

Psychiatry, HIV/AIDS, consultation-liaison, medication adherence, gay/lesbian, transgender, gender dysphoria, sexuality, homeless/marginally housed, mood disorders, teaching/supervision

CLINICAL ACTIVITIES SUMMARY

As psychiatrist for the Positive Health Practice at Ward 86, I evaluated and treated patients with psychiatric illness and HIV. I provide consultation to internists, fellows, and nurse practitioners on managing psychiatric illness in their patients. Clinical work includes attention to the needs of special populations, including working with a multidisciplinary team in a drop-in clinic for HIV-positive women, and addressing issues emerging in HIV and Hepatitis C co-infection. As psychiatrist at the UCSF Alliance Health Project, I evaluated and treated patients and I am co-chair of the Gender Team, which provides assessment and care for transgender patients. As psychiatrist for the Transgender Life Care program and Dimensions Clinic, I evaluate and treat transgender patients, working with a multidisciplinary team at Castro Mission Health Center. In my faculty practice, I treated transgender, gender dysphoric, and HIV-positive patients referred from providers across Northern California, and I provide consultation on challenging cases to psychologists and other psychotherapists working with transgender and gender dysphoric patients.

MEMBERSHIPS

1992 - present Northern California Psychiatric Society

1992 - present American Psychiatric Association

2000 - 2019 Bay Area Gender Associates (an organization of psychotherapists working with transgendered clients)

2001 - present World Professional Association for Transgender Health

SERVICE TO PROFESSIONAL ORGANIZATIONS

1981 - 1982	The Occidental	News Editor
1984 - 1985	Yale University School of Medicine	Class President
1989 - 1991	Kaposi's Sarcoma Group, AIDS Project Los Angeles	Volunteer Facilitator
1992 - 1996	Early Career Psychiatrist Committee, Association of Gay and Lesbian Psychiatrists	Chair and
1992 - 1996	Board of Directors, Association of Gay and Lesbian Psychiatrists	Member

1993 - 1993	Local Arrangements Committee, Association of Gay and Lesbian Psychiatrists	Chair
1994 - 1995	Educational Program, Association of Gay and Lesbian Psychiatrists, 1995 Annual Meeting	Director
1994 - 1998	Board of Directors, BAY Positives	Member
1994 - present	Committee on Lesbian, Gay, Bisexual and Transgender Issues, Northern California Psychiatric Society	Member
1995 - 1997	Board of Directors, Bay Area Young Positives. BAY Positives is the nation's first community-based organization providing psychosocial and recreational services to HIV-positive youth	President
1995 - 1997	Executive Committee, Bay Area Young Positives.	Chair
1996 - 2004	Committee on Lesbian, Gay, Bisexual and Transgender Issues, Northern California Psychiatric Society	Chair
1998 - 2002	City of San Francisco Human Rights Commission, Lesbian, Gay Bisexual Transgender Advisory Committee	Member
2000 - 2004	Association of Gay and Lesbian Psychiatrists. for the organization's educational programs	Vice President Responsible
2004 - 2005	Association of Gay and Lesbian Psychiatrists	President-elect
2005 - 2007	Caucus of Lesbian, Gay, and Bisexual Psychiatrists of the American Psychiatric Association	Chair
2005 - 2007	Association of Gay and Lesbian Psychiatrists	President
2007 - 2009	Association of Gay and Lesbian Psychiatrists	Immediate Past President
2009 - 2010	Consensus Committee for Revision of the Sexual and Gender Identity Disorders for DSM-V, GID of Adults subcommittee. (Wrote WPATH recommendations as advisory body to the APA DSM V Committee for the Sexual and Gender Identity Disorders chapter revision.)	Member
2010 - 2011	Scientific Committee, 2011 WPATH Biennial Symposium, Atlanta	Member
2010 -2022	World Professional Association for Transgender Care Standards of Care Workgroup and Committee (writing seventh and eighth revisions of the WPATH Standards of Care, which is used internationally for transgender care.)	Member
2010 - 2018	ICD 11 Advisory Committee, World Professional Association for Transgender Health	Member
2012 - 2014	Psychiatry and Diagnosis Track Co-chair, Scientific Committee, 2014 WPATH Biennial Symposium, Bangkok	Member
2014 - 2016	Scientific Committee, 2016 WPATH Biennial Symposium, Amsterdam	Member

2014 - 2018	Board of Directors (elected to 4 year term), World Professional Association for Transgender Health	Member
2014 - 2018	Public Policy Committee, World Professional Association for Transgender Health	Chair
2014 - 2018	WPATH Global Education Initiative: Training providers and specialty certification in transgender health	Trainer and Steering Committee Member
2014 - 2016	American Psychiatric Association Workgroup on Gender Dysphoria	Member
2016 - present	American Psychiatric Association Workgroup on Gender Dysphoria	Chair
2016	USPATH: Inaugural WPATH U.S. Conference, Los Angeles, 2017	Conference Chair

SERVICE TO PROFESSIONAL PUBLICATIONS

2011 - present Journal of Sexual Medicine, reviewer

2014 - present International Journal of Transgenderism, reviewer

2016 - present LGBT Health, reviewer

INVITED PRESENTATIONS - INTERNATIONAL

2009	World Professional Association for Transgender Health, Oslo, Norway	Plenary Session Speaker
2009	World Professional Association for Transgender Health, Oslo, Norway	Symposium Speaker
2009	Karolinska Institutet, Stockholm Sweden	Invited Lecturer
2012	Cuban National Center for Sex Education (CENESEX), Havana, Cuba	Invited Speaker
2013	Swedish Gender Clinics Annual Meeting, Stockholm, Sweden	Keynote Speaker
2013	Conference on International Issues in Transgender care, United Nations Development Programme - The Lancet, Beijing, China	Expert Consultant
2014	World Professional Association for Transgender Health, Bangkok, Thailand	Track Chair
2014	World Professional Association for Transgender Health, Bangkok, Thailand	Invited Speaker
2014	World Professional Association for Transgender Health, Bangkok, Thailand	Invited Speaker
2015	European Professional Association for Transgender Health, Ghent, Belgium	Invited Speaker
2015	European Professional Association for Transgender Health, Ghent, Belgium	Symposium Chair

2015	Israeli Center for Human Sexuality and Gender Identity, Aviv	Invited Speaker Tel
2016	World Professional Association for Transgender Health, Amsterdam	Symposium Chair
2016	World Professional Association for Transgender Health, Amsterdam	Invited Speaker
2016	World Professional Association for Transgender Health, Amsterdam	Invited Speaker
2017	Brazil Professional Association for Transgender Health, Paulo	Sao
2017	Vietnam- United Nations Development Programme Asia Transgender Health Conference, Hanoi	
2018	United Nations Development Programme Asia Conference on Transgender Health and Human Rights, Bangkok	
2018	World Professional Association for Transgender Health, Buenos Aires	Invited Speaker
2021	Manitoba Psychiatric Association, Keynote Speaker	

INVITED PRESENTATIONS - NATIONAL

1990	Being Alive Medical Update, Century Cable Television	Televised Lecturer
1992	Institute on Hospital and Community Psychiatry, Toronto	Symposium Speaker
1992	Academy of Psychosomatic Medicine Annual Meeting, San Diego	Symposium Speaker
1994	American Psychiatric Association 150th Annual Meeting, Philadelphia	Workshop Chair
1994	American Psychiatric Association 150th Annual Meeting, Philadelphia	Workshop Speaker
1994	American Psychiatric Association 150th Annual Meeting, Philadelphia	Paper Session Co-chair
1995	Spring Meeting of the Association of Gay and Lesbian Psychiatrists, Miami Beach	Symposium Chair
1996	American Psychiatric Association 152nd Annual Meeting, New York	Workshop Speaker
1997	American Psychiatric Association Annual Meeting, San Diego	Workshop Speaker
1997	Gay and Lesbian Medical Association Annual	Invited Speaker Symposium
1998	American Psychiatric Association Annual Meeting,	Workshop Chair

	Toronto	
1998	American Psychiatric Association Annual Meeting, Toronto	Workshop Chair
1998	American Psychiatric Association Annual Meeting, Toronto	Media Session Chair
1998	American Psychiatric Association Annual Meeting, Toronto	Media Session Chair
1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Symposium Chair
1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Symposium Presenter
1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Workshop Chair
2000	American Psychiatric Association Annual Meeting, Chicago	Workshop Chair
2000	National Youth Leadership Forum On Medicine, University of California, Berkeley	Invited Speaker
2001	American Psychiatric Association Annual Meeting, New Orleans	Workshop Chair
2001	American Psychiatric Association Annual Meeting, New Orleans	Media Program Chair
2001	Association of Gay and Lesbian Psychiatrists Symposium, New Orleans	Chair
2001	Harry Benjamin International Gender Dysphoria Association Biennial Meeting, Galveston, Texas	Invited Speaker
2002	American Psychiatric Association Annual Meeting, Philadelphia	Media Program Chair
2002	American Psychiatric Association Annual Meeting, Philadelphia	Workshop Chair
2002	American Psychiatric Association Annual Meeting, Philadelphia	Workshop Chair
2003	Association of Gay and Lesbian Psychiatrists CME	Chair Conference
2003	American Psychiatric Association Annual Meeting, San Francisco	Symposium Chair
2003	American Psychiatric Association Annual Meeting, San Francisco	Symposium Co-Chair
2003	American Psychiatric Association Annual Meeting, San Francisco	Workshop Chair

2003	American Public Health Association Annual Meeting, San Francisco	Invited Speaker
2004	Mission Mental Health Clinic Clinical Conference	Invited Speaker
2004	Association of Gay and Lesbian Psychiatrists Conference, New York	Co-Chair
2004	Mental Health Care Provider Education Program: Los Angeles. Sponsored by the American Psychiatric Association Office of HIV Psychiatry	Invited Speaker
2005	American Psychiatric Association Annual Meeting, Atlanta	Workshop Speaker
2005	Association of Gay and Lesbian Psychiatrists Saturday Symposium	Invited Speaker
2008	Society for the Study of Psychiatry and Culture, San Francisco	Invited Speaker
2009	American Psychiatric Association Annual Meeting, San Francisco	Symposium Speaker
2011	National Transgender Health Summit, San Francisco	Invited Speaker
2011	National Transgender Health Summit, San Francisco	Invited Speaker
2011	American Psychiatric Association Annual Meeting, Honolulu, HI	Symposium Chair
2011	American Psychiatric Association Annual Meeting, Honolulu, HI	Symposium Speaker
2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA	Invited Speaker
2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA	Invited Speaker

Invited Speaker

2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA	
2011	Institute on Psychiatric Services, San Francisco	Invited Speaker
2012	Gay and Lesbian Medical Association Annual Meeting	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	American Psychiatric Association Annual Meeting, San Francisco	Invited Speaker
2013	Gay and Lesbian Medical Association, Denver, CO	Invited Speaker
2014	American Psychiatric Association Annual Meeting, New	Invited Speaker York
2014	Institute on Psychiatric Services, San Francisco	Moderator
2014	Institute on Psychiatric Services, San Francisco	Invited Speaker
2014	Institute on Psychiatric Services, San Francisco	Invited Speaker
2015	National Transgender Health Summit, Oakland, CA	Invited Speaker
2015	National Transgender Health Summit, Oakland, CA	Invited Speaker
2015	American Psychiatric Association Annual Meeting, Toronto	Workshop Speaker
2015	American Psychiatric Association Annual Meeting, Toronto	Course Faculty
2016	American Psychiatric Association Annual Meeting	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Atlanta	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Springfield, MO	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Fort Lauderdale, FL	Course Faculty
2017	World Professional Association for Transgender Health, GEI, Los Angeles Course Faculty	
	World Professional Association for Transgender Health	

Surgeon's Training, Irvine, CA Course Faculty

2017 American Urological Association Annual Meeting, San Francisco CA Invited Speaker

2018 World Professional Association for Transgender Health GEI, Portland OR, Course Faculty

2018 World Professional Association for Transgender Health GEI, Palm Springs, Course Faculty

2019 American Society for Adolescent Psychiatry Annual Meeting, San Francisco, Speaker

2019 American Psychiatric Association Annual Meeting, San Francisco, Session Chair

2020 Psychiatric Congress, Invited Speaker

INVITED PRESENTATIONS - REGIONAL AND OTHER INVITED PRESENTATIONS

1990 Advanced Group Therapy Seminar, UCLA Neuropsychiatric Institute Invited Lecturer

1991 Joint Project of the Southern California AIDS Interfaith Council and UCLA School of Medicine Symposium Speaker

1991 Joint Project of the Southern California AIDS Interfaith Council and UCLA School of Medicine Workshop Panelist

1992 Advanced Group Therapy Seminar, UCLA Neuropsychiatric Institute Invited Lecturer

1993 UCSF School of Nursing Invited Lecturer

1995 UCSF/SFGH Department of Medicine Clinical Care Conference Invited Speaker

1996 UCSF School of Nursing Invited Speaker

1996 Psychopharmacology for the Primary Care AIDS/Clinician, series of four lectures, UCSF Department of Medicine Invited Lecturer

1996 UCSF AIDS Health Project Psychotherapy Internship Training Program

1996 UCSF/SFGH Department of Medicine AIDS Quarterly Update Invited Speaker

Invited Speaker

1996 San Francisco General Hospital, Division of Addiction Medicine Invited Speaker

1996 UCSF Langley Porter Psychiatric Hospital and Clinics Invited Speaker Grand Rounds

1997 UCSF School of Nursing Invited Speaker

1997 UCSF Department of Medicine AIDS Program Invited Speaker

1997 Northern California Psychiatric Society Annual Meeting, Monterey Workshop Speaker

1997 San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds

1997 San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds

1997 Northern California Psychiatric Society LGBT Committee Chair Fall Symposium

1997 Progress Foundation, San Francisco Invited Speaker

1998 San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds

1999 Northern California Psychiatric Society Annual Meeting, Santa Rosa Invited Speaker

1999 Northern California Psychiatric Society Annual Meeting, Santa Rosa Invited Speaker

1999 University of California, Davis, Department of Psychiatry Invited Speaker Grand Rounds

1999 California Pacific Medical Center Department of Invited Speaker Psychiatry Grand Rounds

1999 San Francisco General Hospital Department of Psychiatry Discussant Departmental Case Conference

2000 Langley Porter Psychiatric Hospital and Clinics Invited Speaker Consultation Liaison Seminar

2000 San Francisco General Hospital, Psychopharmacology Invited Speaker Seminar

2000 UCSF Transgender Health Conference, Laurel Heights Invited Speaker Conference Center

2000 Psychiatry Course for UCSF Second Year Medical Invited Lecturer Students

2000 Community Consortium Treatment Update Symposium, California Pacific Medical Center, Davies Campus Invited Speaker

2000	San Francisco General Hospital Department of Psychiatry Grand Rounds	Invited Speaker
2001	Psychiatry Course for UCSF Second Year Medical Students	Invited Lecturer
2003	Tom Waddell Health Center Inservice	Invited Speaker
2003	San Francisco Veterans Affairs Outpatient Clinic	Invited Speaker
2004	San Francisco General Hospital Psychiatric Emergency Service Clinical Conference	Invited Speaker
2004	South of Market Mental Health Clinic, San Francisco	Invited Speaker
2005	Northern Psychiatric Psychiatric Society Annual Meeting	Invited Speaker
2005	Equality and Parity: A Statewide Action for Transgender Prevention and Care, San Francisco	Invited Speaker HIV
2005	San Francisco General Hospital Department of Psychiatry Grand Rounds.	Invited Speaker
2006	SFGH/UCSF Department of Psychiatry Grand Rounds	Invited Speaker
2007	UCSF Department of Medicine, HIV/AIDS Grand Rounds, Positive Health Program	Invited Speaker
2007	California Pacific Medical Center LGBT Health Symposium, San Francisco LGBT Community Center	Invited Speaker
2007	UCSF CME Conference, Medical Management of HIV/AIDS, Fairmont Hotel, San Francisco	Invited Speaker
2008	UCSF Department of Medicine, Positive Health Program, HIV/AIDS Grand Rounds	Invited Speaker
2008	San Francisco General Hospital Psychiatry Grand Rounds	Invited Speaker
2008	UCSF CME Conference, Medical Management of HIV/AIDS, Fairmont Hotel, San Francisco	Invited Speaker
2010	Northern California Psychiatric Society Annual Meeting, Monterey, CA	Invited Speaker
2011	Transgender Mental Health Care Across the Life Span, Stanford University	Invited Speaker
2011	San Francisco General Hospital Department of Psychiatry Grand Rounds	Invited Speaker
2012	UCSF AIDS Health Project Invited Speaker 2012 San Francisco Veterans Affairs Medical Center.	
2013	Association of Family and Conciliation Courts Conference, Los Angeles, CA	Invited Speaker
2014	UCSF Transgender Health elective	Invited Speaker
2014	UCSF Department of Psychiatry Grand Rounds	Invited Speaker

2014	California Pacific Medical Center Department of Grand Rounds	Invited Speaker Invited Speaker Psychaitry
2014	UCLA Semel Institute Department of Psychiatry Grand Rounds	Invited Speaker
2015	UCSF Transgender Health elective	Invited Speaker
2015	Fenway Health Center Boston, MA (webinar)	Invited Speaker
2015	Transgender Health Symposium, Palm Springs	Invited Speaker
2015	Transgender Health Symposium, Palm Springs	Co-Chair
2015	Santa Clara Valley Medical Center Grand Rounds	Invited Speaker
2016	UCSF School of Medicine Transgender Health elective	Invited Speaker
2016	Langley Porter Psychiatric Institute APC Case Conference	Invited Speaker (2 session series)
2016	Zuckerberg San Francisco General Department of Psychiatry Grand Rounds	Invited Speaker
2016	UCSF Mini-Medical School Lectures to the Public	Invited Speaker
2021	Los Angeles County Department of Mental Health,	Invited Speaker

CONTINUING EDUCATION AND PROFESSIONAL DEVELOPMENT ACTIVITIES

2005	Northern California Psychiatric Society
2005	Northern California Psychiatric Society Annual Meeting, Napa
2005	Association of Gay and Lesbian Psychiatrist Annual Conference
2006	Annual Meeting, American Psychiatric Association, Atlanta
2006	Annual Meeting, American Psychiatric Association, Toronto
2006	Institute on Psychiatric Services, New York
2007	Association of Gay and Lesbian Psychiatrists Annual Conference
2007	American Psychiatric Association Annual Meeting, San Diego
2007	The Medical Management of HIV/AIDS, a UCSF CME Conference
2008	Society for the Study of Psychiatry and Culture, San Francisco
2009	American Psychiatric Association, San Francisco
2009	World Professional Association for Transgender Health, Oslo, Norway
2010	Annual Meeting of the Northern California Psychiatric Society, Monterey, CA

2011	Transgender Mental Health Care Across the Life Span, Stanford University
2011	National Transgender Health Summit, San Francisco
2011	American Psychiatric Association Annual Meeting, Honolulu, HI
2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA
2011	Institute on Psychiatric Services, San Francisco
2012	Gay and Lesbian Medical Association Annual Meeting, San Francisco
2013	National Transgender Health Summit, Oakland, CA
2013	American Psychiatric Association Annual Meeting, San Francisco
2013	Gay and Lesbian Medical Association, Denver, CO
2014	American Psychiatric Association Annual Meeting, New York
2014	Institute on Psychiatric Services, San Francisco
2015	European Professional Association for Transgender Health, Ghent, Belgium
2015	National Transgender Health Summit, Oakland
2015	American Psychiatric Association Annual Meeting, Toronto
2016	American Psychiatric Association Annual Meeting, Atlanta
2016	World Professional Association for Transgender Health, Amsterdam

GOVERNMENT AND OTHER PROFESSIONAL SERVICE

1998 - 2002	City and County of San Francisco Human Rights Member Commission LGBT Advisory Committee

SERVICE ACTIVITIES SUMMARY

I am currently the course director for the LGBTQ Mental Health Course for UCSF Psychiatry Residents in Training.

I worked with urologist Maurice Garcia, MD on developing protocols as well as outcome measures for the UCSF Transgender Surgery Program at UCSF Medical Center. I am on the Medical Advisory Board of the UCSF Center of Excellence for Transgender Care, and have cowritten the mental health section of the original Primary Care Protocols and the new revision. I have chaired the Mental Health Track of UCSF's National Transgender Health Summit since its inception in 2011. I am a founder and co-chair of the Gender Team at the UCSF Alliance Health Project. I helped develop, and participated as a trainer, in the San Francisco
Department of Public Health provider training program for care of transgender patients and for mental health assessments for surgery, and have worked in program development for the SFDPH Transgender Health Services surgery program.

I am the chair of the American Psychiatric Association Workgroup on Gender Dysphoria, which developed a CME course fort the 2015 and 2016 APA Annual Meetings, and is now embarking on a larger educational mission to train American psychiatrists to better care for transgender patients. I have been leading education efforts in transgender health at APA meetings since 1998. On the APA Workgroup on Gender Dysphoria, I am a co-author of a paper of transgender issues that has been approved by the American Psychiatric Association as a resource document and is in press for the American Journal of Psychiatry. I am also the sole author of the chapter on transgender care in the American Psychiatric Press's Clinical Manual of Cultural Psychiatry, Second Edition.

I have been active internationally in transgender health through my work as a member of the Board of Directors of the World Professional Association for Transgender Health. I am an author of the WPATH Standards of Care, Version 7, and am Chapter Lead for the Mental Health Chapter of SOC 8.
I chaired of the WPATH Public Policy Committee and was a member of the Global Education Initiative, which developed a specialty certification program in transgender health. I helped plan the 2016 WPATH Amsterdam conference, and was on the scientific committee for the last four biennial international conferences. I was on the founding committee of USPATH, the national affiliate of WPATH, and I chaired the inaugural USPATH conference, in Los Angeles in 2017. As a member of the steering committee of the WPATH Global Educational Initiative, I helped train over 2000 health providers in transgender health, and helped develop a board certification program and examination in transgender health.

UNIVERSITY SERVICE UC SYSTEM AND MULTI-CAMPUS SERVICE

1991 - present HIV/AIDS Task Force Member

1992 - 1993 HIV Research Group Member

1992 - 1997 Space Committee Member

1992 - present Gay, Lesbian and Bisexual Issues Task Force Member

1994 - 1997 SFGH Residency Training Committee Member

1996 - 1997 Domestic Partners Benefits Subcommittee. Chair

1996 - 2000 Chancellor's Advisory Committee on Gay, Lesbian, and Transgender Issues. Member Bisexual

1996 - 2003 HIV/AIDS Task Force Co-Chair

1996 - 2003 Cultural Competence and Diversity Program Member

2009 - present Medical Advisory Board, UCSF Center of Excellence for Transgender Health Member

2010 - 2013 Steering Committee, Child Adolescent Gender Center Member

2011 – 2017 Mental Health Track, National Transgender Health Summit Chair

DEPARTMENTAL SERVICE

1991 - present San Francisco General Hospital, Department of Psychiatry, Member HIV/AIDS Task Force

1992 - 1993 San Francisco General Hospital, Department of Psychiatry, Member HIV Research Group

1992 - 1997 San Francisco General Hospital, Department of Psychiatry, Member Space Committee

1992 - 2003 San Francisco General Hospital, Department of Psychiatry, Member GLBT Issues Task Force

1994 - 1997 San Francisco General Hospital, Department of Psychiatry, Member Residency Training Committee

1996 - 2003 San Francisco General Hospital, Department of Psychiatry, Member Cultural Competence and Diversity Program

1996 - 2003 San Francisco General Hospital, Department of Psychiatry, Co-Chair HIV/AIDS Task Force

2012 - 2020 San Francisco Department of Public Health Gender Member Competence Trainings Committee

2013 - 2020 San Francisco Department of Public Health Transgender Member Health Implementation Task Force

2014 - 2020San Francisco General Hospital, Department of Psychiatry, Member Transgender Surgery Planning Workgroup

PEER REVIEWED PUBLICATIONS

1. Berliner JA, Frank HJL, **Karasic D**, Capdeville M. Lipoprotein-induced insulin resistance in aortic endothelium. Diabetes. 1984; 33:1039-44.
2. Bradberry CW, **Karasic DH**, Deutch AY, Roth RH. Regionally-specific alterations in mesotelencephalic dopamine synthesis in diabetic rats: association with precursor tyrosine. Journal of Neural Transmission. General Section, 1989; 78:221-9.
3. Targ EF, **Karasic DH**, Bystritsky A, Diefenbach PN, Anderson DA, Fawzy FI. Structured group therapy and fluoxetine to treat depression in HIV-positive persons. Psychosomatics. 1994; 35:132-7.
4. Karasic DH. Homophobia and self-destructive behaviors. The Northern California Psychiatric Physician. 1996; 37 Nov.-Dec. Reprinted by the Washington State Psychiatric Society and the Southern California Psychiatric Society newsletters.
5. Karasic D. Anxiety and anxiety disorders. Focus. 1996 Nov; 11(12):5-6. PMID: 12206111
6. Polansky JS, **Karasic DH**, Speier PL, Hastik KL, Haller E. Homophobia: Therapeutic and training considerations for psychiatry. Journal of the Gay and Lesbian Medical Association. 1997 1(1) 41-47.
7. Karasic DH. Progress in health care for transgendered people. Editorial. Journal of the Gay and Lesbian Medical Association, 4(4) 2000 157-8.
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EXPERT WITNESS AND CONSULTATION ON TRANSGENDER CARE AND RIGHTS

2008 Consultant, California Department of State Hospitals

2012 Dugan v. Lake, Logan UT

2012 XY v. Ontario http://www.canlii.org/en/on/onhrt/doc/2012/2012hrto726/2012hrto726.html

2014 Cabading v California Baptist University

2014 CF v. Alberta
http://www.canlii.org/en/ab/abqb/doc/2014/2014abqb237/2014abqb237.html

2017 United Nations Development Programme consultant, transgender health care and legal rights in the Republic of Vietnam; Hanoi.

2017- Forsberg v Saskatchewan; Saskatchewan Human Rights v Saskatchewan
2018 https://canliiconnects.org/en/summaries/54130
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2018 United Nations Development Programme consultant, transgender legal rights in Southeast Asia; Bangkok.

2018 Consultant, California Department of State Hospitals

2019, 2021 Consultant/Expert, Disability Rights Washington

2019, 2021 Consultant/Expert, ACLU Washington

2021 Consultant, California Department of Corrections and Rehabilitation

2021 Expert, Kadel v. Folwell, 1:19-cv-00272 (M.D.N.C.).

2021 Expert, Drew Glass v. City of Forest Park - Case No. 1:20-cv-914 (Southern District Ohio)

2021-2022 Expert, Brandt et al v. Rutledge et al. 4:21-cv-00450 (E.D. Ark.)

2021-2022 Expert, Fain v. Crouch, 3:20-cv-00740 (S.D.W. Va.)

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EXHIBIT B

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IN 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

EXPERT DECLARATION OF LOREN S. SCHECHTER, M.D.

I, Loren Schechter, pursuant to 28 U.S.C. §1746, declare as follows:

1. I am over the age of eighteen and submit this expert declaration based on my personal knowledge.

2. I am a board-certified plastic surgeon. I specialize in performing gender confirming surgeries[1] (including chest reconstruction surgeries, genital

[1] I refer to the family of procedures discussed in this report as "gender confirmation," "gender confirming surgeries," or "gender affirming surgeries" because they are one of the therapeutic tools used to enable people to be comfortable living in accordance with their gender identities. Out of the myriad of labels I've heard for these procedures—"sex reassignment surgery," "gender reassignment surgery," and "sex change operation," to name but a few—none is as accurate when it comes to describing what is actually taking place as "gender confirmation" or "gender affirmation surgery." Most, if not all, of the other names used for these procedures suggest that a person is making a choice to switch genders, or that there is a single "surgery" involved. From the hundreds of discussions I have had with patients over the years, nothing could be further from the truth. This is not about choice; it is about using one or more surgical procedures as therapeutic tools to enable people to live authentically.

reconstruction surgeries, and other procedures to feminize or masculinize the face and body, as described in more detail below), and I am a recognized expert in this field.

3. I have been retained by counsel for Plaintiffs in the above-captioned lawsuit to provide an expert opinion on the standards of care for treating individuals diagnosed with gender dysphoria. In particular, I have been asked whether: 1) gender confirming surgeries are safe and effective medical treatment for gender dysphoria experienced by transgender people, including adults over 21 and adolescents up to age 21; and 2) a categorical exclusion on Medicaid coverage for gender confirming surgeries violates the prevailing standards of care for treating transgender people, including adults over 21 and adolescents up to age 21, who have been diagnosed with gender dysphoria. Additionally, I submit this declaration to respond to points raised in both the assessment drafted by Patrick W. Lappert, M.D. ("Lappert Assessment") and the Florida Agency for Health Care Administration's "Florida Medicaid Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria" report ("GAPMS Report").

4. If called to testify in this matter, I would testify truthfully and based on my expert opinion. The opinions and conclusions I express herein are based on a reasonable degree of scientific certainty.

Qualifications and Experience

5. The information provided regarding my professional background, experiences, publications, and presentations are detailed in my curriculum vitae ("CV"). A true and correct copy of my most up-to-date CV is attached as Exhibit A.

6. I received my medical degree from the University of Chicago, Pritzker School of Medicine. I completed my residency and chief residency in plastic and reconstructive surgery and a fellowship in reconstructive microsurgery at the University of Chicago Hospitals.

7. I previously served as a Clinical Professor of Surgery at the University of Illinois at Chicago, and resigned that position to become the Director of Gender Affirmation Surgery at Rush University Medical Center in April 2022. I am also a Professor of Surgery at Rush University Medical Center. I also maintain a clinical practice in plastic surgery in Illinois where I treat patients from around the country, as well as from around the world.

8. I have been performing gender confirming surgeries for more than 27 years. For at least the past five years, I have been performing approximately 150 gender confirmation procedures every year. I have performed over 1,500 gender confirmation surgeries during my medical career. Currently, approximately 90 percent of the patients in my clinical practice are transgender people seeking gender confirmation surgeries.

9. I was a contributing author to the Seventh Version (current) of the World Professional Association for Transgender Health's ("WPATH") Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People ("Standards of Care"). In particular, I wrote the section focused on the relationship of the surgeon with the treating mental health professional and the physician prescribing hormone therapy. WPATH is in the final stages of drafting the eighth version of the Standards of Care, and I am the co-lead author of the surgical and postoperative care chapter.

10. The Standards of Care provide clinical guidance for health professionals based on the best available science and expert professional consensus. The purpose of the Standards of Care is to assist health providers in delivering medical care to transgender people in order to provide them with safe

and effective treatment for gender dysphoria, in order to maximize their overall health, psychological well-being, and self-fulfillment.

11. In addition, I have written a number of peer-reviewed journal articles and chapters in professional textbooks about gender confirmation surgeries. In 2016, I published Surgical Management of the Transgender Patient, the first surgical atlas (a reference guide for surgeons on how to perform surgical procedures using safe, well-established techniques) dedicated to gender confirming surgeries. In 2020, I published a guide for surgeons entitled Gender Confirmation Surgery: Principles and Techniques for an Emerging Field. I am also a co-investigator on a study regarding uterine transplantation for transgender women. A full and complete list of my publications is included in my CV.

12. I am a guest reviewer for several peer-reviewed medical journals, including the Journal of Plastic and Reconstructive Surgery, the Journal of Reconstructive Microsurgery, the Journal of the American College of Plastic Surgeons, the Journal of Plastic and Aesthetic Research, and the Journal of Sexual Medicine. I also serve on the editorial board of both Transgender Health and the International Journal of Transgender Health. Each of these

publications is a peer-reviewed medical journal. A full and complete list of my reviewerships and editorial roles is included in my CV.

13. I am actively involved in training other surgeons to perform gender confirmation surgeries. In 2017, I started the surgical fellowship in gender surgery, now placed at Rush University Medical Center in Chicago.

14. I have given dozens of public addresses, seminars, and lectures on gender confirming surgery, including many through the American Society of Plastic Surgeons. I have also taught a number of courses through WPATH's Gender Education Institute, which provides training courses toward a member certification program in transgender health for practitioners around the world. In addition, in 2018, I co-directed the first live surgery course in gender confirming procedures at Mount Sinai Hospital in New York City, and I am the Director for that live surgery course in 2022. In 2019, I directed the inaugural Gender Affirming Breast, Chest, and Body Master Class for the American Society of Plastic Surgeons.

15. I am also a founding member and president of the American Society of Gender Surgeons; a current member of the Executive Committee of the Board of Directors of the World Professional Association for Transgender Health, where I serve as treasurer; and a former member of the Board of

Governors of the American College of Surgeons. I am a guest examiner for the American Board of Plastic Surgery, which involves administering the plastic surgery oral board exam to surgeons who have completed their plastic surgery training and seek board certification. I am the former Chair of the Patient Safety Committee for the American Society of Plastic Surgeons. In 2017, I was an invited discussant at the Pentagon regarding transgender servicemembers.

16. In the past four years, I have testified as an expert and provided testimony in the following matters: *Willis v. Flagg, Cook County*, IL (trial); *Bruce v. South Dakota*, D. S.D. (deposition); *Boyden v. State of Wisconsin*, W.D. Wis. (deposition); *Kadel v. Folwell*, M.D.N.C. (deposition); *Toomey v. State of Arizona*, D. Ariz. (deposition); and *Fain v. Crouch*, S.D.W.V. (deposition).

17. I am being compensated at an hourly rate of $400/hour plus expenses for my time spent preparing this declaration, and providing local testimony (including deposition or providing hearing testimony by telephone or video-teleconference). I will be compensated a flat daily rate of $7,500 for any out-of-town deposition or hearing testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

Basis for Opinions

18. My opinions contained in this declaration are based on all of the following: (1) my clinical experience of over 27 years of caring for transgender patients, including adolescents and young adults; (2) my review and familiarity with relevant peer-reviewed literature,[2] including my own, regarding gender confirming surgeries, which reflects the clinical advancements in these procedures and the corresponding growth in research related to the safety and effectiveness of these procedures in treating gender dysphoria; and (3) discussions with colleagues and other experts in the field, including attendance and participation in various educational conferences both nationally and internationally. The research I relied on in preparing this declaration is cited in the footnotes and detailed in the reference list attached as Exhibit B to this declaration.

[2] I regularly and routinely perform literature searches as an educator, including in my roles as a Professor of Surgery at Rush University Medical Center and attending surgeon at Rush University, where I participate in fellow, resident, and student education; Director of Gender Affirmation Surgery at Rush University Medical Center; lecturer for the Global Education Initiative for WPATH; invited lecturer at national and international conferences; co-lead author of the surgery and post-operative care chapter of the upcoming WPATH Standards of Care Version 8; an editor and reviewer for peer-reviewed publications; and a course director for various educational opportunities for WPATH, American Society of Plastic Surgeons, and other organizations.

19. Additionally, in preparing this declaration, I reviewed the Lappert Assessment and GAPMS Report.

20. I have personal knowledge of the matters stated in this declaration. I may further supplement these opinions in response to information produced by Defendants or from Defendants' experts.

DISCUSSION

BACKGROUND ON GENDER IDENTITY AND GENDER DYSPHORIA

21. The term "transgender" is used to describe a diverse group of individuals whose gender identity, or internal sense of gender, differs from the sex they were assigned at birth.

22. Many transgender people experience gender dysphoria at some point in their lives. Gender dysphoria is a serious medical condition, defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) published by the American Psychiatric Association as "a difference between one's experienced/expressed gender and assigned gender, and significant distress or problems functioning." Gender dysphoria is also recognized by the International Classification of Diseases-11 (ICD-11), under the label of gender incongruence, and the International Classification of Diseases-10 (ICD-10). Individuals diagnosed with gender dysphoria have an intense and persistent

discomfort with the primary and/or secondary sex characteristics of the sex they were assigned at birth. Gender dysphoria can lead to debilitating anxiety and depression, as well as serious incidents of self-harm, including self-mutilation, suicide attempts, and suicide.

23. Appropriate medical care, including mental health services, hormone therapy, and gender confirmation surgeries can help alleviate gender dysphoria. Gender confirmation surgeries, which bring a person's body into better alignment with their gender identity, have been shown to be an effective treatment for gender dysphoria.

GENDER CONFIRMING SURGERIES ARE STANDARD, MEDICALLY ACCEPTED, AND MEDICALLY NECESSARY TREATMENTS FOR GENDER DYSPHORIA FOR TRANSGENDER PEOPLE

24. It is my professional opinion, supported by the prevailing consensus of the medical community, that procedures used to treat gender dysphoria are medically necessary treatments for many transgender people; these procedures are properly considered as medically necessary, and are not cosmetic in nature; and these procedures are safe and effective treatments for gender dysphoria.

Applicable Standards of Care for Treating Gender Dysphoria

25. WPATH is a non-profit professional and educational organization devoted to transgender health. WPATH's mission is "to promote evidence-based care, education, research, advocacy, public policy, and respect in transgender health."[3] WPATH publishes the Standards of Care. The Standards of Care are based on the best available scientific evidence and expert professional consensus. WPATH published the first version of the Standards of Care in 1979. Since that time, the guidelines have been updated through seven versions, reflecting the significant advances made in the understanding, management, and care of transgender individuals. The Standards of Care are widely recognized guidelines for the clinical management of transgender people with gender dysphoria. Most surgeons who regularly treat people experiencing gender dysphoria, including myself, practice in accordance with the Standards of Care.

26. As indicated in the Standards of Care, effective treatment options for gender dysphoria include mental health care, hormone therapy, and various surgical procedures to align a person's primary and/or secondary sex

[3] WPATH, Mission and Vision, https://www.wpath.org/about/mission-and-vision.

characteristics with the person's gender identity. (Standards of Care at 9-10.) Surgery is often the last and most considered of the treatment options for gender dysphoria in transgender people. Not every transgender person may undergo every available surgical procedure. In fact, the Standards of Care note that "[t]he number and sequence of surgical procedures may vary from patient to patient, according to their clinical needs." (Standards of Care at 58.) Evidence shows that while some transgender people do not require surgery, "for many others surgery is essential and medically necessary to alleviate their gender dysphoria. For the latter group, relief from gender dysphoria cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity." (Standards of Care at 54-55.)

27. The Standards of Care set forth criteria for initiation of surgical treatment. The Endocrine Society—the leading professional organization devoted to research on hormones and the clinical practice of endocrinology—has also issued clinical guidelines for the treatment of transgender people.[4]

[4] Wylie C Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. Clin. Endocrinology & Metabolism 3869 (2017).

The guidelines indicate, that for transgender people, gender confirming surgeries often are necessary and effective treatments.[5]

28. The broader medical community, including the American Medical Association, American Academy of Pediatrics, American Psychological Association, American Psychiatric Association, American College of Obstetricians and Gynecologists, American Academy of Family Physicians, and World Health Organization, recognizes that gender confirming surgeries are standard, appropriate, and often necessary treatments for adults and adolescents with gender dysphoria.

Surgical Treatments for Gender Dysphoria

29. For transgender women, surgical treatment options that are generally accepted in the medical community and are consistent with the Standards of Care include, but are not limited to:

- Chest reconstruction surgery: augmentation mammoplasty (breast implants);
- Genital reconstruction surgeries: penectomy (removal of the penis), orchiectomy (removal of the testes), vaginoplasty, clitoroplasty,

[5] *Id.*

and/or vulvoplasty (creation of female genitalia including the labia minora and majora);

- Non-genital, non-breast surgical interventions: facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal augmentation (implants/lipofilling), and hair reconstruction, among others.

30. For transgender men, surgical treatment options that are generally accepted in the medical community and are consistent with the Standards of Care include, but are not limited to:

- Chest reconstruction surgery: subcutaneous mastectomy, creation of a male chest;
- Genital surgery: hysterectomy/oophorectomy, reconstruction of the urethra, which can be combined with a metoidioplasty or with a phalloplasty (employing a pedicled or free vascularized flap), vaginectomy, scrotoplasty, and implantation of erection and/or testicular prostheses;
- Non-genital, non-breast surgical interventions: liposuction, lipofilling, pectoral implants, various aesthetic procedures, and sometimes voice surgery (rare).

31. The Standards of Care set forth medical necessity criteria for initiation of surgical treatment. For adults seeking chest and/or genital reconstruction procedures, the criteria are:

- The patient has the capacity to make fully informed decisions and to consent for treatment.
- If the patient has other significant medical or mental health concerns, they are reasonably well-controlled prior to surgery.
- The patient has persistent gender dysphoria as documented by at least one mental health professional for chest reconstruction surgeries and two such professionals for genital reconstruction surgeries.
- Prior to genital reconstruction surgery, the patient has undergone 12 continuous months of hormone therapy, unless hormone therapy is not clinically indicated for that patient.[6] The purpose of the prerequisite is to introduce a period of estrogen or testosterone suppression before the patient undergoes a surgical intervention.

[6] While not an explicit criterion, the Standards of Care recommend that individuals undergo 12 months of continuous hormone therapy prior to breast augmentation surgery to obtain the best possible outcome. (SOC at 59).

- Prior to certain genital reconstruction procedures – metoidioplasty, phalloplasty, or vaginoplasty – the patient has lived for 12 continuous months in a gender role that is congruent with their gender identity. The prerequisite ensures that the patient has ample opportunity to experience and socially adjust in their desired gender role, before undergoing this surgery.[7] (SOC at 60).

32. In addition, the Standards of Care, Version 7 recognize that male chest reconstruction surgery *may* be indicated for transgender young people under eighteen. As with all medical care, the standards recommend that clinicians take a case-by-case approach to evaluate whether and when the procedure is medically necessary for a particular patient. (SOC at 21). As with all medical care, the Standards of Care recommend that clinicians take a case-by-case approach to evaluate whether and when the procedure is medically necessary for a particular patient. (SOC at 21). Beyond those recommendations, the Standards of Care state criteria for initiation of surgical treatment: "Genital and breast/chest surgeries as medically necessary treatments for gender dysphoria are to be undertaken only after assessment of the patient by qualified

[7] While not an explicit criterion, the Standards of Care recommend that these individuals see a mental health or other medical professional during this 12 month period. (SOC at 60).

mental health professionals, as outlined in section VII of the SOC. These surgeries may be performed once there is written documentation that this assessment has occurred and that the person has met the criteria for a specific surgical treatment. By following this procedure, mental health professionals, surgeons, and patients share responsibility for the decision to make irreversible changes to the body." (SOC at 55).

Gender Confirmation Surgeries are Medically Necessary

33. The medical community and insurance providers recognize a distinction between surgery which is medically necessary, and cosmetic surgery, which generally is not. No particular procedure is inherently cosmetic or inherently medically necessary; rather, the underlying diagnosis determines whether the procedure is considered cosmetic or medically necessary.

34. With respect to surgical treatments for gender dysphoria, the medical community generally considers those surgeries to be medically necessary. This is true even though the same surgical procedures might be considered cosmetic when performed on someone without gender dysphoria. Gender confirming surgeries are not cosmetic because, when performed in accordance with the Standards of Care, they are clinically indicated to treat the underlying medical condition of gender dysphoria. Indeed, as explained further

below, the surgical procedures listed above to treat gender dysphoria are similar to surgical procedures performed for other diagnoses (e.g., breast cancer). Because these medically necessary procedures help transgender people live and present in a manner more consistent with their gender identity and therefore reduce and/or treat their gender dysphoria, the professional medical consensus is that these are appropriately categorized as medically necessary.

35. Certain surgical procedures are medically necessary when used to treat gender dysphoria or another medical condition, but are cosmetic when they are used only to alter one's appearance without an underlying medical diagnosis (e.g., a cisgender woman obtaining a breast augmentation for aesthetic reasons). While the procedures themselves are technically similar, the reasons for performing the procedures are not.

36. Dr. Lappert asserts that distinguishing "cosmetic breast surgery from 'medically necessary' surgery is based upon the diagnosis of the underlying pathology." Lappert Assessment at 13. I agree. What Dr. Lappert fails to acknowledge, however, is that breast augmentation or mastectomy may be medically indicated for the treatment of gender dysphoria, in addition to

other pathologies.[8] Gender-confirming surgeries are not cosmetic surgeries because, when performed in accordance with the Standards of Care, they are clinically indicated to treat the medical condition of gender dysphoria. The professional medical consensus recognizes that these are appropriately categorized as reconstructive procedures.

37. Dr. Lappert misunderstands that gender dysphoria is a medical condition for which there are effective medical and surgical treatments. While plastic surgeons may encounter individuals with mental health conditions, such as body dysmorphic disorder, surgery for this condition is highly ineffective. This is in contrast to surgery as treatment for gender dysphoria; where medically indicated, surgical procedures for gender dysphoria are both safe and medically effective.

38. Additionally, reconstructive surgery often has the additional benefit of promoting and improving a patient's quality of life and well-being; which is often a component of medically necessary care. Indeed, aside from the primary purpose of alleviating or reducing a patient's gender dysphoria, gender confirmation surgery also has been demonstrated to have other salutary effects,

[8] Dr. Lappert incorrectly refers to breast growth in transgender women as "gynecomastia." Gynecomastia refers to enlargement of the male breast, not to breast growth in transgender women.

such as improving quality of life and reducing negative health outcomes. In a study published in 2019 by Miller, et al., 100% of transgender women who underwent breast augmentation reported improvement in their gender dysphoria and "would undergo the operation again."[9] In a prospective study utilizing a validated quality of life assessment tool, Alcon, et al. demonstrated significant improvements in quality of life up to 1 year following chest surgery.[10] The authors indicated that "the effect sizes were large and…exhibited excellent internal validity." The authors report that "every patient surveyed at 1 year reported that gender-affirming surgery changed their life for the better" and that, "every patient surveyed after surgery said they would choose it (surgery) again knowing what they know." In addition, in a 2006 study published in Quality of Life Research, Newfield, et al. found that, "Chest reconstruction not only enhances the FTM transgender identity, increases self-esteem, and improves body image, but provides some security and safety for those who remove their shirts in public areas, such as gyms or beaches. Those who had

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[9] Travis J. Miller et al., *Breast Augmentation in Male-to-Female Transgender Patients: Technical Considerations and Outcomes*, 21 JPRAS Open 63-74 (2019).

[10] Loren S. Schechter, *Discussion: Quantifying the Psychosocial Benefits of Masculinizing Mastectomy in Trans Male Patients with Patient-Reported Outcomes: The University of California, San Francisco*, Gender Quality of Life Survey, 147 Plastic & Reconstructive Surgery 741e-742e (2021).

received top surgery reported higher QOL (quality of life) scores than those who had not received surgery, statistically significant findings ($p<0.01$) for the General Health, Social Functioning, and all three mental health concepts."[11]

GENDER CONFIRMING SURGERIES ARE SAFE AND EFFECTIVE

39. The prevailing peer-reviewed clinical research, as well as my own clinical expertise as a plastic surgeon specializing in gender confirmation surgeries, shows that surgical procedures for gender dysphoria are safe, effective, and medically accepted; and that many of these procedures are analogous to surgical procedures used to treat other medical conditions.

Gender Confirming Surgeries are Safe

40. It is my professional opinion, based on my clinical experience and review of available peer-reviewed research, that gender confirmation surgeries are safe. Notably, when performing gender confirmation surgeries, surgeons use many of the same procedures that they use to treat other medical conditions. The fact that the medical community deems these analogous procedures sufficiently safe to treat conditions other than gender dysphoria is by itself more than sufficient to support the safety of those surgeries to treat gender dysphoria.

[11] Emily Newfield et al., *Female-to-Male Transgender Quality of Life*, 15 Quality of Life Research 1447-1457 (2006).

There is no medical basis to conclude that the same surgical procedures are more or less safe simply because they are used to treat gender dysphoria, versus other underlying medical conditions.

41. For example, surgeons regularly perform mastectomies and chest/breast reconstruction, hysterectomies/salpingo-oophorectomies (which includes removal of the fallopian tubes and ovaries), and orchiectomies to treat individuals with cancer, or a genetic predisposition to cancer (BRCA 1, 2 genes in the case of prophylactic mastectomy or oophorectomy). Similarly, surgeons perform procedures to reconstruct external genitalia for individuals who have certain medical conditions (e.g., cancer) or who have suffered traumatic injuries or disabling infections to their genitalia. This would include procedures to correct conditions such as hypospadias (a disorder in which the urinary opening is not in the typical location on the glans penis), epispadias (a condition where the urethra is not properly developed), exstrophy (where the bladder develops outside the fetus), fournier's gangrene (where tissue dies because of an infection), penile webbing, or buried penis (which can occur as a result of obesity, diabetes, or recurrent infections). This would also include procedures to correct conditions such as congenital absence of the vagina or reconstruction

of the vagina/vulva following oncologic resection, traumatic injury, or infection.

42. Notably, Dr. Lappert concedes that chest reconstructive surgery in the form of a mastectomy is "very safe, and typically performed in the outpatient setting." Lappert Assessment at 13. Dr. Lappert also concedes that "[s]urgical enhancement procedures are exactly the same in both men and women." *Id*.

Gender Confirmation Surgeries Effectively Treat Gender Dysphoria

43. It is my professional opinion, based on decades of clinical experience, as well as a substantial body of peer-reviewed research, that standard medical surgical treatments for gender dysphoria are effective when performed in accordance with the Standards of Care.

44. Peer-reviewed studies find that transgender women who undergo one or more gender confirmation surgeries report positive health outcomes. For example, a peer-reviewed study of transgender women found that those who underwent breast reconstruction surgeries experienced statistically significant improvements in their psychosocial well-being.[12] Another peer-reviewed study

[12] Weigert, R., Frison, E., Sessiecq, Q., Mutairi, K. A., & Casoli, V. (2013). Patient Satisfaction with Breasts and Psychosocial, Sexual, and Physical Well-Being after Breast Augmentation in

of transgender women who had vaginoplasty found that study participants' mean improvement in quality of life after surgery was 7.9 on a scale from one to ten.[13] Another study of transgender women found that surgical interventions were highly correlated with alleviating gender dysphoria.[14] A recent literature review concluded that in appropriately selected individuals, gender confirmation surgery is effective at improving quality of life, overall happiness, and sexual functioning in transgender women who are diagnosed with gender dysphoria.[15] Another recent post-operative and six-month follow-up survey of transgender female patients found improvements in quality of life in a significant majority of patients.[16]

Male-to-Female Transsexuals. Plastic and Reconstructive Surgery, 132(6), 1421-1429. doi:10.1097/01.prs.0000434415.70711.49.

[13] Horbach, S. E. R., Bouman, M., Smit, J. M., Ozer, M., Buncamper, M. & Mullender, M. G. (2015). Outcome of Vaginoplasty in Male-to-Female Transgenders: A Systematic Review of Surgical Techniques.

[14] Hess, J., Neto, R., Panic, L., Rubben, H. & Senf, W. (2014). Satisfaction with Male-to-Female Gender Reassignment Surgery. (Among survey respondents, the majority (90.2%) said that that their expectations for life as a woman were fulfilled after surgery. A similarly high percentage (85.4%) saw themselves as women.)

[15] Hadj-Moussa, M.,et al. Feminizing Genital Gender-Confirmation Surgery, 2018, 1-14. 2018 Jul;6(3):457-468.e2. doi: 10.1016.

[16] Papadopulos, N.A., et al. Male-to-Female Sex Reassignment Surgery Using the Combined Technique Leads to Increase Quality of Life in a Prospective Study. Plast Reconstr Surg. 2017 Aug;140(2):286-294. doi: 10.1097.

45. The available peer-reviewed literature likewise concludes that when performed in accordance with the prevailing standards of care, male chest reconstruction surgery is safe and effective in alleviating gender dysphoria. For example, one study found that transgender men who received chest reconstruction experienced few clinical complications and were overwhelmingly satisfied with their surgical outcomes.[17] Another peer-reviewed study of transgender men who received chest reconstruction found that the procedure improved psychosocial well-being and physical well-being among participants.[18] Numerous other studies have reached similar conclusions.[19] These findings extend to adolescents; for example, a recent study in JAMA Pediatrics concluded that: "Chest dysphoria was high among

[17] Frederick, M. et al., (2017), Chest Surgery in Female to Male Transgender Individuals, Annals of Plastic Surgery, 78(3), 249-253.

[18] Agarwal, C. et al., (2018). Quality of life improvement after chest wall masculinization in female-to-male transgender patients: A prospective study using the BREAST-Q and Body Uneasiness Test, 71, 651-657.

[19] *E.g.*, Olson-Kennedy, J. et al., (2018), Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults, JAMA Pediatrics, 172(5), 431-436; Van de Grift, T., et al., (2017), Surgical Indications and Outcomes of Mastectomy in Transmen: A Prospective Study of Technical and Self-Reported Measures. Plastic and Reconstructive Surgery, 140(3), 415e-424e. doi:10.1097/PRS.0000000000003607; Berry, M.G. et al., (2012), Female-to-male transgender chest reconstruction: A large consecutive, single-surgeon experience. Journal of Plastic, Reconstructive & Aesthetic Surgery 65, 711-719.

presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults."[20]

46. The overwhelming majority of patients who obtain gender confirmation surgery in a manner consistent with the Standards of Care are both satisfied and experience a reduction of gender dysphoria. For the vast majority of transgender people who seek such surgery, the surgery is successful at treating gender dysphoria and alleviating a lifelong struggle to find peace of mind and comfort with their bodies.

GENDER CONFIRMATION SURGERIES ARE STANDARD, MEDICALLY ACCEPTED TREATMENTS FOR GENDER DYSPHORIA AND ARE NOT EXPERIMENTAL

47. It is my professional medical opinion that the contention of Dr. Lappert, that gender-confirming surgeries are experimental is unsupported by the professional medical consensus and prevailing standards of care for treating gender dysphoria, and is inconsistent with mainstream medical standards. To the contrary, the prevailing consensus of the medical community recognizes that procedures used to treat gender dysphoria are reconstructive, not experimental, and are medically necessary.

[20] Olson-Kennedy, J. *supra* at n. 19. Additionally, Frederick et al., *supra* at n. 17, included adolescents aged 15-17, as well as adults.

48. Surgical care is not considered experimental when it uses accepted techniques and has demonstrative benefits. The techniques used in gender-affirming care are employed in other surgeries and are well-established. For example, urethroplasties, orchiectomies, skin grafts, and mastectomies are all accepted techniques for congenital, oncological, and traumatic conditions. They are not experimental simply because they are applied to the well-established diagnosis of gender dysphoria.

49. Gender-affirming surgery has been performed for decades, utilizes accepted surgical techniques, and yields demonstrated benefits for patients. In addition, gender-affirming surgeries are: 1) part of the core curriculum in plastic surgery resident education; and 2) a component of both the written and oral board exams in plastic surgery. I have given presentations at multiple professional societies—including, the American Society of Plastic Surgeons, American Association of Plastic Surgeons, American Society for Reconstructive Microsurgery, American College of Surgeons—and none of those societies consider gender-affirming surgery experimental. In the disclosures required to give presentations of this kind there is no requirement that they be called experimental. It is widely accepted by professional surgical societies that gender-affirming surgeries are not experimental. Indeed, gender-

affirming surgery is part of the standard resident education in plastic surgery and, it is included in both the written and oral exams (in order to obtain board certification).

THE OPINIONS OF DR. LAPPERT ARE INCONSISTENT WITH THE MAINSTREAM MEDICAL CONSENSUS

Qualifications of Dr. Lappert

50. Based on the disclosures in Dr. Lappert's Assessment, he appears to lack the requisite qualifications to offer his opinions. Dr. Lappert's board certification with the American Board of Plastic Surgery is expired. Dr. Lappert is neither board-certified in plastic surgery, nor does he appear to hold any board-certification from a member board of the American Board of Medical Specialties.

51. Dr. Lappert is not a member of the American Society of Plastic Surgeons (ASPS), despite its role as the largest plastic surgery specialty organization in the world. ASPS represents 93% of all board-certified plastic surgeons in the United States, and more than 8,000 plastic surgeons worldwide. *See* plasticsurgery.org (website of ASPS). Dr. Lappert does not appear to be a member of any other major or relevant surgical organization, such as the American College of Surgeons.

52. Dr. Lappert lists no current hospital affiliations, nor does he appear to perform surgical procedures any longer. Dr. Lappert has no recent or relevant scientific publications pertaining to the field of gender-affirming surgery. Dr. Lappert references having performed an unspecified number of surgeries for patients who previously identified as transgender, however, he does not disclose any experience in treating individuals in a manner consistent with the Standards of Care.

53. Additionally, Dr. Lappert is not a member of WPATH, which is recognized by the mainstream medical consensus as the authoritative entity that has established comprehensive Standards of Care in this field.

Quality of Evidence

54. The quality of the evidence supporting gender-affirming surgeries is comparable to that supporting many surgeries and clinical procedures. Prospective, randomized, double-blind, placebo-controlled studies cannot be used to evaluate many clinical procedures. For example, there are simply inherent limitations to our ability to conduct such studies in clinical medicine. First, it is unethical to withhold medically necessary care. As such, in many situations, clinicians cannot conduct a study that uses a control group who is deprived of the treatment being studied. Practice guidelines published in 2013

by the Royal College of Psychiatrists indicated that a randomized controlled study to evaluate feminizing vaginoplasty would be "impossible to carry out."[21] The withholding of medically necessary care that would be required for such a comparison would be considered unethical.

55. It is not possible to perform a double-blind study of surgeries that modify body parts, nor is there a placebo that can mimic such a surgery – unlike studies that use placebo drug regimens, for example, people will know if they have had an operation or not. For relatively uncommon conditions like gender dysphoria, sample sizes of individuals with the condition who are available to participate in a clinical study tend to be small. This is especially true where treatment for a condition has not been covered by insurance programs and plans, and where additional barriers (such as ongoing stigmatization) prevent patients from accessing care. That very lack of access to the procedure results in there being fewer people who have received treatment and who can participate in a prospective study of that treatment's effect.

56. Put simply, the scientific literature pertaining to gender-affirming surgical interventions is similar to that of other accepted plastic surgery

[21] Good Practice Guidelines for the Assessment and Treatment of Adults with Gender Dysphoria, Royal College of Psychiatrists 1-59 (2013).

procedures. The recommendation for ongoing research is a standard recommendation in many, if not most or all clinical scenarios. This recommendation for ongoing study in a particular clinical area does not mean that surgical care is withheld.

Informed Consent

57. Dr. Lappert appears to assert that the process of obtaining informed consent for surgical procedures to treat gender dysphoria is not possible because of the purported insufficiency of the evidence supporting this care. Lappert Assessment at 4. Gender-affirming surgical procedures, however, have been shown beneficial by multiple surgeons, in multiple countries, over decades. The risks of gender-affirming surgical procedures are well-known and well-described in the literature.[22] Additionally, because analogous surgical techniques have long been used to treat other underlying diagnoses, the risks of these techniques are well-understood.

58. The Standards of Care specifically discuss the obligation of the surgeon to obtain informed consent and recommend mental health assessments

[22] *See, e.g.*, Loren S. Schechter, *The Surgeon's Relationship with the Physician Prescribing Hormones and the Mental Health Professional: Review for Version 7 of the World Professional Association for Transgender Health's Standards of Care*, 11 International Journal of Transgenderism 222-225 (2009).

prior to these gender-affirming surgical interventions. The options, including the potential complications, and risks and benefits of each, are discussed with patients. For adolescents, these discussions include the caregiver or parents who must consent as well.

59. The process of securing informed consent is done in a multidisciplinary way. One component of the preoperative mental health evaluation is an assessment of the individual's ability to provide informed consent. This represents a clinical standard which exceeds the threshold to perform many other types of surgical interventions, including those that are sterilizing.

Few Patients Experience Regret When Gender Confirming Surgery is Provided in Accordance with the Standards of Care

60. Dr. Lappert suggests that gender confirming surgery is not safe and effective because some patients could later regret their transition and the procedure. *See, e.g.*, Lappert Assessment at 10-11. All available research—as well as my own clinical experience—indicates that very few patients experience regret when gender confirming surgery is provided in accordance with the WPATH SOC and by a qualified surgeon. Regret of any kind is rare (0.6% in

transgender women and 0.3% in transgender men),[23] but "true regrets," as opposed to regrets due to lack of social or familial acceptance, comprise an even smaller percentage (approximately half this group, roughly 0.3% in transgender women and 0.15% in transgender men).[24] Having performed gender confirming surgeries for over 20 years, I have never had a patient request a reversal of male chest reconstruction.

61. In a recent study I co-authored regarding regret following gender-affirming surgery, Narayan, et al. queried 154 surgeons surgically treating between 18,125 to 27,325 individuals.[25] The rate of regret was found to be between 0.2-0.3%, consistent with previous literature.

62. Moreover, issues pertaining to regret following surgical procedures are not limited to gender-affirming surgical interventions.[26] Some cisgender

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[23] Wiepjes, et. al., *The Amsterdam Cohort of Gender Dysphoria Study 1972-2015: Trends in Prevalence, Treatment, And Regrets*. J Sex Med. 2018 Apr; 15(4):582-590. doi: 10.1016.

[24] *Id*. at 585, 587 (researchers classified "social regrets" as those experienced by individuals who still identified as transgender women, but reported feeling "ignored by surroundings" or regretted loss of relatives," and classified "true regrets" as those experienced by individuals who "thought gender affirming treatment would be a 'solution' for, for example, homosexuality or [lack of] personal acceptance, but, in retrospect, regretted the diagnosis and treatment").

[25] Sasha Karan Narayan et al., *Guiding the Conversation—Types of Regret After Gender-Affirming Surgery and Their Associated Etiologies*, 9 Annals of Translational Medicine 605-616 (2021).

[26] Toni Zhong et al., *Decision Regret Following Breast Reconstruction: The Role of Self-Efficacy and Satisfaction With Information in the Preoperative Period*, 132 Plastic and Reconstructive Surgery 724e-734e (2013).; Leslie L. Montgomery et al., *Issues of Regret in*

women experience regret following breast reconstruction (40%), some cisgender women (6%) expressed regret following prophylactic mastectomy and prophylactic oophorectomy (7%).

Patient Self-Reporting

63. Dr. Lappert claims that gender-confirming surgeries are based on "the patient's subjective report of dysphoria." Lappert Assessment at 13. Dr. Lappert misrepresents the preoperative process and multidisciplinary assessment that occurs prior to gender-affirming surgical interventions.[27]

64. Dr. Lappert's statements demonstrate a lack of familiarity with both the process of diagnosis done by mental health professionals before the transgender patient is eligible for surgery, and also the role and responsibility of the surgeon in providing this care.

65. When a person is referred to a surgeon to receive gender confirming surgery, the surgeon receives in writing one or more assessments of

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Women With Contralateral Prophylactic Mastectomies, 6 Annals of Surgical Oncology 546-552 (1999).; Elizabeth M. Swisher et al., *Prophylactic Oophorectomy and Ovarian Cancer Surveillance*, 46 The Journal of Reproductive Medicine 87-94 (2001).

[27] *See* the Standards of Care; Loren S. Schechter, *The Surgeon's Relationship with the Physician Prescribing Hormones and the Mental Health Professional: Review for Version 7 of the World Professional Association for Transgender Health's Standards of Care*, 11 International Journal of Transgenderism 222-225 (2009) (now International Journal of Transgender Health).

the patient's diagnosis and medical necessity of the care by one or more mental health professionals, as required for the relevant procedure under the Standards of Care. But that is only one step in the assessment for surgical interventions. Contrary to Dr. Lappert's suggestions, the surgeon remains ultimately responsible for deciding whether a particular surgical intervention is medically indicated. The surgeon evaluates the patient and makes the final decision about whether it is safe and medically indicated to proceed. This includes an evaluation of the patient's understanding of the condition, their self-awareness, and their goals and expectations for the intervention. The surgeon also evaluates other factors that would affect the patient's fitness for the surgery, such as obesity or smoking, and determines whether additional information might be required, such as x-rays or laboratory work. The surgeon also typically obtains an assessment from the person's primary care physician about their overall health. In my own clinical practice, I have declined to perform a requested intervention based on my exercise of professional judgment.

THE GAPMS REPORT MISREPRESENTS THE LITERATURE IN MEDICAL NECESSITY, SAFETY, AND EFFECTIVENESS

66. The overwhelming weight of the scientific and medical literature supports the benefits of gender-affirming surgical interventions. Gender-affirming interventions have been performed for decades, and the safety and

efficacy of these procedures have been reported by multiple surgeons practicing at different institutions in different countries and continents.

67. The Agency's GAPMS Report cites a study by Dhejne, et al. to imply that because individuals who received gender confirming surgeries had higher morbidity and mortality rates compared to the general population, the surgeries are not effective. GAPMS Report at 24-25. The Agency misunderstands that study. First, the study itself clearly states that it is not intended to evaluate whether gender-affirming surgeries are "an effective treatment or not." Second, the study found that those who receive medically necessary surgery generally have reduced morbidity and mortality compared to those with the same condition who do not, even if morbidity and mortality for both groups is higher than average. Third, the study includes patients who had surgery prior to the development of the current standards of care. Finally, the fact that gender confirming surgeries do not entirely resolve all possible causes of morbidity and mortality among transgender individuals is completely unsurprising. While surgery can treat gender dysphoria by aligning transgender people's bodies with their gender identity, surgery alone cannot fully eliminate the stigma and discrimination that transgender people face. Moreover, it is rare for any surgery to eliminate morbidity and mortality. For example, people who

have surgery to remove a cancerous tumor may still experience higher rates of morbidity and mortality than the general population, but that does not mean that they should not undergo the surgery. In addition, individuals suffering from other medical conditions (including chronic conditions and traumatic injuries such as burns) are also at elevated risk of suicide. The increased risk of suicide does not preclude treatment of burn patients.[28]

68. The fact that surgery does not always reduce morbidity for everyone who receives it does not mean that the surgery is not safe or effective, particularly given the number of potential confounding factors that can impact morbidity. Similarly, the continued existence of elevated morbidity and mortality rates, compared to the population at large, say nothing about whether a treatment is a safe and effective way to treat a particular condition. Moreover, while suicide is not necessarily the correct marker for efficacy of treatment, in the Dhejne study, suicide attempts in the years 1989-2003 were reduced (and death by suicide during that time is listed as NA). Additionally, the number of mental health visits following surgical care is not a marker for treatment efficacy. For example, people receiving care for cancer will continue to see

[28] Sheera F Lerman et al., *Suicidality After Burn Injuries: A Systematic Review*, 42 Journal of Burn Care & Research 357-364 (2021).

their oncologist—this does not imply that care received for the treatment of cancer was not successful and, we continue to provide care to patients with cancer even though treatments may be "temporary" (i.e., some forms of care may extend the lifespan of a patient with cancer for several years). This does not suggest that withholding medically necessary care is appropriate for patients with cancer, any more than it is for transgender people.

69. The GAPMS Report also misunderstands Medicare policy on coverage of gender affirming surgery. In 2014, an impartial adjudicative board in the Department of Health & Human Services concluded, based on decades of studies, that surgical care to treat gender dysphoria is safe, effective, and medically necessary.[29] Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Div., Decision No. 2676 (May 30, 2014), hhs.gov/sites/default/files/static/dab/decisions/board-decisions/2014/dab2576.pdf. As a result, the Centers for Medicare & Medicaid

[29] That decision also discussed the quality of data demonstrating the efficacy of surgical care to treat gender dysphoria, noting regardless of whether the studies were randomized double-blind trials, there was sufficient evidence to prove "a consensus among researchers and mainstream medical organizations that transsexual surgery is an effective, safe and medically necessary treatment for [gender dysphoria]." Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Div., Decision No. 2676, at 20 (May 30, 2014), hhs.gov/sites/default/files/static/dab/decisions/board-decisions/2014/dab2576.pdf.

Services (CMS) within HHS started covering surgical care for gender dysphoria and continues to provide that coverage, including for patients in my practice.

70. In 2016, CMS decided not to issue national standards (called a National Coverage Determination or "NCD") for determining under what circumstances Medicare will cover gender confirming surgical care because "the clinical evidence is inconclusive *for the Medicare population*." Ctrs. for Medicare & Medicaid Servs., *Decision Memo for Gender Dysphoria and Gender Reassignment Surgery* (Aug. 30, 2016) ("CMS Decision Memo") (emphasis added). The result of CMS's review of the evidence is not applicable to other population groups. For the most part, the Medicare population consists of individuals over the age of 65. While the number of older adults who have gender affirming surgery is increasing, most individuals who undergo gender affirming surgery are under age 65, meaning that fewer older adults have been included in studies assessing the effectiveness of the treatment. That was a significant factor in CMS's decision. As CMS articulated, "older adults may respond to health care treatments differently than younger adults." CMS Decision Memo at 57. "These differences can be due to, for example, multiple health conditions or co-morbidities, longer duration needed for healing, metabolic variances, and impact of reduced mobility." *Id*.

71. What is more, CMS acknowledged that gender confirming surgery may be necessary for certain Medicare beneficiaries and concluded that the appropriateness of surgical care for this population should continue to be determined on a case-by-case basis, as is already required by the WPATH SOC. Many widely accepted surgical procedures and surgical conditions do not have NCDs under Medicare. The fact that gender confirming surgery does not have an NCD is not unusual.

72. Notably, I have performed gender confirming surgeries on a number of Medicare beneficiaries in recent years, and Medicare has covered the cost of that care. Indeed, most medical and surgical care provided to patients should be individualized, taking into account each patient's unique clinical circumstances. In contrast, the exclusion challenged in this case does not evaluate the medical necessity of surgical care for gender dysphoria on a case-by-case basis. It categorically excludes all coverage regardless of an individualized showing of medical necessity.

SUMMARY OF OPINIONS AND CONCLUSIONS

73. Based on over 27 years of clinical experience performing gender confirmation procedures and caring for transgender people, my knowledge of the standards of care and relevant peer-reviewed literature, and my discussions

and interactions with experts throughout the world, it is my professional opinion that gender confirmation surgeries are safe, effective, and medically necessary treatments for gender dysphoria in transgender people. In my experience, the overwhelming number of individuals who undergo gender confirmation procedures describe relief and/or reduction of their gender dysphoria and improvement in their quality of life and overall functioning.

74. Furthermore, based on my clinical and professional experience and my ongoing review of the literature, it is my professional opinion that the denial of necessary medical care is likely to perpetuate gender dysphoria and create or exacerbate other medical issues, such as depression and anxiety, leading to an increased possibility of self-harm, negative health outcomes, and even suicide.

75. In conclusion, it is my professional opinion that the categorical exclusion of transition-related surgical care in Florida's Medicaid Program is 1) inconsistent with the Standards of Care for treating transgender individuals diagnosed with gender dysphoria, 2) inconsistent with the peer-reviewed scientific and medical research demonstrating that gender confirmation surgeries are safe, effective, and more cost efficient treatments for gender dysphoria over the long-term, 3) and inconsistent with expert medical and surgical consensus. To the extent the exclusion is premised on the conclusion

in the GAPMS report that gender confirmation surgical care is not medically necessary, that conclusion is wrong. The Standards of Care confirm, based on clinical evidence, that gender confirmation surgeries are medically necessary to help people alleviate the often serious and life-threatening symptoms of gender dysphoria.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 9th day of September, 2022.

Loren S. Schechter, M.D.

EXHIBIT A

Curriculum Vitae

Curriculum Vitae

NAME: **LOREN SLONE SCHECHTER, MD, FACS**

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Chicago, Il 60640
Tel: 847.967.5122
Fax: 847.967.5125

E-MAIL: lorenschechter1@gmail.com

MARITAL STATUS: Married (Rebecca Brown Schechter, MD)

CERTIFICATION: The American Board of Plastic Surgery, 2001
Certificate Number 6271
Date Issued: September 2001
Maintenance of Certification: 2011
Maintenance of Certification: 2021

EDUCATION:

1986-1990	The University of Michigan	BS, 1990
1990-1994	The University of Chicago Pritzker School of Medicine	MD, 1994

POSTGRADUATE TRAINING:

Residency:	The University of Chicago Hospitals Coordinated Training Program in Plastic and Reconstructive Surgery	1994-1999
Chief Resident:	The University of Chicago Hospitals Section of Plastic and Reconstructive Surgery	1998-1999
Fellowship:	Reconstructive Microsurgery The University of Chicago Hospitals Section of Plastic and Reconstructive Surgery	1999-2000

TEACHING APPOINTMENT:

Professor of Surgery, Chief Section of Gender-Affirmation Surgery, Rush University Medical Center-In Process

Clinical Professor of Surgery, The University of Illinois at Chicago-resigned to accept position at Rush University

Adjunct Assistant Professor, Dept. of Surgery, Rush University Medical Center

Associate Professor, Physician Assistant Program, College of Health Professionals, Rosalind Franklin University

LICENSURE:

Illinois
Illinois Controlled Substance
DEA

STAFF APPOINTMENTS:

Rush University Medical Center
Advocate Lutheran General Hospital
Louis A. Weiss Memorial Hospital
Illinois Sports Medicine and Orthopedic Surgery Center

HONORS AND AWARDS:

2021	Chicago Magazine Top Doctor-Surgery
2020	The University of Minnesota Program in Human Sexuality, recipient of 50 Distinguished Sexual and Gender Health Revolutionaries
2017-2020	Castle Connolly Top Doctor (Chicago)
2017	Chicago Consumer Checkbook Top Doctor
2015	University of Minnesota Program in Human Sexuality Leadership Council
2014-2015	Rosalind Franklin University of Medicine and Science Chicago Medical School Honors and recognizes for dedication and commitment to teaching
2014	National Center for Lesbian Rights honored guest
2013	Illinois State Bar Association Award for Community Leadership
2010	Advocate Lutheran General 2009 Physicians Philanthropy Leadership Committee-Outstanding Leadership
2009	Advocate Lutheran General Hospital Value Leader (received for compassion)
1994	Doctor of Medicine with Honors
1994	University of Chicago Department of Surgery Award for Outstanding Performance in the Field of Surgery
1994	Catherine Dobson Prize for the Best Oral Presentation Given at the 48th Annual Senior Scientific Session in The Area of Clinical Investigation
1993	Alpha Omega Alpha

1991	University of Chicago National Institutes Of Health Summer Research Award
1990	Bachelor of Science with High Distinction And Honors in Economics
1990	James B. Angell Award for Academic Distinction
1989	Omicron Delta Epsilon-National Economic Honor Society
1988	College Honors Program Sophomore Honors Award For Academic Distinction
1988	Class Honors (Dean's List)

MEMBERSHIPS:

2018-	The American Association of Plastic Surgeons
2016-	The American Society for Gender Surgeons (founding member and president-elect)
2010-	World Society for Reconstructive Microsurgery
2005-	The University of Chicago Plastic Surgery Alumni Association
2005-	The Chicago Surgical Society
2004-	The American Society for Reconstructive Microsurgery
2003-	The American College of Surgeons
2002-	The American Society of Plastic Surgeons
2001-	Illinois Society of Plastic Surgeons (formerly Chicago Society of Plastic Surgeons)
2001-	The American Society of Maxillofacial Surgeons
2001-	American Burn Association
2001-	Midwest Association of Plastic Surgeons
2001-	WPATH
1994-	The University of Chicago Surgical Society
1994-	The University of Chicago Alumni Association
1992-	American Medical Association
1992-	Illinois State Medical Society
1992-	Chicago Medical Society
1990-	The University of Michigan Alumni Association

CURRENT HOSPITAL COMMITTEES:

Director, Center for Gender Confirmation Surgery, Louis A. Weiss Memorial Hospital

PROFESSIONAL SOCIETY COMMITTEES:

WPATH Executive Committee

Treasurer, The World Professional Association for Transgender Health

Chair, Finance and Investment Committee, The American Society of Plastic Surgeons

WPATH 2020 Biennial Meeting Steering Committee

American Society of Breast Surgeons Research Committee, ASPS representative

American Board of Plastic Surgery, Guest Oral Board Examiner

WPATH Ethics Committee

American College of Radiology Committee on Appropriateness Criteria Transgender Breast Imaging Topic, Expert Panel on Breast Imaging: Transgender Breast Cancer Screening Expert Panel on Breast Imaging

American Society of Plastic Surgeons, Finance and Investment Committee

Board of Directors, at-large, The World Professional Association for Transgender Health

PlastyPac, Board of Governors

Medicare Carrier Advisory Committee

OTHER:

American Board of Plastic Surgery-Oral Board Guest Examiner (2020, 2021)

Guest Reviewer, Pain Management

Guest Reviewer, Plastic and Aesthetic Research

Guest Reviewer, European Medical Journal

Guest Reviewer, Open Forum Infectious Diseases

Guest Reviewer, The Journal of The American College of Surgeons

Guest Book Reviewer, Plastic and Reconstructive Surgery

Editorial Board, Transgender Health

Editorial Board (Associate Editor), International Journal of Transgenderism

Fellow of the Maliniac Circle

Guest Reviewer, Journal of Reconstructive Microsurgery

Guest Reviewer, Journal of Plastic and Reconstructive Surgery

Guest Reviewer, Journal of Sexual Medicine

Guest Editor, Clinics in Plastic Surgery, Transgender Surgery (Elsevier Publishing)

Guest Reviewer, The Journal of Plastic and Reconstructive Surgery

PREVIOUS EDITORIAL ROLE:

Guest Reviewer, EPlasty, online Journal

Module Editor for Patient Safety, Plastic Surgery Hyperguide

Editorial Advisory Board, Plastic Surgery Practice

Guest Reviewer, International Journal of Transgenderism

Guest Reviewer, Pediatrics

PREVIOUS ACADEMIC APPOINTMENT:

Visiting Clinical Professor in Surgery, The University of Illinois at Chicago

Chief, Division of Plastic and Reconstructive Surgery, Chicago Medical School, Rosalind Franklin University of Medicine and Science

Associate Professor of Surgery, The College of Health Professionals, Rosalind Franklin University

Clinical Associate in Surgery, The University of Chicago

PREVIOUS HOSPITAL COMMITTEES:

Division Director, Plastic Surgery, Lutheran General Hospital

Division Director, Plastic Surgery, St. Francis Hospital

Medical Staff Executive Committee, Secretary,
Advocate Lutheran General Hospital

Credentials Committee, Lutheran General Hospital

Pharmacy and Therapeutics Committee Lutheran General Hospital

Operating Room Committee, St. Francis Hospital

Cancer Committee, Lutheran General Hospital
-Director of Quality Control

Risk and Safety Assessment Committee, Lutheran General Hospital

Nominating Committee, Rush North Shore Medical Center

Surgical Advisory Committee, Rush North Shore Medical Center

Section Director, Plastic Surgery, Rush North Shore Medical Center

PREVIOUS SOCIETY COMMITTEES:

PlastyPac, Chair, Board of Governors

Chair of the Metro Chicago District #2 Committee on Applicants, American College of Surgeons

American Society of Plastic Surgery, Health Policy Committee

American Society of Plastic Surgery, Patient Safety Committee

American Society of Plastic Surgeons, Coding and Payment Policy Committee

American Society of Plastic Surgeons, Practice Management Education Committee

Board of Governors, Governor-at-large, The American College of Surgeons

American College of Surgeons, International Relations Committee

Chair, Government Affairs Committee, American Society of Plastic Surgeons

President, The Metropolitan Chicago Chapter of The American College of Surgeons

2012 Nominating Committee, American Society of Plastic Surgeons

Program Committee, The World Society for Reconstructive Microsurgery, 2013 Bi-Annual Meeting

President, Illinois Society of Plastic Surgeons

Vice-President, The Illinois Society of Plastic Surgeons (formerly the Chicago Society of Plastic Surgery)

Vice-President, The Metropolitan Chapter of the American College of Surgeons

American Society of Plastic Surgery, Chairman, Patient Safety Committee

2006-2007 Pathways to Leadership, The American Society of Plastic Surgery

2005 & 2006 President, The University of Chicago Plastic Surgery Alumni Association

2003 Leadership Tomorrow Program, The American Society of Plastic Surgery

Senior Residents Mentoring Program, The American Society of Plastic Surgery

American Society of Maxillofacial Surgery, Education Committee

Alternate Councilor, Chicago Medical Society

American Society of Aesthetic Plastic Surgery, Electronic Communications Committee

American Society of Aesthetic Plastic Surgery,
Intranet Steering Committee

American Society of Aesthetic Plastic Surgery, International Committee

Membership Coordinator, The Chicago Society of Plastic Surgeons
The Illinois State Medical Society, Governmental Affairs Council

The Illinois State Medical Society, Council on Economics

Chicago Medical Society, Physician Review Committee
-Subcomittee on Fee Mediation

Chairman, Chicago Medical Society, Healthcare Economics Committee

Secretary/Treasurer, The Metropolitan Chicago Chapter of the American College of Surgeons

Scientific Committee, 2007 XX Biennial Symposium WPATH

Local Organizing Committee 2007 WPATH

Secretary, The Chicago Society of Plastic Surgeons

Treasurer, The Chicago Society of Plastic Surgeons

Council Member, The Metropolitan Chicago Chapter of the American College of Surgeons

INTERNATIONAL MEDICAL SERVICE:

Northwest Medical Teams
Manos de Ayuda (Oaxaca, Mexico)

Hospital de Los Ninos (San Juan, Puerto Rico)

COMMUNITY SERVICE:

Alumni Council, The University of Chicago Medical and Biological Sciences Alumni Association

The University of Minnesota Presidents Club Chancellors Society

Board of Directors, Chicago Plastic Surgery Research Foundation

National Center for Gender Spectrum Health Advisory Council

PREVIOUS COMMUNITY SERVICE:

Board of Directors, Committee on Jewish Genetic Diseases, Jewish United Fund, Chicago, Illinois

Governing Council, Lutheran General Hospital, Park Ridge, Il

Lutheran General Hospital Development Council, Park Ridge, Il

Lutheran General Hospital Men's Association, Park Ridge, Il

Advisory Board, Committee on Jewish Genetic Diseases, Cancer Genetics Subcommittee, Jewish United Fund, Chicago, Illinois

Health Care Advisory Board, Congressman Mark Kirk, 10th Congressional District, Illinois

Major Gifts Committee, Saint Francis Hospital Development Council, Evanston, Il

Visiting Professor:

1. University of Utah, Division of Plastic Surgery, November 6-8, 2014.
2. Northwestern University, Division of Plastic Surgery, April 21-22, 2016.
3. The University of North Carolina, Division of Plastic Surgery, March 28-29, 2017
4. Georgetown University, Department of Plastic Surgery, May 17-18, 2017
5. The University of Basel, Basel, Switzerland, August 31-September 1, 2018
6. The Ochsner Health System, New Orleans, LA January 28-January 30, 2019
7. The University of Toronto, Toronto, Ontario, Canada, February 21-22, 2019
8. The University of Michigan, October3-4, 2019, Ann Arbor, MI,

Invited Discussant:

1. Department of Defense, Military service by people who are transgender, Invitation from Terry Adirim, M.D., M.P.H.Deputy Assistant Secretary of Defense for Health Services Policy & Oversight, The Pentagon, November 9, 2017

2. Aesthetic Surgery Journal, Invited Discussant May 7, 2019, Journal Club. "What is "Nonbinary" and What Do I need to Know? A Primer for Surgeons Providing Chest Surgery for Transgender Patients."

Research Interests:

1. Role of Omental Stem Cells in Wound Healing (Grant: Tawani Foundation)

2. Robotic-Assisted Bilateral Prophylatic Nipple Sparing Mastectomy with Immediate Tissue Expander/Implant Reconstruction (Pending submission to the FDA for Investigational Device Exemption in association with Intuitive Surgical)

3. Transgender Health and Medicine Research Conference, National Institutes of Health, Bethesda, MD May 7-8, 2015

4. Uterine Transplantation, Rush University Medical Center (IRB pending)

5. Gender Affirmation Surgery Prospective Surveys (Rush University-IRB approved)

6. National Network for Gender Affirming Surgeries: Canadian Institute of Health Research, Training Grant – LGBQT 2S Stigma Reduction & Life Course Mental Wellness (application in process)

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PEER REVIEWED ARTICLES:

1. E. Wall, D. A. Schoeller, **L. Schechter**, L.J. Gottlieb: Measured Total Energy Requirements of Adult Patients with Burns. *The Journal of Burn Care and Rehabilitation* 20:329, 1999.

2. David C. Cronin, II, **Loren Schechter**, Somchi Limrichramren, Charles G. Winans, Robert Lohman, and J. Michael Millis, Advances in Pediatric Liver Transplantation: Continuous Monitoring of Portal Venous and Hepatic Artery Flow with an Implantable Doppler Probe. *Transplantation 74(6):887-889, 2002.*

3. Robert F. Lohman**, Loren S. Schechter**, Lawrence S. Zachary, Solomon Aronson: Evaluation of Changes in Skeletal Muscle Blood Flow in the Dog with Contrast Ultrasonography Revisited: Has the Technique Been Useful, and Where are We Headed Now? *The Journal of Plastic and Reconstructive Surgery* 111(4):1477-1480, 2003.

4. Alvin B. Cohn, Eric Odessey, Francis Casper, **Loren S. Schechter**: Hereditary Gingival Fibromatosis: Aggressive Two-Stage Surgical Resection in Lieu of Traditional Therapy, *The Annals of Plastic Surgery Vol 57, Number 5, November 2006*.

5. Eric Odessey, Al Cohn, Kenneth Beaman, and **Loren Schechter**: Mucormycosis of the Maxillary Sinus: Extensive Destruction with an Indolent Presentation, *Surgical Infections*, Vol. 9, Number 1, 2008

6. Iris A. Seitz, MD, David Tojo, MD, **Loren S. Schechter**, MD Anatomy of a Medication Error: Inadvertent Intranasal Injection of Neosynephrine During Nasal Surgery – A Case Report

and Review of The Literature Plast Reconstr Surg. 2010 Mar;125(3):113e-4e. doi: 10.1097/PRS.0b013e3181cb68f9

7. Iris Seitz, MD Craig Williams, MD, Thomas Weidrich, MD, John Seiler, MD, Ginard Henry, MD, and **Loren S. Schechter, MD**: Omental Free Tissue Transfer for Coverage of Complex Upper Extremity Defects: The Forgotten Flap *(N Y). 2009 Dec;4(4):397-405. doi: 10.1007/s11552-009-9187-6. Epub 2009 Mar 25.*

8. Michael Salvino and **Loren S. Schechter**: Microvascular Reconstruction of Iatrogenic Femoral Artery Thrombus in an Infant: A Case Report and Review of the Literature ePlasty Volume 9 ISSN: 19357-5719, E-location ID: e20

9. Phillip C. Haeck, MD, Jennifer A. Swanson, BS, Med, Ronald E. Iverson, MD., **Loren S. Schechter, MD**, Robert Singer, MD, Bob Basu, MD, MPH, Lynn A. Damitz, MD, Scott Bradley Bradley Glasberg, MD, Lawrence S. Glasman, MD, Michael F. McGuire, MD, and the ASPS Patient Safety Committee: Evidence-Based Patient Safety Advisory: Patient Selection and Procedures in Ambulatory Surgery, Supplement to Plastic and Reconstructive Surgery, Volume 124, Number 4s, October Supplement 2009.

10. Philip C. Haeck, MD, Jennifer A. Swanson, BS, Med, **Loren S. Schechter, MD**, Elizabeth J. Hall-Findlay, MD, Noel B. McDevitt, MD, Gary Smotrich, MD, Neal R. Reisman, MD, JD, Scot Bradley Glasberg, MD, and the ASPS Patient Safety Committee: Evidence-Based Patient Safety Advisory: Blood Dyscrasias, Patient Selection and Procedures in Ambulatory Surgery, Supplement to Plastic and Reconstructive Surgery, Volume 124, Number 4s, October Supplement 2009.

11. **Loren S. Schechter, MD**, The Surgeon's Relationship with The Physician Prescribing Hormones and the Mental Health Professional: Review for Version 7 of the World Professional Association of Transgender Health's Standards of Care *International Journal of Transgenderism* 11 (4), p.222-225 Oct-Dec 2009

12. Iris A Seitz, MD, PhD, Craig Williams, MD, **Loren S. Schechter, MD**, Facilitating Harvest of the Serratus Fascial Flap With Ultrasonic Dissection, *Eplasty 2010 Feb 23;10:e18*

13. Seitz, I, Friedewald SM, Rimler, J, **Schechter, LS**, Breast MRI helps define the blood supply to the nipple-areolar complex, Plastische Chirurgie, Supplement 1, 10. Jahrgang, September 2010, p. 75

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13. American Society of Reconstructive Microsurgery, Annual Scientific Meeting, January 11-15, 2003, Kauai, Hawaii: "Advances in Pediatric Liver Transplantation: Continuous Monitoring of Portal Venous and Hepatic Artery Flow With an Implantable Doppler Probe"

14. The 5th Annual Chicago Trauma Symposium, August 8-10, 2003, Chicago, Illinois: "Soft Tissue Salvage: Where Are We in 2003?"

15. The Midwestern Association of Plastic Surgeons, 42nd Annual Meeting, Chicago, Il May 1-2, 2004: "The Gastrocnemius-Achilles Tendon Myocutaneous Flap (GAT Flap) for Single Stage Reconstruction of Combined Soft Tissue and Extensor Mechanism Defects of the Knee: An Eighteen Year Experience"

16. The 6th Annual Chicago Trauma Sympsoium, August 12-15, 2004, Chicago, Il "Complex Wound Management"

17. The American Society of Plastic Surgery, October 9-13, 2004, Philadelphia, Pennsylvania: "The Gastrocnemius-Achilles Tendon Myocutaneous Flap (GAT Flap) for Single Stage Reconstruction of Combined Soft Tissue and Extensor Mechanism Defects of the Knee: An Eighteen Year Experience"

18. The American Society for Reconstructive Microsurgery, January 15-18, 2005, Fajardo, Puerto Rico: "Surviving as a Plastic Surgeon"

19. American Hernia Society, Poster Presentation, February 9-12, 2005, San Diego, California: "When Component Separation Isn't Enough"

20. The Midwestern Association of Plastic Surgeons, April 23-24, Chicago, Il: "Hereditary Gingival Fibromatosis in Monozygotic Twins: First Reported Case"

21. The Midwestern Association of Plastic Surgeons, April 23-24, Chicago, Il: "Modified Components Separation Technique for Two Massive Ventral Hernias"

22. The Midwestern Association of Plastic Surgeons, April 23-24, Chicago, Il: "Mucormycosis of the Head and Neck: A Fatal Disease?"

23. The 7th Annual Chicago Trauma Symposium, August 11-14, 2005, Chicago, Il "Management of Complex Injuries"

24. Current Concepts in Advanced Wound Healing: *A Practical Overview*, Rush North Shore Medical Center, Skokie, Il September 18, 2005 "From Flaps to Grafts"

25. Taizoon Baxamusa, M and Loren S.Schechter, MD, Abdominoplasty: Use in Reconstruction of the Mangled Upper Extremity, The American Association For Hand Surgery Annual Scientific Meeting, January 11-14, 2006, Tucson, Arizona.

26. The American Academy of Orthopedic Surgeons 2006 Annual Meeting, March 22-26, 2006, Chicago, Il "Methods of Patella-Femoral and Extensor Mechanism Reconstruction for Fracture and Disruption After Total Knee Arthroplasty"

27. Midwestern Association of Plastic Surgeons 44th Annual Meeting, April 29-30, 2006, Oak Brook, Illinois "Elective Abdominal Plastic Surgery Procedures Combined with Concomitant Intra-abdominal Operations: A Single Surgeon's Four Year Experience"

28. Midwestern Association of Plastic Surgeons 44th Annual Meeting, April 29-30, 2006, Oak Brook, Illinois "Hereditary Gingival Fibromatosis: Aggressive Two-Stage Surgical Resection Versus Traditional Therapy"

29. Midwestern Association of Plastic Surgeons 44th Annual Meeting, April 29-30, 2006, Oak Brook, Illinois "Abdominoplasty Graft & VAC Therapy: Two Useful Adjuncts in Full-Thickness Grafting of the Mangled Upper Extremity"

30. The American Association of Plastic Surgeons 85th Annual Meeting, May 6-9, 2006 Hilton Head, South Carolina "Excision of Giant Neurofibromas"

31. The 8th Annual Chicago Trauma Symposium, July 27-30, 2006, Chicago, Il "Management of Complex Injuries"

32. The American Society of Plastic Surgeons Annual Meeting, October 6-12, 2006, San Francisco, California "Excision of Giant Neurofibromas"

33. The American College of Surgeons Poster Presentation, October, 2006, Chicago, Il "Abdominoplasty: Use in Reconstruction of the Mangled Upper Extremity"

34. American Medical Association-RFS 3rd Annual Poster Symposium, November 10, Las Vegas, NV, 2006 "Abdominal Wall Reconstruction With Alloderm"

35. Advocate Injury Institute: "Trauma 2006: The Spectrum of Care), November 30-December 2, 2006, Lisle, Il, "Pit Bull Mauling: A Case Study"

36. The 9th Annual Chicago Trauma Symposium, August 10-12, 2007, Chicago, Il "Management of Complex Injuries"

37. The World Professional Association for Transgender Health (WPATH) 2007 XX Biennial Symposium, September 5-8. 2007, Chicago, Il Revision Vaginoplasty With Sigmoid Interposition: "A Reliable Solution for a Difficult Problem"

38. Metropolitan Chicago Chapter of the American College of Surgeons, 2008 Annual Meeting, March 15, 2008 "ER Call: Who's Job is it Anyway"

39. The 10th Annual Chicago Trauma Symposium, August 7-10, 2008, Chicago, Il "Management of Complex Injuries"

40. 23nd Annual Clinical Symposium on Advances in Skin & Wound Care: The Conference for Prevention and Healing October 26-30, 2008, Las Vegas, Nevada,poster presentation "Use of Dual Therapies Consisting of Negative Pressure Wound Therapy (NPWT) and Small Intestine Mucosa (SIS) on a Complex Degloving Injury With an Expose Achilles Tendon: A Case Report**."**

41. The American Society of Plastic Surgeons Annual Meeting, October 31-November 3, 2008, Chicago, Il "Panel: Fresh Faces, Real Cases"

42. The American Association for Hand Surgery Annual Meeting, January 7-13, 2009, Maui, Hawaii, poster session: "Omental Free Tissue Transfer for Coverage of Complex Upper Extremity and Hand Defects-The Forgotten Flap."

43. Plastic Surgery At The Red Sea Symposium, March 24-28, 2009 Eilat, Israel, "Omental Free Tissue Transfer for Coverage of Complex Upper Extremity and Hand Defects-The Forgotten Flap."

44. ASPS/IQUAM Transatlantic Innovations Meeting, April 4-7, 2009 Miason de la Chimie, Paris, France, "Advertising in Plastic Surgery?"

45. ASPS/IQUAM Transatlantic Innovations Meeting, April 4-7, 2009 Miason de la Chimie, Paris, France, "Cost-Effectiveness of Physician Extenders in Plastic Surgery"

46. Midwestern Association of Plastic Surgeons, 47th Annual Meeting, April 18-19, 2009, Chicago, Il, "Microvascular Reconstruction of Iatrogenic Femoral Artery Injury in a Neonate"

47. Midwestern Association of Plastic Surgeons, 47th Annual Meeting, April 18-19, 2009, Chicago, Il,"Two Birds, One Stone: Combining Abdominoplasty with Intra-Abdominal Procedures"

48. The 11th Annual Chicago Trauma Symposium, August 1, 2009, Chicago, Il "Management of Complex Injuries"

49. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, "Omental Free Tissue Transfer for Coverage of Complex Extremity Defects: The Forgotten Flap."

50. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, "Challenging Cases."

51. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, "President's Panel: The Future of the Solo Practice-Can We, Should We Survive?"

52. The 12th Annual Chicago Trauma Symposium, August 5-8, 2010, Chicago, Il "Management of Complex Injuries"

53. Breast MRI to Define The Blood Supply to the Nipple-Areolar Complex. German Society of Plastic, Reconstructive and Aesthetic Surgery (DGPRAEC), Dresden, Germany, September 2010

54. Roundtable Discussion: Electronic Health Records-Implications for Plastic Surgeons, The American Society of Plastic Surgeons Annual Meeting, October 3, 2010, Toronto, CA

55. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, The American Society of Plastic Surgeons Annual Meeting, October 3, 2010, Toronto, CA.

56. ASPS/ASPSN Joint Patient Safety Panel: Patient Selection and Managing Patient Expectations, The American Society of Plastic Surgeons Annual Meeting, October 4, 2010, Toronto, CA

57. Lunch and Learn: Prevention of VTE in Plastic Surgery Patients, The American Society of Plastic Surgeons Annual Meeting, October 5, 2010, Toronto, CA

58. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, 16th Congress of The International Confederation for Plastic Reconstructive and Aesthetic Surgery, May 22-27, 2011, Vancouver, Canada

59. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, The 6th Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland

60. Applications of the Omentum for Limb Salvage: The Largest Reported Series, The 6th Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland

61. Successful Tongue Replantation Following Auto-Amputation Using Supermicrosurgical Technique, Poster Session, The 6th Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland

62. The 13th Annual Chicago Trauma Symposium, August 25-28, 2011, Chicago, Il "Soft Tissue Defects-Getting Coverage"

63. WPATH: Pre-conference Symposium, September 24, 2011, Atlanta, GA "Surgical Options and Decision-Making"

64. American Society of Plastic Surgeons Annual Meeting, September 27, 2011, Denver, CO Closing Session Lunch and Learn: Pathways to Prevention-Avoiding Adverse Events, Part I: Patient Selection and Preventing Adverse Events in the Ambulatory Surgical Setting

65. American Society of Plastic Surgeons Annual Meeting, September 27, 2011, Denver, CO Closing Session Lunch and Learn: Pathways to Prevention-Avoiding Adverse Events, Part III: Preventing VTE

66. XXIV Congresso Nazionale della Societa Italiana di Microchirugia congiunto con la American Society for Reconstructive Microsurgery, October 20-22, 2011, Palermo, Sicily: 3 Step Approach to Lower Extremity Trauma

67. XXIV Congresso Nazionale della Societa Italiana Microchirugia congiunto con la American Society for Reconstructive Microsurgery, October 20-22, 2011, Palermo, Sicily: Applications of the Omentum for Limb Salvage: The Largest Reported Series

68. American Society for Reconstructive Microsurgery, Poster Presentation, January 14-17, 2012, Las Vegas, NV: Neonatal Limb Salvage: When Conservative Management is Surgical Intervention

69. The 14th Annual Chicago Trauma Symposium, August 2-5, 2012, Chicago, Il "Soft Tissue Defects-Getting Coverage"

70. The Annual Meeting of The American Society of Plastic Surgeons, October 25th-30, 2012, New Orleans, LA "Reimbursement in Breast Reconstruction"

71. The Annual Meeting of The American Society of Plastic Surgeons, October 25th-30, 2012, New Orleans, LA "Thriving in a New Economic Reality: Business Relationships and Integration in the Marketplace"

72. The 15th Annual Chicago Trauma Symposium, August 2-5, 2013, Chicago, Il "Soft Tissue Defects-Getting Coverage"

73. 2014 WPATH Symposium, Tansgender Health from Global Perspectives, February 14-18, 2014, "Short Scar Chest Surgery."

74. 2014 WPATH Symposium, Transgender Health from Global Perspectives, February 14-18, 2014, "Intestinal Vaginoplasty with Right and Left Colon."

75. 24th Annual Southern Comfort Conference, September 3-7, 2014, Atlanta, Georgia, "Gender Confirmation Surgery: State of the Art."

76. The 15th Annual Chicago Trauma Symposium, September 4-7, 2014, Chicago, Il "Soft Tissue Defects-Getting Coverage"

77. The Midwest Association of Plastic Surgeons, May 30, 2015, Chicago, Il "Gender Confirmation Surgery: A Single-Surgeon's Experience"

78. The Midwest Association of Plastic Surgeons, May 30, 2015, Chicago, Il, Moderator, Gender Reassignment.

79. the American Society of Plastic Surgeons 2015 Professional Liability Insurance and Patient Safety Committee Meeting, July 17, 2015, "Gender Confirmation Surgery."

80. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. From Fee-for-Service to Bundled Payments

81. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Moderator, Transgender Surgery

82. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Efficient Use of Physician Assistants in Plastic Surgery.

83. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Patient Safety: Prevention of VTE

84. The World Professional Association for Transgender Health, Objective Quality Parameters for Gender Confirmation Surgery, June 18-22, 2016, Amsterdam, Netherlands

85. The World Professional Association for Transgender Health, Resident Education Curriculum for Gender Confirmation Surgery, June 18-22, 2016, Amsterdam, Netherlands

86. The World Professional Association for Transgender Health, Urologic Management of a Reconstructed Urethra(Poster session #195), June 18-22, 2016, Amsterdam, Netherlands

87. The World Professional Association for Transgender Health, Construction of a neovagina for male-to-female gender reassignment surgery using a modified intestinal vaginoplasty technique, poster session (Poster session #198), June 18-22, 2016, Amsterdam, Netherlands

88. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Genital Aesthetics: What are we trying to achieve?, Washington, DC June 23-25, 2016

89. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Female to Male Gender Reassignment, Washington, DC June 23-25, 2016

90. Aesthetica Super Symposium, The American Society of Plastic Surgeons, The journal of retractions, what I no longer do, Washington, DC June 23-25, 2016

91. Aesthetica Super Symposium, The American Society of Plastic Surgeons, The three minute drill, tips and tricks, Washington, DC June 23-25, 2016

92. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Moderator, Mini master class: Male genital plastic surgery, Washington, DC June 23-25, 2016

93. The 16th Annual Chicago Trauma Symposium, August 18-21, 2016, Chicago, Il "Soft Tissue Defects-Getting Coverage"

94. USPATH Poster Session, Feb 2-5, 2017, Los Angeles, CA, Partial Flap Failure Five Weeks Following Radial Forearm Phalloplasty: Case Report and Review of the Literature

95. USPATH Poster Session, Feb 2-5, 2017, Los Angeles, CA, Urethroplasty for Stricture after Phalloplasty in Transmen Surgery for Urethral Stricture Disease after Radial Forearm Flap Phalloplasty–Management Options in Gender Confirmation Surgery

96. USPATH, Feb 2-5, 2017, Los Angeles, CA, Patient Evaluation and Chest Surgery in Transmen: A Pre-operative Classification

97. USPATH, Feb 2-5, 2017, Los Angeles, CA Single Stage Urethral Reconstruction in Flap Phalloplasty: Modification of Technique for Construction of Proximal Urethra

98. USPATH, Feb 2-5, 2017, Los Angeles, CA, Use of Bilayer Wound Matrix on Forearm Donor Site Following Phalloplasty

99. USPATH, Feb 2-5, 2017, Los Angeles, CA, Vaginoplasty: Surgical Techniques

100. USPATH, Feb 2-5, 2017, Los Angeles, CA, Positioning of a Penile Prosthesis with an Acellular Dermal Matrix Wrap following Radial Forearm Phalloplasty

101. USPATH, Feb 2-5, 2017, Los Angeles, CA, Principles for a Gender Surgery Program

102. USPATH, Feb 2-5, 2017, Los Angeles, CA, Construction of a Neovagina Using a Modified Intestinal Vaginoplasty Technique

103. The 18th Annual Chicago Orthopedic Symposium, July 6-9, 2017, Chicago, Il "Soft Tissue Defects-Getting Coverage"

104. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Moderator: Genital Surgery Trends for Women

105. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Adding Transgender Surgery to Your Practice, Moderator and Speaker

106. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Transbottom Surgery

107. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018 A Novel Approach to IPP Implantation Post Phalloplasty: The Chicago Experience

108. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018, A Novel Approach for Neovagina Configuration During Vaginoplasty for Gender Confirmation Surgery

109. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018 Developlment of a Pelvic Floor Physical Therapy Protocol for Patients Undergoing Vaginoplasty for Gender Confirmation

110. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018 Establishing Guidelines for Gender Confirmation Surgery: The Perioperative Risk of Asymptomatic Deep Venous Thrombosis for Vaginoplasty

111. The 19th Annual Chicago Trauma Symposium, August 16-19, 2018, Chicago, Il "Soft Tissue Defects-Getting Coverage"

112. Midwest LGBTQ Health Symposium, September 14-15, 2018, Chicago, Il "Quality Parameters in Gender Confirmation Surgery"

113. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Poster Session, Proposed Guidelines for Medical Tattoo Following Phalloplasty; An Interdisciplinary Approach

114. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Establishment of the First Gender Confirmation Surgery Fellowship

115. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, ISSM Lecture, The Importance of Surgical Training

116. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Tracking Patient-Reported Outcomes in Gender Confirmation Surgery

117. "Theorizing the Phantom Penis," The Psychotherapy Center for Gender and Sexuality's 6th Biannual Conference, Transformations, March 29-March 30, 2019, NY, NY

INSTRUCTIONAL COURSES:

1. Emory University and WPATH: Contemporary Management of Transgender Patients: Surgical Options and Decision-Making, September 5, 2007 Chicago, Il

2. Craniomaxillofacial Trauma Surgery: An Interdisciplinary Approach, February 16-17, 2008, Burr Ridge, Il

3. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, Moderator: Free Papers, Lower Extremity

4. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Moderator: ASPS/ASPSN Patient Panel: Effective Communication-A Key to Patient Safety and Prevention of Malpractice Claims

5. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Instructional Course: Strategies to Identify and Prevent Errors and Near Misses in Your Practice

6. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Roundtable Discussion: Electronic Health Records-Implications for Plastic Surgeons

7. 10th Congress of The European Federation of Societies for Microsurgery, May 2—22, 2010, Genoa, Italy, "The Mangled Lower Extremities: An Algorithm for Soft Tissue Reconstruction."

8. Mulitspecialty Course for Operating Room Personnel-Craniomaxillofacial, Orthopaedics, and Spine, A Team Approach, AO North American, June 26-27, 2010, The Westin Lombard Yorktown Center.

9. Management of Emergency Cases in the Operating Room, The American Society of Plastic Surgeons Annual Meeting, October 4, 2010, Toronto, CA.

10. Surgical Approaches and Techniques in Craniomaxillofacial Trauma, November 6, 2010, Burr Ridge, Il.

11. The Business of Reconstructive Microsurgery: Maximizing Economic value (Chair)The American Society for Reconstructive Microsurgery, January 14-17, 2012, Las Vegas, Nevada.

12. Strategies to Identify and Prevent Errors and Near Misses in Your Practice, The Annual Meeting of The American Society of Plastic Surgeons, October 25th-30th, 2012, New Orleans, LA

13. Strategies to Identify and Prevent Errors and Near Misses in Your Practice, The Annual Meeting of The American Society of Plastic Surgeons, October 11th-15th, 2013, San Diego, CA

14. Mythbusters: Microsurgical Breast Reconstruction in Private Practice, The Annual Meeting of The American Society of Plastic Surgeons, October 11th-15th, 2013, San Diego, CA

15. Minimizing Complications in Perioperative Care, The American Society for Reconstructive Microsurgery, January 11-14, 2014, Kauai, Hawaii

16. Genitourinary and Perineal Reconstruction, The American Society for Reconstructive Microsurgery, January 11-14, 2014, Kauai, Hawaii

17. Transgender Breast Surgery, The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA

18. Gender Confirmation Surgery, The School of the Art Institute (recipient of American College Health Fund's Gallagher Koster Innovative Practices in College Health Award), October 27, 2015, Chicago, Il

19. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Overview of Surgical Treatment Options

20. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015 Chicago, Il Surgical Procedures

21. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Surgical Complications

22. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Post-operative Care

23. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Case Discussions: The Multidisciplinary Team

24. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, January 20-23,2016, Atlanta, GA Overview of Surgical Treatment Options

25. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, January 20-23, 2016, Atlanta, GA Surgical Treatment Options

26. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, March 30-April 1, 2016, Springfield, MO, Surgical Treatment Options.

27. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, March 30-April 1, 2016, Springfield, MO, Multi-disciplinary Case Discussion.

28. Introduction to Transgender Surgery, ASPS Breast Surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

29. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course, September 28, 2016, Ft. Lauderdale, FL.

30. Cirugias de Confirmacion de Sexo Paso a Paso, XXXV Congreso Confederacion Americana de Urologia (CAU), Panama City, Panama, October 4-8, 2016.

31. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course, December 3, 2016, Arlington, VA.

32. PSEN (sponsored by ASPS and endorsed by WPATH), Transgender 101 for Surgeons, January 2017-March 2017

33. Surgical Anatomy and Surgical Approaches to M-to-F Genital Gender Affirming Surgery and the Management of the Patient Before, During and After Surgery: A Human Cadaver Based Course, Orange County, CA, Feb. 1, 2017

34. Gender Confirmation Surgery, ALAPP, 2 Congreso Internacional de la Asociacion Latinoamericana de Piso Pelvico, Sao Paulo, Brasil, 9-11 de marzo de 2017

35. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course, Overview of Surgical Treatment, March 31-April 2, 2017, Minneapolois Minnesota.

36. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course, The Multi-Disciplinary Team Case Discussions, March 31-April 2, 2017, Minneapolois Minnesota.

37. Transfeminine Cadaver Course, WPATH, May 19-20, 2017, Chicago, Il

38. Transgender/Penile Reconstruction-Penile Reconstruction: Radial Forearm Flap Vs. Anterolateral Thigh Flap, Moderator and Presenter, The World Society for Reconstructive Microsurgery, June 14-17, 2017, Seoul, Korea

39. Primer of Transgender Breast Surgery, ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017

40. Confirmation Surgery in Gender Dysphoria: current state and future developments, International Continence Society, Florence, Italy, September 12-15, 2017

41. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, ASPS/WPATH Joint Session, Session Planner and Moderator

42.Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course: Overview of Surgical Treatment, Columbus, OH, October 20-21, 2017

43. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course: Medical Care in the Perioperative Period, Aftercare: Identifying Potential Complications, Columbus, OH, October 20-21, 2017

44. Webinar: Gender Affirming Surgeries 101: Explore The Latest Topics in Gender Affirmation Surgery, PSEN, April 18, 2018

45. Course Director: MT. Sinai/WPATH Live Surgery Training Course for Gender Affirmation Procedures, April 26-28, 2018, New York, NY

46. Philadelphia Trans Wellness Conference, Perioperative Care of the Transgender Woman Undergoing Vaginoplasty (Workshop), Philadelphia, PA, August 3, 2018

47. Philadelphia Trans Wellness Conference, Gender Confirmation Surgery (Workshop), Philadelphia, PA, August 3, 2018

48. Gender Confirmation Surgery, 2018 Oral and Written Board Preparation Course, The American Society of Plastic Surgeons, August 16-18, 2018, Rosemont, Il

49. Confirmation Surgery in Gender Dysphoria: Current State and Future Developments, The International Continence Society, Philadelphia, PA August 28, 2018

50. WPATH Global Education Initiative, Foundations Training Course, “Overview of Surgical Treatment,” Cincinnati, OH, September 14-15, 2018

51. WPATH Global Education Initiative, Foundations Training Course, “The Multi-Disciplinary Team: Case Discussions,” Cincinnati, OH, September 14-15, 2018

52. WPATH Global Education Initiative, Advanced Training Course, “Medical Care in the Perioperative Period After Care: Identifying Potential Complications,” Cincinnati, OH, September 14-15, 2018

53. 25th WPATH Symposium, Surgeons Conference, November 1, 2018, Buenos Aires, Argentina, Moderator

54. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Global Education Initiative (GEI): Surgery and Ethics

55. WPATH GEI: Best Practices in Medical and Mental Health Care, Foundations in Surgery, New Orleans, March 22, 2019

56. WPATH GEI: Best Practices in Medical and Mental Health Care, Advanced Surgery, New Orleans, March 22, 2019

57. Program Chair: ASPS/WPATH GEI Inaugural Gender-Affirming Breast, Chest, and Body Master Class, Miami, Fl, July 20, 2019

58. Overview of Surgical Management and The Standards of Care (WPATH, v. 7) ASPS/WPATH GEI Inaugural Gender-Affirming Breast, Chest, and Body Master Class, Miami, Fl, July 20, 2019

59. Program Director, Gender Affirming Breast,Chest, and Body Master Class, The American Society of Plastic Surgeons, Miami, Fl, July 20, 2019

60. Gender Confirmation Surgery, The American Society of Plastic Surgeons Oral and Written Board Preparation Course, August 15, 2019, Rosemont, Il

61. Upper Surgeries (chest surgery & breast augmentation), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

62. Preparing for Upper Surgeries-Case Based (chest surgery & breast augmentation), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

63. Preparing for Feminizing Lower Surgeries-Case Based (vaginoplasty), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

64. Lower Surgeries-Masculinizing (phalloplasty & metoidioplasty), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

65. Preparing for Masculinizing Lower Surgeries-Case Based (phalloplasty & metoidioplasty), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

66. Panel Discussion about Ethics in Surgery and Interdisciplinary Care, WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

67. Discussion about Ethics and Tensions in Child and Adolescent Care, WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

68. Transgender Health: Best Practices in Medical and Mental Health Care Foundation Training Courses, Hanoi, Viet Nam, Jan 14-17, 2020 (Foundations in Surgery, Advanced Medical-surgery and complicated case studies), Planning & Documentation (upper surgeries-chest surgery and breast augmentation, preparing for upper surgeries-case based (chest surgery and breast augmentation), lower surgeries (feminizing-vaginoplasty), preparing for feminizing lower surgeries-case based, lower surgeries-masculinizing (phalloplasty and metoidioplasty), preparing

for masculinizing lower surgeries-case-based (phalloplasty and metoidioplasty), Ethics-panel discussion about ethics in surgery and interdisciplinary care)

69. WPATH GEI Panel Cases Discussion, via Webinar, May 29, 30, 31, 2020

70. WPATH GEI: Illinois Dept. of Corrections, Foundations in Surgery, November 20, 2020

71. WPATH GEI: Illinois Dept. of Corrections, Ethical Considerations in Transgender Healthcare, November 20, 2020

72. WPATH GEI: Illinois Dept. of Corrections, Foundations in Surgery, February 26, 2021

73. WPATH GEI: Illinois Dept. of Corrections, Ethical Considerations in Transgender Healthcare, February 26, 2021.

74. Current Concepts in Gender Affirming Surgery for Women in Transition, March 11-12, 2021 (online event), Moderator, Transgender Health.

75. GEI Foundations Course, Live Q&A, March 21, 2021

76. GEI Foundations Course, Live Case Panel Discussion, March 23, 2021

77. GEI Advanced Ethics Workshop; Surgical and Interdisciplinary care ethics panel, May 1, 2021 (virtual)

78. Wpath GEI Foundations course for the Illinois Dept of Corrections, Foundations in Surgery, May 21, 2021

79. Wpath GEI, Foundations course for the Illinois Dept of Corrections, Ethical considerations in Transgender Healthcare, May 21, 2021

80. WPATH GEI, Online GEI Foundations Course, Moderator, August 31, 2001.

81. WPATH Health Plan Provider (HPP) Training, Q&A Panel, September 13, 14, 21 2021, via Zoom

82. WPATH, GEI Advanced Medical Course, Upper and Lower Surgery (via zoom), December 9, 2021

SYMPOSIA:

1. Program Director, 2011 Chicago Breast Symposium, October 15, 2011, The Chicago Plastic Surgery Research Foundation and The Chicago Medical School at Rosalind Franklin University, North Chicago, IL,

2. Fundamentals of Evidence-Based Medicine & How to Incorporate it Into Your Practice, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

3. Understanding Outcome Measures in Breast & Body Contouring Surgery, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

4. Benchmarking Complications: What We Know About Body Contouring Complication Rates from Established Databases, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

5. Special Lecture: VTE Prophylaxis for Plastic Surgery in 2011, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

6. Nipple Sparing Mastectomy: Unexpected Outcomes, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

7. Program Director, 2011 Chicago Breast Symposium, October 13-14, 2012, The Chicago Plastic Surgery Research Foundation and The Chicago Medical School at Rosalind Franklin University, North Chicago, Il

8. Practice Strategies in a Changing Healthcare Environment, Moderator, Midwestern Association of Plastic Surgeons, April 27-28, 2013, Chicago, Il

9. Moderator: Breast Scientific Paper Session, The Annual Meeting of The American Society of Plastic Surgery, October 12, 2014, Chicago, Il.

10. Moderator: The World Professional Association for Transgender Health, Tuesday, June 21, Surgical Session (0945-1045), June 18-22, 2016, Amsterdam, Netherlands

11. Course Director: Transmale Genital Surgery: WPATH Gender Education Initiative, October 21-22, 2016 Chicago, Il

12. Co-Chair and Moderator: Surgeon's Only Session, USPATH, Los Angeles, CA, Feb. 2, 2017

13. Vascular Anastomosis: Options for Lengthening Vascular Pedicle, Surgeon's Only Session, USPATH, Los Angeles, CA, Feb. 2, 2017

14. Transgender Healthcare Mini-Symposium, Chicago Medical School of Rosalind Franklin University, North Chicago, Il March 10, 2017.

15. Moderator: Penile Transplant: Genito-urinary trauma/penile cancer, The European Association of Urologists, Meeting of the EAU Section of Genito-Urinary Reconstructive Surgeons (ESGURS), London, United Kingdom, March 23-26, 2017

16: 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Mini-Symposium: A Comprehensive Approach to Gender Confirming Surgery

17. Program Director, 2nd Annual Live Surgery Conference for Gender Affirmation Procedures, Ichan School of Medicine at Mt. Sinai, NY, NY February 28, 2019-March 2, 2019.

18. Moderator, "Genital Reassignment for Adolescents: Considerations and Conundrums," Discussions on gender affirmation: surgery and beyond, Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

19. Moderator, "Reconstructive Urology and Genitourinary Options in Gender Affirming Surgery," Discussions on gender affirmation: surgery and beyond, Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

20. Moderator, "Complications in Masculinizing Genital Reconstruction Surgery," Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

21. Moderator, "Preparing for Surgery and Recovery," Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

22. Discussant, "WPATH Standards of Care Version 8 Preview," Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

23. Program Coordinator, Surgeon's Only Course, USPATH, September 5, 2019, Washington, DC

24. Master Series in Transgender Surgery 2020: Vaginoplasty and Top Surgery, course co-director, Mayo Clinic, Rochester, MN, August 7-8, 2020

25. WPATH 2020 Surgeons' Program, Co-Chair, November 6-7, 2020, Virtual Symposium (due to covid-19 cancellation of Hong Kong meeting)

26. WPATH Journal Club #3, Uterine Transplantation and Donation in Transgender Individuals; Proof of Concept, December 13, 2021 (Zoom)

FACULTY SPONSORED RESEARCH:

1. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, "Free Tissue Transfer in the Treatment of Zygomycosis." Presented by Michelle Roughton, MD

2. Hines/North Chicago VA Research Day, Edward Hines, Jr., VA Hospital, Maywood, Il, April 29, 2010, "Breast MRI Helps to Define the Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.

3. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Breast MRI Helps to Define the Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.

4. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Achieving Soft Tissue Coverage of Complex Upper and Lower Extremity Defects with Omental Free Tissue Transfer." Presented by Iris A. Seitz, MD, PhD.

5. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Facilitating Harvest of the Serratus Fascial Flap with Ultrasonic Dissection." Presented by Iris A. Seitz, MD, PhD.

6. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010,"Patient Safety: Abdominoplasty and Intra-Abdominal Procedures." Presented by Michelle Roughton, MD

7. The Midwestern Association of Plastic Surgeons, 49th Annual Scientific Meeting, May 15th, 2010, "Breast MRI Helps Define The Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.

8. Jonathan M. Hagedorn, BA, **Loren S. Schechter**, MD, FACS, Dr. Manoj R. Shah, MD, FACS, Matthew L. Jimenez, MD, Justine Lee, MD, PhD, Varun Shah. Re-examining the Indications for Limb Salvage, 2011 All School Research Consortium at Rosalind Franklin University. Chicago Medical School of Rosalind Franklin University, 3/16/11.

9. Jonathan Bank, MD, Lucio A. Pavone, MD, Iris A. Seitz, Michelle C. Roughton, MD, Loren S. Schechter, MD Deep Inferior Epigastric Perforator Flap for Breast Reconstruction after Abdominoplasty The Midwestern Association of Plastic Surgeons, 51st Annual Educational Meeting, April 21-22, 2012, Northwestern Memorial Hospital, Chicago, Illinois

10. Samuel Lake, Iris A. Seitz, MD, Phd, Loren S. Schechter, MD, Daniel Peterson, Phd Omentum and Subcutaneous Fat Derived Cell Populations Contain hMSCs Comparable to Bone Marrow-Derived hMSCsFirst Place, Rosalind Franklin University Summer Research Poster Session

11. J. Siwinski, MS II, Iris A. Seitz, MD PhD, Dana Rioux Forker, MD, Lucio A. Pavone, MD, Loren S Schechter, MD FACS. Upper and Lower Limb Salvage With Omental Free Flaps: A Long-Term Functional Outcome Analysis. Annual Dr. Kenneth A. Suarez Research Day, Midwestern University, Downers Grove, IL, May 2014

12. Whitehead DM, Kocjancic E, Iacovelli V, Morgantini LA, **Schechter LS**. A Case Report: Penile Prosthesis With an Alloderm Wrap Positioned After Radial Forearm Phalloplasty. Poster session presented at: American Society for Reconstructive Microsurgery Annual Meeting, 2018 Jan 13-16; Phoenix, AZ.

13. Whitehead DM, Kocjancic E, Iacovelli V, Morgantini LA, **Schechter LS**. An Innovative Technique: Single Stage Urethral Reconstruction in Female-to-Male Patients. Poster session presented at: American Society for Reconstructive Microsurgery Annual Meeting, 2018 Jan 13-16; Phoenix, AZ.

14. Whitehead, DM Inflatable Penile Prosthesis Implantation Post Phalloplasty: Surgical Technique, Challenges, and Outcomes, MAPS 2018 Annual Scientific Meeting, April 14, 2018, Chicago, Il

15. Whitehead, DM, Inverted Penile Skin With Scrotal Graft And Omission of Sacrospinal Fixation: Our Novel Vaginoplasty Technique MAPS 2018 Annual Scientific Meeting, April 14, 2018, Chicago, Il

16. S. Marecik, J. Singh. **L. Schechter**, M. Abdulhai, K. Kochar, J. Park, Robotic Repair of a Recto-Neovaginal Fistula in a Transgender Patient Utilizing Intestinal Vaginoplasty, The American College of Surgeons Clinical Congress 2020, October 7, 20

Keynote Address:

1. University of Utah, Gender Confirmation Surgery, Transgender Provider Summit, November 8, 2014

INVITED LECTURES:

1. Management of Soft Tissue Injuries of the Face, Grand Rounds, Emergency Medicine, The University of Chicago, August, 1999

2. Case Report: Excision of a Giant Neurofibroma, Operating Room Staff Lecture Series, Continuing Education Series, St. Francis Hospital, Evanston, Il March 2000

3. Wounds, Lincolnwood Family Practice, Lincolnwood, Il April 2000

4. The Junior Attending, Grand Rounds, Plastic and Reconstructive Surgery, The University of Chicago, June 2000

5. Case Report: Excision of a Giant Neurofibroma, Department of Medicine Grand Rounds, St. Francis Hospital, Evanston, Il June 2000

6. Facial Trauma, Resurrection Medical Center Emergency Medicine Residency, September 2000

7. Plastic Surgery of the Breast and Abdomen, Grand Rounds, Dept. of Obstetrics and Gynecology, Evanston Hospital, September, 2000

8. Change of Face; Is Cosmetic Surgery for You?, Adult Education Series, Rush North Shore Medical Center, October, 2000

9. Reconstructive Surgery of the Breast, Professional Lecture Series on Breast Cancer, St. Francis Hospital, October, 2000

10. Plastic Surgery of the Breast and Abdomen, Grand Rounds, Dept. of Obstetrics and Gynecology, Lutheran General Hospital, December, 2000

11. Change of Face; Is Cosmetic Surgery for You?, Adult Education Series, Lutheran General Hospital and The Arlington Heights Public Library, December, 2000

12. Updates in Breast Reconstruction, The Breast Center, Lutheran General Hospital, January 2001

13. Abdominal Wall Reconstruction, Trauma Conference, Lutheran General Hospital, February 2001

14. Wound Care, Rush North Shore Medical Center, March 2001

15. Breast Reconstruction, Diagnosis and Treatment Updates on Breast Cancer, Lutheran General Hospital, April 2001

16. Wound Care and V.A.C. Therapy, Double Tree Hotel, Skokie, Il October 2001

17. The Role of the V.A.C. in Reconstructive Surgery, LaCrosse, WI November 2001

18. Dressing for Success: The Role of the V.A.C. in Reconstructive Surgery, Grand Rounds, The University of Minnesota Section of Plastic and Reconstructive, Minneapolis, MN January, 2002

19. The Vacuum Assisted Closure Device in the Management of Complex Soft Tissue Defects, Eau Claire, WI February, 2002

20. The Vacuum Assisted Closure Device in Acute & Traumatic Soft Tissue Injuries, Orland Park, Il March, 2002

21. Body Contouring After Weight Loss, The Gurnee Weight Loss Support Group, Gurnee, Il April, 2002

22. An Algorithm to Complex Soft Tissue Reconstruction With Negative Pressure Therapy, Owensboro Mercy Medical Center, Owensboro, Ky, April, 2002

23. Breast and Body Contouring, St. Francis Hospital Weight Loss Support Group, Evanston, Il April, 2002

24. The Wound Closure Ladder vs. The Reconstructive Elevator, Surgical Grand Rounds, Lutheran General Hospital, Park Ridge, Il, May, 2002.

25. An Algorithm for Complex Soft Tissue Reconstruction with the Vacuum Assisted Closure Device, The Field Museum, Chicago,Il, May, 2002

26. The Role of Negative Pressure Wound Therapy in Reconstructive Surgery, Kinetic Concepts, Inc. San Antonio, Texas, July 31, 2002

27. Management of Complex Soft Tissue Injuries of the Lower Extremity, Chicago Trauma Symposium, August 2-5, 2002, Chicago, Illinois:

28. Wound Bed Preparation, Smith Nephew, Oak Brook, Il, August 6, 2002

29. Getting Under Your Skin...Is Cosmetic Surgery for You?, Rush North Shore Adult Continuing Education Series, Skokie, Il August 28, 2002.

30. The Role of Negative Pressure Therapy in Complex Soft Tissue Wounds, Columbia/St. Mary's Wound, Ostomy, and Continence Nurse Program, Milwaukee, Wi, September 17, 2002

31. A Systematic Approach to Functional Restoration, Grand Rounds, Dept. of Physical Therapy and Rehabilitation Medicine, Lutheran General Hospital, September 19, 2002

32. The Role of Negative Pressure Wound Therapy in Reconstructive Surgery, Ann Arbor, Mi September 26, 2002

33. Dressing for Success: The Role of the Vaccuum Assisted Closure Device in Plastic Surgery, Indianopolis, In November 11, 2002

34. The Wound Closure Ladder Versus the Reconstructive Elevator, Crystal Lake, Il November 21, 2002

35. A Systematic Approach to Functional Restoration, Grand Rounds, Dept. of Physical Therapy, Evanston Northwestern Healthcare, Evanston, Il February 13, 2003

36. Case Studies in Traumatic Wound Reconstruction, American Association of Critical Care Nurses, Northwest Chicago Area Chapter, Park Ridge, Il February 19, 2003

37. Reconstruction of Complex Soft Tissue Injuries of the Lower Extremity, Podiatry Lecture Series, Rush North Shore Medical Center, Skokie, Il March 5, 2003

38. The Use of Negative Pressure Wound Therapy in Reconstructive Surgery, Kalamazoo, Mi March 19, 2003

39. Updates in Breast Reconstruction, The Midwest Clinical Conference, The Chicago Medical Society, Chicago, Il March 21, 2003

40. Updates of Vacuum Assisted Closure, Grand Rounds, The Medical College of Wisconsin, Department of Plastic Surgery, Milwaukee, Wi March 26, 2003

41. Breast Reconstruction, Surgical Grand Rounds, Lutheran General Hospital, Park Ridge, Il March 27, 2003

42. Decision-Making in Breast Reconstruction: Plastic Surgeons as Members of a Multi-Disciplinary Team, 1st Annual Advocate Lutheran General Hospital Breast Cancer Symposium, Rosemont, Il, April 11, 2003

43. The Wound Closure Ladder Versus The Reconstructive Elevator, Duluth, Mn, April 24, 2003

44. Dressing For Successs: The Role of The Wound VAC in Reconstructive Surgery, Detroit, Mi, May 9, 2003

45. Plastic Surgery Pearls, Grand Rounds Orthopedic Surgery Physician Assistants Lutheran General Hospital and Finch University of Health Sciences, Park Ridge, Il, June 5, 2003

46. A Systematic Approach to Complex Reconstruction, 12th Annual Vendor Fair "Surgical Innovations," October 18, 2003, Lutheran General Hospital, Park Ridge, Il 2003

47. Dressing For Success: The Role of the Wound VAC in Reconstructive Surgery, American Society of Plastic Surgery, October 26, 2003, San Diego, CA

48. Beautiful You: From Botox to Weekend Surgeries, 21st Century Cosmetic Considerations, March 21, 2004 Hadassah Women's Health Symposium, Skokie, Il

49. Updates in Breast Reconstruction, The 2nd Annual Breast Cancer Symposium, Advocate Lutheran General, Hyatt Rosemont, April 2, 2004

50. Head and Neck Reconstruction, Grand Rounds, The University of Illinois Metropolitan Group Hospitals Residency in General Surgery, Advocate Lutheran General Hospital, May 6, 2004

51. Abdominal Wall Reconstruction, Surgeons Forum, LifeCell Corporation, May 15, 2004, Chicago, Il

52. 4th Annual Chicagoland Day of Sharing for Breast Cancer Awareness, Saturday, October 2, 2004, Hoffman Estates, Il

53. Abdominal Wall Reconstruction, University of Illinois Metropolitan Group Hospitals Residency in General Surgery, November 19, 2004, Skokie, Il

54. Advances in Wound Care, Wound and Skin Care Survival Skills, Advocate Good Samaritan Hospital, Tuesday, February 8, 2005, Downer's Grove, Il

55. Plastic Surgery: A Five Year Perspective in Practice, Grand Rounds, The University of Chicago, May 18, 2005, Chicago, Il

56. New Techniques in Breast Reconstruction, The Cancer Wellness Center, October 11, 2005 Northbrook, Il

57. Principles of Plastic Surgery; Soft Tissue Reconstruction of the Hand, Rehab Connections, Inc., Hand, Wrist, and Elbow Forum, October 28, 2005, Homer Glen, Il

58. Principles of Plastic Surgery, Lutheran General Hospital Quarterly Trauma Conference, November 9, 2005, Park Ridge, Il

59. Principles of Plastic Surgery, Continuing Medical Education, St. Francis Hospital, November 15, 2005, Evanston, Il

60. Dressing for Success: A Seven Year Experience with Negative Pressure Wound Therapy, Kinetic Concepts Inc, November 30, 2005, Glenview, Il.

61. Breast Reconstruction: The Next Generation, Breast Tumor Conference, Lutheran General Hospital, May 9, 2006.

62. Complex Wound Care: Skin Grafts, Flaps, and Reconstruction, The Elizabeth D. Wick Symposium on Wound Care, *Current Concepts in Advanced Healing: An Update*, Rush North Shore Medical Center, November 4, 2006.

63. An Approach to Maxillofacial Trauma: Grand Rounds, Lutheran General Hospital/Univ. of Illinois Metropolitan Group Hospital Residency in General Surgery, November 9, 2006.

64. "From Paris to Park Ridge", Northern Trust and Advocate Lutheran General Hospital, Northern Trust Bank, June 7, 2007.

65. "Private Practice Plastic Surgery: A Seven Year Perspective," Grand Rounds, The University of Chicago, Section of Plastic Surgery.

66. "Meet the Experts on Breast Cancer," 7th Annual Chicagoland Day of Sharing, Sunday, April 13th, 2008

67. Gender Confirmation Surgey: Surgical Options and Decision-Making, The University of Minnesota, Division of Human Sexuality, May 10, 2008, Minneapolis, Minnesota.

68. "Private Practice Plastic Surgery: A Seven Year Perspective," Grand Rounds, Loyola University, 2008 Section of Plastic Surgery.

69. "Management of Lower Extremity Trauma," Grand Rounds, The University of Chicago, Section of Plastic Surgery, October, 8, 2008.

70. "Concepts in Plastic Surgery: A Multi-Disciplinary Approach," Frontline Surgical Advancements, Lutheran General Hospital, November 1, 2008

71. "Surgical Techniques-New Surgical Techniques/Plastic Surgery/Prosthetics," Caldwell Breast Center CME Series, Advocate Lutheran General Hospital, November 12, 2008

72. "Genetics: *A Family Affair*" Panel Discussion: Predictive Genetic Testing, 23rd Annual Illinois Department of Public Health Conference, Oak Brook Hills Marriott Resort, Oak Brook, Il, March 18, 2009

73. "Gender Confirmation Surgery" Minnesota TransHealth and Wellness Conference, May 15, 2009, Metropolitan State University, Saint Paul, MN.

74. "The Role of Plastic Surgery in Wound Care, " Practical Wound Care A Multidisciplinary Approach, Advocate Lutheran General Hospital, October 9-10, 2009, Park Ridge, Il.

75. "In The Family," Panel, General Session III, 2009 Illinois Women's Health Conference, Illinois Dept. of Health, Office of Women's Health October 28-29, 2009, Oak Brook, Il.

76. "Patient Safety in Plastic Surgery," The University of Chicago, Section of Plastic Surgery, Grand Rounds, November 18, 2009.

77. "Compartment Syndrome," 6th Annual Advocate Injury Institute Symposium, Trauma 2009: Yes We Can!, November 19-20, 2009.

78. "Maxillofacial Trauma," 6th Annual Advocate Injury Institute Symposium, Trauma 2009: Yes We Can!, November 19-20, 2009.

79. "Management of Complex Lower Extremity Injuries," Grand Rounds, The Section of Plastic Surgery, The University of Chicago, December 16, 2009, Chicago, Il.

80. "Gender-Confirming MTF Surgery: Indications and Techniques," Working Group on Gender, New York State Psychiatric Institute, March 12, 2010

81. "Gender-Confirmation Surgery," Minnesota Trans Health and Wellness Conference, Metropolitan State University, St. Paul Campus, May 14th, 2010

82. "Physical Injuries and Impairments," Heroes Welcome Home The Chicago Association of Realtors, Rosemont, Illinois, May 25th, 2010.

83. "Genetics and Your Health," Hadassah Heals: Healing Mind, Body, & Soul, Wellness Fair, 2010, August 29, 2010, Wilmette, Illinois.

84. "GCS," Southern Comfort Conference 2010, September 6-11, 2010, Atlanta, GA.

85. "Gender Confirming Surgery," The Center, The LGBT Community Center, October 22, 2010 New York, NY.

86. "Gender Confirming Surgery," the Center, The LGBT Community Center, May 20, 2011, New York, NY.

87. "Gender Confirming Surgery," Roosevelt-St. Lukes Hospital, May 20, 2011, New York, NY

88. "Principles of Plastic Surgery," Learn about Ortho, Lutheran General Hospital, May 25, 2011, Park Ridge, Il.

89. "Forging Multidisciplinary Relationships in Private Practice," Chicago Breast Reconstruction Symposium 2011, September 9, 2011, Chicago, Il

90. "Gender Confirming Surgery," Minnesota TransHealth and Wellness Conference, Diverse Families: Health Through Community, September 10, 2011, Minneapolis, Minnesota

91. "Gender Confirming Surgery," University of Chicago, Pritzker School of Medicine, Anatomy Class, September 16, 2011, Chicago, Il

92. "Facial Trauma," 8th Annual Advocate Injury Institute Symposium, Trauma 2011: 40 years in the Making, Wyndham Lisle-Chicago, November 9-10, 2011

93. "Establishing a Community-Based Microsurgical Practice," QMP Reconstructive Symposium, November 18-20, 2011, Chicago, Il

94. "Surgery for Gender Identity Disorder," Grand Rounds, Dept. of Obstetrics and Gynecology, Northshore University Health System, December 7, 2011

95. "Managing Facial Fractures," Trauma Grand Rounds, Lutheran General Hospital, Park Ridge, Il July 17, 2012

96. "Principles of Transgender Medicine," The University of Chicago Pritzker School of Medicine, Chicago, Il, September 7, 2012

97. "State of the art breast reconstruction," Advocate Health Care, 11th Breast Imaging Symposium, January 26, 2013, Park Ridge, Il.

98. "State of the art breast reconstruction," Grand Rounds, Dept. of Surgery, Mount Sinai Hospital, April 25, 2013, Chicago, Il.

99. "Getting under your skin: is cosmetic surgery right for you?" Lutheran General Hospital community lecture series, May 7, 2013, Park Ridge, Il.

100. "Gender Confirming Surgery," University of Chicago, Pritzker School of Medicine, Anatomy Class, September 27, 2013, Chicago, Il

101. "State of the Art Breast Reconstruction," Edward Cancer Center, Edward Hospital, October 22, 2013, Naperville, Il

102. "Transgender Medicine and Ministry," Pastoral Voice, Advocate Lutheran General Hospital, October 23, 2013, Park Ridge, Il

103. "Principles of Transgender Medicine and Surgery," The University of Illinois at Chicago College of Medicine, January 28, 2014, Chicago, Il

104. "Principles of Transgender Medicine and Surgery," Latest Surgical Innovations and Considerations, 22nd Annual Educational Workshop, Advocate Lutheran General Hospital, March 1, 2014, Park Ridge, Il.

105. "Principles of Transgender Medicine: Gender Confirming Surgery," Loyola University Medical Center, March 12, 2014.

106. "Principles of Plastic Surgery," Grand Rounds, Dept. of Obstetrics and Gynecology, Lutheran General Hospital, September 12, 2014.

107. "Gender Confirmation Surgery," The University of Chicago, Pritzker School of Medicine, October 3, 2014

108. "Private Practice: Is There a Future?" The Annual Meeting of The American Society of Plastic Surgical Administrators/The American Society of Plastic Surgery Assistants, Chicago, Il, October 11, 2014.

109. "Private Practice: Is There a Future?" The Annual Meeting of The American Society of Plastic Surgery Nurses, Chicago, Il, October 12, 2014.

110. "Gender Confirmation Surgery" Grand Rounds, The University of Minnesota, Dept. of Plastic Surgery, Minneapolis, MN, October 29, 2014.

111. "Body Contour After Massive Weight Loss," The Bariatric Support Group, Advocate Lutheran General Hospital, February 5, 2015, Lutheran General Hospital, Park Ridge, Il.

112. "Gender Confirmation Surgery," The School of the Art Institute of Chicago, February 1, 2015, Chicago, Il.

113. “Gender Confirmation Surgery,” The Community Kinship Life/Bronx Lebanon Department of Family Medicine, Bronx, NY, March 6, 2015

114. “Gender Confirmation Surgery,” Educational Inservice, Lutheran General Hospital, Park Ridge, Il, April 20, 2015

115. “Principles of Plastic Surgery, “ Surgical Trends, Lutheran General Hospital, Park Ridge, Il, May 16, 2015

116. “Updates on Gender Confirmation Surgery, “ Surgical Trends, Lutheran General Hospital, Park Ridge, Il, May 16, 2015

117. “Gender Confirmation Surgery,” Lurie Childrens’ Hospital, Chicago, Il, May 18, 2015,Chicago, Il 2015.

118. “Gender Confirmation Surgery,” TransClinical Care and Management Track Philadelphia Trans-Health Conference, June 5, 2015, Philadelphia, Pa.

119. “Gender Confirmation Surgery: A Fifteen Year Experience,” Grand Rounds, The University of Minnesota, Plastic and Reconstructive Surgery and the Program in Human Sexuality, July 30, 2015, Minneapolis, Mn

120. “Gender Confirmation Surgery,” Grand Rounds, Tel Aviv Medical Center, Tel Aviv, Israel, August 13, 2015

121. “Gender Confirmation Surgery,” Grand Rounds, University of Illinois, Dept of Family Medicine, September 2, 2015

122. “Principles of Plastic Surgery,” Grand Rounds, St. Francis Hospital, Evanston, Il September 18, 2015

123. “Gender Confirmation Surgery,” Midwest LGBTQ Health Symposium, Chicago, Il, October 2, 2015

124. “Gender Confirmation Surgery,” Southern Comfort Conference, Weston, Fl, October 3, 2015

125. “Surgical Transitions for Transgender Patients,” Transgender Health Training Institute, Rush University Medical Center, Chicago,Il, October 8, 2015

126. “Gender Confirmation Surgery,” The Transgender Health Education Peach State Conference, Atlanta, GA, October 30, 2015

127. “Gender Confirmation Surgery,” Weiss Memorial Medical Center, November 4, 2015, Chicago, Il

128. "Gender Confirmation Surgery," University of Illinois at Chicago, Operating Room Staff Inservice, November 18, 2015, Chicago, Il

129. "Gender Confirmation Surgery," University of Illinois at Chicago, Plastic Surgery and Urology Inservice, November 18, 2015, Chicago, Il

130. "Gender Confirmation Surgery," Weiss Memorial Medical Center, November 19, 2015, Chicago, Il

131. "Gender Confirmation Surgery," Section of Plastic Surgery, The University of Illinois at Chicago, January 13, 2016, Chicago, Il

132. "Gender Confirmation Surgery," Dept. of Medicine, Louis A. Weiss Memorial Hospital, February 18, 2016, Chicago, Il

133. "Gender Confirmation Surgery," BCBSIL Managed Care Roundtable
March 2, 2016 Chicago, Il

134. "Gender Confirmation Surgery-MtF," Keystone Conference, March 10, 2016, Harrisburg, PA

135. "Gender Confirmation Surgery-FtM," Keystone Conference, March 10, 2016, Harrisburg, PA

136. "Gender Confirmation Surgery," Grand Rounds, Dept. of Ob-Gyn, March 25, 2016, Lutheran General Hospital, Park Ridge, Il 60068

137. "Surgical Management of the Transgender Patient," Spring Meeting, The New York Regional Society of Plastic Surgeons, April 16, 2016, New York, NY

138. "A Three Step Approach to Complex Lower Extremity Trauma," University of Illinois at Chicago, April 27, 2016, Chicago, Il.

139. "Gender Confirmation Surgery," Howard Brown Health Center, July 12, 2016, Chicago, Il

140. "Creating the Transgender Breast M-F; F-M", ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

141. "Overview of Transgender Breast Surgery," ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

142. "VTE Chemoprophylaxis in Cosmetic Breast and Body Surgery: Science or Myth", ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

143. "Gender Confirmation Surgery," Gender Program, Lurie Childrens', Parent Group, September 20, 201, 467 W. Deming, Chicago, Il

144. "Gender Confirmation Surgery," The American Society of Plastic Surgeons Expo, September 24, 2016, Los Angeles, CA

145. Transgender Surgery, Management of the Transgender Patient, Female to Male Surgery, Overview and Phalloplasty, The American College of Surgeons, Clinical Congress 2016 October 16-20,2016 Washington, DC

146. "Gender Confirmation Surgery," The Department of Anesthesia, The University of Illinois at Chicago, November 9, 2016

147. "Gender Confirmation Surgery," The Division of Plastic Surgery, The University of Illinois at Chicago, December 14, 2016

148. "Gender Confirmation Surgery," Nursing Education, The University of Illinois at Chicago, January 10, 2017

149. "F2M-Radial Forearm Total Phalloplasty: Plastic Surgeon's Point of View," The European Association of Urologists, Meeting of the EAU Section of Genito-Urinary Reconstructive Surgeons (ESGURS), London, United Kingdom, March 23-26, 2017

150. "Gender Confirmation Surgery," Grand Rounds, The Department of Surgery, The University of North Carolina, March 29, 2017.

151. "Transgender Facial Surgery," *The Aesthetic Meeting 2017 – 50 Years of Aesthetics* - in San Diego, California April 27– May 2, 2017.

152. "Gender Confirmation Surgery: A New Surgical Frontier," 15th Annual Morristown Surgical Symposium Gender and Surgery, Morristown, NJ, May 5, 2017.

153. "Gender Confirmation Surgery: A New Surgical Frontier," Dept. of Obstetrics and Gynecology, The Medical College of Wisconsin, May 24, 2017

154. "Gender Confirmation Surgery: A New Surgical Frontier," Dept. of Obstetrics and Gynecology, Howard Brown Health Center, August 8, 2017

155. "Current State of the Art: Gynecomastia," ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017

156. "Gender Confirmation Surgery-An Overview," ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017

157. "Gender Confirmation Surgery," Grand Rounds, Dept. of Obstetrics and Gynecology, The University of Chicago, August 25, 2017

158. "Gender Confirmation Surgery," Wake Forest School of Medicine, Transgender Health Conference, Winston-Salem, NC, September 28-29, 2017

159. "Phalloplasty," Brazilian Professional Association for Transgender Health, Teatro Marcos Lindenberg, Universidade Federal de São Paulo (Unifesp), November 1-4, 2017

160. "Gender Confirmation Surgery," Brazlian Professional Association for Transgender Health/WPATH Session, Teatro Marcos Lindenberg, Universidade Federal de São Paulo (Unifesp), November 1-4, 2017

161. "Gender Confirmation Surgery," The Division of Plastic Surgery, The University of Illinois at Chicago, December 13, 2017, Chicago, Il

162. "Gender Confirmation Surgery," Gender and Sex Development Program, Ann and Robert H. Lurie Children's Hospital of Chicago, December 18, 2017, Chicago, Il

163. "Transgender Breast Augmentation," 34th Annual Atlanta Breast Surgery Symposium, January 19-21, 2018, Atlanta, GA

164. "Top Surgery: Transmasculine Chest Contouring," 34th Annual Atlanta Breast Surgery Symposium, January 19-21, 2018, Atlanta, GA

165. "Gender Confirmation Surgery," The 17th International Congress of Plastic and Reconstructive Surgery in Shanghai, March 18-25, 2018, Shanghai, China

166. "Gender Confirmation Surgery: Facial Feminization and Metoidioplasty," 97th Meeting of the American Association of Plastic Surgeons, Reconstructive Symposium, April 7-10, 2018, Seattle, WA

167. Moderator: "Gender Confirmation Surgery: Top Surgery", The Annual Meeting of The American Society of Aesthetic Plastic Surgery, April 26-May 1, 2018, New York, NY

168. "Gender Confirmation Surgery," Econsult monthly meeting, Dept. of Veterans' Affaris, May 24, 2018

169. "Gender Confirmation Surgery," Transgender Care Conference: Improving Care Across the Lifespan, Moses Cone Hospital, Greensboro, NC, June 8, 2018

170. "WPATH State of the Art," 1st Swiss Consensus Meeting on the Standardization of Sex Reassignment Surgery, The University of Basel, August 31, 2018-September 1, 2018

171. "Facial Feminiztion Surgery: The New Frontier?" 1st Swiss Consensus Meeting on the Standardization of Sex Reassignment Surgery, The University of Basel, August 31, 2018-September 1, 2018

172. "Current Techniques and Results in Mastectomies," 1st Swiss Consensus Meeting on the Standardization of Sex Reassignment Surgery, The University of Basel, August 31, 2018-September 1, 2018

173. "Gender Confirmation Surgery," The University of Chicago, Pritzker School of Medicine, September 7, 2018, Chicago, Il.

174. The Business End: Incorporating Gender Confirmation Surgery, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, September 29, 2018, Chicago, Il

175. Body Contouring in Men, Gynecomastia, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, September 30, 2018, Chicago, Il

176. Moderator: Breast Augmentation and Chest Surgery in Gender Diverse Individuals, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, October 1, 2018, Chicago, Il

177. Moderator: Aesthetic Surgery of The Male Genitalia, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, October 1, 2018, Chicago, Il

178. Moderator: Gender Confirmation Surgeries: The Standards of Care and Development of Gender Identity, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, October 1, 2018, Chicago, Il

179. The Center for Gender Confirmation Surgery Lecture Series, "Introduction to Gender Confirmation Surgery," Weiss Memorial Hospital, October 17, 2018, Chicago, Il

180. Institute 3: Gender Dysphoria Across Development: Multidisciplinary Perspectives on the Evidence, Ethics, and Efficacy of Gender Transition, Gender Confirming Care in Adolescence: Evidence, Timing, Options, and Outcomes, The American Academy of Child and Adolescent Psychiatry, 65th Annual Meeting, October 22-27, 2018, Seattle, WA

181. Gender Confirmation Surgery, Combined Endocrine Grand Rounds, The University of Illinois at Chicago, Rush University, Cook County Hospital, January 8, 2019

182. Gender Confirmation Surgery: An Update, Division of Plastic Surgery, The University of Illinois at Chicago, January 23, 2019

183. Gender Confirmation Surgery from Top to Bottom: A 20 Year Experience, Grand Rounds, The Department of Surgery, Ochsner Health System, January 30, 2019, New Orleans, LA

184. Master Series of Microsurgery: Battle of the Masters
One Reconstructive Problem – Two Masters with Two Different Approaches, Gender Affirmation, Male-to-Female Vaginoplasty: Intestinal Vaginoplasty, The American Society for Reconstructive Microsurgery, Palm Desert, California, February 2, 2019

185. Gender Confirmation Surgery: From Top to Bottom, The University of Toronto, Toronto, Canada, February 21, 2019

186. Gender Confirmation Surgery: Where are We, The University of Toronto, Toronto, Canada, February 21, 2019

187. Professors' Rounds: Gender Confirmation Surgery: A Twenty Year Experience, Princess Margaret Hospital, Toronto, Canada, February 22, 2019

188. A 3 Step Approach to Lower Extremity Trauma, Plastic Surgery at The Red Sea, Eilat, Israel, March 6-9, 2019.

189. Gender Surgery: Where are We Now?, Plastic Surgery at The Red Sea, Eilat, Israel, March 6-9, 2019.

190. Gender Confirmation Surgery, A Single Surgeon's 20 Year Experience, Plastic Surgery at The Red Sea, Eilat, Israel, March 6-9, 2019.

191. Gender Confirmation Surgery: Where We Have Been and Where We Are Going, Grand Rounds, The University of Chicago, Section of Plastic Surgery, March 13, 2019

192. Gender Confirmation Surgery: From Top To Bottom, Resident Core Curriculum Conference, The University of Chicago, Section of Plastic Surgery, March 13, 2019.

193. "Gender Confirmation Surgery," WPATH/AMSA Medical School Trans Health Elective, Webinar, March 13, 2019

194. Robotic Vaginoplasty: An Alternative to Penile Inversion Vaginoplasty in Cases of Insufficient Skin, Vaginal Stenosis, and Rectovaginal Fistula. The European Professional Association for Transgender Health, April 9-13, Rome, Italy

195. Current State of Gender-Affirming Surgery in the US and Beyond, Gender-affirming genital surgery presented by the American Urologic Association in collaboration with the Society for Genitourinary Reconstructive Surgeons (GURS), May 2, 2019, Chicago, Il

196. Surgical Training-How Can I get it, The Aesthetic Meeting 2019, New Orleans, LA, May 20, 2019

197. What is the Standard of Care in This New Frontier, The Aesthetic Meeting 2019, New Orleans, LA, May 20, 2019

198. The 20th Annual Chicago Orthopedic Symposium, August 15-18, 2019, Chicago, Il "Soft Tissue Defects-Getting Coverage"

199. Gender Confirmation Sugery, The Potocsnak Family Division of Adolescent and Young Adult Medicine, Ann & Robert H. Lurie Children's Hospital of Chicago, August 19, 2019

200. Anatomy, Embryology, and Surgery, The University of Chicago, First Year Medical Student Anatomy Lecture, September 9, 2019, The University of Chicago, Chicago, Il.

201. Gender Confirmation Surgery, Howard Brown Health Center Gender Affirming Learning Series, September 13, 2019, Chicago, Il.

202. Moderator, Patient Selection in Gender Affirming Survey Surgery, 88th Annual Meeting of The American Society of Plastic Surgeons, September 20-23, 2019, San Diego, CA

203. Breast Augmentation in Transwomen: Optimizing Aesthetics and Avoiding Revisions, 88th Annual Meeting of The American Society of Plastic Surgeons, September 20-23, 2019, San Diego, CA

204. Breast Reconstruction, State of the Art, NYU-Langone Health, NYU School of Medicine, Standards of Care and Insurance Coverage, Saturday, November 23, 2019, New York, NY.

205. ASRM Masters Series in Microsurgery: Think Big, Act Small: The Building Blocks for Success, "Building a Microsurgery Private Practice from the Ground Up", 2020 ASRM Annual Meeting, Ft. Lauderdale, Florida, January 10-14, 2020

206. ASPS/ASRM Combined Panel II: Gender Affirmation Surgery: Reconstruction Challenges of Function and Sensation, 2020 ASRM Annual Meeting, Ft. Lauderdale, Florida, January 10-14, 2020

207. Rush University Medical Center, Division of Urology, Grand Rounds, "Gender Confirmation Surgery: A Single Surgeon's Experience," January 22, 2020

208. Rush University Medical Center, Department of General Surgery, Grand Rounds, "Gender Confirmation Surgery: A Single Surgeon's Experience," February 5, 2020.

209. WPATH/AMSA (American Medical Association) Gender Scholar Course, Webinar, March 11, 2020

210. Rush University Medical Center, Division of Plastic Surgery, Weekly Presentation, Gender Confirmation Surgery: Can a Surgeon Provide Informed Consent?, April 29, 2020

211. Legal Issues Faced by the Transgender Community, ISBA Standing Committee on Women and The Law and the ISBA Standing Committee on Sexual Orientation and Gender Identity, Co-Sponsored by the National Association of Women Judges District 8, Live Webinar, May 28, 2020

212. Principles of Transgender Surgery, National Association of Women's Judges, District 8, Webinar, June 4, 2020

213. Gender-Affirming Surgery, National Association of Women's Judges, District 8, Webinar, July 8, 2020

214. Gender-Affirming Surgery, The University of Chicago, Pritzker School of Medicine, 1st year Anatomy, September 15, 2020

215. Gender-Affirming Surgery, Rush University Medical School, 2nd year Genitourinary Anatomy, September 16, 2020.

216. Surgical Management of the Transgender Patient, Rosalind Franklin University, The Chicago Medical School, Plastic Surgery Interest Group, October 7, 2020

217. Breast Augmentation in Transgender Individuals, The American Society of Plastic Surgeons Spring Meeting, March 20, 2021

218. International Continence Society Institute of Physiotherapy Podcast 5-Pelvic Floor Most Common Disorders and Transgender Patients (recorded April 30, 2021)

219. The American Association of Plastic Surgeons Annual Meeting, Reconstructive Symposium, Gender Affirmation Panel, Complications of GCS, Miami, FL, May 15, 2021 (presented virtually)

220. Gender Confirmation Surgery, Grand Rounds, Rush University, Section of Urology, June 8, 2021.

221. Genitourinary introduction lecture, M2, Rush University School of Medicine, September 2, 2021 (by Zoom)

222. Demystifing Gender: Fostering Gender Friendly Healthcare, Gender Affirmative Care in Adults, Querencia (lady hardinge medical college, WHO Collaborating Center for Adolescent Health, Dept of Paediatrics, JSCH & LHMC, New Delhi, WPATH September 5, 2021 (by zoom)

223. Gender Confirmation Surgery, The University of Chicago Pritzker School of Medicine, MS-1, Anatomy lecture, September, 14, 2021, Chicago Il.

224. Gender Confirmation Surgery, A Single Surgeon's 22 Year Experience: Where are We Now?, Research Seminar, Section of Endocrinology, The University of Chicago, Chicago, Il, October 4, 2011 (by Zoom)

225. Chest Surgery, The Illinois Dept. of Corrections (by zoom), October 13, 2021.

226. Vaginoplasty, The Illinois Dept. of Corrections (by zoom), October 15, 2021.

227. International Continence Society, 20th Physioforum, Pelvic Floor Physical Therapy and Gender-Affirming Surgery, October 16, 2021, Melbourne, Australia (by Zoom)

228. Rush University Division of Plastic Surgery, Gender Affirmation Surgery: Where Are We Now?, educational conference, November 23, 2021, Chicago, Il

229. 51 Congreso Argentino de Cirugia Plastica, Microsurgery Symposium, SACPER-FILACP, 3 Step Approach to Lower Extremity Trauma, November 29, 2021, Mar del Plata, Argentina

230. 51 Congreso Argentino de Cirugia Plastica, Genital Aesthetics and Gender Confirmation Surgery I, "Gestión Quirúrgica de la Disforia de Género: Descripción general del manejo quirúrgico y los estándares de atención,"
December 1, 2021, Mar del Plata, Argentina

231. 51 Congreso Argentino de Cirugia Plastica, Genital Aesthetics and Gender Confirmation Surgery II, Cirugía Genital Masculinizante (Metoidioplastia y Faloplastia), December 2, 2021, Mar del Plata, Argentina

232. 51 Congreso Argentino de Cirugia Plastica, Genital Aesthetics and Gender Confirmation Surgery III, Faloplastia: optimización de resultados y reducción de complicaciones, December 2, 2021, Mar del Plata, Argentina

233. Government of India, Ministry of Health and Welfare, National AIDS Control Organization, Meeting with AIIMS on Gender Affirmation Care (GAC) Clinic Pilot Intervention, December 21,2021, New Delhi (virtual)

EXHIBIT B

Bibliography

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3. M.G. Berry et al., *Female-To-Male Transgender Chest Reconstruction: A Large Consecutive, Single-Surgeon Experience*, 65 Journal of Plastic, Reconstructive & Aesthetic Surgery 711-719 (2012).

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5. Cecilia Dhejne et al., *Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden*, 6 PloS ONE e16885 (2011).

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7. *Good Practice Guidelines for the Assessment and Treatment of Adults with Gender Dysphoria*, Royal College of Psychiatrists 1-59 (2013).

8. Miriam Hadj-Moussa et al., *Feminizing Genital Gender-Confirmation Surgery*, 6 Sexual Medicine Reviews 457-468.e2 (2018).

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Transgenders: A Systematic Review of Surgical Techniques, 12 The Journal of Sexual Medicine 1499-1512 (2015).

12. Sheera F Lerman et al., *Suicidality After Burn Injuries: A Systematic Review*, 42 Journal of Burn Care & Research 357-364 (2021).

13. Travis J. Miller et al., *Breast Augmentation in Male-to-Female Transgender Patients: Technical Considerations and Outcomes*, 21 JPRAS Open 63-74 (2019).

14. Leslie L. Montgomery et al., *Issues of Regret in Women With Contralateral Prophylactic Mastectomies*, 6 Annals of Surgical Oncology 546-552 (1999).

15. Sasha Karan Narayan et al., *Guiding the Conversation—Types of Regret After Gender-Affirming Surgery and Their Associated Etiologies*, 9 Annals of Translational Medicine 605-616 (2021).

16. Emily Newfield et al., *Female-to-Male Transgender Quality of Life*, 15 Quality of Life Research 1447-1457 (2006).

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20. Loren S. Schechter, *Surgical Management of the Transgender Patient*, Surgical Therapy,17–24 (2016)

21. Loren S. Schechter, *The Surgeon's Relationship with the Physician Prescribing Hormones and the Mental Health Professional: Review for Version 7 of the World Professional Association for Transgender Health's Standards of Care*, 11 International Journal of Transgenderism 222-225

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22. Elizabeth M. Swisher et al., *Prophylactic Oophorectomy and Ovarian Cancer Surveillance*, 46 The Journal of Reproductive Medicine 87-94 (2001).

23. U.S. Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Division NCD 140.3, Docket No. A-13-87, Decision No. 2576 (May 30, 2014).

Tim C. van de Grift et al., *Surgical Indications and Outcomes of Mastectomy in Transmen: A Prospective Study of Technical and Self-Reported Measures. Plastic and Reconstructive Surgery*, 140 Plastic & Reconstructive Surgery 415e-424e (2017).

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29. World Professional Association for Transgender Health, *Standards of Care for theHealth of Transsexual, Transgender, and Gender-Nonconforming People*, 7th Ed. (2011).

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IN 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

EXPERT DECLARATION OF
ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C

I, ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C, have been retained by counsel for Plaintiffs in connection with the above-captioned litigation.

1. This declaration provides the following expert opinions, which are explained in further detail below:

2. General Medicaid Policy Rule 59G-1.050 (the Exclusion) excludes certain medical services, which I will refer to as gender-affirming medical care, from coverage when these interventions are used to treat gender dysphoria.[1]

[1] Gender dysphoria is "a marked incongruence between one's experienced/expressed gender and their assigned gender" which is "associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning." American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed. American Psychiatric Publishing; 2013.

3. In the Exclusion and in other supporting documents, the Florida Agency for Health Care Administration (AHCA) persistently mischaracterizes these treatments and singles them out for anomalous treatment by withholding Medicaid coverage for them only when they are used to treat gender dysphoria. Specifically, AHCA mischaracterizes

a. individuals as diagnosing themselves with gender dysphoria,

b. treatments for gender dysphoria and "off-label" treatments as experimental,

c. treatments of gender dysphoria as "eminence-based medicine" and the evidence base supporting many medical treatments, and

d. the informed consent process for the treatment of gender dysphoria in minors.

4. Treatment of gender dysphoria is not experimental, is supported by evidence of its safety and efficacy, and is consistent with generally accepted professional medical standards.

5. I have actual knowledge of the matters stated in this declaration. In preparing this declaration, I reviewed the Exclusion, "Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of

Gender Dysphoria" (GAPMS Memo)[2], including Attachment G[3], a commissioned, unpublished paper written by G. Kevin Donovan, MD, MA, entitled "Medical Experimentation without Informed Consent: An Ethicist's View of Transgender Treatment for Children." I also reviewed the materials listed in the attached Bibliography (Exhibit B), and I may rely on those documents as additional support for my opinions. I have also relied on my years of research and other experience, as set out in my curriculum vitae (Exhibit A), and on the materials listed therein. The materials I have relied upon in preparing this declaration are the same types of materials that experts in medicine and bioethics regularly rely upon when forming opinions on the subject. I may wish to supplement these opinions or the bases for them as a result of new scientific research or publications, or in response to statements and issues that may arise in my area of expertise.

BACKGROUND AND QUALIFICATIONS

6. I am the 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 ("Cincinnati Children's"). I am also

[2] June 2022. Accessed September 6, 2022. Available at https://ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf.

[3] May 12, 2022. Accessed September 6, 2022. Available at https://ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Attachment_G.pdf.

a Professor in the Departments of Pediatrics and Surgery at the University of Cincinnati College of Medicine.

7. In 2000, I received both my medical degree from Washington University School of Medicine in St. Louis, Missouri and my PhD in Religious Ethics from The University of Chicago Divinity School. I completed my Pediatrics residency at the University of Utah in 2003.

8. I have been licensed to practice medicine since 2001 and am currently licensed to practice medicine in Ohio. I have been Board Certified in General Pediatrics since 2004 and in Pediatric Hospital Medicine since the inception of this certification in 2019. I have been certified as a Healthcare Ethics Consultant since the inception of this certification in 2019.

9. I have extensive experience as a practicing pediatrician. I have been in clinical practice since 2003 and approximately 30 percent of my current effort is dedicated to caring for hospitalized patients.

10. I also have extensive experience as a bioethicist. Bioethicists examine the ethical issues that arise in medicine and the life sciences. I was Chair of the Ethics Committee at Primary Children's Medical Center in Salt Lake City, Utah from 2005 to 2012 and have been Director of the Ethics Center at Cincinnati Children's since 2012.

11. I regularly consult on patients in the Transgender Health Clinic at Cincinnati Children's whose care presents unique ethical issues and participate in the Clinic's monthly multidisciplinary team meetings. I remain current with the medical and bioethics literature regarding the treatment of individuals with gender dysphoria, particularly minors. I am also the Chair of Cincinnati Children's Fetal Care Center's Oversight Committee which provides the Center with recommendations on the use of innovative treatments and experimental interventions.

12. I am a member of the American Academy of Pediatrics (AAP), the American Society for Bioethics and Humanities (ASBH), the Association of Bioethics Program Directors, and the Society for Pediatric Research. I was a member of the AAP's Committee on Bioethics from 2005 to 2011. I have also served as a member of the ASBH's Clinical Ethics Consultation Affairs Committee from 2009 to 2014 and currently serve on its Healthcare Ethics Consultant Certification Commission.

13. I am the author of 39 peer-reviewed journal articles, 11 non-peer-reviewed journal articles, 6 book chapters, and 27 commentaries. My peer-reviewed journal articles have been published in high-impact journals including the *Journal of the American Medical Association* and *Annals of Internal Medicine*. I am also an

author of 17 policy statements and technical reports, including 4 as lead author, by the AAP.

14. I am a member of the Executive Editorial Board and the Associate Editor for Ethics Rounds of *Pediatrics*. *Pediatrics* is the AAP's flagship journal and Ethics Rounds is a type of article in which commentators analyze cases that raise ethical issues. I am an active peer reviewer for many medical journals, including the *American Journal of Bioethics* and the *Journal of Pediatrics*. I also review abstracts for the annual meetings of professional organizations, including the Pediatric Academic Societies and ABSH. I was previously a member of the editorial boards of the *Journal of Clinical Ethics* and the *Journal of Medical Humanities*.

15. I previously testified as an expert witness at trial or deposition in the following cases: *Brant v. Rutledge*, Case No. 4:21CV450-JM (E.D. Ark.), *Doe v. Abbott*, No. D-1-GN-22-000977, 2022 WL 628912 (Tex. Dist. 353rd Judicial District, March 2, 2022), and *Eknes-Tucker* v *Marshall*, Case No. 2:22-cv0-184-LCB (M.D. Ala. May 13, 2022).

16. I am being compensated at an hourly rate of $250 per hour for preparation of expert declarations and reports, and $400 per hour for time spent preparing for or giving deposition or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

GENDER DYSPHORIA IS A MEDICAL DIAGNOSIS

17. As the GAPMS Memo correctly acknowledges, gender dysphoria is a medical diagnosis contained in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders (DSM)* 5th ed. The DSM contains specific criteria for clinicians to establish this diagnosis.[4]

18. However, the GAPMS Memo falsely characterizes individuals with gender dysphoria as "self-diagnosing." GAPMS Memo at 30; Attachment G at 5. The diagnosis of gender dysphoria in adolescents and adults, like many other common medical diagnoses, relies on individuals' self-report of symptoms. The diagnosis of migraine headaches, for example, depends on individuals' report of the number, duration, and characteristics of their headaches. The characteristics include the headaches' location, quality, intensity, and aggravating factors as well as the presence of nausea and/or vomiting, and light and sound sensitivity. It is common for diagnostic criteria to utilize qualitative terms, e.g., the intensity of migraine headaches is moderate to severe.[5] Like gender dysphoria, there is no confirmatory laboratory or radiographic study for the diagnosis of migraine headaches. Radiographic studies and electroencephalograms (EEG) are only used if the history

[4] American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed. American Psychiatric Publishing; 2013.

[5] Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211.

and physical examination suggest that the headache is secondary to another condition, e.g., meningitis or subarachnoid hemorrhage.[6]

19. Individuals with symptoms of gender dysphoria may anticipate their diagnosis in the same way that individuals with fever, cough, and difficulty breathing may reasonably suspect that they have pneumonia. It is, however, incorrect to suggest that these patients "self-diagnose," or that such suspicions serve as the basis for the diagnosis or subsequent treatment. Only licensed healthcare providers or teams of providers, based on patient reports and, in the case of minors, parent reports, make the diagnosis of gender dysphoria and any subsequent treatment recommendations.

20. Self-report is also relevant to research on many medical conditions. For example, a study published in the high-impact *New England Journal of Medicine* investigated medications for the treatment of migraines in children and adolescents ages 8 to 17. This study relied on participants' self-reports; they kept a "headache diary" to record the number of days they experienced headaches and other symptoms like fatigue and dry mouth.[7]

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[6] Steiner TJ, Jensen R, Katsarava Z, et al. Aids to management of headache disorders in primary care, 2nd edition. *J Headache Pain.* 2019;20(1):57.

[7] Powers SW, Coffey CS, Chamberlin LA, et al. Trial of amitriptyline, topiramate, and placebo for pediatric migraine. *N Engl J Med.* 2017;376(2):115-124.

GENDER-AFFIRMING MEDICAL CARE IS NOT EXPERIMENTAL

21. Clinical practice and research are distinguished by their goals and methods. The goal of clinical practice is to benefit individual patients, and its method is individualized decision-making. The goal of research is to contribute to generalizable knowledge, and its method uses formal protocols that describe the research study's objectives and procedures.[8]

22. To the extent that the GAPMS Memo uses the term "experimental" or "investigational" to convey that gender-affirming medical care is new, untested, or different, that suggestion is baseless. GAPMS Memo at 29, 30; Attachment G at 1, 4. Hormone treatment for gender dysphoria began after estrogen and testosterone became commercially available in the 1930's. The first documented male to female gender-affirming genital surgery was performed in 1931 and Christine Jorgensen famously underwent gender-affirming surgery in 1952.[9] The use of gonadotropin releasing hormone analogues, also known as puberty blockers or puberty-delaying medications, to treat gender dysphoria in adolescents, while more recent, is also not new. The first reference to this treatment in the medical literature was in 1998, over twenty years ago.[10] Prospective observational trials of puberty blockers began

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[8] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* The Commission; 1978.

[9] Stryker S. *Transgender History*. 2nd ed. Seal Press; 2017.

[10] Cohen-Kettenis PT, van Goozen SH. Pubertal delay as an aid in diagnosis and treatment of a

recruiting participants in 2000.[11] Gender-affirming medical care is supported by clinical studies, the same type of studies that support many other widely accepted medical treatments, as detailed below.

23. The clinical use of puberty blockers, gender-affirming hormone treatment and surgeries is not research or experimentation. When administering these treatments, clinicians seek to benefit individual patients and adjust the treatment based on individual patients' responses.

24. The GAPMS Memo's suggestion that, because puberty blockers and gender-affirming hormone treatment are being used "off-label," they are experimental, untested, or unsafe is also misleading. GAPMS Memo at 8, 14, 16, 19, 21; Attachment G at 4. Off-label use of medications is legal, common, and often evidence-based.

25. Approval by the U.S. Food and Drug Administration (FDA) is not required for all uses of a medication. Once the FDA has approved a medication for one indication,[12] thereby agreeing that it is safe (*i.e.*, its benefits outweigh its

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transsexual adolescent. *Eur Child Adolesc Psychiatry*. 1998;7(4):246-248.

[11] de Vries AL, Steensma TD, Doreleijers TA, Cohen- Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283.

[12] According to the FDA, an indication includes several factors: the particular disease or condition or the manifestation or symptoms of the disease or condition for which the drug is approved; whether the drug is approved for treatment, prevention, mitigation, cure, or diagnosis; and the population, including age group, for which the drug is safe and effective. Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, Food and Drug Administration, U.S. Department of Health and Human Services. Indications and Usage Section

potential risks) and effective for this intended use, as is the case with the medications at issue here, prescribers are generally free to prescribe it for other indications.[13] Prescribing an approved medication for an unapproved indication is colloquially referred to as "off-label" use. The AAP Committee on Drugs states, "[i]t is important to note that the term 'off-label' does not imply an improper, illegal, contraindicated, or investigational use" and "[t]he administration of an approved drug for a use that is not approved by the FDA is not considered research and does not warrant special consent or review if it is deemed to be in the individual patient's best interest."[14]

26. The AAP Committee on Drugs further states "in no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children."[15] Among the reasons for this is that, even if there is substantial evidence

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of Labeling for Human Prescription Drug and Biological Products—Content and Format: Guidance for Industry. July 2018. Accessed August 25, 2022. Available at https://www.fda.gov/files/drugs/published/Indications-and-Usage-Section-of- Labeling-for-Human-Prescription-Drug-and-Biological-Products-%E2%80%94- Content-and-Format-Guidance-for-Industry.pdf. A medication approved for the treatment of asthma in adults would, for example, be prescribed off label if used to treat a different disease, like pneumonia, or a different age group, like children.

[13] U.S. Food & Drug Administration. Understanding unapproved use of approved drugs "off label." February 5, 2018. Accessed August 25, 2022. Available at https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label.

[14] Frattarelli DA, Galinkin JL, Green TP, et al. Off-label use of drugs in children. *Pediatrics*. 2014; 133(3): 563-567.

[15] *Id*.

of safety and efficacy for a new indication, a sponsor may not seek FDA approval for it because doing so is not economically beneficial.[16]

27. "Off-label" use of drugs is common in many areas of medicine, including pediatrics. For example, magnesium sulfate is only approved by the FDA for replacement therapy in magnesium deficiency, in nutrition given by vein to correct or prevent low magnesium levels, or to prevent or control seizures due to high blood pressure during pregnancy.[17] It is, nonetheless, recommend for the short-term prolongation of pregnancy and to prevent neurologic injuries to the fetus and newborn [18] and as an adjunct treatment in severe, unresponsive asthma exacerbations.[19] A recent study of children's hospitals found that in 28.1% of encounters, at least one off-label drug was prescribed.[20] Examples of medications used off-label in this study included: albuterol, which is used to treat asthma; morphine, which is used to treat pain; and lansoprazole (Prevacid®), which is used

[16] Wittich CM, Burkle CM, Lanier WL. Ten common questions (and their answers) about off-label drug use. *Mayo Clin Proc*. 2012;87(10):982-990.

[17] Magnesium Sulfate. February 2016. Accessed August 31, 2022. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019316s024lbl.pdf.

[18] Committee Opinion No 652: Magnesium sulfate use in obstetrics. *Obstet Gynecol*. 2016;127(1):e52-e53.

[19] National Heart, Lung, and Blood Institute. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. 2007. Accessed August 31, 2022. Available at https://www.nhlbi.nih.gov/sites/default/files/media/docs/EPR-3_Asthma_Full_Report_2007.pdf.

[20] Yackey K, Stukus K, Cohen D, Kline D, Zhao S, Stanley R. Off-label medication prescribing patterns in pediatrics: An update. *Hosp Pediatr*. 2019;9(3):186-193.

to treat gastrointestinal reflux. The rate of off-label use may be significantly higher in certain age groups, categories of drugs, and clinical settings.

28. The GAPMS Memo misleadingly notes that testosterone is a Schedule III controlled substance because of its "high probability of abuse." GAPMS Memo at 19. But there is no evidence of abuse or dependence of anabolic-androgenic steroids from therapeutic use. And Schedule III drugs have a moderate to low potential for physical and psychological dependence.[21] Dependence has only been reported among weightlifters and bodybuilders receiving non-therapeutic, supraphysiologic doses.[22]

GENDER-AFFIRMING MEDICAL CARE IS EVIDENCE-BASED

29. AHCA also incorrectly characterizes gender-affirming medical treatment as lacking sufficient evidence of safety and efficacy. GAPMS Memo at 2. Medical care for individuals with gender dysphoria is evidence-based.

30. The major categories of studies used to evaluate innovative treatments are observational studies, which include cross-sectional and longitudinal studies, and randomized trials. In cross-sectional studies, investigators collect data at a single point in time. Cross-sectional design permits investigators to examine potential associations between factors, but it cannot prove one factor caused the other. In

[21] United States Drug Enforcement Administration. Drug scheduling. July 10, 2018. Accessed August 25, 2022. Available at https://www.dea.gov/drug-information/drug-scheduling.

[22] Brower KJ. Anabolic steroid abuse and dependence. *Curr Psychiatry Rep*. 2002;4(5):377-87.

longitudinal studies, researchers follow individuals over time, making continuous or repeated measures. In a randomized trial, participants are randomly assigned to a treatment or a comparison group. In double blind randomized trials neither the investigators nor the participants know to which group the participant is assigned. Placebo-controlled trials compare an active agent to an inactive one. The major benefit of a randomized trial is that it decreases the likelihood that any differences in the outcomes between the groups is the result of baseline differences between the groups rather than the result of the intervention.[23]

31. While randomized control trials are described in the medical literature as "high quality" evidence and observational studies as "low quality" evidence, randomized controlled trials may not be feasible or ethical, may have intrinsic methodological limitations, or may be unavailable in some contexts. "Low quality" evidence can be and frequently is sufficient to justify treatment recommendations.[24]

32. It may, at many times, be unethical to conduct randomized trials. For randomized trials to be ethical, clinical equipoise must exist; that is, there must be

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[23] Guyatt G, Rennie D, Meade MO, et al., eds. *Users' Guide to the Medical Literature: A Manual for Evidence-Based Clinical Practice*. 3rd ed. McGraw Hill Education; 2015; Perry- Parrish C, Dodge R. Research and statistics: Validity hierarchy for study design and study type. *Pediatr Rev*. 2010;31(1):27-29.

[24] Swiglo BA, Murad MH, Schunemann HJ, et al. A case for clarity, consistency, and helpfulness: State-of-the-art clinical practice guidelines in endocrinology using the Grading of Recommendations, Assessment, Development, and Evaluation system. *J Clin Endocrinol Metab*. 2008;93(3):666-673.

uncertainty about whether the efficacy of the intervention or the control is greater. It would be unethical to knowingly expose some trial participants to an inferior intervention. Trials must also be feasible. It would be unethical to expose 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 generate generalizable knowledge due to an inadequate sample size.[25]

33. The use of puberty blockers and gender-affirming hormone treatment to treat gender dysphoria in adolescents are supported by prospective observational studies.[26] There are also ongoing, federally funded, prospective observational studies of gender-affirming healthcare for adolescents with gender dysphoria in the U.S.[27]

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[25] Emanuel EJ, Wendler D. Grady C. What makes clinical research ethical? *JAMA*. 2000; 283(20):2701-2711.

[26] Delemarre-van de Waal HA, Cohen- Kettenis PT. Clinical management of gender identity disorder in adolescents: A protocol on psychological and pediatric endocrinology aspects *Eur J Endocrinol*. 2006;155(suppl 1):S131–S137; de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283; de Vries AL, McGuire JK, Steensma TD, Wagenaar EC, Doreleijers TA, Cohen-Kettenis PT. Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics*. 2014;134(4):696-704.

[27] National Institutes of Health Reporter, The impact of early medical treatment in transgender youth. Accessed August 25, 2022. Available at http://reporter.nih.gov/search/lGJnh68uokiic97N2X00kA/project-details/8965408; Olson-Kennedy J, Chan YM, Garofalo R, et al. Impact of early medical treatment for transgender youth: Protocol for the longitudinal, observational trans youth care study. *JMIR Res Protoc*.

34. A recent systemic review of studies on gender-affirming hormone therapy that were published in English between January 1, 2015 and April 16, 2021, and that focused on mental health and body image, body composition and contours, bone health, cardiovascular and thromboembolic safety, and cancer risk identified 69 studies in adults. Most of these studies were observational, including cross-sectional and longitudinal studies.[28] One randomized, double-blind, placebo-controlled trial compared the effect of testosterone combined with a 5alpha-reductase inhibitor or placebo on muscle strength.[29] It is important to note that this trial compared one form of gender-affirming hormone treatment to another, rather than comparing gender-affirming hormone treatment to no treatment at all.

35. Under the applicable ethical standards, randomized, placebo-controlled trials that compare pharmacological treatment to no pharmacological treatment in gender dysphoria are currently unethical. Potential investigators do not have equipoise between pharmacological treatment and no pharmacological treatment; they believe that pharmacological treatment is superior. It is also highly unlikely that

2019;8(7):e14434.

[28] D'Hoore L, T'Sjoen G. Gender-affirming hormone therapy: An updated literature review with an eye on the future. *J Intern Med*. 2022;291(5):574-592.

[29] Gava G, Armillotta F, Pillastrini P, et al. A randomized double-blind placebo-controlled pilot trial on the effects of testosterone undecanoate plus dutasteride or placebo on muscle strength, body composition, and metabolic profile in transmen. *J Sex Med*. 2021;18(3):646-655.

enough participants would enroll in randomized controlled trials for them to be informative.[30]

36. Even if randomized, placebo-controlled trials comparing pharmacological treatment of gender dysphoria to no pharmacological treatment were ethical, they would provide a lower quality of evidence because of intrinsic limitations in their design. For example, it would be impossible to "blind" the investigators or the participants to whether the participants were receiving the active treatment or a placebo. They would know if the participants were in the intervention or control arm of the study due to the physical changes in their bodies, or the lack thereof, over time. This might bias their perception of the outcomes. Such limitations result in decreases in the grade of evidence.[31]

37. In healthcare, adult patients, and especially parents or guardians of minor patients, must frequently make decisions about medical care without the benefit of randomized trials. Clinical research focusing on children and adolescents is less likely to use randomized trials than is clinical research for adults. Reasons for this disparity include the low prevalence of childhood disease or conditions, small

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[30] Chew D, Anderson J, Williams K, May T, Pang K. Hormonal treatment in young people with gender dysphoria: A systematic review. *Pediatrics*. 2018;141(4):e20173742; Reisner SL, Deutsch MB, Bhasin S, et al. Advancing methods for US transgender health research. *Curr Opin Endocrinol Diabetes Obes*. 2016;23(2):198-207.

[31] Atkins, D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004; 328(7452): 1490.

market share for therapeutic agents in children, low level of National Institutes of Health funding, and difficulty enrolling children and adolescents in research.[32]

38. One directly relevant example of a widely accepted and Florida Medicaid program covered treatment that is based on prospective observational studies is the use of puberty blockers to treat central precocious puberty. Central precocious puberty is the premature initiation of puberty, before age 8 in people assigned female at birth and before age 9 in people assigned male at birth, by the central nervous system. Its negative effects include impairment of final adult height as well as antisocial behavior and lower academic achievement. There are no randomized controlled trials evaluating the adult height of treated and untreated individuals. Most studies are prospective observational and compare pretreatment predicted and actual final height. These studies have additional limitations including small sample sizes. This "low quality" evidence is nonetheless sufficiently strong to support the use of puberty blockers as the standard of care for treatment of central precocious puberty.[33]

39. Professional medical organizations develop evidence-based clinical practice guidelines to provide clinicians with helpful, evidence-based

[32] Martinez-Castaldi C, Silverstein M, Baucher H. Child versus adult research: The gap in high-quality study design. *Pediatrics*. 2008;122(1):52-57.

[33] Mul D, Hughes IA. The use of GnRH agonists in precocious puberty. *Eur J Endocrinol*. 2008;159(Suppl 1):S3-8.

recommendations and improve patient care and outcomes. Organizations develop guidelines using systematic processes to select and review scientific evidence. Guidelines typically rate the quality of the evidence and grade the strength of recommendations.[34]

40. The Endocrine Society, an international medical organization of over 18,000 endocrinology researchers and clinicians, has published a clinical practice guideline for the treatment of gender-dysphoric (GD)/gender-incongruent persons, which may include pubertal suppression, gender-affirming hormone therapy, and gender-affirming surgery. The guideline both rates the quality of the supporting evidence and grades the strength of its recommendations. It recommends both the use of puberty blockers and gender-affirming hormone therapy to treat gender dysphoria in adolescents based on the best available evidence. The guideline recommends delaying gender-affirming genital surgery that removes the testicles, ovaries, and/or uterus until adulthood. The guideline makes recommendations on adverse outcome prevention and long-term care for adults receiving gender-affirming hormone therapy.[35]

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[34]Endocrine Society. Endocrine Society guideline methodology. Accessed September 1, 2022. Available at https://www.endocrine.org/clinical-practice-guidelines/methodology; American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874-877; Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations, *BMJ*. 2004;328(7454):1490.

[35] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin*

41. Recommendations for pediatric care made by professional associations are seldom based on well-designed and conducted randomized controlled trials due to their rarity and are frequently based on observational studies or, if such studies are unavailable, expert opinion. The medical use of the term "expert opinion" in this context differs from what I understand to be the use of this term in legal contexts. It refers to the consensus of experts in the field when studies are not available.

42. For example, none of the Endocrine Society's 84 recommendations in 2 of its other guidelines that focus on the pediatric population—guidelines on pediatric obesity and congenital adrenal hyperplasia—is based on "high quality" evidence. Twenty-four (29%) of the recommendations are based on "moderate," and 49 (58%) on "low" or "very low quality" evidence. The remaining recommendations (11, 13%) are Ungraded Good Practice Statements. Table 1 (Exhibit C).[36]

43. Guidelines issued by other professional associations concerning pediatric medical care unrelated to gender dysphoria are similar. For example, of the 130 recommendations in the American Heart Association's guideline for Pediatric

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Endocrinol Metab. 2017;102(11):3869-3903; World Professional Organization for Transgender Health. *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, Version 7. World Professional Association for Transgender Health (WPATH); 2012.

[36] Speiser PW, Arlt W, Auchus RJ, et al. Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2018;103(11):4043-88; Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity-assessment, treatment, and prevention: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(3):709-757.

Basic and Advanced Life Support, only 1 (1%) is based on "high-quality evidence from more than 1 [randomized clinical trial]" and 3 (3%) on "moderate-quality evidence from 1 or more [randomized clinical trials]." The remainder of the recommendations were based on lower quality evidence.[37] As reflected in medical professional associations' guidelines, medical treatment in pediatrics is infrequently based on "high" quality evidence and commonly based on lower quality evidence, including observational studies.

44. While "high quality" evidence is more common in adult medicine, recommendations are nonetheless frequently based on "low" or "very low quality" evidence. The Endocrine Society, for example, makes 35 recommendations in its clinical practice guideline on the treatment of diabetes in older adults. Forty eight percent of these recommendations are based on "low" or "very low quality" evidence and 14% are ungraded good practice statements.[38] Table 1 (Exhibit C).

PARENTS AND LEGAL GUARDIANS ARE CAPABLE OF PROVIDING INFORMED CONSENT FOR GENDER-AFFIRMING MEDICAL CARE

45. The GAPMS Memo and attachments incorrectly suggest that parents or legal guardians are unable to understand and appreciate the potential risks of gender-

[37] Topjian AA, Raymond TT, Atkins D, et al. Part 4: Pediatric basic and advanced life support: 2020 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2020;142(16_suppl_2):S469-S523.

[38] LeRoith D, Biessels GJ, Braithwaite SS, et al. Treatment of diabetes in older adults: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2019;104(5):1520-1574.

affirming health care and, therefore, are incapable of providing informed consent. GAPMS Memo at 18, 29; Attachment G at 3-4.

46. First and foremost, parents or legal guardians generally must provide informed consent for medical treatment for their minor children, including for gender-affirming medical care. There is no evidence cited by AHCA in support of the assertion that parents of adolescents with gender dysphoria are unable to understand or appreciate the potential risks of gender-affirming medical care. Parents and legal guardians frequently consent to medical treatments for minors unrelated to gender dysphoria which have comparable risks, uncertainty, or levels of evidence.

47. Adolescents generally possess comparable medical decision-making capacity to adults.[39] There is evidence that most adolescents with gender dysphoria have sufficient medical decision-making capacity to make decisions regarding puberty blockers.[40] And there are steps that healthcare providers take to promote adolescents' decision-making capacity.[41]

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[39] Weithorn LA, Campbell SB. The competency of children and adolescents to make informed treatment decisions. *Child Dev*. 1982;53(6):1589-98.

[40] Vrouenraets L, de Vries ALC, de Vries MC, van der Miesen AIR, Hein IM. Assessing medical decision-making competence in transgender youth. *Pediatrics*. 2021;148(6): e2020049643.

[41] Katz AL, Webb SA, Committee on Bioethics. Informed consent in decision-making in pediatric practice. *Pediatrics*. 2016;138(2): e20161485.

48. The current standard of care for treating gender dysphoria in minors is consistent with general ethical principles instantiated in the practices of informed consent and shared decision-making. The Endocrine Society's clinical practice guideline extensively discusses the potential benefits, risks, and alternatives to gender-affirming medical care, and its recommendations regarding the timing of interventions are based in part on the treatment's potential risks and the adolescent's decision-making capacity. The guideline recommends that informed consent for pubertal blockers and gender-affirming hormones include a discussion of the implications for fertility and options for fertility preservation. The Endocrine Society's clinical guideline also advises delaying gender-affirming hormone treatment, which results in partly irreversible physical changes, until an adolescent has developed sufficient medical decision-making capacity. The current version of guideline states clinicians should individualize decision-making for chest surgery in transgender males (individuals assigned female at birth who identify as male) and that chest surgery may be considered in some instances for individuals under 18 years old. The guideline recommends gender-affirming genital surgery involving gonadectomy and/or hysterectomy only in individuals 18 years old or older. [42]

[42]Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

THE EXCLUSION SINGLES OUT GENDER-AFFIRMING CARE FOR ANOMALOUS TREATMENT

49. The Exclusion does not provide a basis for excluding coverage of the provision of gender-affirming medical care to individuals with gender dysphoria and treating it differently from other comparable medical interventions. For example, as previously mentioned, Florida Medicaid provides coverage for the use of puberty blockers to treat central precocious puberty, but now prohibits coverage for the use of puberty blockers to treat gender dysphoria, even though the use of puberty blockers to treat both conditions has comparable risks and is supported by comparable types of evidence. *Supra* paragraph 38 (pp.18).

50. Additionally, while the Exclusion would eliminate coverage of chest surgery for the treatment of gender dysphoria for Medicaid beneficiaries, Medicaid beneficiaries are provided coverage for comparable surgeries, such as those for gynecomastia. Gynecomastia is the proliferation of ductal or glandular breast tissue, as opposed to adipose tissue or fat, in individuals whose sex assigned at birth is male. While surgeries to treat gynecomastia may at times be performed to lessen pain, they are commonly performed to reduce psychosocial distress. Surgery affirms patients' gender identity, that is, to help someone assigned male at birth feel more typically

masculine. Risks associated with the procedure include bruising, bleeding, infection, scarring, poor cosmetic outcome, and loss of sensation.[43]

51. There is nothing unique about chest surgery for gender dysphoria that justifies singling out this and other medical treatments for gender dysphoria for non-coverage based on a concern regarding evidence of safety or efficacy, adult patients, parents or guardians' ability to consent, or adolescents' ability to assent. As with other medical decisions, medical decisions regarding treatment for gender dysphoria should continue to be left to the discretion of adult patients or minor patients and their parents or legal guardians, and their healthcare providers.

CONCLUSION

52. Based on my research and experience as a pediatrician and bioethicist, treatment for gender dysphoria is not experimental and is consistent with generally accepted professional medical standards including standards for informed consent. There is not a sound medical or ethical basis for excluding such care from coverage by Florida Medicaid and so doing is inconsistent with the program's other medical coverage decisions.

[43] Nordt CA, DiVasta AD. Gynecomastia in adolescents. *Curr Opin Pediatr*. 2008;20(4):375-382.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on September 11, 2022

Armand H. Matheny Antommaria
Armand H. Matheny Antommaria (Sep 11, 2022 15:31 EDT)

ARMAND H. MATHENY ANTOMMARIA, MD, PhD

Expert Declaration of Armand Antommaria Florida Litigation 22.09.11 for signature (002)

Final Audit Report 2022-09-11

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EXHIBIT A

CURRICULUM VITAE

Last Updated: August 28, 2022

EDUCATION

1983-1987	BSEE	Valparaiso University, with High Distinction Valparaiso, IN
1983-1987	BS	Valparaiso University (Chemistry), with High Distinction Valparaiso, IN
1987-1989	MD	Washington University School of Medicine
1998-2000		Saint Louis, MO
1989-2000	PhD	The University of Chicago Divinity School (Religious Ethics) Chicago, IL
2000-2003	Resident	University of Utah (Pediatrics) Salt Lake City, UT
2005-2006	Certificate	Conflict Resolution Certificate Program, University of Utah Salt Lake City, UT

BOARD CERTIFICATION

2019 Pediatric Hospital Medicine, American Board of Pediatrics
2019 Healthcare Ethics Consultant-Certified, Healthcare Ethics Consultation Certification Commission
2004 General Pediatrics, American Board of Pediatrics

PROFESSIONAL LICENSES

2012-Present Doctor of Medicine, Ohio
2006-2010 Alternative Dispute Resolution Provider—Mediator, Utah
2001-2014 Physician and Surgeon, Utah
2001-2014 Physician and Surgeon Controlled Substance, Utah

PROFESSIONAL EXPERIENCE

Full Time Positions

2019-Present *Professor*
Cincinnati Children's Hospital Medical Center, Cincinnati, OH
Department of Surgery

2019-Present *Professor of Clinical-Affiliated*
University of Cincinnati, Cincinnati, OH
Department of Surgery

2017-Present *Professor*
Cincinnati Children's Hospital Medical Center, Cincinnati, OH
Division of Pediatric Hospital Medicine

2017-Present *Professor of Clinical-Affiliated*
University of Cincinnati, Cincinnati, OH
Department of Pediatrics

2016-2017 *Associate Professor of Clinical-Affiliated*
University of Cincinnati, Cincinnati, OH
Department of Pediatrics

2012-2017 *Associate Professor*

	Cincinnati Children's Hospital Medical Center, Cincinnati, OH Division of Pediatric Hospital Medicine
2012-Present	*Lee Ault Carter Chair in Pediatric Ethics* Cincinnati Children's Hospital Medical Center
2012-2016	*Associate Professor-Affiliated* University of Cincinnati, Cincinnati, OH Department of Pediatrics
2010-2012	*Associate Professor of Pediatrics* (with Tenure) University of Utah School of Medicine, Salt Lake City, UT Divisions of Inpatient Medicine and Medical Ethics
2010-2012	*Adjunct Associate Professor of Medicine* University of Utah School of Medicine, Salt Lake City, UT Division of Medical Ethics and Humanities
2004-2010	*Assistant Professor of Pediatrics* (Tenure Track) University of Utah School of Medicine, Salt Lake City, UT Divisions of Inpatient Medicine and Medical Ethics
2004-2010	*Adjunct Assistant Professor of Medicine* University of Utah School of Medicine, Salt Lake City, UT Division of Medical Ethics and Humanities
2003-2004	*Instructor of Pediatrics* (Clinical Track) University of Utah School of Medicine, Salt Lake City, UT Divisions of Inpatient Medicine and Medical Ethics
2003-2004	*Adjunct Instructor of Medicine* University of Utah School of Medicine, Salt Lake City, UT Division of Medical Ethics

Part Time Positions

2022- Present	*Expert Witness,* Report and Testimony Eknes-Tucker, et al., v. Marshall, et al., United States District Court Middle District of Alabama Northern Division, Case No. 2:22-cv0-184-LCB.
2022-Present	*Expert Witness,* Report and Testimony Jane Doe, et al., v. Greg Abbott, et al., District Court of Travis County, Texas 353rd Judicial District, Case No. D-1-GN-22-000977
2021-Present	*Expert Witness*, Reports and Deposition Dylan Brandt, et al., v. Leslie Rutledge, et al., United States District Court, Eastern District of Arkansas, Case No.: 5:21-CV-00450-JM-1
2021	*Consultant* Proctor & Gamble, Cincinnati, OH
2019	*Consultant* Sanofi Genzyme, Cambridge, MA
2018-Present	*Consultant* Center for Conflict Resolution in Healthcare, Memphis, TN
2017-2020	*Consultant* Amicus Therapeutics, Cranbury, NJ
2017	*Expert Witness,* Report Robert J. Klickovich, MD, PLLC v. Tristate Arthritis & Rheumatology, PSC, *et*

al., Commonwealth of Kentucky, Boone Circuit Court, Division III, Civil Action No. 16-CI-01690

2017 *Consultant*
Sarepta Therapeutics, Cambridge, MA

2014 *Consultant*
Genzyme, A Sanofi Company, Cambridge, MA

Editorial Experience

Editorial Board

2020-Present *Pediatrics*, Associate Editor for Ethics Rounds and Member of the Executive Editorial Board

2015-2020 *Journal of Clinical Ethics*

2009-2020 *Journal of Medical Humanities*

Guest Academic Editor

2017 *PLOS|ONE*

Ad Hoc Reviewer: *Academic Medicine, Academic Pediatrics, AJOB Primary Research, American Journal of Bioethics, American Journal of Law & Medicine, American Journal of Medical Genetics, American Journal of Transplantation, BMC Medical Ethics, BMJ Open, Canadian Journal of Bioethics, CHEST, Clinical Transplantation, European Journal of Human Genetics, Frontiers in Genetics, Hospital Medicine, International Journal of Health Policy and Management, International Journal of Nursing Studies, Journal of Adolescent and Young Adult Oncology, Journal of Clinical Ethics, Journal of Empirical Research on Human Research Ethics, Journal of General Internal Medicine, Journal of Healthcare Leadership, Journal of Hospital Medicine, Journal of the Kennedy Institute of Ethics, Journal of Law, Medicine & Ethics, Journal of Medical Ethics, Journal of Medical Humanities, Journal of Medicine and Life, Journal of Palliative Care, Journal of Pediatrics, Journal of Pediatric Surgery, Mayo Clinic Proceedings, Medicine, Healthcare and Philosophy, Molecular Diagnosis & Therapy, New England Journal of Medicine, Patient Preference and Adherence, Pediatrics, Pediatrics in Review, Personalized Medicine, PLOS|ONE, Risk Management and Healthcare Policy, Saudi Medical Journal, SSM - Qualitative Research in Health,* and *Theoretical Medicine and Bioethics*

SCHOLASTIC AND PROFESSIONAL HONORS

2021 *Hidden Gem Award,* Cincinnati Children's Hospital Medical Center, Cincinnati, OH

2019-2021 *Presidential Citation,* American Society for Bioethics and Humanities, Chicago, IL

2016 *Laura Mirkinson, MD, FAAP Lecturer,* Section on Hospital Medicine, American Academy of Pediatrics, Elk Grove Village, IL

2016, 2018 *Certificate of Excellence*, American Society for Bioethics and Humanities, Glenview, IL

2013, 2016 *Senior Resident Division Teaching Award,* Cincinnati Children's Hospital Medical Center, Cincinnati, OH

2012	*Role Model*, Quality Review Committee, Primary Children's Medical Center, Salt Lake City, UT
2011	*Member*, Society for Pediatric Research, The Woodlands, TX
2011	*Presidential Citation*, American Society for Bioethics and Humanities, Glenview, IL
2009	*Role Model*, Quality Review Committee, Primary Children's Medical Center, Salt Lake City, UT
2008	*Nominee*, Physician of the Year, Primary Children's Medical Center, Salt Lake City, UT
2005-2006	*Fellow*, Medical Scholars Program, University of Utah School of Medicine, Salt Lake City, UT
1995-1997	*Doctoral Scholar*, Crossroads, A Program of Evangelicals for Social Action, Philadelphia PA
1989-1992	*Fellow*, The Pew Program in Medicine, Arts, and the Social Sciences, University of Chicago, Chicago, IL

ADMINISTRATIVE EXPERIENCE

Administrative Duties

2019-Present	*Chair*, Oversight Committee, Cincinnati Fetal Center, Cincinnati, OH
2014-Present	*Chair*, Ethics Committee, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2012-Present	*Director*, Ethics Center, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2012-Present	*Chair*, Ethics Consultation Subcommittee, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2010	*Co-Chair*, Ethics Subcommittee, Work Group for Emergency Mass Critical Care in Pediatrics, Centers for Disease Control and Prevention, Atlanta, GA
2009	*Chair*, Ethics Working Group, H1N1 and Winter Surge, Primary Children's Medical Center, Salt Lake City, UT
2005-2012	*Chair*, Ethics Committee, Primary Children's Medical Center, Salt Lake City, UT
2005-2012	*Chair*, Ethics Consultation Subcommittee, Primary Children's Medical Center, Salt Lake City, UT
2003-4	*Chair*, Clinical Pertinence Committee, Primary Children's Medical Center, Salt Lake City, UT

Professional & Scientific Committees

Committees

2021	*Member*, EMCO Capacity Collaboration, Ohio Hospital Association, Columbus, OH
2020-2021	*Member*, Allocation of Scarce Resources Work Group, Ohio Hospital Association, Columbus, OH
2020-Present	*Member*, Literature Selection Technical Review Committee, National Library of Medicine, Bethesda, MD
2020	*Member*, Crisis Standards of Care Workgroup, The Health Collaborative, Cincinnati, OH
2019-Present	*Member*, Healthcare Ethics Consultant Certification Commission, Oak Park, IL

2019	*Member*, Expert Panel, Pediatric Oncology End-of-Life Care Quality Markers, Institute for Cancer Outcomes & Survivorship, University of Alabama at Birmingham, Birmingham, AL
2018	*Member*, Resource Planning and Allocation Team Implementation Task Force, Ohio Department of Health, Columbus, OH
2012-Present	*Member*, Gaucher Initiative Medical Expert Committee, Project HOPE, Millwood, VA
2009-2014	*Member*, Clinical Ethics Consultation Affairs Committee, American Society for Bioethics and Humanities, Glenview, IL
2005-2011	*Member*, Committee on Bioethics, American Academy of Pediatrics, Oak Park, IL

Data Safety and Monitoring Boards

2019-Present	*Member*, Data and Safety Monitoring Board, Sickle Cell Domestic Trials, National Heart, Lung, and Blood Institute, Bethesda, MD
2018-2019	*Member*, Standing Safety Committee for P-188-NF (Carmeseal-MD™) in Duchenne Muscular Dystrophy, Phrixus Pharmaceuticals, Inc., Ann Arbor, MI
2017-Present	*Member*, Observational Study Monitoring Board, Sickle Cell Disease Observational Monitoring Board, National Heart, Lung, and Blood Institute, Bethesda, MD
2016-2018	*Member*, Observational Study Monitoring Board, Long Term Effects of Hydroxyurea in Children with Sickle Cell Anemia, National Heart, Lung, and Blood Institute, Bethesda, MD

Reviewer

2020-Present	*Abstract Reviewer*, American Society for Bioethics and Humanities Annual Meeting
2020	*Grant Reviewer*, The Croatian Science Foundation, Hvatska zaklada za znanost (HRZZ)
2018	*Book Proposal Reviewer*, Elsevier
2018-2019	*Category Leader*, Religion, Culture, and Social Sciences, American Society for Bioethics and Humanities Annual Meeting
2017	*Timekeeper*, American Society for Bioethics and Humanities Annual Meeting
2017-Present	*Abstract Reviewer*, Pediatric Academic Societies Annual Meeting
2016-2021	*Workshop Reviewer*, Pediatric Academic Societies Annual Meeting
2016	*Grant Reviewer*, Innovation Research Incentives Scheme, The Netherlands Organisation for Health Research and Development
2016-2017	*Abstract Reviewer*, American Society for Bioethics and Humanities Annual Meeting
2014, 2016	*External Peer Reviewer*, PSI Foundation, Toronto, Ontario, Canada
2014	*Member*, Scientific Committee, International Conference on Clinical Ethics and Consultation
2013	*Abstract Reviewer*, American Society for Bioethics and Humanities Annual Meeting
2013	*Reviewer*, Open Research Area Plus, Agence Nationale de la Research, Deutsche Forschungsgemeinschaft, Economic and Social Research Council, National

	Science Foundation, and Organization for Scientific Research
2011-2012	*Abstract Reviewer*, Pediatric Academic Societies Annual Meeting
2011-2013	*Workshop Reviewer*, Pediatric Academic Societies Annual Meeting
2011-2014	*Abstract Reviewer*, Pediatric Hospital Medicine Annual Meeting
2011-2012	*Religious Studies Subcommittee Leader*, Program Committee, American Society for Bioethics and Humanities Annual Meeting
2010	*Abstract Reviewer*, American Society for Bioethics and Humanities Annual Meeting

Other

2021	*Timekeeper*, American Society for Bioethics and Humanities Annual Meeting
2021	*Mentor*, Early Career Advisor Professional Development Track, American Society for Bioethics and Humanities.
2021	*Mentor*, Early Career Advisor Paper or Project Track, American Society for Bioethics and Humanities.
2109	*Mentor*, Early Career Advising Program, American Society for Bioethics and Humanities
2018	*Passing Point Determination*, Healthcare Ethics Consultant-Certified Examination, Healthcare Ethics Consultant Certification Commission
2018	*Member*, Examination Committee, Healthcare Ethics Consultant-Certified Examination, Healthcare Ethics Consultant Certification Commission
2018	*Item Writer*, Healthcare Ethics Consultant-Certified Examination, Healthcare Ethics Consultant Certification Commission

UNIVERSITY COMMUNITY ACTIVITIES

Cincinnati Children's Hospital Medical Center

2020-Present	*Member*, Faculty Diversity and Inclusion Steering Committee
2020-Present	*Member*, Medical Management of COVID-19 Committee
2020-2021	*Member*, Caregiver Refusal Team
2020-2021	*Member*, COVID-19 Vaccine Allocation Committee
2020	*Member*, Personal Protective Equipment Subcommittee of the COVID-19 Steering. Committee
2018-2019	*Member*, Planning Committee, Center for Clinical & Translational Science & Training Research Ethics Conference
2017-Present	*Member*, Donor Selection Committee
2017-2020	*Member*, Employee Emergency Fund Review Committee
2017	*Member*, Root Cause Analysis Team
2016-2017	*Member*, Planning Committee, Center for Clinical & Translational Science & Training Research Ethics Conference
2015-2019	*Member*, Destination Excellence Medical Advisory Committee
2015-Present	*Member*, Disorders of Sexual Development Case Review Committee
2015-2019	*Member*, Destination Excellence Case Review Committee
2014-2018	*Member*, Genomics Review Group, Institutional Review Board
2014-2017	*Member*, Center for Pediatric Genomics Leadership Committee
2013-2017	*Member*, Genetic Testing Subcommittee, Health Network
2013-2016	*Member*, Schwartz Center Rounds Planning Committee

2013-2014 *Member*, Genomics Ad Hoc Subcommittee, Board of Directors
2012-Present *Member*, Cincinnati Fetal Center Oversight Committee
2012-Present *Member*, Ethics Committee
2012-Present *Member*, G-23
2012-2016 *Member*, Integrated Solid Organ Transplant Steering Committee

University of Utah
2009-2012 *Member*, Consolidated Hearing Committee

University of Utah School of Medicine
2010-2012 *Member*, Medical Ethics, Humanities, and Cultural Competence Thread Committee
2008-2010 *Member*, Fourth Year Curriculum Committee

University of Utah Department of Pediatrics
2010-2011 *Member*, Planning Committee, 25th Annual Biological Basis of Children's Health Conference, "Sex, Gender, and Sexuality"
2009-2012 *Member*, Medical Executive Committee
2005-2012 *Member*, Retention, Promotion, and Tenure Committee
2004-2012 *Interviewer*, Residency Program
2003-2012 *Member*, Education Committee

Intermountain Healthcare
2009-2012 *Member*, System-Wide Bioethics Resource Service
2009-2012 *Member*, Pediatric Guidance Council

Primary Children's Medical Center
2012-2012 *Member*, Shared Accountability Organization Steering Committee
2009 *Member*, H1N1 and Winter Surge Executive Planning Team
2005-2010 *Member*, Continuing Medical Education Committee
2005-2010 *Member*, Grand Rounds Planning Committee
2003-2012 *Member*, Ethics Committee

ACTIVE MEMBERSHIPS IN PROFESSIONAL SOCIETIES

2012-Present Association of Bioethics Program Directors
2011-Present Society for Pediatric Research
2000-Present American Academy of Pediatrics
1999-Present American Society of Bioethics and Humanities

FUNDING

Past Grants
2015-2019 "Better Outcomes for Children: Promoting Excellence in Healthcare Genomics to Inform Policy."
Percent Effort: 9%
National Human Genome Research Institute
Grant Number: 1U01 HG008666-01

Role: Investigator

2015-2016 "Ethics of Informed Consent for Youth in Foster Care"
Direct Costs: $10,000
Ethics Grant, Center for Clinical and Translational Science and Training
University of Cincinnati Academic Health Center
Role: Co-Investigator

2014-2015 "Extreme Personal Exposure Biomarker Levels: Engaging Community Physicians and Ethicists for Guidance"
Direct Costs: $11,640
Center for Environmental Genetics
University of Cincinnati College of Medicine
Role: Investigator

2014-2015 "Child, Adolescent, and Parent Opinions on Disclosure Policies for Incidental Findings in Clinical Whole Exome Sequencing"
Direct Costs: $4,434
Ethics Grant, Center for Clinical and Translational Science and Training,
University of Cincinnati Academic Health Center
Role: Principal Investigator

2013-2014 "Better Outcomes for Children: GWAS & PheWAS in eMERGEII
Percent Effort: 5%
National Human Genome Research Institute
Grant Number: 3U01HG006828-0251
Role: Investigator

2004-2005 "Potential Patients' Knowledge, Attitudes, and Beliefs Regarding Participating in Medical Education: Can They be Interpreted in Terms of Presumed Consent?"
Direct Costs: $8,000
Interdisciplinary Research in Applied Ethics and Human Values, University Research Committee, University of Utah
Role: Principal Investigator

TEACHING RESPONSIBILITIES/ASSIGNMENTS

Course and Curriculum Development

2003-2012 Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100

Course Lectures

2018, 2021 Introduction to Biotechnology, "Ethics and Biotechnology" and "Clinical Ethics," BIOL 3027, University of Cincinnati, Taught 1 time per year, Taken by undergraduate students, Enrollment 25.

2018-Present Biomedical Ethics, "Conscientious Objection in Healthcare" and "Ethical Issues in the Care of Transgender Adolescents," MEDS 4035 & MEDS 4036, University of

Cincinnati College of Medicine, Taught 1 time per year, Taken by senior undergraduate students, Enrollment 52.

2016 Foundations of Healthcare Ethics and Law, "Clinical Ethics," HESA 390, Xavier University.

2014-Present Physicians and Society, "Transfusion and the Jehovah's Witness Faith," "Obesity Management: Ethics, Policy, and Physician Implicit Bias," "Embryos and Ethics: The Ethics of Designer Babies," "Ethics and Genetic Testing," and "Ethics and Direct to Consumer Genetic Testing," 26950112 and 26950116, University of Cincinnati School of Medicine, Taken by first and second year medical students, Enrollment 100.

2014-Present Ethical Issues in Health Care, "Ethical Issues in Managing Drug Shortages: The Macro, Meso, and Micro Levels," HESA 583, College of Social Sciences, Health, and Education Health Services Administration, Xavier University, Taken by health services administration students, Enrollment 25.

2009 Physical Diagnosis II, Internal Medicine 7160, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100

2003-2012 Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught 1 time per year, Taken by fourth year medical students, Enrollment 100

Small Group Teaching

2018-Present Ethics in Research, GNTD 7003-001, University of Cincinnati School of Medicine, Taught 1 time per year, Taken by fellows, MS, and PhD students, Enrollment 110.

2007 Physical Diagnosis I, Internal Medicine 7150, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100

2003-2012 Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught 1 time per year, Taken by fourth medical students, Enrollment 100

2003 Pediatric Organ System, Pediatrics 7020, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100

Graduate Student Committees

2018-Present *Chair*, Scholarship Oversight Committee, William Sveen, Pediatric Critical Care Fellowship, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

2018-2020 *Member*, Scholarship Oversight Committee, Anne Heueman, Genetic Counseling, University of Cincinnati, Cincinnati, OH

2017-2019 *Chair*, Scholarship Oversight Committee, Bryana Rivers, Genetic Counseling, University of Cincinnati, Cincinnati, OH

2013-2015 *Mentor*, Sophia Hufnagel, Combined Pediatrics/Genetics Residency, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

2013-2015 *Co-Chair*, Scholarship Oversight Committee, Andrea Murad, Genetic Counseling, University of Cincinnati, Cincinnati, OH

2013-2014 *Member*, Scholarship Oversight Committee, Grace Tran, Genetic Counseling, University of Cincinnati, Cincinnati, OH

2011-2012 *Chair*, Scholarship Oversight Committee, Kevin E. Nelson, MD, PhD, Pediatric Inpatient Medicine Fellowship, University of Utah, Salt Lake City, UT

Continuing Education Lectures

2008 Choosing Healthplans All Together (CHAT) Exercise Facilitator, 18th Annual Intermountain Medical Ethics Conference, "Setting Priorities for Healthcare in Utah: What Choices are We Ready to Make?," Salt Lake City, Utah, October 3.

2007 *Speaker*, Infant Medical Surgical Unit, Primary Children's Medical Center, "Withholding and Withdrawing Artificial Nutrition and Hydration: Can It Be Consistent With Care?," Salt Lake City, Utah, September 6.

2007 *Faculty Scholar-in Residence*, Summer Seminar, "The Role of Religion in Bioethics," Utah Valley State College, Orem, Utah, May 1.

2006 *Workshop Leader*, Faculty Education Retreat, "Publications and Publishing in Medical Education," University of Utah School of Medicine, Salt Lake City, Utah, September 15.

2006 *Breakout Session*, 16th Annual Intermountain Medical Ethics Conference, "Donation after Cardiac Death: Evolution of a Policy," Salt Lake City, Utah, March 28.

Other Educational Activities

2008 *Instructor*, Contemporary Ethical Issues in Medicine and Medical Research, Osher Lifelong Learning Institute, University of Utah, "Religion and Bioethics: Religiously Based Demands for and Refusals of Treatment," Salt Lake City, Utah, February 7.

2007 *Speaker*, Biology Seminar, Utah Valley State College, "Is He Dead?: Criteria of the Determination of Death and Their Implications for Withdrawing Treatment and Recovering Organs for Transplant," Orem, Utah, September 21.

PEER-REVIEWED JOURNAL ARTICLES

1. Armand H. Matheny Antommaria, Elizabeth Lanphier, Anne Housholder, and Michelle McGowan. (Forthcoming). "A mixed methods analysis of requests for religious exemptions to a COVID-19 vaccine requirement." *AJOB Empirical Bioethics.*
2. Anne C Heuerman, Danielle Bessett, Armand H. Matheny Antommaria, Leandra. K. Tolusso, Nicki Smith, Alison H. Norris and Michelle L. McGowan (2022). "Experiences of reproductive genetic counselors with abortion regulations in Ohio." *Journal of Genetic Counseling*. 31: 641-652. PMID: 34755409.
3. Armand H. Matheny Antommaria and Ndidi I. Unaka. (2021) "Counterpoint: Prioritizing Health Care Workers for Scarce Critical Care Resources is Impractical and Unjust. *Journal of Hospital Medicine.* 16: 182-3. PMID 33617445.
4. Gregory A. Grabowski, Armand H. Matheny Antommaria, Edwin H. Kolodny, and Pramod K. Mistry. (2021) "Gaucher Disease: Basic and Translational Science Needs for More Complete Therapy and Management." *Molecular Genetics and Metabolism*. 132: 59-75. PMID: 33419694.
5. Armand H. Matheny Antommaria, Laura Monhollen, and Joshua K. Schaffzin. (2021) "An Ethical Analysis of Hospital Visitor Restrictions and Masking Requirements During the COVID-19." *Journal of Clinical Ethics.* 32(1): 35-44. PMID 33416516.
6. Armand H. Matheny Antommaria (2020) "The Pediatric Hospital Medicine Core Competencies: 4.05 Ethics." *Journal of Hospital Medicine.* 15(S1): 120-121.
7. Armand H. Matheny Antommaria, Tyler S. Gibb, Amy L. McGuire, Paul Root Wolpe, Matthew K. Wynia, Megan K. Applewhite, Arthur Caplan, Douglas S. Diekema, D. Micah Hester, Lisa Soleymani Lehmann, Renee McLeod-Sordjan, Tamar Schiff, Holly K. Tabor, Sarah E. Wieten, and Jason T. Eberl for a Task Force of the Association of Bioethics Program

Directors (2020) "Ventilator Triage Policies During the COVID-19 Pandemic at U.S. Hospitals Associated With Members of the Association of Bioethics Program Directors." *Annals of Internal Medicine.* 173(3): 188-194. PMID: 32330224.

8. Armand H. Matheny Antommaria (2020) "Conflicting Duties and Reciprocal Obligations During a Pandemic." *Journal of Hospital Medicine.* 5:284-286. PMID: 32379030.
9. Mary V. Greiner, Sarah J. Beal, and Armand H. Matheny Antommaria (2020) "Perspectives on Informed Consent Practices for Minimal-Risk Research Involving Foster Youth." *Pediatrics*. 45:e20192845. PMID: 32156772.
10. Jennifer deSante-Bertkau, Michelle McGowan, and Armand H. Matheny Antommaria (2018) "Systematic Review of Typologies Used to Characterize Clinical Ethics Consultations." *Journal of Clinical Ethics.* 29:291-304. PMID: 30605439.
11. Andrew J. Redmann, Melissa Schopper, Armand H. Matheny Antommaria, Judith Ragsdale, Alessandro de Alarcon, Michael J. Jutter, Catherine K. Hart, and Charles M. Myer. (2018) "To Transfuse or Not to Transfuse? Jehovah's Witnesses and PostOperative Hemorrhage in Pediatric Otolaryngology." *International Journal of Pediatric Otorhinolaryngology*. 115:188-192. PMID: 30368384.
12. Armand H. Matheny Antommaria, Kyle B. Brothers, John A. Myers, Yana B Feygin, Sharon A. Aufox, Murray H. Brilliant, Pat Conway, Stephanie M. Fullerton, Nanibaa' A. Garrison, Carol R. Horowitz, Gail P. Jarvik, Rongling Li, Evette J. Ludman, Catherine A. McCarty, Jennifer B. McCormick, Nathaniel D. Mercaldo, Melanie F. Myers, Saskia C. Sanderson, Martha J. Shrubsole, Jonathan S. Schildcrout, Janet L. Williams, Maureen E. Smith, Ellen Wright Clayton, Ingrid A. Holm. (2018) "Parents' Attitudes toward Consent and Data Sharing in Biobanks: A Multi-Site Experimental Survey." *AJOB Empirical Research.* 21:1-15. PMID: 30240342.
13. Armand H. Matheny Antommaria and Cynthia A. Prows. (2018) "Content Analysis of Requests for Religious Exemptions from a Mandatory Influenza Vaccination Program for Healthcare Personnel" *Journal of Medical Ethics.* 44: 389-391. PMID: 29463693.
14. Armand H. Matheny Antommaria (2017) "May Medical Centers Give Nonresident Patients Priority in Scheduling Outpatient Follow-Up Appointments?" *Journal of Clinical Ethics.* 28: 217-221. PMID: 28930708.
15. Andrea M. Murad, Melanie F. Myers, Susan D. Thompson, Rachel Fisher, and Armand H. Matheny Antommaria (2017) "A Qualitative Study of Adolescents' Understanding of Biobanks and Their Attitudes Toward Participation, Re-contact, and Data Sharing." *American Journal of Medical Genetics: Part A.* 173: 930-937. PMID: 28328120.
16. Saskia Sanderson, Kyle Borthers, Nathaniel Mercaldo, Ellen Wright Clayton, Armand Antommaria, Sharon Aufox, Murray Brillant, Diego Campos, David Carrell, John Connolly, Pat Conway, Stephanie Fullerton, Nanibaa Garrison, Carol Horowitz, Gail Jarvik, David Kaufman, Terrie Kitchner, Rongling Li, Evette Ludman, Cahterine McCarty, Jennifer McCormick, Valerie McManus, Melanie Myers, Aaron Scrol, Janet Williams, Martha Shrubsole, Jonathan Schildcrout, Maureen Smith, and Ingrid Holm (2017) "Public Attitudes Towards Consent and Data Sharing in Biobank Research: A Large Multisite Experimental Survey in the US." *The American Journal of Human Genetics*. 100: 414-427. PMID: 28190457.
17. Maureen E. Smith, Saskia C Sanderson, Kyle B Brothers, Melanie F Myers, Jennifer McCormick, Sharon A Aufox, Martha J Shrubsole, Nanibaa' A Garrison, Nathaniel D Mercaldo, Jonathan S Schildcrout, Ellen Wright Clayton, Armand H. Matheny Antommaria,

Melissa Basford, Murray Brilliant, John J Connolly, Stephanie M Fullerton, Carol R Horowitz, Gail P Jarvik, Dave Kaufman, Terrie Kitchner, Rongling Li, Evette J Ludman, Catherine McCarty, Valerie McManus, Sarah C Stallings, Janet L Williams, and Ingrid A Holm (2016) "Conducting a Large, Multi-Site Survey about Patients' Views on Broad Consent: Challenges and Solutions." *BMC Medical Research Methodology.* 16: 162. PMID: 27881091.

18. Angela Lorts, Thomas D. Ryan, Armand H. Matheny Antommaria, Michael Lake, and John Bucuvalas (2016) "Obtaining Consensus Regarding International Transplantation Continues to be Difficult for Pediatric Centers in the United States." *Pediatric Transplant.* 20: 774-777. PMID: 27477950.
19. Sophia B. Hufnagel, Lisa J. Martin, Amy Cassedy, Robert J. Hopkin, and Armand H. Matheny Antommaria (2016) "Adolescents' Preferences Regarding Disclosure of Incidental Findings in Genomic Sequencing That Are Not Medically Actionable in Childhood." *American Journal of Medical Genetics Part A.* 170: 2083-2088. PMID: 27149544.
20. Nanibaa' A. Garrison, Nila A. Sathe, Armand H. Matheny Antommaria, Ingrid A. Holm, Saskia Sanderson, Maureen E. Smith, Melissa McPheeters, and Ellen Wright Clayton (2016) "A Systematic Literature Review of Individuals' Perspectives on Broad Consent and Data Sharing in the United States." *Genetics in Medicine.* 18: 663-71. PMID: 26583683.
21. Kyle B. Brothers, Ingrid A. Holm Janet E. Childerhose, Armand H. Matheny Antommaria, Barbara A. Bernhardt, Ellen Wright Clayton, Bruce D. Gelb, Steven Joffe, John A. Lynch, Jennifer B. McCormick, Laurence B. McCullough, D. William Parsons, Agnes S. Sundaresan, Wendy A. Wolf, Joon-Ho Yu, and Benjamin S. Wilfond (2016) "When Genomic Research Participants Grow Up: Contact and Consent at the Age of Majority." *The Journal of Pediatrics* 168: 226-31. PMID: 26477867.
22. Erin E. Bennett, Jill Sweney, Cecile Aguayo, Criag Myrick, Armand H. Matheny Antommaria, and Susan L. Bratton (2015) "Pediatric Organ Donation Potential at a Children's Hospital." *Pediatric Critical Care Medicine.* 16: 814-820. PMID: 26237656.
23. Anita J. Tarzian, Lucia D. Wocial, and the ASBH Clinical Ethics Consultation Affairs Committee (2015) "A Code of Ethics for Health Care Ethics Consultants: Journey to the Present and Implications for the Field." *American Journal of Bioethics*. 15: 38-51. PMID: 25970392.
24. Armand H. Matheny Antommaria, Christopher A. Collura, Ryan M. Antiel, and John D. Lantos (2015) "Two Infants, Same Prognosis, Different Parental Preferences." *Pediatrics*, 135: 918-923. PMID: 25847802.
25. Stefanie Benoit, Armand H. Matheny Antommaria, Norbert Weidner, and Angela Lorts (2015) "Difficult Decision: What should we do when a VAD supported child experiences a severe stroke?" *Pediatric Transplantation* 19: 139-43. PMID: 25557132.
26. Kyle B. Brothers, John A. Lynch, Sharon A. Aufox, John J. Connolly, Bruce D. Gelb, Ingrid A. Holm, Saskia C. Sanderson, Jennifer B. McCormick, Janet L. Williams, Wendy A. Wolf, Armand H. Matheny Antommaria, and Ellen W. Clayton (2014) "Practical Guidance on Informed Consent for Pediatric Participants in a Biorepository." *Mayo Clinic Proceedings*, 89: 1471-80. PMID: 25264176.
27. Sophia M. Bous Hufnagel and Armand H. Matheny Antommaria (2014) "Laboratory Policies on Reporting Secondary Findings in Clinical Whole Exome Sequencing: Initial Uptake of the ACMG's Recommendations." *American Journal of Medical Genetics Part A*, 164: 1328-31. PMID: 24458369.

28. Wylie Burke, Armand H. Matheny Antommaria, Robin Bennett, Jeffrey Botkin, Ellen Wright Clayton, Gail E. Henderson, Ingrid A. Holm, Gail P. Jarvik, Muin J. Khoury, Bartha Maria Knoppers, Nancy A. Press, Lainie Friedman Ross, Mark A. Rothstein, Howard Saal, Wendy R. Uhlmann, Benjamin Wilfond, Susan M. Wold, and Ron Zimmern (2013) "Recommendations for Returning Genomic Incidental Findings? We Need to Talk!" *Genetics in Medicine*, 15: 854-859. PMID: 23907645.
29. Armand H. Matheny Antommaria (2013) "An Ethical Analysis of Mandatory Influenza Vaccination of Health Care Personnel: Implementing Fairly and Balancing Benefits and Burdens," *American Journal of Bioethics*, 13: 30-37. PMID: 23952830.
30. Joseph A. Carrese and the Members of the American Society for Bioethics and Humanities Clinical Ethics Consultation Affairs Standing Committee (2012) "HCEC Pearls and Pitfalls: Suggested Do's and Don't's for Healthcare Ethics Consultants," *Journal of Clinical Ethics*, 23: 234-240. PMID: 23256404.
31. Christopher G Maloney, Armand H Matheny Antommaria, James F Bale Jr., Jian Ying, Tom Greene and Rajendu Srivastiva (2012) "Factors Associated with Intern Noncompliance with the 2003 Accreditation Council for Graduate Medical Education's 30-hour Duty Period Requirement," *BMC Medical Education* 12: 33. PMID: 22621439.
32. Armand H. Matheny Antommaria, Jill Sweney, and W. Bradley Poss (2010) "Critical Appraisal of: Triaging Pediatric Critical Care Resources During a Pandemic: Ethical and Medical Considerations," *Pediatric Critical Care Medicine*, 11:396-400. PMID: 20453611.
33. Armand H. Matheny Antommaria, Karen Trotochaud, Kathy Kinlaw, Paul N. Hopkins, and Joel Frader (2009) "Policies on Donation After Cardiac Death at Children's Hospitals: A Mixed-Methods Analysis of Variation," *Journal of the American Medical Association*, 301: 1902-8. PMID: 19436017.
34. Kristine M. Pleacher, Elizabeth S. Roach, Willem Van der Werf, Armand H. Matheny Antommaria, and Susan L. Bratton (2009) "Impact of a Pediatric Donation after Cardiac Death Program," *Pediatric Critical Care Medicine*, 10: 166-70. PMID: 19188881.
35. Flory L. Nkoy, Sarah Petersen, Armand H Matheny Antommaria, and Christopher G. Maloney (2008) "Validation of an Electronic System for Recording Medical Student Patient Encounters," *AMIA [American Medical Informatics Association] Annual Symposium Proceedings*, 6: 510-14. PMID: 18999155. Nominated for the Distinguished Paper Award
36. Armand H. Matheny Antommaria, Sean D. Firth, and Christopher G. Maloney (2007) "The Evaluation of an Innovative Pediatric Clerkship Structure Using Multiple Outcome Variables including Career Choice" *Journal of Hospital Medicine*, 2: 401-408. PMID: 18081170.
37. Armand H. Matheny Antommaria (2006) "'Who Should Survive?: One of the Choices on Our Conscience:' Mental Retardation and the History of Contemporary Bioethics." *Kennedy Institute of Ethics Journal*, 16: 205-224. PMID: 17091558.
38. Armand H. Matheny Antommaria (2004) "Do as I Say Not as I Do: Why Bioethicists Should Seek Informed Consent for Some Case Studies." *Hastings Center Report*, 34 (3): 28-34. PMID: 15281724.
39. Armand H. Matheny Antommaria (2004) "A Gower Maneuver: The American Society for Bioethics and Humanities' Resolution of the 'Taking Stands' Debate." *American Journal of Bioethics*, 4 (Winter): W24-27. PMID: 15035934.

NON PEER-REVIEWED JOURNAL ARTICLES

1. Katherine Wade and Armand H. Matheny Antommaria (2016) "Inducing HIV Remission in Neonates: Children's Rights and Research Ethics." *Journal of Medicine and Biology*, 58(3): 348-54. PMID 27157354.
2. Armand H. Matheny Antommaria (2014) "Response to Open Peer Commentaries on 'An Ethical Analysis of Mandatory Influenza." *American Journal of Bioethics*, 14(7): W1-4. PMID: 24978422.
3. Armand H. Matheny Antommaria and Brent D. Kaziny (2012) "Ethical Issues in Pediatric Emergency Medicine's Preparation for and Response to Disasters." *Virtual* Mentor, 14: 801-4. PMID: 23351860.
4. Armand H. Matheny Antommaria, Tia Powell, Jennifer E. Miller, and Michael D. Christian (2011) "Ethical Issues in Pediatric Emergency Mass Critical Care," *Pediatric Critical Care Medicine*, 12(6 Suppl): S163-8. PMID: 22067926.
5. Armand H. Matheny Antommaria and Emily A. Thorell (2011) "Non-Pharmaceutical Interventions to Limit Transmission of a Pandemic Virus: The Need for Complementary Programs to Address Children's Diverse Needs." *Journal of Clinical Ethics*, 22: 25-32. PMID: 21595352.
6. Armand H. Matheny Antommaria (2010) "Conscientious Objection in Clinical Practice: Notice, Informed Consent, Referral, and Emergency Treatment." *Ave Maria Law Review*, 9: 81-99.
7. Armand H. Matheny Antommaria (2008) "Defending Positions or Identifying Interests: The Uses of Ethical Argumentation in the Debate over Conscience in Clinical Practice," *Theoretical Medicine and Bioethics*, 29: 201-12. PMID: 18821078.
8. Armand H. Matheny Antommaria (2008) "How can I give her IV antibiotics at home when I have three other children to care for?: Using Dispute System Design to Address Patient-Provider Conflicts in Health Care." *Hamline Journal of Public Law & Policy*, 29: 273-86.
9. Armand H. Matheny Antommaria (2007) "Alternative Dispute Resolution and Pediatric Clinical Ethics Consultation: Why the Limits of Ethical Expertise and the Indeterminacy of the Best Interests Standard Favor Mediation." *Ohio State Journal on Dispute Resolution*, 23: 17-59.
10. Armand H. Matheny Antommaria (2006) "Jehovah's Witnesses, Roman Catholicism, and Calvinism: Religion and State Intervention in Parental, Medical Decision-Making," *Journal of Law and Family Studies*, 8: 293-316.
11. Armand H. Matheny Antommaria and James F. Bale, Jr. (2002) "Ethical Issues in Clinical Practice: Cases and Analyses," *Seminars in Pediatric Neurology* 9: 67-76. PMID: 11931129.

REVIEW ARTICLES

Armand H. Matheny Antommaria (2010) "Conceptual and Ethical Issues in the Declaration of Death: Current Consensus and Controversies." *Pediatrics in Review* 31: 427-430. PMID: 20889737.

BOOKS

Armand H. Matheny Antommaria (1998) *A Retrospective, Political and Ethical Analysis of State Intervention into Parental Healthcare Decisions for Infants with Disabilities*. Wynnewood, Pennsylvania: Evangelicals for Social Action.

BOOK CHAPTERS

1. Armand H. Matheny Antommaria (2018) "Against Medical Advice Discharges: Pediatric Considerations." In *Against-Medical-Advice Discharges from the Hospital: Optimizing Prevention and Management to Promote High-Quality, Patient-Centered Care.* David Alfandre. New York, Springer: 143-157.
2. Armand H. Matheny Antommaria (2016) "Conscientious Objection in Reproductive Medicine." In *The Oxford Handbook of Reproductive Ethics.* Leslie Francis. Oxford, Oxford University Press: 209-225.
3. Armand H. Matheny Antommaria (2011) "Patient Participation in Medical Education." In *Clinical Ethics in Pediatrics: A Case-based Approach.* Douglas Diekema, Mark Mercurio, and Mary Beth Adam. Cambridge, Cambridge University Press: 221-225.
4. Armand H. Matheny Antommaria (2011) "State Intervention in Parental Decision Making: *Gone Baby Gone*." In *The Picture of Health: Medical Ethics and the Movies.* Henri Colt, Silvia Quadrelli, and Lester Friedman. Oxford, Oxford University Press: 308-12.
5. Armand H. Matheny Antommaria (2009) "Managing Conflicts of Interest: A Perspective from a Pediatrician." In *Professionalism in Medicine: The Case-Based Guide for Medical Students*. John Spandorfer, Charles Pohl, Thomas Nasca and Susan Lee Rattner. Cambridge, Cambridge University Press: 376-7.
6. Armand H. Matheny Antommaria (2007) "Do-Not-Resuscitate Orders." In *Comprehensive Pediatric Hospital Medicine*. L. B. Zaoutis and V. W. Chiang. Philadelphia, Mosby Elsevier**:** 1200-4.

OTHER

Policy Statements and Technical Reports

1. American Academy of Pediatrics Committee on Bioethics. Armand H. Matheny Antommaria Lead Author. (2013) "Conflicts between Religious or Spiritual Beliefs and Pediatric Care: Informed Refusal, Exemptions, and Public Funding." *Pediatrics.* 132: 962-965. PMID: 24167167.
2. American Academy of Pediatrics Committee on Bioethics. Armand H. Matheny Antommaria Lead Author. (2013) "Ethical Controversies in Organ Donation After Circulatory Death." *Pediatrics.* 131: 1021-1026. PMID: 23629612.
3. American Academy of Pediatrics Committee on Bioethics and Committee on Genetics and the American College of Medical Genetics and Genomics Social, Ethical, and Legal Issues Committee (2013) "Policy Statement: Ethical and Policy Issues in Genetic Testing and Screening of Children." *Pediatrics.* 131: 620-622. PMID: 23428972.
4. Lainie Friedman Ross, Howard M. Saal, Karen L. David, Rebecca R. Anderson and the American Academy of Pediatrics Committee on Bioethics and Committee on Genetics and the American College of Medical Genetics and Genomics Social, Ethical, and Legal Issues Committee (2013) "Technical Report: Ethical and Policy Issues in Genetic Testing and Screening of Children." *Genetics in Medicine.* 15: 234-245. PMID: 23429433.
5. American Academy of Pediatrics Committee for Pediatric Research and Committee on Bioethics (2012) "Human Embryonic Stem Cell (hESC) and Human Embryo Research." *Pediatrics* 130: 972-977. PMID: 23109685.
6. American College of Obstetricians and Gynecologists, Committee on Ethics and American Academy of Pediatrics, Committee on Bioethics (2011) "Maternal-Fetal Intervention and Fetal Care Centers," *Pediatrics* 128; e473-e478. PMID: 21788223.
7. American Academy of Pediatrics Committee on Pediatric Emergency Medicine and Committee on

Bioethics (2011) "Consent for Emergency Medical Services for Children and Adolescents." *Pediatrics* 128: 427-433. PMID: 21788221.

8. Council on School Health and Committee on Bioethics. Robert Murray and Armand H. Matheny Antommaria Lead Authors. (2010) "Honoring –Do-Not-Attempt Resuscitation Requests in Schools." *Pediatrics* 125; 1073-1077. PMID: 20421255.
9. Committee on Bioethics (2010) "Ritual Genital Cutting of Female Minors." *Pediatrics* 125; 1088-1093. PMID: 20421257.
10. Committee on Bioethics. (2010) "Children as Hematopoietic Stem Cell Donors," *Pediatrics* 125; 392-40. PMID: 20100753.
11. Committee on Bioethics. Armand H. Matheny Antommaria Lead Author. (2009) "Physician Refusal to Provide Information or Treatment Based on Claims of Conscience." *Pediatrics.* 124; 1689-93. PMID: 19948636.
12. Committee on Bioethics (2009) "Pediatrician-Family-Patient Relationships: Managing the Boundaries." *Pediatrics* 124; 1685-8. PMID: 19948635.
13. Douglas S. Diekema, Jeffrey R. Botkin, and Committee on Bioethics (2009) "Forgoing Medically Provided Nutrition and Hydration in Children." *Pediatrics* 124; 813-22. PMID: 19651596.
14. Lainie Friedman Ross, J. Richard Thistlethwaite, Jr., and the Committee on Bioethics (2008) "Minors as Living Solid-Organ Donors." *Pediatrics* 122: 454-61. PMID: 18676567.
15. Mary E. Fallat, John Hutter, and Section on Hematology Oncology and Section on Surgery the Committee on Bioethics (2008) "Preservation of Fertility in Pediatric and Adolescent Patients with Cancer." *Pediatrics* 121: 1461-9. PMID: 18450888.
16. Marcia Levetown and Bioethics and the Committee on Bioethics (2008) "Communicating With Children and Families: From Everyday Interactions to Skill in Conveying Distressing Information." *Pediatrics* 121: 1441-60. PMID: 18450887.
17. American Academy of Pediatrics. Committee on Bioethics (2007) "Professionalism in Pediatrics: Statement of Principles." *Pediatrics* 120:895-7. PMID: 17908776.

Ethics Rounds

1. Megan H. Pesch, Phoebe Dazinger, Lainie Friedman Ross, and Armand H. Matheny Antommaria. (2022) "An Ethical Analysis of Newborn Copngenital Cytomegalovirus Screening." *Pediatrics*. 149: e2021055368. PMID: 35641472.
2. Ian D. Wolfe, Don Brunnquell, Rena Sorensen, and Armand H. Matheny Antommaria. (2022) "Should Tactctile Defensiveness Exclude a Life-Sustaining Intervention in an Adolescent With Autism?" *Pediatrics.* 149: e2021054469. PMID: 35229117.
3. Jennifer E. deSante-Bertkau, Timothy K. Knilans, Govind Persad, Patricia J. Zettler, Holly Fernandez Lynch, and Armand H. Matheny Antommaria. (2021) "Off-Label Prescription of COVID-19 Vaccines in Children: Clinical, Ethical, and Legal Issues." *Pediatrics.* 149: e2021054578. PMID: 34615694.
4. Jamilah M. Hackworth, Meera Kotagal, O. N. Ray Bignal, 2nd, Ndidi Unaka, and Armand H. Matheny Antommaria. (2021) "Microaggressions: Privileged Observers' Duty to Act and What They Can Do." *Pediatrics*. 148: e2021052758. PMID: 34417286.
5. Elizabeth Lanphier, Luke Mosley, and Armand H. Matheny Antommaria. (2021) "Assessing Visitor Policy Exemption Requests During the COVID-19 Pandemic." *Pediatrics.* 148: e2021051254. PMID: 33990461.

6. Natalie Lanocha, Tyler Tate, Erica Salter, Nanette Elster, and Armand H. Matheny Antommaria. (2021) "Can Parents Restrict Access to Their Adolescent's Voice?: Deciding About a Tracheostomy." *Pediatrics*. 147: e2021050358. PMID 33785636.
7. Timothy Crisci, Zeynep N. Inanc Salih, Ndidi Unaka, Jehanna Peerzada, and Armand H. Matheny Antommaria. (2021) "What Should an Intern Do When She Disagrees With the Attending?" *Pediatrics.* 147: e2020049646. PMID 33627371.
8. Liza-Marie Johnson, Erica C. Kaye, Kimberly Sawyer, Alex M. Brenner, Stefan J. Friedrichsdorf, Abby R. Rosenberg, Armand H. Mathey Antommaria. (2021) "Opioid Management in the Dying Child With Addiction." *Pediatrics* 147: e2020046219. PMID 33446508.

Continuing Medical Education

1. Armand H. Matheny Antommaria (2014) Authored 4 questions. NEJM Knowledge+ Family Medicine Board Review. NEJM Group.
2. Armand H. Matheny Antommaria (2009) "Hot Topics: Ethics and Donation After Cardiac Death [online course]. PediaLink. American Academy of Pediatrics. October 24. http://ethics.ht.courses.aap.org/. Accessed December 14. 2009.

Editorials

1. Armand H. Matheny Antommaria, Chris Feudtner, Mary Beth Benner, and Felicia Cohn on Behalf of the Healthcare Ethics Consultant-Certified Certification Commission (2020) "The Healthcare Ethics Consultant-Certified Program: Fair, Feasible, and Defensible, But Neither Definite Nor Finished," *American Journal of Bioethics* 20:1-5. PMID: 32105202.
2. Armand H. Matheny Antommaria and Pamela W. Popp (2020) "The Potential Roles of Surrogacy Ladders, Standby Guardians, and Medicolegal Partnerships, in Surrogate Decision Making for Parents of Minor Children," *Journal of Pediatrics* 220:11-13. PMID 31952849.

Commentaries

1. Armand H. Matheny Antommaria and Elizabeth Lanphier. (2022) "Supporting Marginalized Decision-Marker's Autonom(ies)." *American Journal of Bioethics*. 22(6):22-24. PMID: 35616965.
2. Mary V. Greiner and Armand H. Matheny Antommaria. (2022) "Enrolling Foster Youth in Clinical Trials: Avoiding the Harm of Exclusion." *American Journal of Bioethics.* 22(4):85-86. PMID: 35420526.
3. William Sveen and Armand H. Matheny Antommaria. (2020) "Why Healthcare Workers Should Not Be Prioritized in Ventilator Triage." *American Journal of Bioethics.* 20(7): 133-135. PMID: 32716811.
4. Armand H. Matheny Antommaria, William Sveen, and Erika L. Stalets (2020) "Informed Consent Should Not Be Required for Apnea Testing and Arguing It Should Misses the Point," *American Journal of Bioethics.* 20: 25-27. PMID: 32441602.
5. Armand H. Matheny Antommaria (2019) "Relational Potential versus the Parent-Child Relationship," *Hastings Center Report*. 49(3): 26-27. PMID: 31269255.
6. Armand H. Matheny Antommaria, Robert A. Shapiro, and Lee Ann E. Conard (2019) "Psychological Maltreatment and Medical Neglect of Transgender Adolescents: The Need for Recognition and Individualized Assessment." *American Journal of Bioethics.* 19: 72-74. PMID: 31543011.

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8. Armand H. Matheny Antommaria and Judith R. Ragsdale (2018) "Shaken, not Stirred: What are Ethicists Licensed to Do?" *American Journal of Bioethics* 18: 56-58. PMID: 29697345.
9. Armand H. Matheny Antommaria (2017) "Issues of Fidelity and Trust Are Intrinsic to Uncontrolled Donation after Circulatory Determination of Death and Arise Again with Each New Resuscitation Method," *American Journal of Bioethics* 17: 20-22. PMID: 28430053.
10. Armand H. Matheny Antommaria (2016) "Conscientious Objection: Widening the Temporal and Organizational Horizons," *The Journal of Clinical Ethics* 27: 248-250. PMID: 27658282.
11. Armand H. Matheny Antommaria and Ron King. (2016) "Moral Hazard and Transparency in Pediatrics: A Different Problem Requiring a Different Solution." *American Journal of Bioethics* 16: 39-40. PMID: 27292846.
12. Armand H. Matheny Antommaria and Richard F. Ittenabch (2016) "Quality Attestation's Portfolio Evaluation Is Feasible, But Is It Reliable and Valid?" *American Journal of Bioethics* 16: 35-38. PMID: 26913658.
13. Armand H. Matheny Antommaria and Kristin Stanley Bramlage (2015) "Enrolling Research Participants in Private Practice: Conflicts of Interest, Consistency, Therapeutic Misconception, and Informed Consent." *AMA Journal of Ethics*. 17:1122-1126. PMID: 26698585.
14. Armand H. Matheny Antommaria (2015) "Characterizing Clinical Ethics Consultations: The Need for a Standardized Typology of Cases." *American Journal of Bioethics* 15: 18-20. PMID: 25970383.
15. Armand H. Matheny Antommaria (2015) "Intensified Conflict Instead of Closure: Clinical Ethics Consultants' Recommendations' Potential to Exacerbate Ethical Conflicts." *American Journal of Bioethics* 15: 52-4. PMID: 25562231.
16. Lainie Friedman Ross and Armand H. Matheny Antommaria (2014) "The need to promote all pediatric stem cell donors' understanding and interests." *Pediatrics* 133: e1356-e1357. PMID: 24777208.
17. Armand H. Matheny Antommaria (2014) "Pubertal Suppression and Professional Obligations: May a Pediatric Endocrinologist Refuse to Treat an Adolescent with Gender Dysphoria." *American Journal of Bioethics* 13: 43-46. PMID: 24422933.
18. Armand H. Matheny Antommaria (2012) "Empowering, Teaching, and Occasionally Advocating: Clinical Ethics Consultants' Duties to All of the Participants in the Process." *American Journal of Bioethics* 12 11-3. PMID: 22852533.
19. Armand H. Matheny Antommaria (2010) "Dying but not Killing: Donation after Cardiac Death Donors and the Recovery of Organs." *Journal of Clinical Ethics* 21: 229-31. PMID: 21089993.
20. Armand H. Matheny Antommaria and Julie Melini (2010) "Is it Reasonable to Refuse to be Seen by a Nurse Practitioner in the Emergency Department?" *American Journal of Bioethics* 10: 15-17. PMID: 20694899.
21. William Meadow, Chris Feudtner, Armand H. Matheny Antommaria, Dane Sommer, John Lantos (2010) "A Premature Baby with Necrotizing Enterocolitis Whose Parents Are Jehovah's Witnesses." *Pediatrics.* 216: 151-155. PMID: 20566607.
22. C. C. Weitzman, S. Schlegel, Nancy Murphy, Armand H. Matheny Antommaria, J. P. Brosco, Martin T. Stein (2009) "When Clinicians and a Parent Disagree on the Extent of Medical Care." *Journal of Developmental and Behavioral Pediatrics.* 30: 242-3. PMID: 19525718.

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23. Armand H. Matheny Antommaria and Susan Bratton (2008) "Nurses' Attitudes toward Donation after Cardiac Death: Implications for Nurses' Roles and Moral Distress." *Pediatric Critical Care Medicine,* 9: 339-40. PMID: 18446100.
24. Armand H. Matheny Antommaria and Nannette C. Dudley (2007) "Should Families Be Present During CPR?" *AAP Grand Rounds,* 17: 4-5.
25. Armand H. Matheny Antommaria (2006) "The Proper Scope of Analysis of Conscientious Objection in Healthcare: Individual Rights or Professional Obligations" *Teaching Ethics,* 7: 127-31.
26. Armand H. Matheny Antommaria and Rajendu Srivastava (2006) "If Cardiologists Take Care of Patients with Heart Disease, What do Hospitalists Treat?: Hospitalists and the Doctor-Patient Relationship." *American Journal of Bioethics,* 6: 47-9. PMID: 16423793.
27. Armand H. Matheny Antommaria (2003) "I Paid Out-of-Pocket for My Son's Circumcision at Happy Valley Tattoo and Piercing: Alternative Framings of the Debate over Routine Neonatal Male Circumcision," *American Journal of Bioethics* 3: 51-3. PMID: 12859817.

Letters

1. Benjamin S. Wilfond, David Magnus, Armand H Matheny Antommaria, Paul Appelbaum, Judy Aschner, Keith J. Barrington, Tom Beauchamp, Renee D. Boss, Wylie Burke, Arthur L. Caplan, Alexander M. Capron, Mildred Cho, Ellen Wright Clayton, F. Sessions Cole, Brian A. Darlow, Douglas Diekema, Ruth R. Faden, Chris Feudtner, Joseph J. Fins, Norman C. Fost, Joel Frader, D. Micah Hester, Annie Janvier, Steven Joffe, Jeffrey Kahn, Nancy E. Kass, Eric Kodish, John D. Lantos, Laurence McCullough, Ross McKinney, Jr., William Deadow, P. Pearl O'Rourke, Kathleen E. Powderly, DeWayne M. Pursley, Lainie Friedman Ross, Sadath Sayeed, Richard R. Sharp, Jeremy Sugarman, William O. Tarnow-Mordi, Holly Taylor, Tom Tomlison, Robert D. Truog, Yoram T. Unguru, Kathryn L. Weise, David Woodrum, Stuart Youngner (2013) "The OHRP and SUPPORT," *New England Journal of Medicine,* 368: e36. PMID: 23738513.
2. Lainie Friedman Ross and Armand H. Matheny Antommaria (2011) "In Further Defense of the American Academy of Pediatrics Committee on Bioethics 'Children as Hematopoietic Stem Cell Donors' Statement." *Pediatric Blood & Cancer*. 57: 1088-9.
3. Armand H. Matheny Antommaria (2011) "Growth Attenuation: Health Outcomes and Social Services." *Hastings Center Report,* 41(5): 4. PMID: 21980886.
4. Susan Bratton and Armand H. Matheny Antommaria (2010) "Dead Donor Rule and Organ Procurement: The Authors Reply." *Pediatric Critical Care Medicine,* 11: 314-5.
5. Armand H. Matheny Antommaria and Joel Frader (2009) "Policies of Children's Hospitals on Donation After Cardiac Death—Reply." *Journal of the American Medical Association,* 302: 845.

Case Reports

Armand H. Matheny Antommaria (2002) "Case 4.9: Inappropriate Access to a Celebrity's Medical Records." In *Ethics and Information Technology: A Case-Based Approach to a Health Care System in Transition,* James G. Anderson and Kenneth W. Goodman, 79-80. New York: Springer-Verlag.

Book Reviews

1. Armand H. Matheny Antommaria (2021) Review of *When Harry Became Sally: Responding to the Transgender Moment*, by Ryan T. Anderson. *Journal of Medical Humanities* 42: 195-9. PMID 31808021.
2. Armand H. Matheny Antommaria (2012) Review of *The Ethics of Organ Transplantation*, by Steven J. Jensen, ed., *Journal of the American Medical Association* 308: 1482-3.
3. Armand H Matheny Antommaria (2012) Review of *The Soul of Medicine: Spiritual Perspectives and Clinical Practice*, by John R. Peteet and Michael N. D'Ambra, ed., *Journal of the American Medical Association* 308: 87.
4. Armand H. Matheny Antommaria (2009) Review of *Conflicts of Conscience in Health Care: An Institutional Compromise*, by Holly Fernandez Lynch. *American Journal of Bioethics* 9: 63-4.
5. Armand H. Matheny Antommaria (2008) Review of *A Practical Guide to Clinical Ethics Consulting: Expertise, Ethos, and Power*, by Christopher Meyers. *American Journal of Bioethics* 8: 72-3.
6. Armand H. Matheny Antommaria (2004) Review of *Children, Ethics, and Modern Medicine*, by Richard B. Miller. *American Journal of Bioethics* 4: 127-8.
7. Armand H. Matheny Antommaria (2002) Review of *Ward Ethics: Dilemmas for Medical Students and Doctors in Training*, by Thomasine Kushner and David Thomasma, ed. *American Journal of Bioethics* 2: 70-1. PMID: 22494193.
8. Armand H. Matheny Antommaria (1999) Review of *Human Cloning: Religious Responses*, by Ronald Cole-Turner, ed. *Prism* 6 (March/April): 21.
9. Armand H. Matheny Antommaria (1999) Review of *Christian Theology and Medical Ethics: Four Contemporary Approaches*, by James B. Tubbs, Jr. *Journal of Religion* 79 (April): 333-5.
10. Armand H. Matheny Antommaria (1997) Review of *Body, Soul, and Bioethics*, by Gilbert C. Meilaender. *Prism* 4 (May/June): 28.

Newspaper Articles

1. W. Bradley Poss and Armand H. Matheny Antommaria (2010) "Mass casualty planning must incorporate needs of children." *AAP News* 31 (July): 38.
2. Robert Murray and Armand H. Matheny Antommaria (2010) "Pediatricians should work with school nurses to develop action plans for children with DNAR orders." *AAP News* 31 (May): 30..
3. Armand H. Matheny Antommaria (2009) "Addressing physicians' conscientious objections in health care." *AAP News* 30 (December): 32.

UNPUBLISHED POSTER PRESENTATIONS

1. Armand H. Matheny Antommaria. (2018) "Ethical Issues in the Care of International Patients: A Case Study." International Conference on Clinical Ethics and Consultation, Oxford, United Kingdom.
2. Jill S Sweney, Brad Poss, Colin Grissom, Brent Wallace, and Armand H Matheny Antommaria, (2010) "Development of a Statewide Pediatric Pandemic Triage Plan in Utah." Pediatric Academic Societies Annual Meeting, Vancouver, Canada. E-PAS20103713.147.
3. Christopher G. Maloney, Armand H. Matheny Antommaria, James F. Bale, Thomas Greene, Jian Ying, Gena Fletcher, and Rajendu Srivastava (2010) "Why Do Pediatric Interns Violate

the 30 Hour Work Rule?" Pediatric Academic Societies Annual Meeting, Vancouver, Canada. E-PAS20101500.596

4. Armand H. Matheny Antommaria and Edward B. Clark (2007) "Resolving Conflict through Bioethics Mediation." 3rd International Conference on Ethics Consultation and Clinical Ethics, Toronto, Canada.
5. Elizabeth Tyson, Tracy Hill, Armand Antommaria, Gena Fletcher, and Flory Nkoy (2007) "Physician Practice Patterns Regarding Nasogastric Feeding Supplementation and Intravenous Fluids in Bronchiolitis Patients." Pediatrics Academic Societies Annual Meeting, Toronto, Canada. E-PAS2007:61300.

ORAL PRESENTATIONS

Keynote/Plenary Lectures

International

1. 2021, *Panelist*, Partnership for Quality Medical Donations, Charitable Access Programming for Rare Diseases, "Ethical Issues," Webinar, April 6.
2. 2017, *Invited Speaker*, Spina Bifida Fetoscopic Repair Study Group and Consortium, "Ethics of Innovation and Research in Fetal Surgery," Cincinnati, Ohio, October 26.
3. 2014, *Invited Speaker*, CIC 2013 CCI: Canadian Immunization Conference, "Condition-of-Service Influenza Prevention in Health Care Settings," Ottawa, Canada, December 2.
4. 2014, *Invited Speaker*, National Conference of the Chinese Pediatric Society, "A Brief Introduction to Pediatric Research and Clinical Ethics," Chongqing, China, September 12.

National

1. 2020, *Panelist*, Children's Mercy Bioethics Center, "Ethical Issues in the COVID Pandemic at Children's Hospitals," Webinar, March 2.
2. 2019, *Invited Speaker*, North American Fetal Therapy Network (NAFTnet), "Ethics of Innovation," Chicago, Illinois, October 12.
3. 2019, *Panelist*, National Society of Genetic Counselors Prenatal Special Interest Group, "Fetal Intervention Ethics," Webinar, September 12.
4. 2017, *Invited Participant*, American College of Epidemiology Annual Meeting, Preconference Workshop, "Extreme Personal Exposure Biomarker Levels: Guidance for Study Investigators," New Orleans, Louisiana, September 24.
5. 2016, *Invited Speaker*, American Academy of Pediatrics National Conference & Exhibition, Joint Program: Section on Hospital Medicine and Section on Bioethics, "Resource Allocation: Do We Spend Money to Save One Patient with Ebola or Over a 1,000?" San Francisco, California, October 23.
6. 2016, *Invited Speaker*, 26th Annual Specialist Education in Extracorporeal Membrane Oxygenation (SEECHMO) Conference, "Ethical Issues in ECMO: The Bridge to Nowhere," Cincinnati, Ohio, June 5.
7. 2015, *Invited Speaker*, Extracorporeal Life Support Organization (ELSO) 26th Annual Conference, "ECMO-Supported Donation after Circulatory Death: An Ethical Analysis," Atlanta, Georgia, September 20.
8. 2014, *Invited Speaker*, Pediatric Evidence-Based Practice 2014 Conference: Evidence Implementation for Changing Models of Pediatric Health Care, "Ethical Issues in Evidence-Based Practice," Cincinnati, Ohio, September 19.

9. 2014, *Invited Speaker*, 6th Annual David Kline Symposium on Public Philosophy: Exploring the Synergy Between Pediatric Bioethics and Child Rights, "Does Predictive Genetic Testing for Adult Onset Conditions that Are Not Medically Actionable in Childhood Violate Children's Rights?" Jacksonville, Florida, March 6.
10. 2010, *Invited Speaker*, Quest for Research Excellence: The Intersection of Standards, Culture and Ethics in Childhood Obesity, "Research Integrity and Religious Issues in Childhood Obesity Research," Denver, Colorado, April 21.
11. 2010, *Invited Speaker*, Symposium on the Future of Rights of Conscience in Health Care: Legal and Ethical Perspectives, J. Reuben Clark Law School at Brigham Young University and the Ave Maria School of Law, "Conscientious Objection in Clinical Practice: Disclosure, Consent, Referral, and Emergency Treatment," Provo, Utah, February 26.
12. 2009, *Invited Speaker*, Pediatric Organ Donation Summit, "Research Findings Regarding Variations in Pediatric Hospital Donation after Cardiac Death Policies," Chicago, Illinois, August 18.
13. 2008, *Meet-the-Experts*, American Academy of Pediatrics National Conference & Exhibition, "Physician Refusal to Provide Treatment: What are the ethical issues?" Boston, Massachusetts, October 11.
14. 2008, *Invited Conference Faulty*, Conscience and Clinical Practice: Medical Ethics in the Face of Moral Controversy, The MacLean Center for Clinical Medical Ethics at the University of Chicago, "Defending Positions or Identifying Interests: The Uses of Ethical Argumentation in the Debate over Conscience in Clinical Practice," Chicago, IL, March 18.
15. 2007, *Symposium Speaker*, Alternative Dispute Resolution Strategies in End-of-Life Decisions, The Ohio State University Mortiz College of Law, "The Representation of Children in Disputes at the End-of-Life," Columbus, Ohio, January 18.
16. 2005, *Keynote Speaker*, Decisions and Families, *Journal of Law and Family Studies* and The University of Utah S.J. Quinney College of Law, "Jehovah's Witnesses, Roman Catholicism, and Calvinism: Religion and State Intervention in Parental, Medical Decision-Making," Salt Lake City, Utah, September 23.

<u>Regional/Local</u>

1. 2021, *Panelist*, Pediatric Residency Noon Conference, University of Tennessee Health Science Center, "Bioethics Rounds—Ethical Issues in the Care of Transgender Adolescents," Memphis, Tennessee, September 21.
2. 2020, *Keynote Speaker*, 53rd Annual Clinical Advances in Pediatrics, "Referral to a Fetal Care Center: How You Can Help Patients' Mothers Address the Ethical Issues," Kansas City, Kansas, September 16.
3. 2019, *Speaker*, Patient and Family Support Services, Primary Children's Hospital, "Ethical Issues in the Care of Trans Adolescents," Salt Lake City, Utah, December 5.
4. 2019, *Speaker*, Evening Ethics, Program in Medical Ethics and Humanities, University of Utah School of Medicine, "Patients, Parents, and Professionals: Ethical Issues in the Treatment of Trans Adolescents," Salt Lake City, Utah, December 4.
5. 2019, *Speaker*, Pediatric Hospital Medicine Board Review Course, "Ethics, Legal Issues, and Human Rights including Ethics in Research," Cincinnati, Ohio, September 8.
6. 2019, *Speaker*, Advances in Fetology, "Evolving Attitudes Toward the Treatment of Children with Trisomies," Cincinnati, Ohio, September 6.

7. 2019, *Speaker,* Half-Day Ethics Training: Ethics Consultation & Ethics Committees, "Navigating the Rapids of Clinical Ethics Consultation: Intake, Recommendations, and Documentation," Salt Lake City, Utah, June 1.
8. 2019, *Speaker*, Scientific and Ethical Underpinnings of Gene Transfer/Therapy in Vulnerable Populations: Considerations Supporting Novel Treatments, BioNJ, "What Next? An Ethical analysis of Prioritizing Conditions and Populations for Developing Novel Therapies," Cranbury, New Jersey, March 7.
9. 2018, *Panelist*, Periviability, 17th Annual Regional Perinatal Summit, Cincinnati, Ohio, October 12.
10. 2018, *Speaker,* Regional Advance Practice Registered Nurse (APRN) Conference, "Adults are Not Large Children: Ethical Issues in Caring for Adults in Children's Hospitals," Cincinnati, Ohio, April 26.
11. 2018, *Speaker*, Southern Ohio/Northern Kentucky Sigma Theta Tau International Annual Conference, "Between Hope and Hype: Ethical Issues in Precision Medicine," Sharonville, Ohio, March 2.
12. 2017, *Speaker*, Advances in Fetology 2017, "Ethics of Innovation and Research: Special Considerations in Fetal Therapy Centers," Cincinnati, Ohio, October 27.
13. 2016, *Speaker*, End-of-Life Pediatric Palliative Care Regional Conference, "Ethical/Legal Issues in Pediatric Palliative Care," Cincinnati, Ohio, September 15.
14. 2016, *Speaker*, 26th Annual Bioethics Network of Ohio (BENO) Conference, "When Does Parental Refusal of Medical Treatment for Religious Reasons Constitute Neglect?" Dublin, Ohio, May 29.
15. 2014, *Speaker,* Cincinnati Comprehensive Sickle Cell Center Symposium: Research Ethics of Hydroxyurea Therapy for Sickle Cell Disease During Pregnancy and Lactation, "Ethical Issues in Research with Pregnant and Lactating Women," Cincinnati, Ohio, October 30.
16. 2014, *Speaker,* Advances in Fetology 2014, "The 'Miracle Baby' and Other Cases for Discussion," Cincinnati, Ohio, September 26.
17. 2014, *Speaker,* Advances in Fetology 2014, "'Can you tell me …?': Achieving Informed Consent Given the Prevalence of Low Health Literacy," Cincinnati, Ohio, September 26.
18. 2014, *Panelist*, Center for Clinical & Translational Science & Training, Secrets of the Dead: The Ethics of Sharing their Data, Cincinnati, Ohio, August 28.
19. 2014, *Speaker,* Office for Human Research Protections Research Community Forum: Clinical Research … and All That Regulatory Jazz, "Research Results and Incidental Findings: Do Investigators Have a Duty to Return Results to Participants," Cincinnati, Ohio, May 21.
20. 2013, *Opening Presentation*, Empirical Bioethics: Emerging Trends for the 21st Century, University of Cincinnati Center for Clinical & Translational Science & Training, "Empirical vs. Normative Ethics: A Comparison of Methods," Cincinnati, Ohio, February 21.
21. 2012, *Videoconference,* New York State Task Force on Life and the Law, "Pediatric Critical Care Triage," New York, New York, March 1.
22. 2011, *Presenter,* Fall Faculty Development Workshop, College of Social Work, University of Utah, "Teaching Ethics to Students in the Professions, " Salt Lake City, Utah, November 14.
23. 2011, *Speaker,* 15th Annual Conference, Utah Chapter of the National Association of Pediatric Nurse Practitioners, "Ethical Issues in Pediatric Practice," Salt Lake City, Utah, September 22.
24. 2011, *Speaker,* Code Silver! Active Shooter in the Hospital, Utah Hospitals & Health Systems Association, Salt Lake City, Utah, March 21.

25. 2009, *Speaker*, Medical Staff Leadership Conference, Intermountain Healthcare, "The Ethics of Leadership," Park City, Utah, October 30.
26. 2008, *Speaker*, The Art and Medicine of Caring: Supporting Hope for Children and Families, Primary Children's Medical Center, "Medically Provided Hydration and Nutrition: Ethical Considerations," Salt Lake City, Utah, February 25.
27. 2005, *Speaker*, Utah NAPNAP (National Association of Pediatric Nurse Practitioners) Chapter Pharmacology and Pediatric Conference, "Immunization Update," Salt Lake City, Utah, August 18.
28. 2005, *Keynote Speaker*, 17th Annual Conference, Utah Society for Social Work Leadership in Health Care, "Brain Death: Accommodation and Consultation," Salt Lake City, March 18.
29. 2004, *Continuing Education Presentation*, Utah NAPNAP (National Association of Pediatric Nurse Practitioners), "Febrile Seizures," Salt Lake City, Utah, April 22.
30. 2004, *Speaker*, Advocacy Workshop for Primary Care Providers, "Ethics of Advocacy," Park City, Utah, April 3.
31. 2002, *Speaker*, 16th Annual Biologic Basis of Pediatric Practice Symposium, "Stem Cells: Religious Perspectives," Deer Valley, Utah, September 14.

Meeting Presentations

International

1. 2018, *Speaker*, International Conference on Clinical Ethics and Consultation, "A Systematic Review of Typologies Used to Characterize Clinical Ethics Consultations," Oxford, United Kingdom, June 21.

National

1. 2022, *Speaker*, APPD/PAS Fellow Core Curriculum Workshop, Pediatric Academic Societies Annual Meeting, "From Idea to Implementation: Navigating the Ethical Landscape of Pediatric Clinical Research," Denver, Colorado, April 22.
2. 2021, *Panelist*, Pediatric Endocrine Society Annual Meeting, Difference of Sex Development Special Interest Group, Virtual Conference, April 29.
3. 2020, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Is This Child Dead? Controversies Regarding the Neurological Criteria for Death," Virtual Conference, October 17.
4. 2020, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Contemporary Ethical Controversy in Fetal Therapy: Innovation, Research, Access, and Justice," Virtual Conference, October 15.
5. 2020, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "K-12 Schools and Mandatory Public Health Programs During the COVID-19 Pandemic," Virtual Conference, October 15.
6. 2019, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Ethical Issues in Translating Gene Transfer Studies Involving Children with Neurodegenerative Disorders," Pittsburgh, Pennsylvania, October 26.
7. 2019, *Moderator*, Pediatric Academic Societies Annual Meeting, Clinical Bioethics, Baltimore, Maryland, April 28.
8. 2018, *Presenter*, American Society for Bioethics and Humanities Annual Meeting, "Looking to the Past, Understanding the Present, and Imaging the Future of Bioethics and Medical Humanities' Engagement with Transgender Health," Anaheim, California, October 19.

9. 2018, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Should Vaccination Be a Prerequisite for Sold Organ Transplantation?" Anaheim, California, October 18.
10. 2018, Lindsey Douglas, Armand H. Matheny Antommaria, Derek Williams. *Workshop Presenter*, Pediatric Hospital Medicine Annual Meeting, "IRB Approved! Tips and Tricks to Smooth Sailing through the Institutional Review Board (IRB)." Atlanta, Georgia, July 20.
11. 2018, Alan Schroeder, Armand H. Matheny Antommaria, Hannah Bassett, Kevin Chi, Shawn Ralston, Rebecca Blankenburg. *Workshop Speaker*, Pediatric Hospital Medicine Annual Meeting, "When You Don't Agree with the Plan: Balancing Diplomacy, Value, and Moral Distress," Atlanta, Georgia, July 20.
12. 2018, Alan Schroeder, Hannah Bassett, Rebecca Blankenburg, Kevin Chi, Shawn Ralston, Armand H. Matheny Antommaria. *Workshop Speaker*, Pediatric Academic Societies Annual Meeting, "When You Don't Agree with the Plan: Balancing Diplomacy, Value, and Moral Distress," Toronto, Ontario, Canada, May 7.
13. 2017, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Tensions in Informed Consent for Gender Affirming Hormone Therapy and Fertility Preservation in Transgender Adolescents," Kansas City, Missouri, October 19.
14. Lindsey Douglas, Armand H. Matheny Antommaria, and Derek Williams. 2017, *Workshop Leader*, PHM[Pediatric Hospital Medicine]2017, "IRB Approved! Tips and Tricks to Smooth Sailing through the Institutional Review Board (IRB) Process," Nashville, Tennessee, July 21.
15. 2016, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Ethical Challenges in the Care of International Patients: Organization, Justice, and Cultural Considerations," Washington, DC, October 9.
16. 2015, *Coauthor*, The American Society of Human Genetics Annual Meeting, "Adolescents' Opinions on Disclosure of Non-Actionable Secondary Findings in Whole Exome Sequencing," Baltimore, Maryland, October 9.
17. 2012, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "A Public Health Ethics Analysis of the Mandatory Immunization of Healthcare Personnel: Minimizing Burdens and Increasing Fairness," Washington, DC, October 21.
18. Armand H. Matheny Antommaria, Valerie Gutmann Koch, Susie A. Han, Carrie S. Zoubul. 2012, *Moderator*, American Society for Bioethics and Humanities Annual Meeting, "Representing the Underrepresented in Allocating Scarce Resources in a Public Health Emergency: Ethical and Legal Considerations," Washington, DC, October 21.
19. 2012, *Platform Presentation*, Pediatric Academic Societies Annual Meeting, "Qualitative Analysis of International Variation in Donation after Circulatory Death Policies and Rates," Boston, Massachusetts, April 30. Publication 3150.4.
20. 2011, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "The Intersection of Policy, Medicine, and Ethics during a Public Health Disaster: Special Considerations for Children and Families," Minneapolis, Minnesota, October 13.
21. Armand H. Matheny Antommaria and Joel Frader. 2010, *Workshop Leader*, Pediatric Academic Societies Annual Meeting, "Conscientious Objection in Health Care: Respecting Conscience and Providing Access," Vancouver, British Columbia, Canada. May 1. Session 1710.
22. 2009, *Workshop Leader*, American Society for Bioethics and Humanities Annual Meeting, "Advanced Clinical Ethics Consultation Skills Workshop: Process and Interpersonal Skills," Washington, DC, October 15.

23. 2009, *Platform Presentation*, Pediatric Academic Societies Annual Meeting, "Qualitative Analysis of Donation after Cardiac Death Policies at Children's Hospitals," Baltimore, Maryland, May 2. Publication 2120.6.
24. 2008, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Qualitative Analysis of Donation After Cardiac Death (DCD) Policies at Children's Hospitals," Cleveland, Ohio, October 26.
25. 2007, *Participant*, Hamline University School of Law Biennial Symposium on Advanced Issues in Dispute Resolution, "An Intentional Conversation About Conflict Resolution in Health Care," Saint Paul, Minnesota, November 8-10.
26. *2007, Speaker*, American Society of Bioethics and Humanities Annual Meeting, "Bioethics Consultation and Alternative Dispute Resolution: Opportunities for Collaboration," Washington, DC, October 21.
27. 2007, *Speaker*, American Society of Bioethics and Humanities Annual Meeting, "DNAR Orders in Schools: Collaborations Beyond the Hospital," Washington, DC, October 18.
28. Armand H. Matheny Antommaria and Jeannie DePaulis. 2007, *Speaker*, National Association of Children's Hospitals and Related Institutions Annual Meeting, "Using Mediation to Address Conflict and Form Stronger Therapeutic Alliances," San Antonio, Texas, October 9.
29. 2006, *Speaker*, American Society of Bioethics and Humanities Annual Meeting, "Bioethics Mediation: A Critique," Denver, Colorado, October 28.
30. 2005, *Panelist*, American Society of Bioethics and Humanities Annual Meeting, "How I See This Case: 'He Is Not His Brain,'" Washington, DC, October 20.
31. 2005, *Paper Presentation*, Pediatric Ethics: Setting an Agenda for the Future, The Cleveland Clinic, "'He Is Not His Brain:' Accommodating Objections to 'Brain Death,'" Cleveland, Ohio, September 9.
32. 2004, *Speaker*, American Society for Bioethics and Humanities Spring Meeting, "Verification and Balance: Reporting Within the Constraints of Patient Confidentiality," San Antonio, Texas, March 13.
33. 2002, *Panelist*, American Society for Bioethics and Humanities Annual Meeting, "'Who Should Survive?:' Mental Retardation and the History of Bioethics," Baltimore, Maryland, October 24.

Invited/Visiting Professor Presentations

1. 2013, Visiting Professor, "How to Listen, Speak and Think Ethically: A Multidisciplinary Approach," Norton Suburban Hospital and Kosair Children's Hospital, Louisville, Kentucky, May 22.
2. 2010, Visiting Professor, Program in Bioethics and Humanities and Department of Pediatrics, "What to Do When Parents Want Everything Done: 'Futility' and Ethics Facilitation," University of Iowa Carver College of Medicine, Iowa City, Iowa, September 10.

Grand Round Presentations

1. 2019, David Green Lectureship, "Establishing Goals of Care and Ethically Limiting Treatment," Primary Children's Hospital, Salt Lake City, Utah, December 5.
2. 2018, "The Ethics of Medical Intervention for Transgender Youth," El Rio Health, Tucson, Arizona, September 29.
3. 2018, Pediatrics, "Patient Selection, Justice, and Cultural Difference: Ethical Issues in the Care of International Patients," Cleveland Clinic, Cleveland, Ohio, April 10.

4. 2018, Bioethics, "Reversibility, Fertility, and Conflict: Ethical Issues in the Care of Transgender and Gender Nonconforming Children and Adolescents," Cleveland Clinic, Cleveland, Ohio, April 9.
5. 2017, Heart Institute, "'Have you ever thought about what you would want—if god forbid—you became sicker?': Talking with adult patients about advance directives," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 16.
6. 2017, Pediatrics, "Respectful, Effective Treatment of Jehovah's Witnesses," with Judith R. Ragsdale, PhD, MDiv and David Morales, MD, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, March 14.
7. 2017, Pediatrics, "Ethical Dilemmas about Discharging Patients When There Are Disagreements Concerning Safety," Seattle Children's Hospital, Seattle, Washington, January 19.
8. 2015, Pediatrics, "'Nonbeneficial' Treatment: What must providers offer and what can they withhold?," Greenville Health System, Greenville, South Carolina, May 10.
9. 2014, Advance Practice Providers, "Common Ethical Issues," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, August 13.
10. 2014, Respiratory Therapy, "Do-Not-Resuscitate (DNR) Orders," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, July 15.
11. 2013, Heart Institute, "No Not Months. Twenty-Two *Years*-Old: Transiting Patients to an Adult Model of Care." Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 21.
12. 2013, Division of Neonatology, "This Premature Infant Has a *BRCA1* Mutation!?: Ethical Issues in Clinical Whole Exome Sequencing for Neonatologists." Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 11.
13. 2013, Department of Pediatrics, "Adults are Not Large Children: Ethical Issues in Caring for Adults in Children's Hospitals," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, February 26.
14. 2012, "Mandate or Moratorium?: Persisting Ethical Controversies in Donation after Circulatory Death," Cedars-Sinai Medical Center, Los Angeles, California, May 16.
15. 2011, Division of Pediatric Neurology Friday Lecture Series, "Inducing or Treating 'Seizures' with Placebos: Is It Ever Ethical?," University of Utah, Salt Lake City, Utah, October 7.
16. 2011, Department of Surgery, "DNR Orders in the OR and other Ethical Issues in Pediatric Surgery: Case Discussions," Primary Children's Medical Center, Salt Lake City, Utah, October 3.
17. 2009, Department of Pediatrics, "What to Do When Parents Want Everything Done: 'Futility' and Bioethical Mediation," Primary Children's Medical Center, Salt Lake City, Utah, September 17.
18. 2008, Division of Pulmonology and Critical Care, "Futility: May Clinicians Ever Unilaterally Withhold or Withdraw Medical Treatment?" Utah Valley Regional Medical Center, Provo, Utah, April 17.
19. 2007, Division of Otolaryngology-Head and Neck Surgery, "Advance Directives, Durable Powers of Attorney for Healthcare, and Do Not Attempt Resuscitation Orders: Oh My!," University of Utah School of Medicine, Salt Lake City, Utah, June 20.

Outreach Presentations

1. 2019, *Panelist*, Cincinnati Edition, WVXU, "The Ethics of Human Gene Editing," Cincinnati, Ohio, June 13.
2. 2019, *Speaker*, Adult Forum, Indian Hill Church, "Medical Ethics," Indian Hill, Ohio, March 24.
3. 2016, *Speaker*, Conversations in Bioethics: The Intersection of Biology, Technology, and Faith, Mt. Washington Presbyterian Church, "Genetic Testing," Cincinnati, Ohio, October 12.
4. 2008, *Speaker*, Science in Society, Co-sponsored by KCPW and the City Library, "Death—Choices," Salt Lake City, Utah, November 20.
5. 2003, *Panelist*, Utah Symposium in Science and Literature, "The Goodness Switch: What Happens to Ethics if Behavior is All in Our Brains?" Salt Lake City, Utah, October 10.
6. 2002, *Respondent*, H. Tristram Englehardt, Jr. "The Culture Wars in Bioethics," Salt Lake Community College, Salt Lake City, Utah, March 29.

Podcasts

1. 2021, "Ethics of COVID Vaccines in Kids," PHM from Pittsburgh, August 12.
2. 2020, COVID Quandaries: Episode 1, "Is Getting Sick Just Part of the Job?" Hard Call, October 6.

EXHIBIT B

BIBLIOGRAPHY

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EXHIBIT C

TABLE 1: Strength of Recommendation and Quality of Evidence in Recommendations Made by the Endocrine Society

Strength of the Recommendation/ Quality of the Evidence[1]	Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons	Pediatric Obesity-Assessment, Treatment, and Prevention	Congenital Adrenal Hyperplasia Due to Steroid 21-Hydroxylase Deficiency	Treatment of Diabetes in Older Adults
Strong|High	0 (0)[2]	0 (0)	0 (0)	8 (23)
Strong|Moderate	3 (11)	4 (13)	18 (33)	4 (11)
Strong|Low	5 (18)	6 (20)	13 (25)	6 (17)
Strong|Very Low	2 (7)	1 (3)	1 (2)	1 (3)
Weak|High	0 (0)	0 (0)	0 (0)	0 (0)
Weak|Moderate	0 (0)	0 (0)	2 (4)	1 (3)
Weak|Low	9 (32)	5 (17)	4 (7)	6 (17)
Weak|Very Low	3 (11)	12 (40)	7 (13)	4 (11)
Ungraded Good Practice Statement[3]	6 (21)	2 (7)	9 (17)	5 (14)
Either Low or Very Low	19 (68)	24 (80)	25 (46)	17 (48)
Total	28	30	54	35

[1] Quality of the Evidence

High: "Consistent evidence from well-performed RCTs [Randomized Controlled Trials] or exceptionally strong evidence from unbiased observational studies"

Moderate: "Evidence from RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise evidence), or unusually strong evidence from unbiased observational studies"

Low: "Evidence for at least one critical outcome from observational studies, from RCTs with serious flaws, or indirect evidence"

Very Low: "Evidence for at least one of the critical outcomes from unsystematic clinical observations or very indirect evidence"

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2008;93(3):666-73.

[2] n (%)

[3]Ungraded Good Practice Statement: "Direct evidence for these statements was either unavailable or not systematically appraised and considered out of the scope of this guideline. The intention of these statements is to draw attention to these principles." Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

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IN 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 AUGUST DEKKER

I, August Dekker, hereby declare and state as follows:

1. My name is August Dekker.[1] I am a plaintiff in the above-captioned action and submit this declaration in support of Plaintiffs' Motion for a Preliminary Injunction.

2. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this Declaration and would testify completely to those facts if called to do so.

3. I am 28 years old, and I live in Hernando County, Florida. I have lived in Florida since I was 10 years old, when my family moved here from California.

[1] My given, legal name is Kori Dekker. I use August Dekker as my name because it is more consistent with who I am and my male gender identity.

4. I am unemployed and receive Supplemental Security Income due to disability, as I am living with debilitating rheumatoid arthritis.

5. I have been a Medicaid beneficiary in Florida since 2014.

6. I am a man who is also transgender. Although I was incorrectly assigned the sex female at birth, my gender identity is male.

7. I experience and have been diagnosed with gender dysphoria due to the significant distress caused by the disconnect between my sex assigned at birth, along with some of my primary and secondary sex characteristics, and my gender identity.

8. As a child, even as early as 5 years of age, I remember feeling uncomfortable being perceived as a girl. For example, I would always choose to play a male character when I was roleplaying with my brothers and would also play male characters when I would play "house."

9. Around the age of 13, I was extremely distraught when I got my first period, because it never occurred to me that I would as I was not a girl. I remember running to my mom crying and wondering what was happening because I did not feel that I was a girl.

10. However, because of my family's religious beliefs, I felt forced to suppress my gender identity as a child and adolescent, which caused me great distress and anxiety.

11. Once I graduated high school in 2012, I felt freer to explore my gender expression and come to terms with my gender identity as a man. By 2015, I began to socially transition and live openly as the man that I am.

12. Because of the affirmation I felt through my social transition, not long after, I decided to seek out medical care. It took me a while to find a provider that would be qualified, and I felt comfortable with. Once I found a provider at Metro Inclusive Health in Tampa, I began working with a therapist before starting hormone therapy. The therapist diagnosed me with gender dysphoria in 2017.

13. Following the diagnosis of gender dysphoria and working with and under the care of my medical and mental health providers, I began undergoing hormone therapy as medically necessary treatment for my gender dysphoria in 2017, which was recommended by my providers at Metro Inclusive Health.

14. I have since obtained different medical and mental health providers. I am now seeing a therapist at Solace Behavioral Health in Tampa and I obtain my hormone therapy through Planned Parenthood in Tampa.

15. At present, I am being prescribed testosterone as treatment for my gender dysphoria. I see my medical provider approximately every six months, and I fill my prescription every month. Medicaid has covered my testosterone hormone therapy.

16. In addition, in consultation with and under the care of my medical and mental health providers, I obtained top surgery as treatment for my gender dysphoria in April 2022. This surgical treatment, which was covered by Medicaid, was recommended by my providers as medically necessary treatment for my gender dysphoria.

17. As a Medicaid beneficiary, I receive my health coverage through Humana. Medicaid has always covered my medically necessary gender-affirming medical care as recommended by my medical and mental health providers to treat my gender dysphoria.

18. Being able to obtain hormone therapy in the form of testosterone injections and to obtain top surgery has allowed me to bring my body into alignment with who I am and provided a great deal of relief and comfort. It has given me the ability to not hate myself or my body, and has brought great comfort to my life.

19. Having access to this medically necessary care has allowed me to be the version of myself that I pictured growing up. It feels natural and normal for me be able to live as the man that I am.

20. Following my top surgery, I was able to celebrate my birthday with some friends outdoors in a state park. Having a more masculine chest that conformed with my identity allowed me to be shirtless in public for the first time

ever. It was an afternoon full of joy and laughter. And I had never felt more euphoric about my body than I did in that moment.

21. I understand, however, that the Florida Agency for Health Care Administration (AHCA) has adopted a new regulation that will prohibit Medicaid from covering medical services for the treatment of gender dysphoria. I understand that this new regulation went into effect on August 21, 2022.

22. AHCA's adoption of a new regulation prohibiting Medicaid from covering gender-affirming care has caused me a great deal of distress and anxiety. When I first learned of the new regulation, I felt a great sense of dread. I am very fearful of the future, not just for me but for other trans people, particularly the younger trans people in Florida who will no longer have access to puberty blockers and hormone therapy that they may need.

23. My only source of income is my monthly Supplemental Security Income payments of $841. I use this limited income to pay for my rent, food, and necessities. I simply cannot afford my medically necessary hormone therapy without Medicaid, as I understand it would cost $60-65 per month.

24. I know of other Medicaid participants who were in the process of obtaining coverage for their surgical care who are now scrambling for a way to be able to access that medically necessary care.

25. While I can ask and beg some family and friends for money to continue coverage, that is neither guaranteed nor sustainable. It feels dehumanizing and shameful to have to ask for help all the time, especially when my hormone therapy is medically necessary health care recommended by my doctors and which Medicaid has covered previously.

26. I also have experienced the physical effects of having to stop hormone therapy for a period of time. That experience caused me to lose muscle mass, have a higher pitched voice, and lose some of my body and facial hair to a degree that people started perceiving me as a woman instead of the man that I am. It caused me great discomfort and anguish to be perceived as such, and I would not want to ever have to experience that again.

27. The adoption of the exclusion of gender-affirming care by AHCA, along with actions taken by Florida's current administration targeting transgender people, have shaken me to my core and caused me to lose hope. It no longer feels safe to be an out transgender person in Florida. Because of the discrimination I see stoked by Florida's policy decisions to target transgender people, I often worry that someone will perceive me as transgender and decide they want to hurt me. I am frightened about the possibility that losing access to my medically necessary gender-affirming care will cause physical changes that will make it more likely for someone to perceive me as transgender or more feminine. If someone perceives me as

transgender or more feminine, I am afraid that they will verbally or physically assault me.

28. It is incredibly stressful and debilitating to have to worry about whether I will be able to get the medical care that I need, or whether in its absence, I will be incorrectly perceived as female. I want to be able to spend time with my friends outside. And I want to exist in a way that I feel safe. Everyone deserves that, and the fact that I and so many other trans people are being denied that right now, by actions like AHCA's adoption of the exclusion, is very taxing.

29. The actions by AHCA and Florida's state government threaten the health and wellbeing of transgender Medicaid beneficiaries, like me. I am challenging AHCA's new regulation not just to preserve my access to the health care that I need, but also for the many other transgender Medicaid beneficiaries who will be harmed as a result of this rule.

I declare under penalty of perjury that the foregoing is true and correct. Executed this __th day of September 2022.

Respectfully Submitted,

_____

August Dekker

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendant*.	No. 4:22-CV-00325-RH-MAF

DECLARATION OF BRIT ROTHSTEIN

I, Brit Rothstein, hereby declare and state as follows:

1. My name is Brit Rothstein. I am a plaintiff in the above-captioned action and submit this declaration in support of Plaintiffs' Motion for a Preliminary Injunction.

2. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this Declaration and would testify completely to those facts if called to do so.

3. I am 20 years old, and I live in Orange County, Florida where I attend the University of Central Florida (UCF). When I am not at school, I live in Broward County, Florida with my dad and my twin sister. I have lived in Florida all of my life.

4. I receive my health insurance coverage through Medicaid, as administered through Sunshine Health because of my age and my family's limited income.

5. I am a junior in college and I am studying digital media and minoring in information technology. I am taking 15 credits this semester and I also participate in a federal work study program which, provides part-time jobs for students with financial need. I have a full scholarship to attend UCF, and that is the only way that I am able to go to college, as my family is low-income and could not otherwise afford tuition and living expenses.

6. I am a man and I am also transgender. I was incorrectly assigned the sex female at birth, but my gender identity is male.

7. I experience gender dysphoria related to the disconnect between my sex assigned at birth and my gender identity. Since the third grade, I have been aware of my gender identity. When I was younger, my mom would try to force me to wear dresses to church but I hated dresses and I only wanted to wear slacks. I didn't understand why I couldn't have short hair, I didn't understand why boys were allowed to like blue but girls were expected to like pink, and I came to understand that gender expectations were often based on stereotypical assumptions about how people should look and dress and behave. Those rigid societal rules never made sense to me, even as a child.

8. In the sixth grade, my anxiety and depression surrounding my sex assigned at birth was exacerbated, and I would become physically ill when I had to go into the girls' locker room for P.E. Fortunately, there was a guidance counselor who understood the discomfort I experienced in the locker room and the manifesting anxiety and distress it caused, so she helped me transfer out of P.E.

9. In the seventh grade, I was seeing a therapist in the Broward County school system due to unrelated issues, Dr. Renae Lapin, LMFT. She saw how much I was struggling with not being able to live my life as a boy and, through my sessions with Dr. Lapin, I became more comfortable with how I was feeling and came to understand that I was a boy. Dr. Lapin helped me navigate how to talk to others about my gender identity.

10. After a lot of research about how to explain to my family how I felt and that I was transgender, I came out to my dad in 2015 and asked that I be treated in accordance with my male gender identity. My parents are divorced and my mom is not accepting of LGBTQ+ people and would not have understood, so I came out only to my dad at first. He was very supportive and allowed me to wear a binder (a garment that helps to give the appearance of a flatter chest) at his house and live as my true authentic self when I was there. I was not able to do so at my mom's house because she disapproved of my living in accordance with my gender identity. When I did finally come out to my mom in 2016, she called me an "abomination" and

disowned me. I unfortunately do not have any contact with her or her side of the family.

11. In July of 2016, when I was 14 years old, I began seeing Dr. Deborah Grayson, and I continued therapy with her until I went to college. Dr. Grayson diagnosed me with gender dysphoria and, after a couple of years of consistent counseling, she referred me to Joe DiMaggio Children's Hospital to meet with a pediatric endocrinologist. Because my mother objected to my care for my gender dysphoria, I was not able to receive gender-affirming care until my dad went to court and was finally granted sole decision making as it related to issues involving my gender identity. My dad understood how important it was for me to access medically necessary care recommended by doctors with expertise in gender dysphoria.

12. After a long road of fighting for access to gender-affirming healthcare, I was finally able to see Dr. Sarah Hart-Unger, a pediatric endocrinologist at Joe DiMaggio, when I was 17 years old. I had been diagnosed with gender dysphoria four years prior and had been in consistent and regular counseling since that time. I was living in accordance with my male gender identity to the extent possible, given my family situation. Dr. Hart-Unger determined that it was medically necessary for me to begin hormone blockers, and she prescribed them for me and oversaw my treatment. I began cross-sex hormone therapy as medically necessary treatment for my gender dysphoria at Dr. Hart-Unger's recommendation. Medicaid has covered

my gender-affirming healthcare needs, including therapy, blood tests, office visits, and my prescriptions for hormone blockers and testosterone.

13. Hormone therapy, in the form of testosterone, has impacted my life in so many positive ways, including the changes to my physical body, my mental and emotional health, and even the self-confidence I have gained through existing in a body that feels more like my own.

14. When I was 18, I was able to obtain a court order for legal name change, changing my legal name to Brit Andrew Rothstein, which aligned with my gender identity and who I know myself to be. I also amended my legal government-issued identification documents to reflect my new legal name and my legal gender marker, male.

15. I continue to experience significant dysphoria related to my chest. Ever since my chest developed, I have hated the way it looks and feels and have long known that I need to have top surgery to bring my body into alignment with who I am.

16. I wear a binder almost every day, usually for 10-12 hours per day, depending on my schedule. My binder causes me discomfort, it leaves skin indentations, and sometimes causes bruising on my ribcage. Once, in 2018, I had to go to the Emergency Room for chest contusions caused by wearing my binder for too long. Having top surgery will mean that I no longer have to wear a restrictive

binder all of the time just to navigate my daily life. Unfortunately, there are very few medical providers in Florida who are both competent in performing top surgery, and even fewer who also take Medicaid.

17. I finally found Dr. Danker, a surgeon at the University of Miami who accepts Medicaid for top surgeries, in January of 2022. I had my consultation with her in May and she recommended that I undergo gender-affirming chest surgery, which was approved by Medicaid. When I received my approval, I felt blessed to finally have the chance to obtain the gender affirming care I needed. But in an unfortunate turn of fate, I finally received the approval for the prior authorization on Thursday, August 11, 2022, and the next day I learned that the Agency for Health Care Administration (AHCA) had just adopted a rule that banned my care from being covered.

18. I cannot describe the elation that I experienced upon learning I would finally be getting the surgery, and that I even had a date scheduled: December 22, 2022. The countdown began immediately, and to say I was looking forward to it would be an understatement. It was finally real and attainable - I would be having top surgery and bringing my body into alignment with who I am. I would no longer have to wear a restrictive and painful binder to hide that part of my body. It was a punch in the gut to learn the very next day that the state of Florida had decided to

strip life-affirming medically necessary healthcare away from all transgender Floridians on Medicaid. It was the highest high followed by the lowest low.

19. I cannot afford to pay for my testosterone prescriptions out of pocket, and I cannot afford to pay for my surgery that is scheduled for December 22nd out of pocket. If this ban remains in place, I will lose access to the care for my gender dysphoria that medical professionals have determined is medically necessary for my health and well-being.

20. I do not have family members who can pay for my care. My dad is a single parent, who has arranged his entire life around being the sole-caretaker for my twin sister, who has cerebral palsy and other disabilities. My dad needs to have the same schedule as my sister because she requires around the clock care and attention. As such, he has worked as a teachers' assistant for students with special education needs in the Broward County School District, a job which pays approximately $21,000 per year. He is barely able to make ends meet and could not afford to financially help me get access to the medical care I need.

21. I worked hard to obtain a Florida Bright Futures scholarship so that I would be able to attend college. I also received a Top Ten Knights Scholarship from the University of Central Florida. I have spent so long fighting to become the man that I know myself to be. I have overcome obstacles and worked hard to get where I am today, yet the state has created an unnecessary additional barrier blocking me

from care that would allow me to feel like my body is truly mine. I am legally male in the eyes of the state and federal government, I have testosterone circulating through my body and I have grown facial hair, yet I still live in fear every day that I will be misperceived as female due to my chest, or perceived as transgender for that reason. For transgender people, especially in places like here in Florida, discrimination, harassment, and violence against our community is common, and this puts me at risk of danger just for existing.

22. I am challenging this discriminatory rule not only for myself, but for every trans person out there who is being told by the state that their health and well-being does not matter. Though I have always been very shy, I have also always stood up for what is right. In high school, I recognized how lucky I was to have a supportive parent who loved me for who I was. Not everyone has that. There were multiple transgender students at my school alone who attempted or died by suicide, so I decided that I needed to advocate for those who didn't have the support that I had. I was invited to join the Broward County Superintendent's LGBTQ+ Advisory Council, and I was the President of my school's GSA. I supported my fellow transgender classmates the best that I could, because everyone deserves to feel accepted for who they are. I know what is right and what is wrong, and stripping transgender people, like myself, of healthcare and treating us differently than others solely for being transgender is wrong.

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

Executed this 9th day of September 2022.

Respectfully Submitted,

DocuSigned by:

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Brit Rothstein

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

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

DECLARATION OF JANE DOE

I, Jane Doe[1], hereby declare and state as follows:

1. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this Declaration and would testify completely to those facts if called to do so.

2. I, along with my husband, John Doe, am next friend of my minor child, Susan Doe, who is a Plaintiff in this action.

3. I am a Florida resident. I live in Brevard County with my husband John, our daughter Susan, who is 12 years old, and our son, who is 15 years old.

[1] Jane Doe, John Doe, and Susan Doe are pseudonyms. My daughter (who is a minor), husband, and I are proceeding under pseudonyms to protect our right to privacy and ourselves from discrimination, harassment, and violence, as well as retaliation for seeking to protect our rights.

4. John works for the federal government. He has worked there for 19 years.

5. I am a mother and homemaker. I do not work outside the home.

6. John and I adopted Susan and her brother out of medical foster care in Florida. We adopted Susan when she was 2 years old.

7. Susan is transgender.

8. When we adopted Susan out of foster care, Susan had several medical issues. She was originally placed in regular foster care and was then moved into the medical foster care program after an incident where she stopped breathing as an infant. At the time she came into our care, she had severe acid reflux that was treated with antacids, acid blockers, and dietary changes. In addition, Susan was barely meeting developmental milestones. From the time she was two, she received weekly occupational therapy to support her development. She also received speech therapy for a period of time as a toddler, and later behavioral therapy.

9. Because we adopted Susan out of foster care, Susan is eligible for Medicaid coverage until she turns 18. She has been eligible for and enrolled in the program since she entered Florida's foster care system as an infant. We have maintained Susan and her brother on Medicaid in order to ensure continuity of care with their existing providers and to ensure that their medical needs are met.

10. Although Susan was assigned male at birth, she has known that she is a girl from a very young age. When she was 3 years old, she first told me that she was a girl. We monitored her developmental milestones and noted that she always preferred toys typically marketed towards girls. John and I discussed that when he presented Susan with toys marketed towards boys, Susan would refuse them, and she would show distress if not allowed to play with girl toys. Recognizing the strong distress Susan displayed when not allowed to play with girl toys and her strong interest in all things feminine, we researched how to best support our child and allowed her to explore her gender expression in deliberate and gradual steps. Susan had a large say with respect to how she presented herself. For example, she liked to wear ribbons in her hair and pink bracelets to school, even when she still wore typical boy clothes and had not yet grown out her hair. We kept princess dresses for her at home and she would often change into a dress as soon as she came home from school.

11. When she was in first grade, Susan became extremely unhappy with her assigned gender. Before that time, she had mostly been a very happy-go-lucky child, but starting in first grade she began getting angry and frustrated easily, and then would become incredibly sad, often crying for 20 minutes or more. We consulted resources online and researched gender dysphoria in children, and as her

parents we had to acknowledge that the discrepancy between her sex assigned at birth and how she felt inside was causing her to suffer.

12. We looked for a therapist for Susan, but it was difficult to find someone in our area who had experience working with youth who felt the way our daughter did. Susan and I were able to go to one session with a therapist when she was 6, and the therapist talked with me about how best to support Susan. She told me to keep listening to Susan and to allow her to express herself, as we had been doing. She suggested buying clothes from the girls' department that were gender neutral so Susan could wear them to school without attracting attention about her gender presentation. She had her last short haircut when she was 6 years old, and when she saw how it looked, she started crying because she felt like the short haircut did not reflect her identity. After that, she started growing out her hair. I later found out that, around this same time, Susan had started to introduce herself to people with her chosen name, which has since become her legal name, and is more typically feminine.

13. During the summer of 2017, which was the summer before Susan started second grade, she told us emphatically "I need to be a girl and wear girl clothes to school." In order to ensure that we were properly supporting Susan, we began to see a therapist as a family. The therapist, Dr. Linda Ouellette, diagnosed Susan with gender dysphoria. Dr. Ouellette also made clear to us that Susan knows

exactly who she is and that any problems stemmed from when people question Susan's identity. Dr. Ouellette thus recommended we continue to support Susan in her social transition.

14. Following the advice we had received from Dr. Ouellette, we followed Susan's lead and bought Susan more traditionally feminine clothes, including dresses and skirts to wear to school. We also worked with the principal and teachers at Susan's school to try to make sure that they used the appropriate name and pronouns for Susan. Dr. Ouellette shared with John and me, and we in turn shared with Susan's school, the latest research on helping children with gender dysphoria adjust well at school, in addition to in the home.

15. After she was able to socially transition and live in accordance with her firmly asserted female gender identity, we observed Susan feeling a sense of joy. She was happy and comfortable in her own skin.

16. Dr. Ouellette further recommended that Susan see a pediatric endocrinologist, who could monitor her hormone levels for the onset of puberty and assist with any future medical needs.

17. We looked for someone close to us, but ultimately began working with Dr. Bethel Steindel-Spargo at Joe DiMaggio Children's Hospital in south Florida. Susan has been seeing Dr. Steindel-Spargo since 2019. We drive three hours there and three hours back for every appointment. Dr. Steindel-Spargo

closely monitored Susan's hormone levels to determine the onset of puberty. We had visits approximately every three months.

18. We have been very deliberate in our approach to supporting Susan. Our goal has always been to support our daughter while following the advice and recommendations of medical and health professionals experienced in dealing with gender identity and gender dysphoria.

19. In July 2020, after Susan began the onset of puberty, Dr. Steindel-Spargo started Susan on a puberty deferring medication called Lupron as medically necessary treatment for Susan's gender dysphoria. The medication, which Medicaid has been covering, prevents Susan from developing secondary sex characteristics consistent with male puberty. According to Dr. Steindel-Spargo, it is medically necessary for Susan to receive a Lupron injection every three months in order for her to live authentically in a manner consistent with her gender identity and to treat her gender dysphoria. By preventing the physical manifestations that accompany male puberty, Susan is also able to avoid negative social and emotional consequences associated with her being forced to develop the characteristics aligned with a gender with which she does not identify.

20. When Susan learned that the puberty deferring medication was necessary to suppress male puberty, she was happy at the prospect. Though Susan is usually nervous about shots, after Dr. Steindel-Spargo explained that the shot

would help her in her transition process, Susan's hesitation was entirely overcome. There is nothing worse in Susan's mind then male puberty; she describes it as a "nightmare."

21. Dr. Steindel-Spargo is currently monitoring Susan to determine when it would be medically appropriate for her to begin hormone therapy. Susan is very eager to go through female puberty. Notwithstanding Susan's eagerness to begin female puberty, we continue to follow the advice and direction of Susan's medical and mental health providers. At this point, Dr. Steindel-Spargo thinks that Susan could be ready to start hormone therapy in a year or two.

22. In August 2021, Dr. Ouellette retired from her practice, and Susan went without mental health services for a period of time. In early November 2021, Susan began seeing Rebecca Thipsingh, who is a Licensed Clinical Social Worker. Like Dr. Ouellette, Ms. Thipsingh diagnosed Susan with gender dysphoria. Ms. Thipsingh has further supported Susan in managing the symptoms of her dysphoria.

23. I understand that due to a new state regulation adopted by the Florida Agency for Health Care Administration ("AHCA"), beginning on August 21, 2022, Florida Medicaid will no longer provide coverage for medical treatments for gender dysphoria. Thus, we understand that Medicaid will no longer cover Lupron for Susan as treatment for her gender dysphoria. The regulation will also prohibit

Medicaid from covering hormone therapy as treatment for Susan's gender dysphoria when Susan is ready to begin the treatment, per the medical guidance of Dr. Steindel-Spargo.

24. Susan is due to have her next Lupron injection on October 3, 2022. In light of the new regulation prohibiting Medicaid coverage for medical treatments for gender dysphoria, Medicaid will refuse to pay for the medically necessary Lupron injection when it is needed.

25. I worry about the potential physical and mental health consequences of depriving Susan of the medically necessary treatment recommended by her doctors. Not providing such treatment is not an option for us. We believe providing Susan with the medical treatment for gender dysphoria that she requires is necessary to ensure her health and well-being.

26. If Susan had to stop taking Lupron and go through male puberty as a result of the new regulation, she would be devastated. Susan has been living as a girl in every aspect of her life since 2017. Her legal name was changed to her affirmed name in 2018, and in 2020, her birth certificate was amended to reflect that she is female. If she were no longer able to access the medical care that she needs to align her body with her gender identity, her mental health would suffer tremendously. She wouldn't want to leave the house, and I fear that she might engage in self-harm or even contemplate suicide. Going through male puberty

would be torture for her. And it would be agony to watch her suffer needlessly when this could be easily eliminated with what I understand through first-hand experience to be an evidence-based medication that other children are commonly prescribed for the treatment of precocious puberty and that all the medical associations recommend for the treatment of gender dysphoria. Through my experience with my daughter's medical treatment and extensive conversations with her medical providers over the past five years, I understand that the treatment my daughter is receiving for her gender dysphoria is medically necessary, safe, and effective.

27. John and I have access to health care coverage as a result of his job.

28. While we can add Susan to our health plan, it is our understanding that we cannot do so until the open enrollment period near the end of the year, and her coverage would not start before January 1, 2023. Thus, given her need for her next Lupron shot in October 2022, this is not a feasible solution. What is more, as a child adopted out of foster care, Susan is entitled to have her medical needs covered by Medicaid, and we should not have to move Susan to John's employer-provided health plan.

29. With Medicaid no longer covering Susan's Lupron treatment, we will have no choice but to try to pay for her upcoming Lupron injection out of pocket. Based on my research, the retail price for a single Lupron shot is roughly $11,000

or more. We don't have sufficient resources to provide this care without sacrifice. We would have to put it on a credit card, and it would be a hardship for us.

30. Even if we add Susan to John's employer-provided health plan, Susan's health care would be more expensive for us as a family. We would have a $300 annual deductible for Susan and higher cost-sharing for her gender-affirming care (including Lupron).

31. Florida is our home. We are part of a community here. I worry not only about the multitude of harms caused to my own family through AHCA's new regulation, but also about the effect that the actions by AHCA and the current state government will have on other transgender people and their families. We know families that cannot afford to pay out of pocket, nor do they have any other options by which they could obtain health care coverage, if Medicaid stopped paying for their transgender child's medically necessary, physician recommended treatment.

32. We have begun considering moving out of state if we need to in order to protect our daughter from state-sponsored discrimination because of who she is. We do not wish to move if it can be avoided, as, among other things, it could mean John having to switch jobs and separating Susan and our son from their long-term health care providers, friends, and family. That said, the health and wellbeing of our children are paramount to John and me.

33. The state's decision to stop covering medically necessary gender-affirming medical care through Medicaid is tragic. It is also dehumanizing. We are concerned about the message the State of Florida is sending by excluding transgender people from Medicaid coverage to which they otherwise would be entitled simply because they are transgender.

34. In addition, my husband and I keep in touch with other families in the LGBTQ+ affirming foster care community. Even before this rule, I have seen other families have trouble accessing services just because their kids are transgender. Now, I'm hearing about foster families giving up their placements because of the state's hostility toward LGBTQ+ people and concerns about being able to meet the health care needs of those children through Medicaid.

35. The actions by AHCA and Florida's state government threaten the health and wellbeing of transgender Medicaid recipients, like my daughter Susan. We are challenging the new state regulation promulgated by AHCA to help not only Susan, but also the many other transgender Medicaid beneficiaries who will be harmed.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 9 day of September, 2022.

Respectfully Submitted,

Jane Doe

Jane Doe

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al., *Plaintiffs*, v. SIMONE MARSTILLER, et al., *Defendants*.	No.

DECLARATION OF JADE LADUE

I, Jade Ladue, hereby declare and state as follows:

1. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this Declaration and would testify completely to those facts if called to do so.

2. I, along with my husband, Joshua Ladue, am next friend of our minor child, K.F., who is a Plaintiff in this action.

3. I am a Florida resident. I live in Sarasota County with Joshua, our son K.F., who is 12 years old (almost 13), and our four other children who range in age from five to sixteen years old.

4. Joshua receives Social Security Disability Insurance because he is diagnosed with venous malformation, a type of vascular malformation that results from the veins in his leg having developed abnormally. Legally, Joshua is K.F.'s stepfather and has raised K.F. since he was three years old. K.F. considers and calls Joshua "dad."

5. I am employed as a patient coordinator at a dental office.

6. Our family moved to Florida from Massachusetts in August 2020.

7. Our son, K.F., is transgender.

8. Because of K.F.'s age and our family income, he is eligible for Medicaid and enrolled in Humana's Florida Medicaid managed care plan. He has been eligible for and enrolled in the program since we moved to Florida. Prior to our move, he was enrolled in Massachusetts' Medicaid program.

9. Although K.F. was assigned female at birth, he has known he was a boy from a very young age. When he was 7 years old, he came out to his grandparents during a camping trip, telling them that he has known since he was four years old that he is a boy and would one day be a father. In looking back on K.F.'s childhood, Joshua and I can both see that K.F. was showing us that he was a boy well before that conversation he had with his grandparents; he has always wanted to wear traditional boy clothes (no dresses or skirts), he insisted on his hair being kept short, and he loved to play shirtless with other boys in our neighborhood.

10. K.F. has never wavered about his gender identity. As his mother, it is clear to me that he has known his whole life what gender he is. Joshua and I marvel at K.F.'s self-confidence and self-assurance; he continues to develop as an intelligent, well-grounded, and mature young man. We are so proud of the person he is becoming.

11. After the camping trip, Joshua and I were a bit overwhelmed, like many parents upon first learning that their child is transgender. But we love our children for exactly who they are, so we adjusted quickly. We were fortunate to also have an extremely supportive extended family who have always been allies of the LGBTQ+ community.

12. As with all of our children before their pre-teen years, we established strict limitations on K.F.'s consumption of television, movies, videos, and video games. His internet

access was supervised by myself or my husband, and he had no access to social media until just two years ago, when he received his first cell phone. At the age of seven, when K.F. came out as transgender, he had never heard of the concept of gender dysphoria, or transgender people, beyond his own experience, which he described first to his grandparents, and then to us, as simply "being a boy."

13. After K.F. confided in us, I decided the next best step would be to locate a therapist who specializes in gender dysphoria. Within a week, K.F. had his first appointment with Eileen Casella Rider, a Licensed Mental Health Counselor. I remember being impressed by her thoroughness during that first appointment. We returned bi-weekly for appointments. After thorough evaluation, she was the first to diagnose K.F. with gender dysphoria. I really appreciated Eileen's knowledge and support; she made sure we understood K.F.'s diagnosis and walked us carefully through what we should expect as K.F. got older.

14. At Eileen's recommendation, I later joined the local PFLAG group, an organization which is dedicated to supporting, educating, and advocating for LGBTQ+ people and their families. I joined the group because it was important to me and my husband that we demonstrate to K.F. our commitment to supporting him.

15. K.F. was living in accordance with his male gender identity in every aspect of his life, and he wanted to be treated accordingly at school. Just before K.F. entered the second grade, Eileen helped facilitate a meeting between me and his school administrators, school nurse, and teachers to talk about K.F.'s gender identity and what actions the school should take to ensure he was fully affirmed and supported as a boy with his classmates in the school environment.

16. Our next step was to establish with a pediatric endocrinologist. I setup an appointment for K.F. to establish care with the Gender Multispecialty Service (GeMS) Program at

Boston Children's Hospital, the first pediatric and adolescent transgender health program in the United States. K.F. had his first appointment with the GeMS Program on September 13, 2015. That first appointment was incredibly thorough, lasting over two hours, and was overall a very happy occasion. It was clear K.F. would be receiving the best possible care and the team of providers confirmed everything that Eileen told us: that K.F. is a transgender boy and that his parents and extended family supporting him in his affirmation of his male gender identity was the best possible decision for his health and well-being. GeMS started him with pediatric nurse practitioner, Sarah Pilcher. Pilcher's role was to monitor K.F.'s hormone levels for the onset of puberty and assist with any future gender-affirming healthcare needs. We continued K.F.'s care with GeMS until we moved to Florida in August 2020.

17. Before we moved, in June 2020, Pilcher determined that based on the onset of K.F.'s puberty, it was medically necessary for K.F. to receive his first puberty delaying medication. At the recommendation of Pilcher, K.F. received the SUPPRELIN implant medication which would prevent the onset of secondary sex characteristics typical of girls and women. K.F. received the implant on August 8, 2020, and it was fully covered by Massachusetts' Medicaid program.

18. According to Pilcher and K.F.'s current medical providers, it is medically necessary for K.F. to receive SUPPRELIN so that K.F. can live authentically in a manner consistent with his gender identity and to treat his gender dysphoria. By preventing the physical manifestations that would accompany the puberty of his sex assigned at birth, K.F. is also able to avoid negative social and emotional consequences associated with his being forced to develop secondary sex characteristics that do not align with his male gender identity. As his parent, it is also important to me that K.F. be able to *choose* with whom to disclose this deeply personal, private information

about himself. Because of the puberty delaying medication, he has that option, and the inherent protection and privacy that it provides.

19. When we decided to move to Florida, I researched programs in the state that offered the same or similar level of care afforded by GeMS. Finding a program that offers high quality gender-affirming care *and* that accepts Medicaid can be challenging. Fortunately, through that research, I found the Emerge Gender & Sexuality Clinic for Children, Adolescents and Young Adults based at Johns Hopkins All Children's Hospital (Johns Hopkins Gender Clinic) located in St. Petersburg, Florida.

20. Once we moved, K.F. initiated care with Dr. Kevin Lewis, a doctoral-level pediatric nurse practitioner specializing in endocrinology at the Johns Hopkins Gender Clinic. On April 6, 2022, K.F. received his second SUPPRELIN implant which was fully covered by his Florida Medicaid plan, Humana.

21. K.F. typically visits the Johns Hopkins Gender Clinic every six months. Recently, however, K.F. has had more frequent visits because Dr. Lewis is monitoring whether K.F.'s second SUPPRELIN implant is adequately suppressing puberty. Unfortunately, Dr. Lewis has indicated that K.F.'s bloodwork is showing elevated estrogen and Luteinizing Hormone (LH) levels. Ultimately, K.F. may need a different type of puberty delaying medication to suppress puberty and successfully continue his medical transition. K.F. has another appointment scheduled at the end of October 2022 to check in with Dr. Lewis. Additionally, K.F. is in the coming months to recheck the implant's efficacy. If Dr. Lewis determines that the SUPPRELIN is not adequately suppressing puberty, then K.F. will likely need to switch to another puberty delaying medication that will need approximately every three months.

22. When having conversations with us and Dr. Lewis about suppressing puberty, K.F. is adamant that he does not want breasts and would eventually like to have facial hair and muscles. The idea of developing typically female secondary sex characteristics makes K.F. extremely anxious: he prays that his puberty delaying medication will be successful. Since K.F. came to understand and express the dysphoria he experienced resulting from his sex assigned at birth at an early age, we were able to get him the mental health and medical treatment that was necessary, and as a result K.F. is accepted by other people as male and very few people know he is transgender. Developing secondary sex characteristics typically associated with girls and women, instead of those aligned with his male gender identity, would be tremendously emotionally and physically painful for K.F.

23. In the event K.F.'s current implant is not effective, and because Florida Medicaid now excludes coverage of puberty delaying medication, we would have to pay out of pocket for the other puberty delaying shots. Those shots would cost $3000-$3600 per shot out of pocket. Our family has limited income, and we are very worried because we would not be able to afford these treatments without Medicaid coverage.

24. K.F.'s medical providers have also told us that likely within the next year, when K.F. is fourteen years old, that it will be medically indicated for him to begin cross-sex hormone therapy (testosterone) at a dose appropriate to his age and body composition. K.F. is very excited about starting testosterone therapy. K.F. usually hates receiving shots but he told me he would be happy to take a monthly shot if it meant that he would experience the male puberty that is aligned with his gender identity, such as his voice deepening and growing facial hair.

25. We are so grateful that K.F. was confident enough and felt safe to come out to us at such a young age. Identifying his gender dysphoria at a young age, combined with a loving and

supportive immediate and extended family means that we were able to ensure that K.F. received the health care appropriate for him as soon as possible. As a result, his gender dysphoria has been well managed. While K.F. has always dealt with some level of anxiety, before he came out to us as transgender, it was much worse. He experienced what I would describe as "night terrors" and had a persistent stomachache. We would get calls from his school that he was not doing well and was often in the nurse's office. We went to doctors to determine the source of his distress, but no one could identify what was causing the problem. After he had firmly established gender-affirming care with GeMS, he became a completely different child; it was like night and day. He had a smile on his face, a light in his eye, and even a glow about him. His performance and attendance in school improved, as did his peer relationships. Like any parent, Joshua and I were relieved to see our child happy and thriving.

26. K.F. has also begun the process of legal transition. He has legally changed his name and we are currently in the process of having his gender marker changed on his birth certificate and records with the Social Security Administration. His school has been great; they have ensured all records identify his new legal name and otherwise ensure he is treated the same as any other boy in the school.

27. I understand that due to a new state regulation adopted by the Florida Agency for Health Care Administration ("AHCA"), beginning on August 21, 2022, Florida Medicaid will no longer provide coverage for medical treatments for gender dysphoria. I understand this to mean that Medicaid will no longer cover puberty delaying medications for K.F. as treatment for his gender dysphoria. AHCA's regulation will also prohibit Medicaid from covering hormone therapy as a medically necessary treatment for K.F.'s gender dysphoria when K.F., pursuant to the medical expertise and recommendations of his physicians, is ready to begin that treatment.

28. I am incredibly worried about the potential physical and mental health consequences of depriving K.F. the medically necessary treatment recommended by his health care providers. K.F. has been living as a boy in every aspect of his life, medically, legally, and socially, since 2017. If he were no longer able to access the medication that aligns his body with his gender identity, his mental health would suffer tremendously; he would be devastated. He, and the whole family with him, would go down a dark and scary road fast. Most likely, he would not leave his bedroom and he would refuse to go to school. He would cut off his communications with his friends, teammates, and teachers. Given how much his gender-affirming care has improved his life and mental health, Joshua and I can only assume that reversing that course of treatment would result in the unthinkable happening.

29. Because of these concerns, K.F. going without treatment is simply not an option. We believe providing K.F. with the medical treatment for gender dysphoria that he requires is necessary to ensure his health and well-being. I do not believe that there is any way we could deprive K.F. of the necessary, medically recommended health care that he requires.

30. We are under 138% of the federal poverty limit; that is why our children, including K.F., qualify for Florida's Medicaid program. Whether it be paying for a different puberty delaying medication if K.F.'s provider determines the SUPPRELIN is not working or beginning K.F.'s course of hormone therapy in the next year, we simply do not have sufficient resources to provide K.F. the gender affirming care he requires. We could not pay out of pocket for the cost of K.F.'s care, even if we sacrificed everything.

31. Joshua receives his health insurance through Medicare. He cannot add K.F. to his health insurance. I have access to health care coverage for family members because of my job, but the cost of adding K.F. is unaffordable for our family.

32. Florida is our home. We are part of a community, comprised of family and friends that have been supportive and affirming of K.F. I worry not only about the multitude of harms caused to my own family through AHCA's new regulation, but also about the effect that the discriminatory actions by AHCA and the current state government will have on other transgender people and their families. We know families that cannot afford to pay out of pocket, nor do they have any other options by which they could obtain healthcare coverage, if their transgender child loses access to the medically necessary, physician recommended treatment.

33. Ultimately, if we need to protect our son's access to medication that is necessary for his health and well-being then we will move out of Florida. We do not wish to move if it can be avoided, as, among other things, it would mean I would have to find a new job, Joshua would have to establish his Social Security payment through a new field office, and our kids would be uprooted and forced to start at new schools and make new friends. We are Christian and just joined a church that we attend every Sunday. So far, we have felt very welcome and would be sad to break a tie with this faith community and the other communities and relationships we have established here in South Florida.

34. For K.F., this would be a particularly difficult and painful transition. K.F. is doing well academically, socially, and athletically. He is on the golf team at his school and he is looking forward to upcoming tryouts out for the baseball team in our town. It is awful to even think that K.F. would have to end this participation and leave his teammates because Florida refuses to provide him the medical treatment that he needs to live and thrive, medical treatment that is available to many other cisgender young people, simply because he is transgender.

35. The state's decision to stop covering medically necessary gender-affirming medical care through Medicaid is tragic. It is also dehumanizing. We are concerned about the

message the State of Florida is sending by excluding transgender people from Medicaid coverage to which they otherwise would be entitled simply because they are transgender.

36. The actions by AHCA and Florida's state government threaten the health and well-being of transgender Medicaid beneficiaries, like my son, K.F. K.F. did not choose this nor did anyone else for whom this treatment is medically necessary. It is who he is; it is who they are. Thus, we are challenging the new state regulation promulgated by AHCA to help not only K.F., but also the many other transgender Medicaid beneficiaries who will be harmed.

I declare under penalty of perjury that the foregoing is true and correct. Executed this ___ day of September 2022.

Respectfully Submitted,

Jade Ladue