No. 23-477

In the Supreme Court of the United States

UNITED STATES OF AMERICA, PETITIONER

v.

JONATHAN THOMAS SKRMETTI, ATTORNEY GENERAL AND REPORTER FOR TENNESSEE, ET AL., RESPONDENTS

and

L.W., BY AND THROUGH HER PARENTS AND NEXT FRIENDS, SAMANTHA WILLIAMS AND BRIAN WILLIAMS, ET AL., RESPONDENTS IN SUPPORT OF PETITIONER

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

JOINT APPENDIX
(Volume 1)

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TABLE OF CONTENTS

Page

Volume 1

Table of Contents—Continued: Page

Volume 2

Table of Contents—Continued: Page

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

Case No.

L.W., BY AND THROUGH HER PARENTS AND NEXT FRIENDS, SAMANTHA WILLIAMS AND BRIAN WILLIAMS; SAMANTHA WILLIAMS; BRIAN WILLIAMS; JOHN DOE, BY AND THROUGH HIS PARENTS AND NEXT FRIENDS, JANE DOE AND JAMES DOE; JANE DOE; JAMES DOE; RYAN ROE, BY AND THROUGH HIS PARENT AND NEXT FRIEND, REBECCA ROE; REBECCA ROE; AND SUSAN N. LACY, ON BEHALF OF HERSELF AND HER PATIENTS, PLAINTIFFS

v.

JONATHAN SKRMETTI, IN HIS OFFICIAL CAPACITY AS THE TENNESSEE ATTORNEY GENERAL AND REPORTER; TENNESSEE DEPARTMENT OF HEALTH; RALPH ALVARADO, IN HIS OFFICIAL CAPACITY AS THE COMMISSIONER OF THE TENNESSEE DEPARTMENT OF HEALTH; TENNESSEE BOARD OF MEDICAL EXAMINERS; MELANIE BLAKE, IN HER OFFICIAL CAPACITY AS THE PRESIDENT OF THE TENNESSEE BOARD OF MEDICAL EXAMINERS; STEPHEN LOYD, IN HIS OFFICIAL CAPACITY AS VICE PRESIDENT OF THE TENNESSEE BOARD OF MEDICAL EXAMINERS; RANDALL E. PEARSON, PHYLLIS E. MILLER, SAMANTHA MCLERRAN, KEITH G. ANDERSON, DEBORAH CHRISTIANSEN, JOHN W. HALE, JOHN J. MCGRAW, ROBERT ELLIS, JAMES DIAZ-BARRIGA, AND JENNIFER CLAXTON, IN THEIR OFFICIAL CAPACITIES AS MEMBERS OF THE TENNESSEE BOARD OF MEDICAL EXAMINERS; AND LOGAN GRANT, IN HIS OFFICIAL CAPACITY AS THE EXECUTIVE DIRECTOR OF THE TENNESSEE HEALTH FACILITIES COMMISSION, DEFENDANTS

Filed: Apr. 20, 2023

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs,[1] by and through their attorneys, bring this Complaint against the above-named Defendants, and state the following in support thereof:

PRELIMINARY STATEMENT

1. On March 2, 2023, Tennessee Governor Bill Lee signed into law Senate Bill 1, codified in Tennessee Code Annotated § 68-33-101 *et seq*. (hereinafter the "Health Care Ban" or "Ban"), which bans the provision of medically necessary and potentially lifesaving healthcare to transgender adolescents. The law was passed over the sustained and robust opposition of medical experts in Tennessee and across the country. It was also passed over the pleas of families across Tennessee who urged lawmakers not to interfere in the medical decision-making of parents, their minor children, and their doctors. Absent intervention by this Court, the law will go into effect on July 1, 2023, disrupting or preventing medical care for hundreds of adolescents across Tennessee. The Heath Care Ban violates the constitutional rights of Tennessee adolescents and their parents,

[1] Plaintiffs John Doe, Jane Doe, James Doe, Ryan Roe, and Rebecca Roe have filed a separate motion to proceed using these pseudonyms, rather than their legal names, in order to protect their privacy regarding the minor plaintiffs' transgender status and their medical condition and treatment.

and—if it goes into effect—will cause severe and irreparable harm.

2. Gender dysphoria is a serious medical condition characterized by clinically significant distress caused by incongruence between a person's gender identity and the sex they were designated at birth. All of the major medical associations in the United States recognize that adolescents with gender dysphoria may require medical interventions to treat severe distress. For instance, puberty-delaying treatment and hormone therapy are medically indicated to alleviate severe distress associated with gender dysphoria, and for some older adolescents, chest surgery may be medically necessary. In providing this medically necessary healthcare, sometimes referred to as "gender-affirming care," medical providers are guided by widely accepted protocols for assessing and treating transgender adolescents.

3. The Health Care Ban interferes with the ability of doctors to follow these evidence-based protocols by prohibiting any "medical procedure"—including prescribing, administering, or dispensing any puberty blocker or hormone—from being performed "for the purpose of . . . [e]nabling a minor to identify with" a gender identity different from the sex they were designated at birth or "[t]reating purported discomfort or distress from a discordance between the minor's sex and asserted identity." Tenn. Code Ann. § 68-33-103(a)(1)(A)-(B) (2023). In so doing, the Health Care Ban denies adolescents medically necessary treatment and prevents parents from exercising their fundamental rights to obtain medically necessary care for their adolescent children. It further prohibits doctors from treating their patients in accordance with well-established standards

of care and subjects doctors to potential civil liability and regulatory discipline.

4. While the Health Care Ban purports to protect young people from risks allegedly associated with the prohibited health care, decades of clinical experience and research have shown that gender-affirming health care is safe, effective, and improves the health and well-being of adolescents with gender dysphoria. Moreover, all of the treatments prohibited by the Health Care Ban are permitted when undertaken for any reason *other* than to affirm a gender identity that differs from a patient's sex designated at birth.

5. If the Health Care Ban goes into effect, it will have devastating consequences for transgender youth and their families in Tennessee. Transgender adolescents with gender dysphoria will be unable to obtain medical care that those who understand their medical needs—their doctors and parents—agree is medically necessary. Untreated gender dysphoria is associated with severe harm including anxiety, depression, and suicidality. Cutting vulnerable adolescents off from treatment or withholding necessary care will inevitably cause significant harm.

6. Some parents of transgender children are making plans to flee the State to protect their children's health and safety and to obtain the medical treatment their children need. Those with the resources to do so will have to leave their jobs, businesses, extended families, and communities. Others will have to shoulder the hardship of disruptive and expensive travel to secure medical care for their children, often at the expense of the child's time in school and the parents' time at work. Other families that do not have the resources or are oth-

erwise unable to leave or travel are terrified about what will happen if the law takes effect. For these parents and hundreds of others across Tennessee, the Ban is creating a sense of desperation at the prospect of watching their children's suffering resume and symptoms possibly worsen as they lose access to the care that has transformed their lives.

7. Plaintiffs urgently seek relief from this Court.

THE PARTIES

A. The Minor Plaintiffs and Their Families

1. The Williams Family

8. Plaintiffs L.W., Samantha Williams, and Brian Williams live in Tennessee. Samantha and Brian are the parents of L.W., their fifteen-year-old daughter. L.W. is transgender and is currently receiving medically necessary care that would be prohibited by the Health Care Ban.

2. The Roe Family

9. Plaintiffs Ryan Roe and Rebecca Roe live in Tennessee. Rebecca is the parent of Ryan Roe, her fifteen-year-old son. Ryan Roe is transgender and is currently receiving medically necessary care that would be prohibited by the Health Care Ban.

3. The Doe Family

10. Plaintiffs John Doe, Jane Doe, and James Doe live in Tennessee. Jane and James Doe are the parents of John Doe, their twelve-year-old son. John Doe is transgender and is currently receiving medically necessary care that would be prohibited by the Health Care Ban.

11. Plaintiffs L.W., Ryan Roe, and John Doe are collectively referred to herein as the "Minor Plaintiffs." Their parents, Samantha Williams, Brian Williams, Rebecca Roe, Jane Doe, and James Doe are collectively referred to herein as the "Parent Plaintiffs."

B. Provider Plaintiff

12. Plaintiff Dr. Susan Lacy (the "Provider Plaintiff") is a physician licensed to practice medicine in Tennessee. Dr. Lacy operates a private practice in Memphis, Tennessee, and she provides gender-affirming care that would be prohibited by the Health Care Ban. She is bringing her claims on behalf of herself and her patients.

C. Defendants

13. Defendant Jonathan Skrmetti is the Attorney General and Reporter of the State of Tennessee. The Attorney General/Reporter is headquartered at 500 Dr. Martin Luther King Jr. Blvd., Nashville, TN 37219, and has additional offices throughout Tennessee. Under the Health Care Ban, Defendant Skrmetti is tasked with bringing legal actions against any "healthcare provider that knowingly violates [the Health Care Ban]." Tenn. Code Ann. § 68-33-106(b). He is also authorized to "establish a process by which violations of [the Health Care Ban] may be reported." Tenn. Code Ann. § 68-33-106(a). Defendant Skrmetti is sued in his official capacity.

14. Defendant Tennessee Department of Health (the "DOH") is the primary agency of the State of Tennessee responsible for all aspects of public health and provides health services to many Tennesseans across the state. The DOH is headquartered at 710 James Robertson Parkway, Nashville, TN 37243. Each county in Tennes-

see has a county health department, which operates under the direct supervision of the DOH. In 2014, roughly 1.4 million people were served by these county health departments in Tennessee's 89 rural/suburban counties and six metropolitan counties. The DOH is a "health program or activity" within the meaning of section 1557 of the Patient Protection and Affordable Care Act ("ACA"), 42 U.S.C. § 18116 ("Section 1557"), and it is a recipient of federal financial assistance, including grants, contracts, and other financial assistance from the United States Department of Health and Human Services, as well as federal Medicare and Medicaid funds. The Health Care Ban provides that any violation of the statute "requires emergency action by an alleged violator's appropriate regulatory authority," which expressly includes "[t]he department of health." Tenn. Code Ann. §§ 68-33-102(2)(A), 107.

15. Defendant Ralph Alvarado, MD, FACP is the Commissioner of the DOH. Defendant Alvarado oversees and directs the functions of the DOH, including the activities of licensure regulation entities, such as the Tennessee Board of Medical Examiners, which is "attached" to the DOH. Tenn. Code Ann. § 68-33-102. Defendant Alvarado is sued in his official capacity.

16. Defendant Tennessee Board of Medical Examiners (the "Medical Board") is a "board . . . attached to the" DOH, Tenn. Code Ann. § 68-33-102(2)(B), with the power to license, regulate and discipline health care providers within the State of Tennessee. The Medical Board is headquartered at 710 James Robertson Parkway, Nashville, TN 37243. The Health Care Ban provides that any violation of the statute "requires emergency action by an alleged violator's appropriate regulatory authority," which expressly includes any "agen-

cy, board, council, or committee attached to the department of health." Tenn. Code Ann. §§ 68-33-102(2)(B), 107.

17. Defendant Melanie Blake, MD is the President of the Medical Board. Defendant Stephen Loyd, MD is the Vice President of the Medical Board. Defendants Randall E. Pearson, MD; Phyllis E. Miller, MD; Samantha McLerran, MD; Keith G. Anderson, MD; Deborah Christiansen, MD; John W. Hale, MD; John J. McGraw, MD; Robert Ellis; James Diaz-Barriga; and Jennifer Claxton (collectively and together with Defendants Blake and Loyd, the "Medical Board Defendants") are members of the Medical Board. The Medical Board Defendants are sued in their official capacities.

18. Defendant Logan Grant is the Executive Director of the Tennessee Health Facilities Commission (the "Health Facilities Commission"). The Health Facilities Commission is headquartered at 665 Mainstream Drive, 2nd Floor, Nashville, TN 37243, and has additional offices throughout Tennessee. The Health Facilities Commission is an agency of the State of Tennessee with responsibility for, among other things, conducting investigations of health care facilities in Tennessee to ensure compliance with state and federal regulations. The Health Care Ban provides that any violation of the statute "requires emergency action by an alleged violator's appropriate regulatory authority," which expressly includes "[t]he health facilities commission." Tenn. Code Ann. §§ 68-33-102(2)(C), 107. Defendant Grant is sued in his official capacity.

19. Defendant Skrmetti, Defendant Alvarado, the Medical Board Defendants, and Defendant Grant (collectively, the "State Official Defendants") are all gov-

ernmental actors and/or employees acting under color of State law for purposes of 42 U.S.C. § 1983 and the Fourteenth Amendment. Defendants are therefore liable for both their violation of the right to equal protection and for their violation of Parent Plaintiffs' fundamental rights under 42 U.S.C. § 1983.

JURISDICTION AND VENUE

20. This action arises under the U.S. Constitution, 42 U.S.C. § 1983, and 42 U.S.C. § 18116(a).

21. This Court has subject matter jurisdiction pursuant to Article III of the U.S. Constitution and 28 U.S.C. §§ 1331, 1343, and 1367.

22. This Court is authorized to issue a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

23. Venue in this district is proper pursuant to 28 U.S.C. § 1391(b)(1) and (b)(2), because one or more Defendants reside in this district and because a substantial part of the events giving rise to the claims occurred in this district.

FACTUAL BACKGROUND

A. Standards of Care for Treating Adolescents with Gender Dysphoria

24. Gender identity refers to a person's core sense of belonging to a particular gender, such as male or female. Every person has a gender identity.

25. Living in a manner consistent with one's gender identity is critical to the health and well-being of any person, including transgender people.

26. Although the precise origin of gender identity is unknown, a person's gender identity is a fundamental

aspect of human development. There is a general medical consensus that there are significant biological roots to gender identity.

27. A person's gender identity cannot be altered voluntarily or changed through medical intervention.

28. A person's gender identity usually matches the sex they were designated at birth based on the appearance of their external genitalia. The terms "sex designated at birth" or "sex assigned at birth" are more precise than the term "biological sex" because all of the physiological aspects of a person's sex are not always aligned with each other. For these reasons, the Endocrine Society, an international medical organization representing over 18,000 endocrinology researchers and clinicians, warns practitioners that the terms "biological sex" and "biological male or female" are imprecise and should be avoided.

29. Most boys are designated male at birth based on their external genital anatomy, and most girls are designated female at birth based on their external genital anatomy. But transgender people have a gender identity that differs from the sex they were designated at birth. A transgender boy or man is someone who has a male gender identity but was designated a female sex at birth. A transgender girl or woman is someone who has a female gender identity but was designated a male sex at birth.

30. Gender dysphoria is the clinical diagnosis for the significant distress that results from the incongruity between one's gender identity and sex they were designated at birth. It is a serious medical condition, and it is codified in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders,

Fifth Edition, Text Revision (DSM-5-TR) (DSM-5 released in 2013 and DSM-5-TR released in 2022).

31. Being transgender is not itself a medical condition to be cured. But gender dysphoria is a serious medical condition that, if left untreated, can result in debilitating anxiety, severe depression, self-harm, and suicide.

32. The World Professional Association for Transgender Health ("WPATH") has issued Standards of Care for the Health of Transgender and Gender Diverse People ("WPATH Standards of Care" or "SOC 8") since 1979. The current version is SOC 8, published in 2022. The WPATH Standards of Care provide guidelines for multidisciplinary care of transgender individuals, including children and adolescents, and describe criteria for medical interventions to treat gender dysphoria —including puberty-delaying medication, hormone treatment, and surgery when medically indicated—for adolescents and adults. Every major medical organization in the United States recognizes that these treatments can be medically necessary to treat gender dysphoria.

33. The SOC 8 is based upon a rigorous and methodological evidence-based approach. Its recommendations are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options, as well as expert consensus. The SOC 8 incorporates recommendations on clinical practice guideline development from the National Academies of Medicine and the World Health Organization. SOC 8's recommendations were graded using a modified GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) methodology considering the

available evidence supporting interventions, risks and harms, and feasibility and acceptability.

34. A clinical practice guideline from the Endocrine Society (the "Endocrine Society Guideline") provides protocols for the medically necessary treatment of gender dysphoria similar to those outlined in the WPATH Standards of Care.

35. The guidelines for the treatment of gender dysphoria outlined in the WPATH Standards of Care and in the Endocrine Society Guideline are comparable to guidelines that medical providers use to treat other conditions.

36. Doctors in Tennessee and throughout the country follow these widely accepted guidelines to diagnose and treat people with gender dysphoria.

37. Medical guidance to clinicians differs depending on whether the treatment is for a pre-pubertal child, an adolescent, or an adult. In all cases, the precise treatment recommended for gender dysphoria will depend upon each person's individualized needs.

38. Before puberty, gender-affirming care does not include any pharmaceutical or surgical intervention. Care for pre-pubertal children may include "social transition," which means supporting a child living consistently with the child's persistently expressed gender identity. Such care might include support around adopting a new name and pronouns, wearing clothes that feel more appropriate to a particular gender, and changing one's hairstyle.

39. Under SOC 8 and the Endocrine Society Guideline, medical interventions may become medically necessary and appropriate as transgender youth reach pu-

berty. In providing medical treatments to adolescents, pediatric endocrinologists and other clinicians work with qualified mental health professionals experienced in diagnosing and treating gender dysphoria.

1. Puberty-Delaying Treatment

40. For many transgender adolescents, going through puberty in accordance with the sex designated to them at birth can cause extreme distress. For these adolescents, puberty-delaying medication—known as gonadotropin-releasing hormone ("GnRH") agonists—can minimize and potentially prevent the heightened gender dysphoria and permanent, unwanted physical changes that puberty would cause.

41. Under the Endocrine Society Guideline, transgender adolescents may be eligible for puberty-delaying treatment if:

- A qualified mental health professional has confirmed that:
    - the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria;
    - gender dysphoria 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; and

- the adolescent has sufficient mental capacity to give informed consent to this (reversible) treatment.

- 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; and
  - has given informed consent, and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable law) 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; and
  - has confirmed that there are no medical contraindications to GnRH agonist treatment.

42. Puberty-delaying treatment has been shown to be safe and effective at treating gender dysphoria in adolescents.

43. Puberty-delaying treatment works by pausing a person's endogenous puberty at the stage of pubertal development that the person is in at the time of treat-

ment. For transgender girls, this treatment pauses the physiological changes typical of male puberty and prevents the development of associated secondary sex characteristics like facial hair and a pronounced "Adam's apple." It also prevents the deepening of the young person's voice and genital growth. For transgender boys, puberty-delaying treatment prevents the development of breasts and menstruation. The use of these interventions after the onset of puberty can eliminate or reduce the need for surgery later in life. If gender-affirming hormones are prescribed to initiate hormonal puberty consistent with gender identity after puberty-delaying treatment, transgender adolescents will develop secondary sex characteristics typical of peers with their gender identity.

44. On its own, puberty-delaying treatment does not permanently affect fertility.

45. Because puberty-delaying treatment followed by gender-affirming hormone therapy can affect fertility, patients are counseled about the risks and benefits of treatment and provided information about fertility preservation.

46. Puberty-delaying treatment is reversible. If puberty-delaying treatment is stopped and no gender-affirming hormone therapy is provided, there are no lasting effects of treatment. Endogenous puberty resumes and patients undergo puberty in a timeline typical of their peers.

47. If gender-affirming hormone treatment is provided after puberty-delaying treatment, patients undergo puberty consistent with their gender identity on a timeline typical of their peers.

2. Hormone Therapy

48. For some adolescents, it may be medically necessary and appropriate to treat their gender dysphoria with gender-affirming hormone therapy (testosterone for transgender boys, and testosterone suppression and estrogen for transgender girls).

49. Under the Endocrine Society Guideline, transgender adolescents may be eligible for gender-affirming hormone therapy if:

- A qualified mental health professional has confirmed:
  - the persistence of gender dysphoria; and
  - 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 environment and functioning are stable enough to start sex hormone treatment.
- The adolescent:
  - has been informed of the partly irreversible effects and side effects of treatment (including potential loss of fertility and options to preserve fertility);
  - the adolescent has sufficient mental capacity to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to the treatment; and
- has given informed consent, and (particularly when the adolescent has not reached the age of

legal medical consent, depending on applicable laws) 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; and
  - has confirmed that there are no medical contraindications to sex hormone treatment.

50. For transgender boys, hormone therapy involves treatment with testosterone and for transgender girls, treatment with testosterone suppression and estrogen.

51. Through decades of clinical experience and research, gender-affirming hormone therapy has been shown to be safe and effective at treating gender dysphoria in adolescents.

52. Side effects from gender-affirming hormone therapy are rare when treatment is provided under clinical supervision.

53. Puberty-delaying medications and gender-affirming hormones are prescribed only after a comprehensive psychosocial assessment by a qualified health professional who: (i) assesses for the diagnosis of gender dysphoria and any other co-occurring diagnoses, (ii) ensures the child can assent and the parents/guardians can consent to the relevant intervention after a thorough review of the risks, benefits, and alternatives of the intervention, and (iii) ensures that, if co-occurring mental health conditions are present, they do not interfere with the accuracy of the diagnosis of gender dys-

phoria or impair the ability of the adolescent to assent to care.

B. The General Assembly's Passage of the Health Care Ban

54. On February 23, 2023, the Tennessee General Assembly passed the Health Care Ban, prohibiting healthcare providers from performing or administering medical procedures "[e]nabling a minor to identify with, or live as, a purported identity inconsistent with the minor's sex" or "[t]reating purported discomfort or distress from a discordance between the minor's sex and asserted identity." Tenn. Code Ann. § 68-33-103(a)(1). The Ban also prohibits "any person" from "knowingly" providing "hormone therapy" or "puberty blocker[s]" to a minor in any manner not in compliance with the provisions of the Ban. Tenn. Code Ann. § 68-33-104. The Ban defines "medical procedure" broadly, such that the term means: "(A) Surgically removing, modifying, altering, or entering into tissues, cavities, or organs of a human being; or (B) Prescribing, administering, or dispensing any puberty blocker or hormone to a human being." Tenn. Code Ann. § 68-33-102(5). It further defines "sex" to "mean[] a person's immutable characteristics of the reproductive system that define the individual as male or female, as determined by anatomy and genetics existing at the time of birth." Tenn. Code Ann. § 68-33-102(9).

55. The Ban includes a phase-out period, which allows health care providers to continue to provide medical procedures proscribed in the Ban if "the medical procedure on the minor began prior to the effective date of this act [July 1, 2023] and concludes on or before March 31, 2024." Tenn. Code Ann § 68-33-103(b)(1)(B).

The Ban does not allow the initiation of new gender-affirming care during that period.

56. The Ban states that healthcare professionals who provide or offer to provide such procedures are subject to professional discipline by the appropriate regulatory agency, Tenn. Code Ann. § 68-33-107, and may be sued by the Attorney General and Reporter or private parties, Tenn. Code Ann. §§ 68-33-105, 106.

57. The General Assembly declared that the Ban was necessary to "protect the health and welfare of minors," Tenn. Code Ann. § 68-33-101(a), despite the banned medical treatment being part of well-established standards of care for the treatment of gender dysphoria in adolescents.

58. The General Assembly rejected an amendment to the Ban that would have banned surgical procedures, but not gender-affirming medication, for minors for the purpose of "[e]nabling a minor to identify with, or live as, a purported identity inconsistent with the minor's sex" or "[t]reating purported discomfort or distress from a discordance between the minor's sex and asserted identity."

59. The General Assembly also rejected amendments to the Ban that would have banned all cosmetic surgeries conducted on minors, regardless of the purpose for which the minor and/or their parent sought the surgery.

60. The General Assembly passed the Ban despite hearing testimony from Tennessee doctors about the lifesaving benefits of the banned care for their patients and the grave harm to their patients' health and well-being if they are prohibited from receiving this care.

This included testimony about the high rate of suicide attempts by transgender adolescents as well as detailed explanations of the rigorous standards of diagnosis and treatment doctors follow when providing gender-affirming treatment to minors.

61. Not a single doctor with experience treating transgender youth testified in support of the bill. The only doctor who did testify in support likened "greater awareness of and education around gender identity" to "intentional grooming" and "psychological manipulation." He also compared gender-affirming care for transgender youth to removing the leg and an eye of a minor who identified as a pirate.

62. The General Assembly passed the Ban despite hearing testimony from transgender Tennesseans who shared their experiences of years of struggle, feelings of hopelessness, and desire to end their lives prior to receiving gender-affirming care and the positive and transformational impact that gender-affirming medical treatment had on their health and overall well-being.

63. The General Assembly also passed the Ban despite hearing testimony of parents of transgender children with gender dysphoria, who pleaded with lawmakers not to risk their children's health by stripping them of the medical care that enables them to thrive. Multiple parents spoke about the torture in wondering whether their child would die by suicide prior to gender-affirming treatment, and then the relief that came from watching their child's despair lessen with gender-affirming treatment.

64. At various points during legislative debates, proponents of the Ban within the General Assembly defended the bill based on general criticisms and stereo-

types of transgender people. The sponsor of the House companion bill described practitioners who provide gender-affirming care as "indulging the child's perception of his or her sex." A co-sponsor of the House bill expressed that being transgender was a "fiction" and a "fantasy." Addressing trans youth in Tennessee, one House member referenced the views of his preacher, stating: "If you don't know what you are, a boy or girl, male or female, just go in the bathroom and take your clothes off and look in the mirror and you'll find out."

65. The Health Care Ban is just one piece of a robust discriminatory legislative agenda targeting transgender persons. In addition to the Health Care Ban, the Senate has already passed three other bills this legislative session that focused on transgender people; the House has passed one of these bills, and the other two are pending. The bill that passed in both bodies of the General Assembly and will go into effect if signed into law by Governor Lee, SB1237/HB0306, allows private schools to ban transgender students from participation in athletic activities. Another bill pending in the General Assembly, SB1440, defines "sex" in the Tennessee Code to be the "immutable biological sex as determined by anatomy and genetics existing at the time of birth" and the "sex listed on the person's original birth certificate." SB466, also being considered, states that teachers are not required to use a transgender student's preferred pronouns. Both chambers are also considering bills (HB1215 and SB1339) that would block TennCare, Tennessee's Medicaid program, from reimbursing providers for gender-affirming care for all transgender people in the state.

C. The Banned Treatment Is Permitted for Other Purposes

66. The Health Care Ban prohibits the use of well-established treatments for gender dysphoria in transgender adolescents—including puberty-delaying treatment, hormone therapy (testosterone for transgender boys, and estrogen and testosterone suppressants for transgender girls), and chest surgery—because these treatments are provided "for the purpose of" "[e]nabling a minor to identify with" a gender identity different from the sex they were designated at birth or "[t]reating purported discomfort or distress from a discordance between the minor's sex and asserted identity." Tenn. Code Ann. § 68-33-103(a)(1). The Ban permits the use of these same treatments for any other purpose. Tenn. Code Ann. § 68-103(b)(1)(A).

67. For instance, puberty-delaying medication is commonly used to treat central precocious puberty. Central precocious puberty is the premature initiation of puberty by the central nervous system—before 8 years of age in people designated female at birth and before 9 years of age in people designated male. When untreated, central precocious puberty can lead to the impairment of final adult height as well as antisocial behavior and lower academic achievement. The Health Care Ban permits puberty-delaying treatment for central precocious puberty because it is not provided for purposes of "[e]nabling a minor to identify with" a gender identity different from the sex designated at birth or "[t]reating purported discomfort or distress from a discordance between the minor's sex and asserted identity." Tenn. Code Ann. § 68-33-103(a)(1).

68. Likewise, the Health Care Ban prohibits hormone therapy when the treatment is used to treat transgender adolescents with gender dysphoria but allows that same hormone therapy when prescribed to non-transgender patients. For example, non-transgender boys with delayed puberty may be prescribed testosterone if they have not begun puberty by 14 years of age. Without testosterone, for most of these patients, puberty would eventually initiate naturally. However, testosterone is prescribed to avoid some of the social stigma that comes from undergoing puberty later than one's peers and failing to develop the secondary sex characteristics consistent with their gender at the same time as their peers. Likewise, non-transgender girls with primary ovarian insufficiency, hypogonadotropic hypogonadism (delayed puberty due to lack of estrogen caused by a problem with the pituitary gland or hypothalamus), or Turner's Syndrome (a chromosomal condition that can cause a failure of ovaries to develop) may be treated with estrogen. Moreover, non-transgender girls with polycystic ovarian syndrome (a condition that can cause increased testosterone and, as a result, symptoms including facial hair) may be treated with testosterone suppressants.

69. The side effects of the proscribed treatments are comparable when used to treat gender dysphoria and when used to treat other conditions. In each circumstance, doctors advise patients and their parents about the risks and benefits of treatment and tailor recommendations to the individual patient's needs. For adolescents, parents consent to treatment and the patient gives their assent.

D. There Are No Legitimate Justifications for the Health Care Ban

70. In passing the Health Care Ban, the General Assembly's findings cited a purported need to "protect[] minors from physical and emotional harm," "protect[] the ability of minors to develop into adults who can create children of their own," "promot[e] the dignity of minors," "encourage[e] minors to appreciate their sex, particularly as they undergo puberty," and "protect[] the integrity of the medical profession." Tenn. Code Ann. § 68-33-101(m).

71. These purported concerns do not justify prohibiting medical procedures—including prescribing, administering, or dispensing any puberty blocker or hormone—only when used to provide gender-affirming care to treat transgender adolescents when the same care is allowed for other purposes.

72. The banned treatment is supported by a substantial body of research and clinical evidence and is not experimental.

73. The body of research supporting the safety and efficacy of the banned care is comparable to the research supporting other treatments, but only gender-affirming medical care for adolescents is banned.

74. Clinicians, including clinicians in Tennessee, have documented the safety and efficacy of treatment for gender dysphoria in adolescents over decades.

75. Even if the banned treatments were "experimental in nature" (which they are not), experimental treatments are permitted in Tennessee and are not banned. Wrongly labelling gender-affirming care as "experimental" cannot justify categorically banning

only this one form of allegedly "experimental" treatment.

76. The law bans the only evidence-based treatments for gender dysphoria in adolescents.

77. The General Assembly's purported interest in protecting minors from potential physical and emotional risks associated with the prohibited medical care likewise cannot justify the Health Care Ban. The majority of potential risks and side effects related to puberty-delaying treatment, hormone therapy, and chest surgeries for gender dysphoria are comparable to those risks and side effects when such treatments are used for other indications. Further, Tennessee does not ban other forms of care carrying similar risks, such as treatments that carry fertility risks.

78. Every medical intervention carries potential risks and potential benefits. Weighing the potential benefits and risks of the treatment for gender dysphoria is a prudential judgment similar to other judgments made by healthcare providers, adolescent patients, and their parents. Adolescent patients and their parents often make decisions about treatments with less evidence and/or greater risks than the treatments prohibited by the Health Care Ban.

79. The current standards of care for treating gender dysphoria in minors are consistent with general ethical principles of informed consent. Existing clinical practice guidelines for providers extensively discuss the potential benefits, risks, and alternatives to treatment, and providers' recommendations regarding the timing of interventions are based in part on the treatment's potential risks and the adolescent's decision-making capacity.

80. There is nothing unique about any of the medically accepted treatments for adolescents with gender dysphoria that justify singling out these treatments for prohibition based on the concern about adolescents' inabilities to assent or their parents' inabilities to consent.

81. The Health Care Ban subjects medical care for transgender adolescents with gender dysphoria to a double standard. The law singles out such care for sweeping prohibitions while permitting the same medical treatments carrying the same potential risks when prescribed to treat non-transgender patients for any other purpose.

E. The Health Care Ban Will Cause Severe Harm to Transgender Youth

82. Withholding gender-affirming medical treatment from adolescents with gender dysphoria when it is medically indicated puts them at risk of severe irreversible harm to their health and well-being.

83. Adolescents with untreated gender dysphoria can suffer serious medical consequences, including possible self-harm and suicidal ideation. In one survey, more than half of transgender youth who participated had seriously contemplated suicide. Studies have found that as many as 40% of transgender people have attempted suicide at some point in their lives.

84. When adolescents are able to access puberty-delaying medication and hormone therapy, their distress recedes and their mental health improves. Both clinical experience and medical studies confirm that, for many young people, this treatment is transformative, and they go from experiencing pain and suffering to thriving.

85. The effects of undergoing one's endogenous puberty may not be reversible even with subsequent hormone therapy and surgery in adulthood, thus exacerbating lifelong gender dysphoria in adolescent patients who are unable to access gender-affirming medical care. For instance, bodily changes from puberty as to stature, bone structure, genital growth, voice, and breast development can be impossible or more difficult to counteract.

86. Medical treatment in adolescence can reduce life-long gender dysphoria, possibly eliminating the need for surgical intervention in adulthood, and can improve mental health outcomes significantly.

87. Gender-affirming medical care can be a lifesaving treatment for minors experiencing gender dysphoria. The major medical and mental health associations support the provision of such care and recognize that the mental and physical health benefits to receiving this care outweigh the risks. These groups include the American Academy of Pediatrics, American Medical Association, the Endocrine Society, the Pediatric Endocrine Society, the American Psychological Association, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the National Association of Social Workers, and WPATH.

F. The Impact of the Health Care Ban on Plaintiffs

1. The Minor Plaintiffs and Their Families

(1) The Williams Family

88. L.W. is a fifteen-year-old girl, a freshman in high school, and has lived in Tennessee her entire life. When

she is not at school, she likes playing video games, listening to music, and building with Legos.

89. Here is a photo of L.W. with her mother Samantha Williams, and her father Brian Williams.

90. L.W. is transgender. She is a girl with a female gender identity, but when she was born, she was designated as male.

91. Growing up, L.W. felt uncomfortable in her body. She remembers feeling like she was drowning and trapped in the wrong body. She avoided changing clothes in front of anyone, tried to hide her body behind baggy clothing, and was not comfortable hugging her family.

92. Before she understood what she was feeling, L.W. experienced significant stress and anxiety. The discomfort of using the boys' restroom at school would cause her to avoid using the restroom altogether and led

to her developing urinary tract infections. She had trouble focusing at school. She could not connect with her friends. Her anxiety was constant.

93. In 2019, an extended family member came out as transgender, and L.W. began to realize she was feeling the same way as her family member described feeling. L.W. started doing her own research about what it meant to be transgender and began her social transition by telling a close friend in her neighborhood that she was a girl.

94. It took L.W. a little while to build up the courage to talk to her parents about being transgender. She was incredibly nervous about what their reaction would be. She first told her mother in November 2020. L.W.'s mother had a lot of questions, but was supportive of her daughter and told L.W. that she and L.W.'s father would always love her. L.W. came out to her father and brother shortly after. She finally felt like she could talk about and be who she was with them.

95. At first, L.W. asked her family to use "they" and "them" pronouns because she thought she might be non-binary, a term commonly used by individuals whose gender identity is neither male nor female. However, after exploring her gender identity more, she asked her family to use "she" and "her." At this time, she began growing her hair long and wore girls' clothes, which made her feel better about her appearance.

96. A few months after L.W. came out as transgender to her parents, she asked them to take her to see a doctor to talk about being transgender and medical treatments that might help address her dysphoria. L.W.'s parents first found her a therapist so that she could discuss what she was feeling with a mental health

professional. In December 2020, L.W. started seeing a therapist, who conducted a mental health assessment and diagnosed her with gender dysphoria. L.W. started seeing the therapist once a month thereafter.

97. In June 2021, at the recommendation of L.W.'s pediatrician and therapist, L.W.'s parents took her to Vanderbilt Children's Hospital, where she met with a team of doctors who informed L.W. and her parents about medications L.W. could take to stop male puberty. This was a relief to L.W., who worried that her gender dysphoria would get worse if she were to undergo male puberty. After undergoing various tests and learning about the risks and possible side effects, L.W. and her parents consented to L.W. starting to take puberty-delaying medications.

98. The medication made a big difference for L.W. She no longer felt fear and anxiety about her body changing in ways inconsistent with her gender, which greatly improved her mental health.

99. L.W. told her classmates and teachers in January 2022 that her name is "L.," that she is a girl, and that her pronouns are "she" and "her." L.W.'s school is very supportive of her.

100. After taking puberty-delaying medication for more than a year, undergoing additional evaluations, and assessing the potential risks and side effects of treatment with her family, L.W. began estrogen hormone therapy so that her body would undergo feminine pubertal changes. L.W.'s family monitors her physical and mental health and brings her to Vanderbilt for routine follow-up evaluations.

101. Since beginning gender-affirming treatment, L.W. no longer experiences the "near-constant feeling" of gender dysphoria, feels more confident and comfortable, and gives and accepts hugs from her family. Her mother has noticed a huge change in her daughter, who is now outgoing and thriving. L.W. looks forward to a future where she continues receiving the treatment she needs and feels comfortable and at home in her body.

102. L.W. and her family are afraid of the impact the Health Care Ban will have on L.W. and her family if it goes into effect. L.W. is scared that losing access to her medication, which she has been taking for almost two years, will mean that her body will undergo unwanted, permanent changes that are inconsistent with her gender identity. Her mother worries about the debilitating stress and anxiety associated with L.W.'s gender dysphoria returning if she loses access to gender-affirming care. Beginning on July 1, 2023, if L.W. is to receive medication in Tennessee, her medication will be titrated down in preparation for the cutoff imposed by the Ban.

103. L.W. has spent her entire life in Tennessee; her school, friends, and family are in Tennessee. Her parents have jobs that they love in Tennessee. However, L.W. and her family are concerned about L.W.'s health and well-being if she can no longer receive the medical care she needs in Tennessee. They have discussed needing to leave Tennessee so that L.W. can get the medical care she needs.

(2) The Roe Family

104. Ryan Roe is fifteen years old and in his freshman year of high school, where his favorite subjects are math and science. Outside school, he likes exploring

cafes and coffee shops with his friends, and he hopes to become a lawyer.

105. Ryan is a boy. Ryan is also transgender. He has a male gender identity, but when he was born, he was designated as female.

106. Ryan knew from a young age that he did not feel comfortable with his designation as a girl. As he approached puberty, Ryan experienced more anxiety about his body changing in feminine ways.

107. In fifth grade, when Ryan started to go through puberty, he tried to find ways to cover up his body by wearing baggy clothes. He chose to wear boys' clothes and cut his hair short. His depression and anxiety got worse.

108. When Ryan got his period in fifth grade, he had a panic attack because "everything felt wrong about living in [his] body." His anxiety and distress confirmed for him that he is transgender, and he came out to his parents.

109. When Ryan told his mother, Rebecca Roe, that he was transgender, she did not understand what it meant to be transgender, but she was scared that her son would be discriminated against or even physically attacked as a transgender person in the world.

110. Rebecca wanted to make sure Ryan had appropriate mental health support, and he began to see the therapist at his pediatrician's office.

111. Although Ryan met with his therapist, he continued to experience anxiety and discomfort about his body. It reached the point that he barely spoke in public and would not participate in school because of distress over the sound of his voice.

112. His anxiety grew so severe that he went through a period of time when he would vomit every day before school.

113. In the summer before eighth grade, Ryan's therapist diagnosed him with gender dysphoria. With his distress worsening, Rebecca took Ryan to Vanderbilt Children's Hospital to meet with doctors about treatment options for his gender dysphoria. During his first visit to Vanderbilt, the doctors determined that he was too far into puberty for puberty-delaying medication. He was prescribed medication to stop his period, which was a source of significant distress.

114. The doctors at Vanderbilt also provided Rebecca and Ryan with information about gender-affirming testosterone treatment. At home, the Roes discussed the treatment, including all of the potential side effects and risks, as a family.

115. In January 2022, Rebecca and Ryan went back to Vanderbilt for a follow-up appointment to discuss the initiation of testosterone. At that appointment, the Vanderbilt providers discussed the risks and benefits of treatment with the Roes, conducted tests, and determined that Ryan would benefit from the initiation of testosterone. Rebecca consented to the treatment and Ryan began testosterone after that visit. In Rebecca's words, the process of beginning testosterone "was the most deliberate and careful medical process" that the Roes had ever been through for Ryan.

116. In Ryan's words, beginning testosterone "changed [his] life."

117. Ryan has been receiving hormone therapy for more than a year. This treatment has given him hope

and a positive outlook on the world. As his body has undergone physiological changes that align with who he is, his confidence and comfort have grown. He participates in class again and no longer feels anxious by the sound of his own voice. As a result of the hormone therapy, Ryan feels more comfortable in his own skin and likes looking at himself in the mirror and in photos.

118. Due to the Health Care Ban, Rebecca and Ryan were informed by Vanderbilt that they would no longer be providing treatment to current patients under the age of 18 beginning on July 1, 2023. If Ryan is to receive medication in Tennessee after July 1, 2023, his medication will be titrated down in preparation for the cutoff imposed by the statute.

119. Rebecca began to call around to providers in other states, but many have long waitlists, and traveling out of state to continue treatment will be costly and difficult.

120. It is not an option for Ryan to discontinue the medical treatment that has saved his life. He is terrified of going back to a time when he does not have access to this care. The prospect of losing access to gender-affirming medical care has caused both Ryan and his parents enormous stress. Ryan's biggest fear is that losing access to gender-affirming healthcare will have a serious negative effect on his mental health. He is not sure if he will survive not being able to continue receiving the treatment that allows him to live in a way consistent with his gender.

121. To enable Ryan's access to the medical care that has changed his life, Ryan and his family have discussed traveling, or even moving, out of state if the Health Care Ban goes into effect. Ryan feels terrible

that his family would need to move so that he could continue his care and feels like he is losing his childhood by constantly needing to worry about how to access gender-affirming care.

(3) The Doe Family

122. John Doe is twelve years old, and has lived in Tennessee for his entire life. He is in sixth grade and enjoys playing guitar, baseball, and virtual reality games.

123. John is a boy. He is also transgender. John has a male gender identity, but when he was born, he was designated as female.

124. From a very early age, John remembers getting very upset when people treated him as a girl. He cried when his parents tried to make him wear dresses, he did not want to play with dolls or dress-up like girls his age, and he wanted to wear the boys' costumes in his dance recitals. John repeatedly told his mother, Jane Doe, that he wanted to be a boy.

125. Before John began second grade, John's mother contacted a local LGBTQ resource center who connected them with a therapist. This therapist diagnosed John with gender dysphoria. John has regularly seen this therapist for sessions over the past five years.

126. By second grade, John had begun his social transition. John had chosen a typically male name for himself when he was younger. Having his parents use his chosen name made John feel amazing, and he knew he wanted things to stay that way forever. As part of his transition, John also told his classmates and teachers that he is a boy. Subsequently, John's parents ob-

tained a court order updating John's legal name to reflect his chosen name.

127. As John learned about female puberty, he became upset thinking about the possibility of those changes happening to his body. His mother told him about medication that could prevent these changes, and John told her he wanted to explore receiving this medication.

128. John's pediatrician referred him to Vanderbilt Children's Hospital to begin discussing treatment options for his gender dysphoria. For two years, the doctors at Vanderbilt monitored John and discussed the risks, benefits, and side effects of medication with John and his family.

129. Eventually, doctors prescribed John with medication to delay puberty. John says that taking this medication has made him much more comfortable at school and around others. As soon as his doctors decide he is ready, John will begin taking testosterone so that he can continue developing through puberty like other boys.

130. The idea of losing access to his medication is horrifying to John. He cannot imagine losing control of his life for the next six years and fears permanent changes to his body if he undergoes the wrong puberty. His parents fear for John's safety as a transgender individual should he lose access to this important healthcare.

131. John's endocrinologist has informed his family that despite the phase-out provision in the law, she cannot continue providing the same puberty-delaying care that he currently receives after July 1, 2023. She in-

formed the family that her understanding is that the law allows her to do nothing more than wean patients off their care beginning July 1, 2023. Because the endocrinologist believes that reducing the dosage of John's medication would be inappropriate and harmful to him, she will not continue to treat him after July 1.

132. John's parents have begun researching out-of-state options for John to receive care, but are concerned about cost, disruption, and insurance coverage issues should they need to resort to these drastic options to ensure their child receives necessary medical care. They have considered moving out of state, but do not want to uproot their lives, and John's, and move away from the only home he has known.

2. Provider Plaintiff—Dr. Lacy

133. Dr. Lacy is a physician licensed to practice medicine in Tennessee. She graduated from Johns Hopkins Medical School in 1993. Following medical school, Dr. Lacy completed residency in Obstetrics and Gynecology in 1997 at the University of Tennessee in Memphis.

134. Dr. Lacy is bringing her claims on behalf of herself and her patients.

135. Dr. Lacy operates a private practice in Memphis, Tennessee, which provides healthcare services to cisgender and transgender people. As part of her practice, Dr. Lacy provides a variety of comprehensive healthcare services to transgender patients, including hormone therapy for patients with gender dysphoria, fertility services, and reproductive healthcare. Dr. Lacy treats post-pubertal, transgender patients from ages 16 and up with hormone therapy. For transgender

children who have not yet started puberty, she refers parents to a pediatric endocrinologist that specializes in providing that care.

136. Dr. Lacy currently treats 350-400 transgender patients. Of those 350-400 patients, twenty patients are currently under age 18. Sixteen other patients were minors when Dr. Lacy started treating them but are now over age 18.

137. Dr. Lacy treats minor transgender patients in accordance with well-established standards of care.

138. Between 2016 and 2019, Dr. Lacy worked at a clinic providing similar services to her current practice where she treated between 100-200 transgender patients with gender dysphoria. When Dr. Lacy began to treat patients with hormone therapy for gender dysphoria in 2016, she had over 15 years of experience prescribing the same hormones to cisgender patients as part of her gynecologic practice.

139. At Dr. Lacy's current practice, she prescribes and administers the same medications she provides to her transgender patients—testosterone, estrogen, testosterone suppressants, and hormonal contraception—to her cisgender patients. For example, Dr. Lacy provides hormonal contraception, which can be used to control one's menstrual cycle and/or for ovulation suppression, to cisgender patients who might have heavy periods. To treat hormonal issues in cisgender women who are pre-menopausal or cisgender men who are approaching andropause (declining levels of testosterone), Dr. Lacy also utilizes hormone therapy to maintain hormones within the typical range for the patient's gender. Additionally, medications used to suppress testosterone can be used to address symptoms of polycystic ovarian

syndrome, which can include unwanted facial hair and body hair, excessive sweating, and body odor in cisgender woman.

140. If the Health Care Ban takes effect, Dr. Lacy will be prohibited from proving these treatments to her transgender patients because they relate to "discordance between the minor's sex and asserted identity," but she will be able to continue providing the same treatments to her non-transgender patients.

141. If the Health Care Ban takes effect, Dr. Lacy will be required to either fully comply with the law and therefore abandon her patients, or risk losing her medical license, which will deprive her of the ability to care for all of her patients and negatively impact her livelihood. Moreover, the Ban will place Dr. Lacy in direct conflict with the accepted, evidence-based guidelines for treating her transgender patients with gender dysphoria.

142. As a medical provider of patients who experience gender dysphoria, Dr. Lacy has developed a close relationship with both her patients and their families. Seeking and receiving treatment for gender dysphoria is a profoundly personal and informed decision based on a person's innermost sense of self and individual needs. It is also a subject that remains very misunderstood by the public at large. Many of her patients therefore require complete privacy, and Dr. Lacy believes that, as a medical provider, it is her duty and obligation to advocate on behalf of her patients who are unable to publicly advocate for themselves.

143. Dr. Lacy knows from personal experience in treating hundreds of adolescents with gender dysphoria that the Health Care Ban, if permitted to take effect,

will significantly compromise the health and well-being of her patients. Dr. Lacy is concerned that if transgender youth cannot access hormone therapy through healthcare providers, some may resort to other methods of accessing care that include buying medication from unauthorized suppliers and using medication that they get from friends. This can lead to transgender adolescents taking the incorrect dosage, and some will not have their hormone levels monitored through lab work, which is vital for patient safety.

144. Dr. Lacy is already seeing the impact of the Health Care Ban on access to hormone therapy. She has observed firsthand the Health Care Ban placing undue stress and pressure on transgender adolescents and their families looking to begin medical treatment, since patients fear that if they have not begun care by the law's arbitrary deadline, they will be cut off from access altogether. If the Health Care Ban goes into effect on July 1, 2023, Dr. Lacy will be barred from providing hormone therapy to treat gender dysphoria in her adolescent patients. In addition, she will be required to stop providing hormone therapy to her adolescent patients who are already receiving treatment for gender dysphoria as of March 31, 2024.

145. Dr. Lacy is deeply concerned for her young transgender patients because her experience leads her to believe that denying her patients access to gender-affirming hormone therapy can lead to depression, increased anxiety, and suicidal ideation.

CAUSES OF ACTION

146. The Health Care Ban violates the Equal Protection Clause of the Fourteenth Amendment because it discriminates on the basis of sex and transgender sta-

tus by prohibiting certain medical treatments *only* for transgender patients and *only* when those treatments are performed "for the purpose of . . . [e]nabling a minor to identify with, or live as," a gender identity other than the sex designated at birth. Tenn. Code Ann. § 68-33-103(a)(1). This discrimination cannot be justified under heightened scrutiny—or, indeed, under any level of scrutiny applicable to equal protection claims. The Health Care Ban also infringes on the fundamental rights of parents guaranteed by the Due Process Clause of the Fourteenth Amendment by preventing parents from seeking appropriate medical care for their children. None of the statute's purported justifications for infringing on parents' fundamental rights withstands heightened scrutiny or even rational basis review.

147. The Health Care Ban also runs afoul of Section 1557 of the ACA in two distinct ways. *First*, the Health Care Ban conflicts with the ACA. The ACA prohibits healthcare providers from discriminating on the basis of sex. But the Health Care Ban requires that providers discriminate on the basis of sex. The result is that providers such as Dr. Lacy must choose between violating federal law (by failing to provide care) and violating state law (by providing care). The Health Care Ban is therefore preempted by the ACA and the State Official Defendants should be enjoined from enforcing it. *Second*, the ACA bars entities which receive federal financial assistance, such as the DOH (and its sub-agencies, such as the Medical Board), from engaging in discrimination on the basis of sex. But the Health Care Ban requires that the DOH and the Medical Board take "emergency action" to remedy any violation of the Health Care Ban, thus requiring them to engage in discrimination on the basis of sex to the substantial detriment of

the Plaintiffs who are unable to receive or provide medical care. The Plaintiffs are therefore entitled to an order prohibiting the DOH and the Medical Board from complying with the Health Care Ban unless and until the DOH stops receiving federal financial assistance.

COUNT ONE

THE HEALTH CARE BAN VIOLATES THE FOURTEENTH AMENDMENT'S GUARANTEE OF EQUAL PROTECTION UNDER THE LAW (ALL PLAINTIFFS AGAINST STATE OFFICIAL DEFENDANTS)

148. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 147 as if fully set forth herein.

149. State Official Defendants are all governmental actors and/or employees acting under color of State law for purposes of 42 U.S.C. § 1983 and the Fourteenth Amendment.

150. The Equal Protection Clause of the Fourteenth Amendment to the United States Constitution, enforceable pursuant to 42 U.S.C. § 1983, provides that no State shall "deny to any person within its jurisdiction the equal protection of the laws." U.S. Const. amend. XIV, § 1.

151. The Health Care Ban bars the provision of various forms of medically necessary care only when the care is "for the purpose of . . . [e]nabling a minor to identify with, or live as," a gender identity different from their sex designated at birth or "[t]reating purported discomfort or distress from a discordance between the minor's sex and asserted identity." Tenn. Code Ann. § 68-33-103(a)(1). It permits the use of these

same treatments for any other purpose. Tenn. Code Ann. § 68-33-103(b)(1)(A).

152. In doing so, the Ban explicitly discriminates against transgender adolescents, including the Minor Plaintiffs and the patients cared for by the Provider Plaintiff, based on their transgender status and sex, including their failure to conform to stereotypes and expected behavior associated with their sex designated at birth. The Ban also discriminates against the parents of Minor Plaintiffs, denying them the same ability to secure urgently-needed medical care for their children that other parents can obtain, and does so on the basis of transgender status- and sex-based grounds.

153. In addition to facially discriminating based on sex and transgender status, the Ban was also passed because of its effects on transgender people, not in spite of it.

154. Discrimination based on transgender status and sex is subject to heightened scrutiny under the Equal Protection Clause and is therefore presumptively unconstitutional, placing a demanding burden of justification upon the State to provide at least an exceedingly persuasive justification for the differential treatment.

155. Transgender people have obvious, immutable, and distinguishing characteristics that define that class as a discrete group. These characteristics bear no relation to transgender people's abilities to perform in, or contribute to, society.

156. Transgender people have historically been subject to discrimination in Tennessee and across the country and remain a very small minority of the American population that lacks political power.

157. Gender identity is a core, defining trait, that cannot be changed voluntarily or through medical intervention, and is so fundamental to one's identity and conscience that a person cannot be required to abandon it as a condition of equal treatment.

158. The Ban does nothing to protect the health or well-being of minors. To the contrary, it gravely threatens the health and well-being of adolescents with gender dysphoria by denying them access to necessary care.

159. The Ban's discriminatory treatment of healthcare for transgender adolescents is not adequately tailored to any sufficiently important government interest, nor is it even rationally related to any legitimate government interest.

160. The asserted justifications for the Ban make no sense in light of how other medical treatments are regulated by the State.

161. The Ban's targeted prohibition on medically necessary care for transgender adolescents is based on generalized fears, negative attitudes, stereotypes, and moral disapproval of transgender people, which are not legitimate bases for unequal treatment under any level of scrutiny.

162. The ban violates the equal protection rights of the Minor Plaintiffs and their parents, and the equal protection rights of Dr. Lacy's current and future adolescent patients.

COUNT TWO
THE HEALTH CARE BAN VIOLATES THE RIGHT TO PARENTAL AUTONOMY GUARANTEED BY THE FOURTEENTH AMENDMENT'S DUE PROCESS CLAUSE (PARENT PLAINTIFFS AGAINST STATE OFFICIAL DEFENDANTS)

163. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 147 as if fully set forth herein.

164. State Official Defendants are all governmental actors and/or employees acting under color of State law for purposes of 42 U.S.C. § 1983 and the Fourteenth Amendment.

165. The Due Process Clause of the Fourteenth Amendment, enforceable pursuant to 42 U.S.C. § 1983, protects the fundamental right of parents to make decisions concerning the care, custody, and control of their children.

166. That fundamental right of parents includes the right to seek and to follow medical advice to protect the health and well-being of their minor children.

167. Parents' fundamental right to seek and follow medical advice is at its apogee when the parents, their minor child, and that child's doctor all agree on an appropriate course of medical treatment.

168. The Health Care Ban's prohibition against well-accepted medical treatments for adolescents with gender dysphoria deprives Tennessee parents of their fundamental right to make decisions concerning the care of their children. The Ban also discriminates against the Parent Plaintiffs with respect to the exercise of this fundamental right.

169. The Ban does nothing to protect the health or well-being of minors. To the contrary, it gravely threatens the health and well-being of adolescents with gender dysphoria by denying their parents the ability to obtain necessary medical care for them.

170. The Ban's prohibition against the provision of medically accepted treatments for adolescents with gender dysphoria is not narrowly tailored to serve a compelling government interest, nor is it rationally related to any legitimate government interest.

171. The Health Care Ban violates the fundamental rights of the parent plaintiffs.

COUNT THREE
THE HEALTH CARE BAN IS PREEMPTED BY SECTION 1557 OF THE AFFORDABLE CARE ACT (PROVIDER PLAINTIFF AGAINST STATE OFFICIAL DEFENDANTS)

172. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 147 as if fully set forth herein.

173. Federal courts have equity jurisdiction to issue injunctive and declaratory relief upon finding a state regulatory action is preempted by federal law.

174. Under Section 1557 of the ACA, "an individual shall not, on [any] ground prohibited under . . . Title IX of the Education Amendments of 1972 (20 U.S.C. 1681, *et seq.*),"—which includes discrimination "on the basis of sex"—"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, including credits, subsidies, or contracts of insurance, or under any

program or activity that is administered by an Executive Agency or any entity established under this title (or amendments)." 42 U.S.C. § 18116(a); 45 C.F.R. § 92.3.

175. Provider Plaintiff is engaged in a health program or activity, i.e., providing medical care as a licensed physician to transgender persons.

176. Provider Plaintiff receives federal financial assistance as contemplated under Section 1557, including reimbursement under the federal Medicaid and Medicare programs.

177. The Health Care Ban prohibits Provider Plaintiff from performing or administering medical procedures performed "for the purpose of . . . [e]nabling a minor to identify with" a gender identity different from the sex they were designated at birth or "[t]reating purported discomfort or distress from a discordance between the minor's sex and asserted identity." Tenn. Code Ann. § 68-33-103(a)(1)(A)-(B).

178. The Ban thus requires Provider Plaintiff to discriminate against adolescents on the basis of their sex. This places Provider Plaintiff in the untenable position of either violating Section 1557 of the *federal* ACA by refusing to provide care to transgender adolescents or violating the *Tennessee* Health Care Ban by continuing to provide care for transgender adolescents. If the Provider Plaintiff refuses to provide care, she will be subject to civil liability for discrimination under Section 1557; and if she provides care, she will be subject to civil liability under the Health Care Ban. This conflict is resolved by the U.S. Constitution. The Supremacy Clause within Article VI of the Constitution dictates that federal law is the "supreme law of the land."

179. The Health Care Ban is thus preempted by the ACA, and the Provider Plaintiff is entitled to declaratory and injunctive relief enjoining the State Official Defendants from enforcing the Health Care Ban.

COUNT FOUR
THE HEALTH CARE BAN VIOLATES SECTION 1557 OF THE AFFORDABLE CARE ACT (ALL PLAINTIFFS AGAINST DEFENDANTS TENNESSEE DEPARTMENT OF HEALTH AND TENNESSEE BOARD OF MEDICAL EXAMINERS)

180. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 147 as if fully set forth herein.

181. Section 1557 of the ACA is enforceable through a private right of action.

182. Under Section 1557, "an individual shall not, on the ground prohibited under . . . Title IX of the Education Amendments of 1972 (20 U.S.C. 1681, *et seq.*)," which includes discrimination "on the basis of sex"—"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, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments)." 42 U.S.C. § 18116(a); 45 C.F.R. § 92.3.

183. The prohibition on sex discrimination in Section 1557 protects transgender individuals from discrimination by healthcare programs and activities.

184. Defendant DOH is engaged in a health program or activity in that it is responsible for many as-

pects of public health in Tennessee and provides health services to many Tennesseans across the state.

185. Defendant Medical Board is a "board . . . attached to the" DOH, Tenn. Code Ann. § 68-33-102(2)(B), with the power to license, regulate and discipline health care providers within the State of Tennessee and is therefore engaged in a health program or activity.

186. Defendant DOH receives federal financial assistance, including grants, contracts, and other financial assistance from the United States Department of Health and Human Services, as well as federal Medicare and Medicaid funds. By virtue of its attachment to the Defendant DOH, Defendant Medical Board also receives federal financial assistance.

187. Minor Plaintiffs and their parents seek the benefits of healthcare regulated by the state, and the Provider Plaintiff seeks to provide those benefits.

188. Minor Plaintiffs will be denied those benefits and subjected to discrimination on account of their sex because the Health Care Ban requires the DOH and agencies, boards, councils, and committees attached to the DOH, including the Medical Board, to take emergency action against healthcare providers who perform or administer medical procedures "for the purpose of . . . [e]nabling a minor to identify with" a gender identity different from the sex they were designated at birth or "[t]reating purported discomfort or distress from a discordance between the minor's sex and asserted identity."

189. The Health Care Ban necessarily requires the DOH and the Medical Board to violate Section 1557 by requiring that it discriminate on the basis of sex and

transgender status, to the substantial injury of the Minor Plaintiffs who will be deprived of medical care, the Parent Plaintiffs who are unable to obtain care for their children, and the Provider Plaintiff who is unable to provide care.

190. The Plaintiffs are therefore entitled to declaratory and injunctive relief prohibiting the DOH and the Medical Board from complying with the Health Care Ban.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray that this Court:

i. Enter a judgment declaring that the Health Care Ban violates the Equal Protection Clause; violates the fundamental rights of parents guaranteed by the Due Process Clause; is preempted by Section 1557 of the Affordable Care Act; and violates Section 1557 of the Affordable Care Act;

ii. Issue preliminary and permanent injunctions enjoining Defendants, their employees, agents, and successors in office from enforcing the Health Care Ban;

iii. Award Plaintiffs their costs and expenses, including reasonable attorneys' fees, pursuant to 42 U.S.C. § 1988 and 42 U.S.C. § 18116(a); and

iv. Grant such other relief as the Court deems just and proper.

Dated: Apr. 20, 2023 Respectfully submitted,

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* *motions to appear pro hac vice pending*
** *application for admission pending*

JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

L.W., et al.

(b) County of Residence of First Listed Plaintiff Davidson County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

(see attachment)

DEFENDANTS

Jonathan Skrmetti, in his official capacity as the Tennessee Attorney General and Reporter, et al.

County of Residence of First Listed Defendant Davidson County
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

Office of the Tennessee Attorney General and Reporter
500 Dr MLK Jr Blvd, Nashville, TN 37219

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☒ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
U.S. Constitution, Fourteenth Amendment; 42 U.S.C. § 18116; 42 U.S.C. § 1983

Brief description of cause:
Challenging Tennessee's ban on gender-affirming care for transgender minors under the Fourteenth Amendment and Affordable Care Act.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY *(See instructions):*

JUDGE _____ DOCKET NUMBER _____

DATE
Apr 20, 2023

SIGNATURE OF ATTORNEY OF RECORD
/s/ Stella Yarbrough

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

Case No. 3:23-cv-00376

L.W., BY AND THROUGH HER PARENTS AND NEXT FRIENDS, SAMANTHA WILLIAMS AND BRIAN WILLIAMS; SAMANTHA WILLIAMS; BRIAN WILLIAMS; JOHN DOE, BY AND THROUGH HIS PARENTS AND NEXT FRIENDS, JANE DOE AND JAMES DOE; JANE DOE; JAMES DOE; RYAN ROE, BY AND THROUGH HIS PARENT AND NEXT FRIEND, REBECCA ROE; REBECCA ROE; AND SUSAN N. LACY, ON BEHALF OF HERSELF AND HER PATIENTS, PLAINTIFFS

AND

UNITED STATES OF AMERICA, PLAINTIFF-INTERVENOR

v.

JONATHAN SKRMETTI, IN HIS OFFICIAL CAPACITY AS THE TENNESSEE ATTORNEY GENERAL AND REPORTER; TENNESSEE DEPARTMENT OF HEALTH; RALPH ALVARADO, IN HIS OFFICIAL CAPACITY AS THE COMMISSIONER OF THE TENNESSEE DEPARTMENT OF HEALTH; TENNESSEE BOARD OF MEDICAL EXAMINERS; MELANIE BLAKE, IN HER OFFICIAL CAPACITY AS THE PRESIDENT OF THE TENNESSEE BOARD OF MEDICAL EXAMINERS; STEPHEN LOYD, IN HIS OFFICIAL CAPACITY AS VICE PRESIDENT OF THE TENNESSEE BOARD OF MEDICAL EXAMINERS; RANDALL E. PEARSON, PHYLLIS E. MILLER, SAMANTHA MCLERRAN, KEITH G. ANDERSON, DEBORAH CHRISTIANSEN, JOHN W. HALE, JOHN J. MCGRAW, ROBERT ELLIS, JAMES DIAZ-BARRIGA, AND JENNIFER CLAXTON, IN THEIR OFFICIAL CAPACITIES AS MEMBERS OF THE TENNESSEE BOARD OF MEDICAL EXAMINERS; AND LOGAN GRANT, IN HIS OFFICIAL CAPACITY AS THE EXECUTIVE DIRECTOR OF THE TENNESSEE HEALTH FACILITIES COMMISSION, DEFENDANTS

Filed: Apr. 26, 2023

COMPLAINT IN INTERVENTION

District Judge RICHARDSON

Magistrate Judge NEWBERN

Plaintiff-Intervenor, the United States of America ("United States"), alleges:

PRELIMINARY STATEMENT

1. This lawsuit challenges a state statute that denies necessary medical care to children based solely on who they are.

2. All people, including transgender youth, deserve to be treated with dignity and respect. And the Fourteenth Amendment demands that Tennessee not "deny to any person within its jurisdiction the equal protection of the laws." U.S. Const. amend. XIV.

3. The United States accordingly files this complaint in intervention to enforce the Constitution's guarantee of equal protection, and to challenge certain provisions in Act No. 2023-SB0001, Senate Bill 1, codified at Tenn. Pub. Acts § 68-33-101, *et seq.* (2023) ("SB 1"): §§ 68-33-103, 104, 106, and 107.

4. SB 1 prohibits certain forms of medically necessary care for transgender minors with a diagnosis of gender dysphoria. Specifically, SB 1 bans certain medical procedures and treatments for minors, including puberty blockers and hormones, if performed for the purpose of enabling a minor to identify with or live with

an identity inconsistent with the minor's sex as assigned at birth, or treating discomfort or distress from discordance between the minor's sex assigned at birth and their asserted identity.

5. While prohibiting certain forms of medically necessary gender-affirming care for transgender minors, SB 1 permits all other minors to access the same procedures and treatments. For example, SB 1 excepts the same medical procedures when they are used "to treat a minor's congenital defect, precocious puberty, disease, or physical injury." The statute specifically excludes gender dysphoria and related conditions from the definition of disease. The legislative history of the statute also makes clear that the statute does not prohibit non-transgender minors from accessing the same procedures and treatments for any other reason.

6. The law thus discriminates against transgender minors by unjustifiably denying them access to certain forms of medically necessary care to treat a diagnosis of gender dysphoria.

7. If health care providers violate SB 1's prohibitions, they can be subject to civil suits by the state Attorney General for up to twenty years after the violation and private suits by the minors who received care or parents who did not consent to the procedure for up to thirty years after the minor turns 18. Health care providers can also be subject to licensing sanctions.

8. SB 1's ban on various forms of medically necessary care only for transgender minors with a diagnosis of gender dysphoria discriminates on the basis of both sex and transgender status in violation of the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

JURISDICTION AND VENUE

9. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1345.

10. The United States is authorized to intervene in this action pursuant to 42 U.S.C. § 2000h-2. The Attorney General of the United States has certified that this case is of general public importance.

11. Venue is proper pursuant to 28 U.S.C. §§ 81(b) and 1391(b).

12. This Court has the authority to enter a declaratory judgment and to provide preliminary and permanent injunctive relief pursuant to Rules 57 and 65 of the Federal Rules of Civil Procedure, and 28 U.S.C. §§ 2201 and 2202.

PARTIES

13. Plaintiff-Intervenor is the United States of America.

14. Defendant Jonathan Skrmetti is the Attorney General and Reporter of the State of Tennessee. The Attorney General and Reporter is headquartered in Nashville. Under SB 1, Attorney General Skrmetti is tasked with bringing legal actions against any health care provider "that knowingly violates [SB 1]." Tenn. Pub. Acts § 68-33-106(b). He is also authorized to "establish a process by which violations of [SB 1] may be reported." Tenn. Pub. Acts § 68-33-106(a). Attorney General Skrmetti is sued in his official capacity.

15. Defendant Ralph Alvarado, MD, FACP is the Commissioner of the Tennessee Department of Health, the primary agency of the State of Tennessee responsible for all aspects of public health. The Department of

Health is headquartered in Nashville. SB 1 provides that any violation of the statute "requires emergency action by an alleged violator's appropriate regulatory authority," which expressly includes "[t]he department of health." Tenn. Pub. Acts §§ 68-33-102(2)(A), 107. Defendant Alvarado oversees and directs the functions of the Department of Health, including the activities of licensure regulation entities, such as the Tennessee Board of Medical Examiners, which is "attached" to the Department of Health. Tenn. Pub. Acts § 68-33-102. Defendant Alvarado is sued in his official capacity.

16. Defendant Melanie Blake, MD is the President of the Tennessee Board of Medical Examiners ("Medical Board"), a "board . . . attached to the" Department of Health, Tenn. Pub. Acts § 68-33-102(2)(B), with the power to license, regulate and discipline health care providers within the State of Tennessee. The Medical Board is headquartered in Nashville. Defendant Stephen Loyd, MD is the Vice President of the Medical Board. Defendants Randall E. Pearson, MD; Phyllis E. Miller, MD; Samantha McLerran, MD; Keith G. Anderson, MD; Deborah Christiansen, MD; John W. Hale, MD; John J. McGraw, MD; Robert Ellis; James Diaz-Barriga; and Jennifer Claxton are members of the Medical Board. SB 1 provides that any violation of the statute "requires emergency action by an alleged violator's appropriate regulatory authority," which expressly includes any "agency, board, council, or committee attached to the department of health." Tenn. Pub. Acts §§ 68-33-102(2)(B), 107. The Medical Board Defendants are sued in their official capacities.

17. Defendant Logan Grant is the Executive Director of the Tennessee Health Facilities Commission (the "Health Facilities Commission"). The Health Facilities

Commission is headquartered in Nashville. The Health Facilities Commission is an agency of the State of Tennessee with responsibility for, among other things, conducting investigations of health care facilities in Tennessee to ensure compliance with state and federal regulations. SB 1 provides that any violation of the statute "requires emergency action by an alleged violator's appropriate regulatory authority," which expressly includes "[t]he health facilities commission." Tenn. Pub. Acts §§ 68-33-102(2)(C), 107. Defendant Grant is sued in his official capacity.

18. Defendant Skrmetti, Defendant Alvarado, the Medical Board Defendants, and Defendant Grant are all governmental actors and/or employees acting under color of State law.

FACTUAL ALLEGATIONS

19. Gender identity refers to a person's core sense of belonging to a particular gender, such as male or female. Every person has a gender identity.

20. Transgender people are people whose gender identity does not align with the sex they were assigned at birth.

21. The American Psychiatric Association has stated "[b]eing transgender or gender diverse implies no impairment in judgment, stability, reliability, or general social or vocational capabilities."

A. Standards of Care for Treating Transgender Youth

22. According to the American Psychiatric Association's Diagnostic & Statistical Manual of Mental Disorders ("DSM-V-TR"), an authoritative source for psychiatric conditions, "gender dysphoria" is the diagnostic term for the condition experienced by some trans-

gender people of clinically significant distress resulting from the lack of congruence between their gender identity and the sex assigned to them at birth.

23. As the DSM-V-TR explains, to be diagnosed with gender dysphoria, an individual must experience the incongruence for at least six months and experience clinically significant distress or impairment in social, occupational, or other important areas of functioning.

24. The American Psychiatric Association recognizes that not all transgender persons have gender dysphoria. A diagnosis of gender dysphoria is currently required in order to receive many forms of gender-affirming care, including puberty blockers and hormone therapy.

25. The DSM-V-TR notes that medical treatment for gender dysphoria addresses the clinically significant distress created by gender dysphoria by helping people who are transgender and diagnosed with gender dysphoria live in alignment with their gender identity.

26. Standards of care for treating transgender youth diagnosed with gender dysphoria have been published by several well-established medical organizations, including the World Professional Association for Transgender Health ("WPATH"), the Endocrine Society, and the American Academy of Pediatrics ("AAP"). The standards of care published by these organizations provide a framework that is widely accepted and endorsed for the treatment of gender dysphoria in children and adolescents.

27. The most recent WPATH Standards of Care (SOC version 8) were published in 2022 and represent expert consensus for clinicians related to medical care

for transgender people, based on the best available science and clinical experience.[1]

28. WPATH's recommendations differ depending on whether the treatment is for a pre-pubertal child, an adolescent (i.e., minors who have entered puberty), or an adult.

29. For children younger than pubertal age, WPATH's recommended treatments do not involve any medications. For prepubertal children with gender dysphoria, treatments may include supportive therapy, encouraging support from loved ones, and assisting the young person through elements of a social transition. Social transition may evolve over time and can include a number of different actions, such as a name change, pronoun change, bathroom and locker use, personal expression, and communication of affirmed gender to others.

30. WPATH's guidelines for children recommend that parents and health care professionals respond supportively to children who desire to be acknowledged as the gender that matches their internal sense of gender identity and to support them as they continue to explore their gender throughout the pre-pubescent years.

31. For transgender adolescents, WPATH's guidelines recommend a multidisciplinary approach to gender-affirming medical care that includes key disciplines such as adolescent medicine/primary care, endocrinology, psy-

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[1] The previous version (SOC version 7) was published in 2012. SOC version 7 was similar to version 8 in the basic tenets of management for transgender adolescents; however, version 8 further reinforces these guidelines with data published since the release of SOC version 7.

chology, psychiatry, speech/language pathology, social work, and support staff.

32. WPATH's guidelines note that studies indicate a general improvement in the lives of transgender adolescents who, following careful assessment, receive medically necessary gender-affirming medical treatment. Conversely, allowing irreversible puberty to progress in adolescents who experience gender dysphoria may have immediate and lifelong harmful effects for the transgender young person.

33. Accordingly, for some adolescents diagnosed with gender dysphoria, WPATH recommends that additional treatments involving medications may be appropriate in some circumstances. Options for treatment after the onset of puberty include the use of gonadotropin-releasing hormone agonists for purposes of preventing progression of pubertal development and hormonal interventions such as testosterone and estrogen administration. WPATH's guidelines emphasize that an individualized approach to clinical care for adolescents is both ethical and necessary.

34. WPATH's guidelines make clear that gender-affirming medical care for transgender adolescents diagnosed with gender dysphoria should only be recommended when certain criteria are met and certain steps have been taken. These criteria include: when the adolescent meets the diagnostic criteria of gender dysphoria as confirmed by a qualified mental health professional; when the experience of gender dysphoria is marked and sustained over time; when the adolescent demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment; when the adolescent's other mental health concerns (if any)

have been addressed; and when the adolescent has been informed of any risks.

35. In 2017, the Endocrine Society published clinical practice guidelines on treatment recommendations for the medical management of gender dysphoria. The Endocrine Society developed these guidelines in collaboration with the Pediatric Endocrine Society, the European Societies for Endocrinology and Pediatric Endocrinology, and WPATH, among others.

36. Like WPATH, the Endocrine Society's recommendations differ for pre-pubertal children and adolescents.

37. The Endocrine Society recommends against puberty blockers and hormone treatment for pre-pubertal children with gender dysphoria.

38. The Endocrine Society also acknowledges that gender dysphoria may worsen with the onset of puberty. For adolescents who meet the diagnostic criteria for gender dysphoria, fulfill the criteria for treatment, and are requesting treatment, the Endocrine Society recommends that they initially undergo treatment to suppress pubertal development. The Endocrine Society further recommends hormone therapy using a gradually increasing dose schedule after a multidisciplinary team of medical and mental health providers has confirmed the persistence of gender dysphoria and there is sufficient mental capacity to give informed consent, which most adolescents have by age 16.

39. Similar to WPATH, the Endocrine Society sets forth certain criteria that must be met before a transgender adolescent is eligible for puberty blockers or hormones, including that a qualified health care profes-

sional has confirmed the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed); gender dysphoria worsened with the onset of puberty; and any coexisting psychological, medical, or social problems that could interfere with treatment have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment. The adolescent must be informed of the effects and side effects of treatment and options to preserve fertility, and must give informed consent (or have their parents' informed consent if they have not reached the age of legal medical consent). The Endocrine Society's criteria also require a pediatric endocrinologist or other clinician experienced in pubertal assessment to agreement with the treatment and to confirm that there are no medical contraindications to treatment.

40. Like WPATH, the Endocrine Society emphasizes that family support is an essential component of gender-affirming care.

41. AAP's 2018 policy statement titled *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents* further codifies the treatment options outlined in the WPATH SOC and the Endocrine Society's Clinical Practice Guideline. AAP notes that most protocols for gender-affirming interventions incorporate WPATH and Endocrine Society recommendations.

42. AAP reinforces that valuing a child for who they are, even at a young age, fosters secure attachment and resilience, not only for the child but for the whole family.

43. AAP's policy statement also emphasizes a multidisciplinary approach to the provision of gender-affirming care, which may include a pediatric provider, a mental health provider, social and legal supports, and a pediatric endocrinologist or adolescent-medicine specialist, if available.

44. AAP agrees that puberty blockers can reduce the distress that may occur with the development of secondary sexual characteristics and allow for gender-affirming care, including mental health support for the adolescent and family. It states that the available data reveal that pubertal suppression for transgender youth generally leads to improved psychological functioning in adolescence and young adulthood. AAP also recognizes that hormone therapy from early adolescence onward can be part of the process of gender affirmation.

B. Senate Bill 1

i. Legislative History

45. During the legislative debate preceding the passage of SB 1, several legislators made comments reflecting moral disapproval or disbelief of youth who identify as transgender and their need for gender-affirming care.

46. For example, Representative William Lamberth, who sponsored the SB 1 companion bill in the Tennessee House of Representatives (HB 1), characterized the increase in the number of youth who identify as transgender as "a growing social contagion of gender dysphoria" driven in part by "social media glorifying the process of transitioning." *Hearing on HB 1 Before the H. Health S. Comm.*, 113th Sess. (Tenn. 2023).

47. At the same hearing, Representative Paul Sherrell said: "If you don't know what you are—a boy or girl, male or female—just go in the bathroom and take your clothes off and look in the mirror, and you'll find out." *Id.*

48. In the House Civil Justice Committee hearing, Representative Gino Bulso referred broadly to being transgender and to gender-affirming care for transgender people to live in alignment with their gender identity as "fiction" and "fantasy." *Hearing on HB 1 Before the H. Civ. Just. Comm.*, 113th Sess. (Tenn. 2023) (statement of Rep. Gino Bulso).

49. Statements made during the legislative debate also reveal the legislators' intention that SB 1 limit access to medical care solely based on the individual's transgender or non-transgender status.

50. For example, Senator Johnson and Representative Lamberth each confirmed that SB 1 and HB 1 do not apply to non-transgender minors who use the same treatments the bills prohibit. *See Hearing on SB 1 Before the S. Health & Welfare Comm.*, 113th Sess. (Tenn. 2023); *Hearing on HB 1 Before the H. Health Comm.*, 113th Sess. (Tenn. 2023). Specifically, when Senator Jeff Yarbro asked Senator Johnson about whether the bill prevents a boy with gynecomastia from getting a double mastectomy or children diagnosed with precocious puberty from using puberty blockers, Senator Johnson said "that treatment would be allowed" and confirmed broadly that "[t]he bill only applies to these [medical] procedures . . . when it is for the purpose of allowing that child to transition to a purported identity other than the child's sex at birth." *Hearing on SB*

1 Before the S. Health & Welfare Comm., 113th Sess. (Tenn. 2023).

51. During hearings, legislators opposing the bill highlighted that intersex and non-transgender youth are still permitted access to these medical procedures. For example, Representative Torrey C. Harris highlighted that the bill excludes "intersex people, cosmetic surgeries, and other practices." *House of Rep. F. Sess.* (Tenn. 2023). Additionally, Representative Gloria Johnson specifically drew her colleagues' attention to the differential treatment, stating, "[t]he reality is, we're targeting a group . . . And we are determining that a certain group of folks cannot have care." *House of Rep. F. Sess.* (Tenn. 2023).

52. Following these comments, the bills passed without change.

ii. Bill Text

53. S.B. 1 was signed into law by Governor Bill Lee on March 2, 2023. The law will become effective on July 1, 2023. Generally, SB 1 prohibits:

> [a] healthcare provider [from] knowingly perform[ing] or offer[ing] to perform on a minor, or administer[ing] or offer[ing] to administer to a minor, a medical procedure if the performance is for the purpose of:
>
> (A) [e]nabling a minor to identify with, or live as, a purported identity inconsistent with the minor's sex; or
>
> (B) [t]reating purported discomfort or distress from a discordance between the minor's sex and asserted identity.

SB 1, § 68-33-103(a)(1).

54. The statute defines "medical procedure" as "[s]urgically removing, modifying, altering, or entering into tissues, cavities, or organs of a human being; or . . . [p]rescribing, administering, or dispensing any puberty blocker or hormone to a human being." *Id.* § 68-33-102(5).

55. The statute defines "sex" as "a person's immutable characteristics of the reproductive system that define the individual as male or female, as determined by anatomy and genetics existing at the time of birth." *Id.* § 68-33-102(9).

56. The statute also prohibits a person (not restricted to medical providers) from "knowingly provid[ing] a hormone or puberty blocker by any means to a minor if the provision of the hormone or puberty blocker is not in compliance with this chapter." *Id.* § 68-33-104.

57. Legislative findings contained in SB 1 characterize gender-affirming medical procedures and treatments as "experimental in nature;" "not supported by high-quality, long-term medical studies;" "harmful;" "unethical;" "immoral;" and encouraging "minors to become disdainful of their sex." *Id.* § 68-33-101(b), (m). In addition, the legislative findings identify several purported interests for adopting this law, including: "protecting minors from physical and emotional harm;" "protecting the ability of minors to develop into adults who can create children of their own;" "promoting the dignity of minors;" "encouraging minors to appreciate their sex, particularly as they undergo puberty;" and "protecting the integrity of the medical profession, including by prohibiting medical procedures that are harm-

ful, unethical, immoral, experimental, or unsupported by high-quality or long-term studies, or that might encourage minors to become disdainful of their sex." *Id.* § 68-33-101(m).

58. SB 1 specifically exempts from liability under the statute any "medical procedure [provided] to a minor if . . . [t]he performance or administration of the medical procedure is to treat a minor's congenital defect, precocious puberty, disease, or physical injury." *Id.* § 68-33-103(b)(1)(A). "'Congenital defect' means a physical or chemical abnormality present in a minor that is inconsistent with the normal development of a human being of the minor's sex, including abnormalities caused by a medically verifiable disorder of sex development, but does not include gender dysphoria, gender identity disorder, gender incongruence, or any mental condition, disorder, disability, or abnormality." *Id.* § 68-33-102(1). The term "disease" also excludes "gender dysphoria, gender identity disorder, gender incongruence, or any mental condition disorder, disability, or abnormality." *Id.* § 68-33-103(b)(2).

59. The bill also exempts conduct for one year, if "performance or administration of the medical procedure on the minor began prior to the effective date of this act and concludes on or before March 31, 2024." *Id.* § 68-33-103(b)(1)(B). In order to permit tapering medication rather than immediate cessation, the minor's treating physician must satisfy a number of conditions, including a certification in writing that ending the medical procedure would be harmful to the minor. *Id.* § 68-33-103(b)(3).

60. SB 1 allows the state Attorney General to bring an action against a health care provider "that knowingly

violates [this law] within twenty (20) years of the violation . . . and to recover a civil penalty of twenty-five thousand dollars ($25,000) per violation." *Id.* § 68-33-106(b).[2]

61. SB 1 requires regulatory authorities to take "emergency action" when notified about an alleged violation of § 68-33-103 and can subject health care providers to licensing sanctions. *Id.* § 68-33-107.

62. Consent of the minor or a parent of the minor "is not a defense [for a health care provider] to any legal liability incurred as the result of a violation of this section . . . " *Id.* § 68-33-103(c)(1).

iii. Impact of SB 1

63. SB 1's ban on various forms of gender-affirming care prohibits transgender minors with a diagnosis of gender dysphoria from accessing certain medical procedures or treatment if they will be used to affirm a gender identity inconsistent with the sex assigned at birth.

64. The law discriminates against transgender minors by unjustifiably denying them access to certain forms of medically necessary care. SB 1 prohibits transgender minors from obtaining care that is widely recognized within the medical community as medically appropriate and necessary, while imposing no comparable limitation on medically necessary care by non-transgender minors.

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[2] SB 1 also establishes a private right of action for minors or parents of minors under certain conditions, *id.* § 68-33-105, and these private rights of action are available within 30 years from the date the minor reaches 18 years or age or within 10 years of the minor's death, if the minor dies. *Id.* § 68-33-105(e).

65. SB 1 permits a doctor to prescribe testosterone for a non-transgender male minor suffering from delayed pubertal development or a condition such as hypogonadism, but the law prohibits the same doctor from prescribing the same testosterone to a transgender male youth to affirm his gender identity.

66. In other words, the sex a minor was assigned at birth determines the legality and availability of medically necessary treatments.

67. SB 1's prohibition on any procedure or treatment that would affirm a minor's gender identity different from the sex assigned at birth requires Tennessee medical professionals to choose between withholding medically necessary treatment from their minor transgender patients or children, on the one hand, or exposing themselves to civil liability and sanctions on the other.

68. The penalties imposed by SB 1 are far more onerous than typical health care liability actions or other civil actions in Tennessee. Tennessee has a separate statutory scheme for health care liability actions when a person alleges that a health care provider caused an injury related to the provision of, or failed to provide, health care services to a person. Tenn. Code Ann. § 29-26-101. This statute provides only for a one-year statute of limitations. Tenn. Code Ann. § 29-26-116(1). While more time is permitted to file suit if the alleged injury is not discovered in the one-year period, the maximum amount of time an injured person has to file a health care liability claim is three years after the date

on which the negligent act or omission occurred. *Id.* at (2)-(3).[3]

69. By contrast, under SB 1, the statute of limitations is twenty years. The Attorney General may impose an injunction, require disgorgement, and levy penalties of up to $25,000 per individual violation on any health care professional who provided gender-affirming care to a transgender minor consistent with well-established standards of care, even if no injury resulted.

70. Further, SB 1 prevents transgender minors with a diagnosis of gender dysphoria from accessing gender-affirming care that is widely recognized within the medical community as the only effective treatment for some individuals diagnosed with gender dysphoria. SB 1 prevents health care providers from considering the recognized standard of care for gender dysphoria and from providing medically necessary gender-affirming care for improving the physical and mental health of their patients.

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[3] Tennessee also limits other civil actions to a one-year statute of limitations, such as actions for injuries to a person, false imprisonment, or cases brought under the federal civil rights statutes. Tenn. Code Ann. § 28-3-104. Tennessee's health care liability statute also limits damages to actual economic losses suffered, but only to the extent such costs are not paid for by insurance or other governmental benefits. Tenn. Code Ann. § 29-26-119.

CAUSE OF ACTION

COUNT ONE
Violation of Equal Protection
U.S. Constitution, Amendment XIV
Against Defendant Skrmetti, Defendant Alvarado, the Medical Board Defendants, and Defendant Grant

71. The United States re-alleges and re-pleads all the allegations of the preceding and subsequent paragraphs of this Complaint and incorporates them herein by reference.

72. The Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution prohibits state and local governments from denying to any person within their jurisdiction the equal protection of the laws.

73. Through this action, the United States challenges four sections of SB 1, 2023 Tenn. Pub. Acts §§ 68-33-103, 104, 106, and 107, which discriminate on the basis of sex and on the basis of transgender status in violation of the Equal Protection Clause.

74. Under the Equal Protection Clause, government classifications based on sex or on transgender status are subject to heightened scrutiny and are presumptively unconstitutional.

75. A statute that classifies on the basis of sex or on transgender status is one that: (1) facially discriminates; (2) is facially neutral but was motivated by an intent to discriminate; or (3) is facially neutral but is administered in a discriminatory manner.

76. These sections of SB 1 classify based on sex or on transgender status, and therefore, are subject to heightened scrutiny.

77. These sections of SB 1 cannot survive heightened scrutiny because they are not substantially related to achieving Tennessee's asserted interests.

78. In the alternative, these sections of SB 1 could not survive any level of scrutiny because they are not rationally related to a legitimate government interest.

79. The above conduct of Defendants has been taken under color of state and local law.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests that this Court:

a. Enter a judgment declaring that SB 1, §§ 68-33-103, 104, 106, and 107 violate the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution;

b. Temporarily restrain, and issue a preliminary and permanent injunction restraining, Defendants from enforcing SB 1, §§ 68-33-103, 104, 106, and 107; and

c. Grant such additional relief as the needs of justice may require.

Dated: Apr. 26, 2023 Respectfully submitted,

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**Pro hac vice motions pending*

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

Case No. 3:23-cv-00376

L.W., BY AND THROUGH HER PARENTS AND NEXT FRIENDS, SAMANTHA WILLIAMS AND BRIAN WILLIAMS, ET AL., PLAINTIFFS

v.

JONATHAN SKRMETTI, IN HIS OFFICIAL CAPACITY AS THE TENNESSEE ATTORNEY GENERAL AND REPORTER, ET AL., DEFENDANTS

DECLARATION OF SAMANTHA WILLIAMS

I, Samantha Williams, pursuant to 28 U.S.C § 1746, declare as follows:

1. I make this declaration of my own personal knowledge, and, if called as a witness, I could and would testify competently to the matters stated herein.

2. I am 40 years old. My husband, Brian Williams, and I are the parents of L.W., our fifteen-year-old daughter, and O.W., our twelve-year-old son. Our family lives in Nashville, Tennessee.

3. My daughter L.W. has always been a smart and curious kid—she was putting together one-hundred-piece puzzles and watching science shows at age three. She carried that curiosity into her adolescence. She loves music and playing video games, and she enjoys building with Legos, specifically Star Wars Legos. She is very interested in politics and debate and excels at

her academic magnet school, taking honors classes and advanced math.

4. L.W. is transgender. She was assigned a male sex at birth, but I noticed things over the years that made me think she was not comfortable in her body. For example, she was very uncomfortable and embarrassed to change clothes in front of me. She was not comfortable with hugs and she wore baggy clothes to hide her body. She would not make eye contact with our family or her friends.

5. In July of 2017, at the end of her third grade, L.'s teacher in the Gifted & Talented Section at her school encouraged me and Brian to take L. for an evaluation at Vanderbilt Children's Hospital. L.W. was diagnosed with High-Functioning Autism Spectrum Disorder, but was told that her diagnosis was not pronounced enough to require extra support at school, nor was she prescribed any medication. We didn't notice many effects on L.W.'s functioning. We had observed some perseverating, where L.W. would talk about something at length but not notice when she lost the attention of whomever she was talking to. Otherwise, it was simply helpful to name the diagnosis.

6. In Spring of 2018, when L.W. was ten years old and in the fourth grade, she started getting sick at school, and Brian and I ultimately found out that she was not using the restroom at school and would routinely develop urinary tract infections. At this time, we did not realize why L.W. was refusing to use the school bathroom, but we knew that she was struggling with something that she was afraid to talk to us about.

7. In November of 2020, L.W. told me that she was struggling with some feelings, and she was going to talk

to one of her oldest friends in the neighborhood about those feelings. I could tell that she was upset.

8. Within a couple of days, L.W. shared with me the intense feelings she was having. One night, we spent hours after dinner talking about what was bothering her —specifically, she said that she did not want to be a guy, and that she might be transgender. She told me that she was not comfortable in her body and that there had to be a better option for her life—another way to make her feel more herself. When she brought this up with me, I first listened and then asked a lot of questions in order to help her process the feelings she was having. That was when she first expressed that she might be transgender. I ended the conversation by telling her that her dad and I supported her and would love her no matter what.

9. Within a week of that first conversation, and after having several more conversations throughout that week, L.W. and I told Brian that L.W. is transgender, and a few days after that, we told her brother O.W. That very evening, we went to Target to look for new clothes for L.W. When I asked L.W. how she imagined herself looking and presenting, she would draw Anime cartoons of girls and show me the outfits she liked.

10. After she was able to name her feelings to me, I could see that she was more comfortable at home. At first, L.W. asked us to use "they" and "them" pronouns, and a gender-neutral version of her birth name. After exploring her gender further in the winter of 2021, L.W. asked that her dad, her brother, and I call her L.W., and use "she" and "her" pronouns when talking about her at home. We all agreed to do so.

11. Once we started acknowledging L.W. as a girl within our family, Brian and I noticed a further decrease in her stress and anxiety levels. It was truly a "night and day" difference in her mood and demeanor. I remember taking L.W. to Macy's where they have make-up counters, and L.W. had a make-over done with yellow eyeshadow. She was so full of joy and all about the eyeliner.

12. I could tell that the steps we took as a family to affirm L.W.'s gender identity were helpful, but not a full solution. L.W. continued to let us know that she was not comfortable in her body, and we thought she would benefit from talking to someone other than Brian and I.

13. In December of 2020, we took L.W. to see a counselor who specializes in working with transgender children like L.W. Brian and I felt that therapy was an important way for L.W. to talk about the feelings that she was having and we knew we needed someone to help us all navigate this journey. L.W.'s therapist conducted a mental health assessment and diagnosed L.W. with gender dysphoria in December of 2020.

14. While it was easy for Brian and me to support L.W. in her social transition as she continued to see her counselor—we wanted L.W. to feel loved and supported—it took us a few months to start being open to exploring medical care. We were initially skeptical and had concerns about whether medical care was the right step. We spent those months researching treatment for transgender youth and we realized we needed the guidance of a medical professional to help us understand the care L.W. needed. I also spoke to my niece, who is transgender, about how being unable to access the medical care she needed brought her to the point of self-harm

and suicidal ideation as an adolescent. I did not want L.W. to have to struggle in the way my niece did, and Brian and I planned to take L.W. to her pediatrician to see what medical care was appropriate.

15. When Brian and I took L.W. to her pediatrician for her annual appointment in March of 2021, she recommended that we take L.W. to see Dr. Cassandra Brady at Vanderbilt Children's Hospital ("Vanderbilt"). We could not get an appointment until the summer, but L.W. continued to see her counselor throughout the spring and was eager to start exploring medical care.

16. We had our first visit at Vanderbilt on June 7, 2021, when L.W. was 13 years old, and the Vanderbilt team was thorough and helpful. Dr. Brady and her team of professionals (including a nurse and a social worker) explained the existing treatment protocols and the data available about treatment for adolescents with gender dysphoria. They evaluated L.W. and confirmed her gender dysphoria diagnosis, and they also conducted a blood test and x-ray scan to examine L.W.'s growth plates. During that visit, Dr. Brady determined that L.W. had begun puberty and was between Tanner Stage 3 and Tanner Stage 4.

17. Given that L.W. had long-standing gender dysphoria and significant distress at the onset of puberty, Dr. Brady explained that it would be appropriate for L.W. to begin medication to delay her endogenous puberty. Before L.W. could begin taking medication, Dr. Brady required Brian, L.W., and me to have a discussion on the risks associated with puberty-delaying treatment and the quality of evidence supporting the medication. She told us that the medication was "off-label," but that it has been used for decades to treat pre-

cocious puberty. She thoroughly explained the potential side effects, including potential impacts on fertility and bone density, and answered all of my questions on how they would monitor L.W.'s care through routinely scheduled blood tests and other check-ups.

18. In August of 2021, we had our second visit which was focused on providing informed consent. Brian and I provided our informed consent, and L.W. provided her assent, to begin treatment, and Dr. Brady began providing L.W. with puberty-delaying treatment.

19. L.W. was relieved to start puberty-delaying treatment so that she would not have to continue going through her endogenous puberty and experiencing the associated physical changes. L.W. told me that continuing to go through a male puberty would seriously impact her mental health. Once L.W. started treatment, I could immediately see the heavy weight being lifted off her shoulders. L.W. has been on puberty-delaying treatment for about 20 months now. L.W. has not experienced any negative side-effects due to the treatment. We continuously monitor L.W.'s mental and physical health and bring her to Vanderbilt for routine follow-up evaluations, including regular blood tests.

20. By winter of 2021, L.W. shared her gender identity, new name, and use of "she" and "her" pronouns with Brian's extended family. By Christmas that year, she was also comfortable telling my extended family, and my mom bought L.W. a bag with a symbol of her new name on it as a holiday present.

21. In September of 2021, at the beginning of her eighth grade, L.W. told Brian and I that she would like people at school to use to use "they" and "them" pronouns, and a gender-neutral version of her birth name.

The school was extremely supportive in doing so. In January of 2022, in the middle of her eighth-grade year, L.W. told me and Brian that she wanted her teachers at school to call her L.W. and to use "she" and "her" pronouns when speaking about her as well. She told us that she had come out as transgender to a few close friends at school before talking to us, and that they gave her the courage to be more open at school. L.W.'s friends, teachers and administrators supported her. The Gender and Sexuality Alliance (GSA) at school has become a place where L.W. can really be herself. She has even taken on leadership and is currently the vice-president of the club.

22. L.W. had follow-up appointments with her team of doctors at Vanderbilt every three months. During those visits, Dr. Brady and her team evaluated her physical and mental health and found that L.W. is doing well both physically and mentally, and Dr. Brady communicated to us that the medication was addressing her gender dysphoria appropriately. Although L.W. was eager to start estrogen therapy and communicated that, Dr. Brady informed L.W., Brian and me that it was not her standard practice to start hormone therapy until L.W. was closer to 14 ½ years old to 15 years old. Eventually, after L.W. turned 14 ½ and Dr. Brady determined she was eligible for home therapy, Dr. Brady again communicated the risks and potential side effects associated with estrogen therapy, and answered our questions on which changes would be irreversible and potential impact on fertility. In September of 2022, Dr. Brady advised us that, in accordance with treatment protocols, L.W. was ready to begin estrogen hormone therapy in addition to the puberty-delaying medication.

We again provided our informed consent, and L.W. provided her assent and began treatment.

23. Since L.W. began treatment, she looks me in the eyes when we speak, she has more confidence, she is fully present, and not only does she accept hugs, but she also gives hugs. Brian and I feel confident that L.W. is receiving medical care that supports her physical and mental health and that is ensuring she can thrive, which is the most important thing to us as parents.

24. It's hard to describe the difference that L.W.'s medical treatment has made in L.W.'s life and our family life. We have a confident, happy daughter now, who is free to be herself. I noticed a huge change at her fourteenth birthday party in February of 2022, the first party we threw for her after she had come out. My daughter was the belle of the ball and was very outgoing and had a huge group of friends attend. I knew this change was due to the care she was receiving, which has allowed her to live authentically.

25. The positive changes that I have seen in L.W. are a large part of the reason I am so afraid of what this legislation will mean for her. The stress and anxiety L.W. experiences because of her gender dysphoria are debilitating, and I do not want to see her go back to the dark place she was in prior to coming out and receiving the life-saving treatment she needs.

26. I have already heard from L.W.'s providers at Vanderbilt that L.W. will no longer be able to receive treatment beginning July 1, 2023. Not only would there be devastating harm to L.W.'s mental health from the loss of access to her medication and healthcare, but there would also be irreversible physical harm as she would experience a puberty completely foreign to her

and inconsistent with her gender. As a mother, I could not bear watching my child go through physical changes that would destroy her well-being and cause her life-long pain.

27. Brian and I have also discussed what this law could mean for our family's future. I have been living in Tennessee for almost 20 years, I met my husband in Tennessee, and gave birth to my two beautiful children in Tennessee. My husband's entire family lives in Tennessee, including his aging parents. This is where our children have lived for their entire lives, and this is their home where all their friends and close family are.

28. This legislation has been so difficult on my youngest child as well. If we had to move out of state, O.W. would be devastated to leave his school and his close group of friends. In fact, he told me what he would say to our state legislature if he had the chance—that these laws don't just harm transgender kids, but also their entire family.

29. Both Brian and I have jobs we love and have created community in the state we love. We want do not want to leave Tennessee, but this legislation would force us to either routinely leave our state to get our daughter the medical care she desperately needs (traveling hours to access care while sacrificing work and personal time), or uproot our entire lives and leave Tennessee. No family should have to make this kind of choice.

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

Dated: Apr. 18, 2023 /s/ SAMANTHA WILLIAMS
SAMANTHA WILLIAMS

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

Case No. 3:23-cv-00376

L.W., BY AND THROUGH HER PARENTS AND NEXT FRIENDS, SAMANTHA WILLIAMS AND BRIAN WILLIAMS, ET AL., PLAINTIFFS

v.

JONATHAN SKRMETTI, IN HIS OFFICIAL CAPACITY AS THE TENNESSEE ATTORNEY GENERAL AND REPORTER, ET AL., DEFENDANTS

DECLARATION OF JANE DOE

I, Jane Doe, pursuant to 28 U.S.C § 1746, declare as follows:

1. I make this declaration of my own personal knowledge, and, if called as a witness, I could and would testify competently to the matters stated herein.

2. I am 52 years old. My husband, James Doe, and I are the parents of John Doe ("John"), our twelve-year-old son. Our family lives in Tennessee.

3. My son has always been a precocious child who hit many milestones early. He was walking by nine months and had an impressive vocabulary at a young age. He was always mature for his years, which is why people often referred to him as an old soul when he was a child. While he could be mischievous, he has a real tenderness with younger children and animals, and his kind heart is one of the many things I love about him.

John picks up many things naturally, from playing the guitar to a variety of different sports, and he is quite gifted athletically. He is also a typical "tween" on the cusp of becoming a teenager, and he loves playing virtual reality games with his friends in between homework and sports practices.

4. John is transgender. He knew from a very young age who he was. I remember that as early as two to three years old he was deeply upset with the typically female clothing I bought for him. I quickly learned that he would shun anything floral, pink, and feminine. He wanted to wear blue and preferred clothing related to Marvel superheroes and Star Wars. We had painted his room very early on in purple and yellow, with a floral design. But John grew happier and happier as we covered the paint up with posters of the Avengers and Star Wars decorations, and a rack for his light sabers.

5. Looking back now, I can see that participating in sex-separated activities with the girls made him miserable, including an all-girls soccer team when he was four years old. He also took part in dance classes, but always wanted to know why he couldn't dance the boy parts. When it was time for formal rehearsals and he needed to wear the girls' costume he would get so upset and ask why he couldn't wear the boys' outfit. I feel some sadness now when I look back on his dance recitals, because I recall how upset it made him when I put makeup and the girls' costumes on him for the performances.

6. Around the age of three, John began saying repeatedly, "I wish I was a boy." He told us this over and over again. We learned around the same time that he had adopted a typically male name for himself and was telling other children that he was a boy. For example,

I remember being at the park with John when he was three or four years old. I recall him running off with some other children to play, and when we eventually got ready to leave his friends said, "Bye, John." That was the first time I understood that he had adopted this new name for himself. We eventually learned that it wasn't just with kids on the playground. He was also telling his friends at school his new name and that he was a boy.

7. I was generally familiar with the concept of being transgender, but I didn't know much about it at the time. I began talking to John's pediatrician, and doing my own research.

8. Then, when John was in the first grade, we noticed that he began trying to make an effort to be more feminine. When I eventually learned the reason why, it broke my heart. He was participating in Girl Scouts that year and grew his hair longer, but he could not change the way he felt and trying to live as a girl made him more and more miserable. One day as we drove home from a Girl Scouts' swim party at the end of his first-grade year in 2018 I could tell that he was really sad, and I asked what was wrong. He said again, "I wish I was a boy." I said something like, "You haven't told us that for some time." He informed me that he had stopped because in his words, "I thought you and Dad weren't listening to me." That was the moment I knew he had simply been pretending to be more feminine during his first-grade year and was suppressing who he was because he thought that's what his parents wanted. Knowing that felt like a dagger through the heart.

9. I pulled my husband aside as soon as we arrived home to tell him what happened, and we both sat down with John and asked him, "What if you could be John,

and just be a boy all the time?" His eyes got as big as saucers—I could see he hadn't even realized that it was a possibility and that he was imagining that kind of happiness in his life. It was as if a light came on for him. While I can't suggest the transition was easy for all of us—there have been a number of hard moments—I have seen him clearly for who he is since that day.

10. We reached out to a local LGBTQ resource center, and they suggested a therapist who treats transgender youth. John has seen that therapist since that time, for approximately five years now. The therapist confirmed that John is transgender and diagnosed him with gender dysphoria.

11. As we prepared for John's second-grade year, I spoke with the principal of his school, fearing that we would need to transfer to find an affirming environment. But the principal told us, "You're not going anywhere. We love all our kids no matter their differences."

12. John began second grade in 2018 and we started planning the timeline for his social transition, so that he could be himself in all aspects of his life and not just at home. Our original plan was to have John come back to school after the Christmas holiday as himself. But that timeline changed after we went on a camping trip during the fall where John got to be himself fulltime, including when he introduced himself to others we met on the trip. He was overjoyed to be himself. When he had to revert to pretending to be a girl after we came back home, his mental health quickly deteriorated. He was depressed, angry, and defiant. We decided to move the timeline up so that he could transition at school after Thanksgiving break. Our principal met with the staff to

facilitate the transition, and we had a meeting with the other parents in John's class. Everyone was supportive, and when John came back after the break, to our profound relief, he simply got to settle in as himself, finally.

13. The following year, in 2019, we obtained a court order updating John's legal name to the typically male name he had chosen for himself years ago. We also helped him choose a new middle name reflecting his male identity.

14. In 2020, when John was approximately nine years old, I got him a book called "The Care and Keeping of You," which is a book designed to help kids understand how their bodies will change during puberty, and how to maintain good grooming habits. I bought the female version because John wasn't yet on any medication to change his body. When I showed him the book, he was absolutely mortified at the notion of his body undergoing the changes of a typical female puberty, and it became clear that we needed to explore the possibility of medical treatment to prevent that.

15. The same year, our pediatrician referred us to Dr. Cassandra Brady at Vanderbilt Children's Hospital ("Vanderbilt"). John's therapist, who had seen John for approximately two years by that point, wrote a letter for Dr. Brady confirming his diagnosis of gender dysphoria. Her letter confirms that he has no co-occurring diagnoses; that his mental health appeared stable; that our family was actively engaged in the process of his treatment; and that John, his father, and I are all able to provide informed consent.

16. Dr. Brady began running tests to monitor the development of John's puberty, which had not yet begun,

and continued to monitor him during that pre-pubertal phase every six months.

17. In approximately February of 2021, Dr. Brady determined that John was beginning puberty, and he received his first shot of Lupron, a puberty-delaying medication. This was an enormous relief for John. Before starting medication he had enormous anxiety about the prospect of developing breasts and starting menstruation. The idea was so distressing to him that he asked us repeatedly about when he could start puberty-delaying medication. But the process through Vanderbilt was slow and deliberative, which was reassuring to us as parents. When John was finally able to start Lupron, I could see that it was like a weight was lifted for him. His relief at no longer having to carry the stress of an impending puberty that felt completely wrong for him was palpable. He could just be himself.

18. The informed consent process was a lengthy one. Even though John was a couple of years away from initiating puberty delaying treatment when we first saw Dr. Brady, she thoroughly reviewed the potential side effects with us during our first visit. For example, she reviewed the fact that patients must be monitored to ensure that the medication does not have any significant effect on bone density, and that it can initially slow one's growth in height. We continued to discuss potential side effects with Dr. Brady in most, if not all, of the subsequent visits. We were also advised that the use of puberty-delaying medication to treat gender dysphoria has not been approved by the U.S. Food and Drug Administration.

19. My husband and I had also done our own research on this medication, which was consistent what

the information Dr. Brady shared with us. We agreed, along with John and Dr. Brady, that the benefits he was likely to gain from the treatment far outweighed the risk of these side effects.

20. Since the initiation of the puberty-delaying treatment, Dr. Brady has monitored John carefully with regular appointments and tests approximately every four to five months to ensure that John is not experiencing serious side effects from the medication. The only thing John has experienced is that he is sometimes more emotional for about a week-and-a-half after each shot, which is now administered by his pediatrician once every three months. Dr. Brady also monitors John carefully to track his bone age, his height and rate of growth, and his body mass index.

21. When the time is right, John wants to begin receiving testosterone. Dr. Brady has made clear that he will not qualify for this treatment for another year or two, which will allow him to go through puberty within the same range as his peers. But that care is banned by the new law, which is devastating.

22. Even setting aside the hormone therapy that we know John will need soon, if we had to stop John's current puberty-delaying care in the interim, it would be extremely emotionally damaging to him. When this legislation was pending, we discussed with John what it would be like if he had to stop puberty-delaying medication. He was horrified at the idea and it was clear that it would wreck him to start a typically female puberty.

23. Resolving this issue is urgent for us. Dr. Brady has informed us that despite the grandfather clause in the law, she cannot continue providing the same puberty-delaying care after July 1, 2023. She informed us that

her understanding is that the law allows her to do nothing more than wean patients off their care after July 1, 2023, and because she believes that would be inappropriate and harmful to John, she will not continue to treat him.

24. Having to end John's gender-affirming care would be my worst nightmare, as it is the one thing that gives me hope that John will have a fulfilling life and that keeps him happy and healthy. The care he is receiving now also preempts the need for surgery later in life and prevents some of the permanent changes in his body that a feminizing puberty would cause.

25. Having control over John's healthcare allows us to protect his safety, because the care allows others to see him as the boy that he is, and he can decide when it's safe to tell others that he is transgender on his own terms. If we had to stop this care for him, I fear not just that his mental health would backslide dramatically, but that he might harm himself too. The thought is unbearable.

26. We have started researching potential locations to seek this care out-of-state should the ban take effect. Having to travel an extensive distance out of state for this care would be disruptive, costly, and time-consuming, including because there is no place we could travel without needing to stay overnight. We would need to pull John out of school to travel for his medical appointments, which would be an extremely frustrating price to pay, in addition to the disruption to our work schedules. We also worry that having to seek the care out of state, and possibly out of network, might affect the insurance coverage that we rely upon to cover the cost of this care.

27. We have also discussed moving to a state in the Midwest where we have other family, but in addition to the stress it would cause to have to find new employment in another state, it is clear that it would upset John to be uprooted from the only home he has ever known and dragged away from all of his friends.

28. John's gender transition has not been easy, and I shed many tears during the first year of this process when John was in the second grade. This is what I think many people don't understand: no parent would choose to make their child different, or choose a harder path in life for their child. As parents, we're supposed to pave the path so that our children's lives can be easier and better. I know that being a boy is who John is and that we have done the only right thing for him. But in a world full of hostility towards transgender people, I feel like the legislature has made it even worse by singling out transgender kids with this law.

29. When I think about how we know that transition was the right thing for John, I just see his face in my mind. I can see him beaming after he was able to put his male name on his folder and his locker at school. I remember the way he smiled when we had a celebration dinner at a restaurant after the court granted his name change petition. I can see vividly how he glowed when he was able to wear a boys' suit on a trip to the Apple store. And I remember how happy and excited he was when he got to start guitar lessons with someone who had never known him pre-transition, so he could meet that person as himself.

30. As parents, you know that if you let your child be who they are, their life might be hard at times, and you don't put yourself and your child through this unless

you know it is the right thing to do. We have questioned ourselves and reevaluated the transition process every step of the way. We waited for some time to legally change John's name because we wanted to make sure we were doing the right thing. He didn't start Lupron until he was 10, three years after his social transition. We did not rush the process at any stage. Instead, we took it slowly and listened to his doctors. While I have worried at times that John will have difficult moments in life as a transgender boy, I know nothing would be harder than denying the reality of who he is.

31. If this law took effect, we know that it would set John and our family back tremendously, and I cannot bear that thought.

* * *

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

Dated: Apr. [17], 2023 /s/ JANE DOE
JANE DOE

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

Case No. 3:23-cv-00376

L.W., BY AND THROUGH HER PARENTS AND NEXT FRIENDS, SAMANTHA WILLIAMS AND BRIAN WILLIAMS, ET AL., PLAINTIFFS

v.

JONATHAN SKRMETTI, IN HIS OFFICIAL CAPACITY AS THE TENNESSEE ATTORNEY GENERAL AND REPORTER, ET AL., DEFENDANTS

DECLARATION OF SUSAN N. LACY, MD, FACOG

I, Susan N. Lacy, MD, FACOG, pursuant to 28 U.S.C § 1746, declare as follows:

1. I make this declaration of my own personal knowledge, and, if called as a witness, I could and would testify competently to the matters stated herein.

2. I graduated from Johns Hopkins Medical School in 1993 and completed a residency in Obstetrics and Gynecology in 1997 at the University of Tennessee in Memphis.

3. I am a physician licensed to practice medicine in the state of Tennessee. I am board-certified by the American Board of Obstetrics and Gynecology, which also qualifies me to be designated as a Fellow of The American Congress of Obstetricians and Gynecologists ("FACOG").

4. I have been practicing medicine in Tennessee for over 25 years.

5. I operate a private practice in Memphis, Tennessee. At my practice we deliver a comprehensive range of reproductive health services and meet the unique needs of both transgender and cisgender people by providing accessible, quality care in gynecology, hormone therapy, transgender care (including providing gender-affirming hormone treatment for gender dysphoria in both adolescent and adult patients), wellness programs, and aesthetic services.

6. Between 2016 and 2019, I worked at clinic providing services similar to my current practice. Before that, I was a general practice obstetrician and gynecologist ("Ob/Gyn") for over a decade.

7. When I began to treat patients with hormone therapy for gender dysphoria in 2016, I had over 15 years of experience prescribing the same hormones to cisgender patients as part of my gynecologic practice.

8. While providing gender-affirming care at the clinic where I worked from 2016 to 2019, I typically treated transgender people ages 16 and up. In addition to hormone therapy, I also provided contraceptive management, general gynecologic care, STI screenings, and HIV prevention. During that time, I treated between 100-200 transgender patients with gender dysphoria.

9. While I was working at the clinic prior to my current practice, my transgender patients often shared with me how hormone therapy helped them start to feel more like themselves. Because I come from a family of scientists, seeing the same, repetitive results across socio-economic and racial backgrounds crystallized how

integral gender-affirming care is to patients' mental and physical health.

10. When I founded my current practice, I knew that I wanted to continue providing gender-affirming care and ensure that the delivery of this healthcare is at the forefront of my practice because of the significant unmet need in the community. I knew that providing gender-affirming care to my transgender patients with gender dysphoria was something I could do to improve the health and wellbeing of transgender community members within Memphis.

11. I currently provide a variety of comprehensive healthcare services to transgender patients, including hormone therapy for patients with gender dysphoria, fertility services, and reproductive healthcare.

12. I treat post-pubertal, transgender patients with hormone therapy from ages 16 and up. For transgender children who have not yet started puberty, I refer parents to a pediatric endocrinologist that specializes in providing that care.

13. When treating transgender patients under 18, I require that they have a gender dysphoria diagnosis and evaluation from a psychotherapist prior to initiating hormone therapy. Additionally, the intake process with transgender patients under 18 always includes the patient's parents who are required to provide consent on behalf of their child for all medical treatment after being informed of the risks and benefits of treatment.

14. I treat my minor transgender patients in accordance with the standards of care developed by the World Professional Association for Transgender Health ("WPATH") and the University of California, San Fran-

cisco Guidelines for the Primary Care of Transgender and Gender Nonbinary People.

15. For my transgender patients who are receiving hormone therapy, I regularly monitor their bloodwork to assess hormone levels, blood count, and liver and kidney function. This type of monitoring helps ensure that patients are generally healthy and also minimizes the risk of any adverse side effects from treatment.

16. At my current practice, the same medications I provide to my transgender patients—testosterone, estrogen, testosterone suppressants, and hormonal contraception—I also provide to cisgender patients. For example, I provide hormonal contraception, which can be used to control one's cycle and/or for ovulation suppression, to cisgender patients who might have heavy periods. To treat hormonal issues in cisgender women who are pre-menopausal or cisgender men who are approaching andropause (declining levels of testosterone), I also utilize hormone therapy to maintain hormones within the typical range for the patient's gender. Additionally, the medications that are used to suppress testosterone can be used to address symptoms of polycystic ovarian syndrome, which can include unwanted facial hair and body hair, excessive sweating, and body odor in cisgender woman.

17. I currently treat 350-400 transgender patients. Of the 350-400 patients I treat, twenty patients are currently under age 18. Sixteen other patients were minors when I started treating them, but are now over age 18. Treating transgender adolescents and continuing to provide treatment for them into adulthood has shown me how access to gender-affirming care, which reduces dysphoria, allows these young adults to thrive.

18. To date, none of my transgender patients have expressed to me that they regret seeking gender-affirming care. I have had a handful of patients who have discontinued hormone therapy but none regretted treatment and all continued to identify as transgender or nonbinary.

19. If Senate Bill 1 ("the Health Care Ban" or "the Ban") takes effect, I will be required to either fully comply with the law and therefore abandon my patients or risk losing my medical license, which will not only deprive me of the ability to provide medical care to all of my patients but also negatively impact my livelihood. I understand that unless enforcement of the law is enjoined, beginning July 1, 2023, I will be barred from providing hormone therapy to treat gender dysphoria in my adolescent patients. Furthermore, it is my understanding that I must stop providing hormone therapy to adolescent patients who are already receiving treatment for gender dysphoria as of March 31, 2024. I anticipate that some of my current minor patients will be able to continue to receive care outside Tennessee after March 31, 2024, but for those who are unable to do so, I will have to modify the course of treatment I would otherwise provide to prepare them for the termination of medically necessary care.

20. I am deeply concerned about the prospect of no longer being able to provide my patients with medically necessary, gender-affirming care. Moreover, the Ban will place me in direct conflict with the accepted, evidence-based guidelines for treating my transgender patients with gender dysphoria. Being prohibited from treating my patients in accordance with existing evidence and clinical guidelines is an awful scenario that no medical provider should be forced to face.

21. The impact of the Ban will lead to delays in transgender adolescents being able to access potentially life-saving healthcare. In my experience, transgender adolescents significantly benefit from having access to compassionate and comprehensive gender-affirming care, including hormone therapy. I am concerned that if transgender adolescents cannot access hormone therapy through healthcare providers, some may resort to other methods of accessing care that include buying medication from unauthorized suppliers and using medication that they get from friends. This can lead to transgender adolescents taking the incorrect dosage and some will not have their hormone levels monitored through lab work. It is vital to have this care administered through a relationship with a qualified medical professional so that it includes ongoing monitoring of hormone levels for patient safety.

22. I am already seeing the impact of the Health Care Ban on access to hormone therapy. Recently, I had a conversation with an adolescent patient and their parents about the impact the Health Care Ban will have on initiating hormone therapy to treat the patient's gender dysphoria. As this conversation illustrated, the law is placing undue stress and pressure for some on the timeline for initiating care, since patients fear that if they have not begun care by the law's arbitrary deadline, they will be cut off from access altogether.

23. As a medical provider of minor patients who experience gender dysphoria, I have developed a close relationship with both my patients and their families. Seeking and receiving treatment for gender dysphoria is a profoundly personal and informed decision based on a person's innermost sense of self and individual needs. It is also a subject that remains very misunderstood by

the public at large. As a result, many of my patients require complete privacy, and I believe that as a medical provider it is my duty and obligation to advocate on behalf of those patients who are unable to publicly advocate for themselves.

24. I am deeply concerned for my young transgender patients because my experience leads me to believe that denying my patients access to gender-affirming hormone therapy can lead to depression, increase anxiety, and possibly lead to suicidal ideation.

25. Being forced to essentially desert patients who have come to trust me and depend on me for this critically-important care runs contrary to the commitment I made as a physician—to not deny my patients access to medically necessary care that can be lifesaving for some.

* * *

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

Dated: Apr. 18, 2023 /s/ DR. SUSAN LACY, MD
DR. SUSAN N. LACY, MD, FACOG

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

Case No. 3:23-cv-00376

L.W., BY AND THROUGH HER PARENTS AND NEXT FRIENDS, SAMANTHA WILLIAMS AND BRIAN WILLIAMS, ET AL., PLAINTIFFS

v.

JONATHAN SKRMETTI, IN HIS OFFICIAL CAPACITY AS THE TENNESSEE ATTORNEY GENERAL AND REPORTER, ET AL., DEFENDANTS

EXPERT DECLARATION OF ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C

I, Armand H. Matheny Antommaria, 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 actual knowledge of the matters stated herein.

3. In preparing this declaration, I reviewed Tennessee Senate Bill 1 (hereafter "the ban"). In addition to this legislation and the materials cited herein, I have also relied on my years of research and other experience, as set out in my curriculum vitae (Exhibit A), in forming my opinions. The materials I have relied upon in preparing this declaration are the same types of materials that experts in my fields of study regularly rely

upon when forming opinions on subjects. 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.

OVERVIEW

4. I am a pediatrician and bioethicist with extensive clinical and research experience. I am the author of 41 peer-reviewed articles, which have been published in high-impact journals including the *Journal of the American Medical Association* and *Annals of Internal Medicine,* and I direct the Ethics Center at Cincinnati Children's Hospital Medical Center. I have reviewed the ban and submit this declaration to explain my disagreement with and concerns about many of the assertions offered in its support.

5. The ban singles out gender transition procedures, which I will refer to as gender-affirming medical care, for anomalous treatment, prohibiting healthcare professionals from providing gender-affirming medical care to minors.

6. The ban holds gender-affirming medical care for adolescents with gender dysphoria to a standard that many accepted medical treatments do not attain. The evidence for gender-affirming care is comparable to the evidence for many other treatments in pediatrics. The legislative findings also mischaracterize the potential benefits and risks of gender-affirming medical care and fail to demonstrate that parents or legal guardians are incapable of providing informed consent for this medical care for their minor adolescents.

7. As a result, the ban puts clinicians in the untenable position of either following state law and violating their ethical duties to promote their patients' well-being and protect them from harm, or facing professional discipline, including permanent revocation of their licenses, and other potential penalties. Either outcome results in harm to patients.

BACKGROUND AND QUALIFICATIONS

8. 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 a Professor in the Departments of Pediatrics and Surgery at the University of Cincinnati College of Medicine.

9. I received my medical degree from Washington University School of Medicine in St. Louis, Missouri in 2000. I received my PhD in Religious Ethics from The University of Chicago Divinity School in 2000. I completed my pediatrics residency at the University of Utah in 2003.

10. 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.

11. I have extensive experience as a pediatrician and as a bioethicist. I have been in clinical practice since 2003 and 30% of my current effort is dedicated to caring for hospitalized patients. 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. I regularly consult on the care of patients in the Transgender Health Clinic at Cincinnati Children's and participate in the Clinic's monthly multidisciplinary team meetings. I remain current with the medical and bioethics literature regarding the treatment of minors with gender dysphoria. I am also part of Cincinnati Children's team that cares for patients born with differences or disorders of sex development (DSD), also known as intersex traits. I chair Cincinnati Children's Fetal Care Center's Oversight Committee, which provides the Center 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 Committee on Bioethics from 2005 to 2011. I have also served as a member of 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 41 peer-reviewed journal articles, 11 non-peer-reviewed journal articles, 6 book chapters, and 28 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*. 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 meetings of professional organizations, including the Pediatric Academic Societies and ASBH. I was previously a member of the editorial boards of the *Journal of Clinical Ethics* and the *Journal of Medical Humanities*.

15. I have previously testified at deposition and trial in *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; and at deposition in *August Dekker, et al., v. Jason Weida, et al.*, United States District Court, Northern District of Florida, Case No. 4:22-cv-00325-RH-MAF. I have also previously testified in the preliminary injunction phase in the following matters: *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; and *Brianna Boe, et al., and United States v. Marshall, et al.*, United States District Court, Middle District of Alabama Northern Division, Case No. 22-cv-184-LCB-CWB. 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.

THE TREATMENT OF GENDER DYSPHORIA IS SUPPORTED BY EVIDENCE COMPARABLE TO THE EVIDENCE FOR MANY OTHER MEDICAL TREATMENTS

Clinical Practice Guidelines

16. Medical professional organizations develop clinical practice guidelines to provide clinicians with helpful, evidence-based recommendations and improve patient care and outcomes. Clinical practice guidelines are developed using systematic processes to select and review scientific evidence. Guidelines typically rate the quality of the evidence and grade the strength of recommendations.[1]

17. Clinical practice has different goals and methods from research or experimentation. Clinical practice's goal is to benefit individual patients and its method is individualized decision-making. Research's goal is to contribute to generalizable knowledge and research is conducted using formal protocols that describe its objectives and procedures.[2] For example, a research study may have restrictive inclusion and exclusion criteria for participants in order to increase the ability of the study to draw scientifically valid conclusions. A clinician may, however, recommend a treatment to a patient who would

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[1] American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874-77; Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

[2] 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.

not have been eligible for the study because the clinician believes the treatment will benefit the patient. The clinician will subsequently make recommendations about whether to modify or discontinue the treatment based on the patient's response to it.

18. In clinical practice guidelines, the quality of evidence has been defined as "the extent to which one can be confident that an estimate of effect is correct."[3] Quality of evidence is based on 4 factors: study design, study quality, consistency, and directness. The Grades of Recommendation Assessment, Development and Evaluation (GRADE) system, one widely used method of grading the quality of the evidence and the strength of recommendations, distinguishes 4 levels of evidence: "high," "moderate," "low," and "very-low." These levels are relative to one another and "low" does not necessarily mean poor or inadequate. As discussed below, a recommendation in a clinical practice guideline may be based on "low" or "very low" quality evidence, not just "high" or "moderate" quality evidence.[4]

19. With respect to study design, randomized trials generally provide "high" quality evidence.[5] In a randomized trial, participants are randomly assigned to a treatment or a comparison group. The major benefit of a randomized trial is that it decreases the likelihood that any differences in the outcomes between the

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[3] Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

[4] Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

[5] Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

groups is the result of baseline differences between the groups rather than the result of the intervention.[6]

20. By comparison, observational studies generally constitute "low" quality evidence.[7] Observational studies include cross-sectional and longitudinal studies. 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. An example of a cross-sectional study related to gender-affirming medical care is Jack L. Turban and colleagues' analysis of data from the 2015 United States (US) Transgender Survey. The survey asked transgender adults, who were recruited through community outreach, about their demographics, past gender-affirming medical care, family support, and mental health outcomes. The investigators found those who received pubertal suppression had lower odds of lifetime suicidal ideation compared to those who wanted treatment with pubertal suppression but did not receive it.[8] In longitudinal studies, researchers follow individuals over time, making continuous or repeated measures.[9] Examples of longitudinal studies include the studies of

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[6] Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2023.

[7] Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

[8] Turban JL, King D, Carswell JM, Keuroghlian AS. Pubertal suppression for transgender youth and risk of suicidal ideation. *Pediatrics*. 2020;145(2):e20191725.

[9] Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2023.

the associations between gender-affirming medical care and psychological outcomes discussed below.[10]

21. The labels "high" and "low" quality evidence can be misleading if the latter is used in the colloquial sense of poor or inadequate. While randomized controlled 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 sufficient to justify treatment recommendations.[11]

22. At times, it may 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 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

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[10] See, for example, 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):2276-83.

[11] 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.

generalizable knowledge due to an inadequate sample size.[12]

23. Clinical research focusing on children is less likely to use randomized trials than is clinical research for adults. Potential reasons for this disparity include the low prevalence of childhood disease, small market share for therapeutic agents in children, low level of National Institutes of Health funding, and difficulty enrolling children in research.[13]

24. When making recommendations, the authors of guidelines consider a variety of factors; the quality of the evidence is only one factor considered in making recommendations. Other considerations include the balance between desirable and undesirable outcomes, confidence and variability in patients' values and preferences, and resource use.[14] The GRADE system distinguishes "strong" and "weak" recommendations; if the authors are highly confident in the balance between desirable and undesirable consequences, they make a "strong" recommendation and, if they are less confident, a "weak" recommendation.[15] The larger the dif-

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[12] Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA*. 2000;283(20):2701-2711.

[13] Martinez-Castaldi C, Silverstein M, Baucher H. Child versus adult research: The gap in high quality study design. *Pediatrics*. 2008;122(1):52-57.

[14] Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490; Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

[15] Andrews J, Guyatt G, Oxman AD, et al. GRADE guidelines: 14. Going from evidence to recommendations: The significance

ferences between the desirable and undesirable consequences and the lesser the variability in patient values and preferences, the more likely a "strong" recommendation is warranted. "Low" quality evidence may be sufficient to make a "strong" recommendation.[16]

25. Recommendations for pediatric care made by professional associations in guidelines are seldom based on well-designed and conducted randomized controlled trials due to their rarity. Instead, recommendations 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 refers to the consensus of experts when studies are not available.

26. For example, of the 130 recommendations in the American Heart Association's guideline for Pediatric Basic and Advanced Life Support, only 1 (0.8%) is based on "high-quality evidence from more than 1 [randomized clinical trial]" and 3 (2.3%) on "moderate-quality evidence from 1 or more [randomized clinical trials]." The remainder of the recommendations were based on lower quality evidence. Among its 57 "strong" recommendations (both Class 1 and Class 3 Harm), 48 (84%) are based on "limited data" or "expert opinion."[17] Table 1 (Exhibit B).

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and presentation of recommendations. *J Clin Epidemiol*. 2013;66(7):719-725.

[16] Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

[17] Topjian AA, Raymond TT, Atkins D, et al. Part 4: Pediatric basic and advanced life support: 2020 American Heart Association

Clinical Practice Guidelines for Gender-Affirming Medical Care for Minors

27. Gender-affirming medical care is not experimental; the level of evidence supporting clinical practice guidelines recommendations regarding gender-affirming medical care for adolescents is comparable to the level of evidence supporting many other pediatric medical treatments.

28. The ban's legislative findings characterize gender-affirming medical care for minors as "experimental" and "not supported by high-quality, long-term medical studies." 68-33-101(b). Gender-affirming care for minors is not experimental in the colloquial or technical senses. It is not new, novel, or unproven. The first reference to the use of puberty blockers for the treatment of gender dysphoria in the medical literature was in 1998, approximately 25 years ago.[18] Prospective observational trials of puberty blockers began recruiting participants in 2000.[19] Evidence for this this medical

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guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2020;142(16_suppl_2):S469-S523. These clinical practice guidelines use different terminology than the GRADE approach for describing the quality of the evidence and the strength of recommendations.

[18] Cohen-Kettenis PT, van Goozen SH. Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent. *Eur Child Adolesc Psychiatry*. 1998;7(4):246-248. See also Gooren L, Delemarre-van de Waal H. The feasibility of endocrine interventions in juvenile transsexuals. *J Psychol Human Sex*. 1996;8(4):69-74.

[19] 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.

care will be discussed in greater detail below. Gender-affirming medical care is also not experimental in the technical sense; it is intended to benefit individual patients and is modified based on individual patients' responses.[20]

29. 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/gender-incongruent persons, including pubertal suppression, sex hormone treatment, and surgery for gender confirmation.[21] Gender-affirming medical care is also recommended by the World Professional Association for Transgender Health's (WPATH's) Standards of Care for the Health of Transgender and Gender Diverse People which is currently in its 8th version ("SOC-8").[22] The treatments outlined in these guidelines are also endorsed by other medical professional associations including the American Academy of Family Physicians,[23]

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[20] 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.

[21] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of genderdysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

[22] Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, Version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259.

[23] American Academy of Family Physicians. Care for the transgender and gender nonbinary patient. Accessed January 8, 2023. Available at https://www.aafp.org/about/policies/all/transgender-nonbinary.html#:~:text=The%20American%20Academy%20of%

the AAP,[24] the American College of Obstetricians and Gynecologists"[25] the American Medical Association,[26]

20Family,patients%2C%20including%20children%20and%20adolescents.

[24] Rafferty J, Committee on Psychosocial Aspects of Child and Family Health, Committee on Adolescence, et al. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. *Pediatrics*. 2018;142(4): e20182162.

[25] American College of Obstetricians and Gynecologists. ACOG Committee Opinion Number 823: Health care for transgender and gender diverse individuals. March 2021. Accessed January 8, 2023. Available at https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals/; American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice and Committee on Health Care for Underserved Women. Health care for transgender and gender diverse individuals: ACOG Committee Opinion, Number 823. *Obstet Gynecol*. 2021;137(3):e75-e88.

[26] American Medical Association. Removing financial barriers to care for transgender patients H-185.950. 2022. Accessed January 8, 2023. Available at https://policysearch.ama-assn.org/policyfinder/detail/H-185.950?uri=%2FAMADoc%2FHOD.xml-0-1128.xml; Madara JL to McBride B. April 26, 2021. Accessed January 8, 2023. Available at https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-4-26-Bill-McBride-opposing-anti-trans-bills-Final.pdf.

the APA,[27] the American Psychological Association (APA),[28] and the Pediatric Endocrine Society.[29]

30. The Endocrine Society clinical practice guideline includes 28 recommendations: 3 (11%) are based on "moderate," and 19 (68%) are based on "low" or "very low" quality evidence. The remaining 6 (21%) recommendations are Ungraded Good Practice Statements.[30] Table 2 (Exhibit C).

31. The quality of the evidence supporting these recommendations is similar to the quality of the evidence supporting the recommendations in other Endocrine Society clinical practice guidelines for the pediatric population. For example, none of the Endocrine Society's 84 recommendations in its 2 other guidelines that focus on the pediatric population—guidelines on pediatric

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[27] American Psychiatric Association. Position statement on treatment of transgender (trans) and gender diverse youth. July 2020. Accessed January 8, 2023. Available at https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Policies/Position-Transgender-Gender-Diverse-Youth.pdf.

[28] American Psychological Association. Transgender, gender identity, and gender expression non-discrimination. August 2008. Accessed January 8, 2023, Available at https://www.apa.org/about/policy/transgender.pdf.

[29] Endocrine Society and Pediatric Endocrine Society. Transgender health: Position Statement. December 2020. Accessed January 8, 2023. Available at https://www.endocrine.org/advocacy/position-statements/transgender-health; Anton BS. Proceedings of the American Psychological Association for the legislative year 2008: Minutes of the annual meeting of the Council of Representatives. *Am Psychol.* 2009;64:372-453.

[30] 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.

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.[31] Table 2 (Exhibit C).

32. With respect to puberty-delaying medication, the Endocrine Society specifically "suggest[s] that adolescents who meet diagnostic criteria for [gender dysphoria]/gender incongruence, fulfill criteria for treatment, . . . and are requesting treatment should initially undergo treatment to suppress pubertal development."[32] The evidence for this recommendation includes a longitudinal study of a group of 70 transgender adolescents who were evaluated using objective measures prior to both pubertal suppression and sex hormone treatment. The mean length of time between the start of pubertal suppression and sex hormone treatment was 1.88 years and ranged from 0.42 to 5.06 years. The study showed statistically significant decreases in

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[31] 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):4043-4088; 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.

[32] 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.

behavioral and emotional problems and depressive symptoms, and increases in general functioning.[33]

33. This is the same level of evidence as supports the use of puberty blockers for the treatment of central precocious puberty which the ban permits. Central precocious puberty is the premature initiation of puberty, before 8 years of age in people assigned female at birth and before 9 in people assigned male, by the central nervous system. The potential negative effects of precocious puberty can include impairment of final adult height as well as antisocial behavior and lower academic achievement. There are no randomized trials evaluating the adult height of treated and untreated individuals. Most studies are observational and compare pretreatment predicted final height with actual final height. These studies have additional limitations including small sample sizes. This "low" quality evidence nonetheless is sufficient to support the use of GnRH agonists as treatment for central precocious puberty.[34] The ban therefore subjects the use of puberty blockers to a double standard. There are no randomized clinical trials for the use of puberty blockers to treat precocious puberty or gender dysphoria, but the evidence is deemed sufficient for the former but not the latter.

34. The evidence supporting the guideline's recommendations regarding gender-affirming hormone treatment in adolescents include Cohen-Kettenis and col-

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[33] See 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.

[34] Mul D, Hughes IA. The use of GnRH agonists in precocious puberty. *Eur J Endocrinol.* 2008;159 Suppl 1:S3-8.

leagues' longer-term follow-up of individuals after pubertal suppression through sex hormone and gender-affirming surgical treatment. Participants' mean age at their initial assessment was 13.6 years and their mean age at their final assessment was 20.7 years. The researchers report the resolution of gender dysphoria and improvement in psychological functioning.[35]

35. As a result of these studies and healthcare providers' subsequent experience, randomized, placebo-controlled trials (trials that compare pharmacological treatment to no pharmacological treatment) of gender-affirming medical care 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 a sufficient number of participants would enroll in randomized controlled trials for them to be informative.[36]

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[35] See 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. Additional longitudinal studies of the psychosocial effects of pubertal suppression to treat gender dysphoria include Costa R, Dunsford M, Skagerberg E, Holt V, Carmichael P, Colizzi M. Psychological support, puberty suppression, and psychosocial functioning in adolescents with gender dysphoria. *J Sex Med.* 2015;12(11):2206-2214 and Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12- to 15-year old young people with persistent gender dysphoria in the UK. *PLoS One.* 2021;16(2):e0243894.

[36] 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

36. Even if such studies could be conducted ethically, 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 participants were in the intervention or other 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 and lower the rating of the study's quality.[37]

GENERALLY APPLICABLE PRINCIPLES OF INFORMED CONSENT APPLY TO PEDIATRIC GENDER-AFFIRMING MEDICAL CARE

37. Before performing any medical intervention, a healthcare provider must generally obtain an adult patient's informed consent. Informed consent is a process in which the provider discloses information, elicits the patient's preferences, offers medical advice, and seeks explicit authorization. In order to participate in the informed consent process, a patient must have medical decision-making capacity. If an adult patient lacks capacity, a proxy decision maker is generally appointed. The healthcare provider's disclosure should include the nature of the intervention and the reasons for it, as well as its potential benefits, risks, and alternatives, including the alternative of not undergoing the intervention.

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health research. *Curr Opin Endocrinol Diabetes Obes*. 2016;23(2):198-207.

[37] Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2023; Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

The patient or the patient's proxy must understand and appreciate this information and express a decision. For the informed consent to be valid, the authorization must be voluntary. Exceptions to the requirement to obtain informed consent exist, such as in the case of an emergency.[38]

38. Medical decision-making and informed consent in pediatrics is more complex than in adult medicine because it involves both minor patients and their parents or legal guardians. Parents and guardians are afforded substantial, but not unlimited, discretion in making medical decisions for their minor children based on their assessment of the individual child's best interest. They generally care about their children and best understand their children's unique needs.[39]

39. Healthcare providers also have an ethical obligation to include children in medical decision-making to the extent that it is developmentally appropriate. For example, a provider examining a toddler for a possible ear infection should not ask a toddler for permission to look in the child's ear because the provider intends to look even if the child says no. The provider could, however, ask the toddler which ear the child would like to have looked in first. As a minor becomes older, the minor should participate more actively in medical decision-making and the minor's assent should be sought. In early adolescence, individuals typically have developed a sense of identity, individual values and

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[38] Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 6th ed. Oxford University Press; 2009.

[39] Diekema DS. Parental refusals of medical treatment: The harm principle as threshold for state intervention. *Theor Med Bioeth.* 2004;25(4):243-264.

preferences, and are developing medical decision-making capacity. Capacity entails the ability to (i) understand the indications and the potential benefits, risks, and alternatives to a treatment, including declining treatment; (ii) appreciate the implications of a treatment decision for their own lives; (iii) evaluate the potential benefits and risks; and (iv) express a preference.[40]

40. The current treatment paradigm for treating gender dysphoria in minors is consistent with general ethical principles instantiated in the practices of informed consent and assent. The Endocrine Society clinical practice guideline extensively discusses the potential benefits, risks, and alternatives to treatment, 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 the informed consent process for puberty blockers and sex hormones include a discussion of the implications for fertility and options for fertility preservation. The Endocrine Society clinical practice guideline also advises delaying gender-affirming hormone treatment, which results in partly irreversible physical changes, until an adolescent is developmentally capable of providing informed consent.[41]

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[40] Katz AL, Webb SA, Committee on Bioethics. Informed consent in decision-making in pediatric practice. *Pediatrics*. 2016;138(2):e20161485; Kon AA, Morrison W. Shared decision-making in pediatric practice: A broad view. *Pediatrics*. 2018; 142(Suppl 3):S129-S132.

[41] See 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 BAN MISCHARACTERIZES GENDER-AFFIRMING MEDICAL CARE, INCLUDING ITS BENEFITS, RISKS, AND ALTERNATIVES

41. The ban's legislative findings inaccurately characterize gender-affirming medical care in several different ways. The legislative findings, for example, dismiss the potential medical benefits of gender-affirming care, exaggerate its potential risks, and ignore the substantial risks of failing to provide adequate treatment. The legislative findings also do not explain why parents or guardians should have their decision-making authority substituted by the government's with respect to gender-affirming medical care.

The Ban Disregards the Benefits of Gender-Affirming Care

42. While the ban refers to medical procedures "performed for the purpose of enabling a minor to identify with, or live as, a purported identity inconsistent with the minor's sex or treating purported discomfort or distress from a discordance between the minor's sex and asserted identity," 68-33-101, it is important to note that gender-affirming medical care is treatment for a serious medical condition—gender dysphoria. Gender dysphoria is a medical diagnosis contained in the APA's Diagnostic and Statistical Manual of Mental Disorders, 5th ed, Text Revision. It is "a marked incongruence between one's experienced/expressed gender and their assigned gender" which is "associated with clinically sig-

nificant distress or impairment in social, occupational, or other important areas of functioning."[42]

43. The potential benefits of gender-affirming medical care include improved physical and psychological outcomes. Starting pubertal suppression in early puberty prevents adolescents with gender dysphoria from developing secondary sex characteristics inconsistent with their gender identity, which can be extremely distressing for them, and that may be difficult, if not impossible, to eliminate once the characteristics have fully developed. Sex hormone therapy results in the development of secondary sex characteristics consistent with individuals' gender identity. Potential psychological benefits include increased quality of life and decreased depression, suicidal ideation and suicide attempts, and anxiety.[43]

The Ban Exaggerates the Risks of Gender-Affirming Medical Care

44. The legislative findings state that gender-affirming care for adolescents "can lead to the minor becoming irreversibly sterile, having increased risk of disease and illness, or suffering from adverse and sometimes fatal psychological consequences" and that "it likely that not all harmful effects associated with these types of medical procedures when performed on a minor are yet fully known." 68-33-101(b). As with all medical treatments,

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[42] American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed, Text Revision. American Psychiatric Publishing; 2022.

[43] See, for example, Baker KE, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. Hormone therapy, mental health, and quality of life among transgender people: A systematic review. *J Endocr Soc*. 2021;5(4):1-16.

gender-affirming medical care entails risks. But the legislative findings exaggerate its potential risks and attribute harms to it without any empirical support. The fact that gender-affirming medical care has risks does not distinguish it from other forms of treatment.

45. The findings overstate the potential effects of gender-affirming care on fertility. Puberty blockers do not, by themselves, permanently impair fertility. Children with central precocious puberty are routinely treated with puberty blockers and have typical fertility in adulthood.[44] These medications are also used for fertility preservation in individuals being treated for cancer.[45]

46. While treatment for gender dysphoria with gender-affirming hormones may impair fertility, this is not universal and may also be reversible. There are transgender men who became pregnant while on or after discontinuing testosterone therapy.[46] Transgender men and women are also capable of producing eggs and

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[44] Lazar L, Meyerovitch J, de Vries L, Phillip M, Lebenthal Y. Treated and untreated women with idiopathic precocious puberty: Long-term follow-up and reproductive outcome between the third and fifth decades. *Clin Endocrinol* (Oxf). 2014;80(4):570-576.

[45] Valsamakis G, Valtetsiotis K, Charmandari E, Lambrinoudaki I, Vlahos NF. GnRH analogues as a co-treatment to therapy in women of reproductive age with cancer and fertility preservation. *Int J Mol Sci*. 2022;23(4):2287.

[46] Light AD, Obedin-Maliver J, Sevelius JM, Kerns JL. Transgender men who experienced pregnancy after female-to-male gender transitioning. *Obstet Gynecol*. 2014;124(6):1120-1127.

sperm respectively both during and after the discontinuation of gender-affirming hormone treatment.[47]

47. Additionally, offering individuals considering gender-affirming medical care methods to potentially preserve their fertility is a component of the clinical practice guidelines discussed above.[48]

48. The risk of infertility is also not unique to treatment for gender dysphoria. For example, parents and legal guardians consent to the treatment of nonmalignant medical conditions for their minor children, including some rheumatologic disorders and hematologic conditions, which may impair fertility.[49]

49. The legislative findings also state that providing gender-affirming care for minors leads to an "increased risk of disease and illness, or suffering from adverse and sometimes fatal psychological consequences." 68-33-101(b). While transgender adolescents have higher rates of depression, anxiety, suicidal ideation, and suicide attempts, there are no studies indicating

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[47] Leung A, Sakkas D, Pang S, Thornton K, Resetkova N. Assisted reproductive technology outcomes in female-to-male transgender patients compared with cisgender patients: A new frontier in reproductive medicine. *Fertil Steril.* 2019;112(5):858-865; de Nie I, van Mello NM, Vlahakis E, et al. Successful restoration of spermatogenesis following gender-affirming hormone therapy in transgender women. *Cell Rep Med.* 2023;4(1):100858.

[48] 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.

[49] Hirshfeld-Cytron J, Gracia C, Woodruff TK. Nonmalignant diseases and treatments associated with primary ovarian failure: An expanded role for fertility preservation. *J Womens Health (Larchmt).* 2011;20(10):1467-1477.

that those higher rates are caused by, or exacerbated by, providing gender-affirming medical care.[50] Rather, contributing factors include conflict between one's appearance and identity, stigma, and rejection.[51] As discussed above, the available evidence indicates that gender-affirming care improves, rather than worsens, psychological outcomes.

50. Finally, not knowing all potential harmful effects associated with a medication is not a sufficient reason for the United States Food and Drug Administration (FDA) to not approve a medication, let alone a state to ban it. The FDA requires post-marketing surveillance of medications' adverse effects because the clinical trials on which the approvals are based cannot identity all possible side effects.[52]

The Ban Ignores the Risks of Harm From Lack of Treatment

51. In determining whether the benefits of treatment outweigh the risks, medical providers and patients must also consider the risks of failing to provide treatment. As stated above, prior to the initiation of gender-affirming medical care, many individuals with gender

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[50] Haas AP, Eliason M, Mays VM, et al. Suicide and suicide risk in lesbian, gay, bisexual, and transgender populations: Review and recommendations. *J Homosex.* 2011;58(1):10-51.

[51] Bauer GR, Scheim AI, Pyne J, Travers R, Hammond R. Intervenable factors associated with suicide risk in transgender persons: A respondent driven sampling study in Ontario, Canada. *BMC Public Health.* 2015;15:525.

[52] U.S. Food & Drug Administration. Postmarketing Surveillance Programs. April 2, 2020. Accessed February 26, 2023. Available at https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs.

dysphoria have significant, unresolved symptoms that treatment improves. Without medical treatment, these symptoms would persist.

52. While the medical care ban's legislative findings assert "a minor's discordance can be resolved by less invasive approaches that are likely to result in better outcomes for the minor," 68-33-101(c), I am unaware of such approaches or any evidence supporting such claim.

The Risks and Benefits of Gender-Affirming Medical Care are Comparable to Those of Other Medical Care to which Parents and Guardians May Consent

53. Medical care for minors can require weighing potential benefits and risks in the face of uncertainty. There is nothing unique about gender-affirming medical care that justifies singling out this medical care for prohibition based on concern for adolescents' inability to assent or parents or guardians' inability to consent. Medical decisions regarding treatment for gender dysphoria should continue to be left to the discretion of adolescents, their parents or guardians, and their healthcare providers.

54. The potential risks of gender affirming medical care are comparable to the risks parents and adolescents are permitted to assume in numerous other treatment decisions, including decisions explicitly authorized by this legislation. Parents of children with some types of malignancies may choose treatments that may damage their children's gonads and result in infertility.[53]

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[53] Delessard M, Saulnier J, Rives A, Dumont L, Rondanino C, Rives N. Exposure to chemotherapy during childhood or adulthood and consequences on spermatogenesis and male fertility. *Int*

Individuals with some types of DSDs, such as complete androgen insensitivity syndrome, are treated with sex hormones, which have comparable risks to the use of these treatments in persons with gender dysphoria.[54] And, parents of children with some types of DSDs may choose to have their children's gonads removed due to the possible elevated risk of malignancy, which causes infertility.[55] It is also my understanding that the medical care ban permits gender-affirming medical treatment of individuals with DSDs, which has similar risks to the use of this treatment in individuals who do not have DSDs. The types of risks present for breast reduction surgery, which may be performed for cosmetic reasons or to reduce physical discomfort, are similar to those of chest surgery to treat gender dysphoria.[56]

Legislative Findings About Regret Do Not Support a Ban

55. The legislative findings state, "many individuals have expressed regret for medical procedures that were performed on or administered to them for such purposes when they were minors." 68-33-101(g). The experience of regret as a result of any medical treatment

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J Mol Sci. 2020;21(4):1454; Blumenfeld Z. Chemotherapy and fertility. *Best Pract Res Clin Obstet Gynaecol*. 2012;26(3):379-390.

[54] Lanciotti L, Cofini M, Leonardi A, Bertozzi M, Penta L, Esposito S. Different clinical presentations and management in complete androgen insensitivity syndrome (CAIS). *Int J Environ Res Public Health*. 2019;16(7):2168.

[55] Abaci A, Catli G, Berberoglu M. Gonadal malignancy risk and prophylactic gonadectomy in disorders of sexual development. *J Pediatr Endocrinol Metab*. 2015;28(9-10):1019-1027.

[56] Manahan MA, Buretta KJ, Chang D, Mithani SK, Mallalieu J, Shermak MA. An outcomes analysis of 2142 breast reduction procedures. *Ann Plast Surg*. 2015;74(3):289-292.

is profoundly unfortunate, and individuals experiencing regret should be provided support and any additional treatment needed.

56. While there have been anecdotal reports of regret, the available studies report that rates of regret are very low. For example, Chantal M. Wiepjes and colleagues report that 0.6% of transgender women and 0.3% of transgender men who had their gonads removed experienced regret.[57] Similarly, R. Hall and colleagues report regret was specifically documented in 1.1% of adult gender-diverse patients.[58] Banning gender-affirming medical care to prevent regret in a small minority of patients would result in harm to the majority of patients who benefit. Support and services should nonetheless be provided to individuals who experience regret.

57. The potential for regret is also not unique to gender-affirming medical care. Ironically, at the same time that Tennessee prohibits gender-affirming medical care for minors in the name of protecting vulnerable children, the statute expressly allows doctors to perform these irreversible genital surgeries on infants and children with DSDs at ages when they are unable to meaningfully participate in medical decision-making. The evidence base for these surgeries is poor and they are highly controversial when performed at such an

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[57] Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in prevalence, treatment, and regrets. *J Sex Med*. Apr 2018;15(4):582-590.

[58] Hall R, Mitchell L, Sachdeva J. Access to care and frequency of detransition among a cohort discharged by a UK national adult gender identity clinic: Retrospective case-note review. *BJPsych Open*. 2021;7(6):e184.

early age.[59] Parents of children who have undergone feminizing genitoplasty and hypospadias repair have experienced regret for their decisions.[60] For example, Rachel S. Fisher and colleagues found that 38% of caregivers of infants with congenital adrenal hyperplasia reported some level of regret about their child's genital surgery.

The Increased Prevalence of Gender-Affirming Care Does Not Support a Ban

58. The legislative findings state that the gender-affirming medical care is being provided "with rapidly increasing frequency." 68-33-101(g). The increased number of transgender individuals and those receiving medical treatment is likely to be multifactorial including increased social acceptance of transgender individuals and availability of gender-affirming medical care.[61] Changes in demographics are not unique to gender dysphoria and have been seen in other conditions such as autism spectrum disorder and childhood-onset type 1

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[59] Jesus LE. Feminizing genioplasties: Where are we now? *J Pediatr Urol*. 2018;14(5):407-415; Frader J, Alderson P, Asch A, et al. Health care professionals and intersex conditions. *Arch Pediatr Adolesc Med*. 2004;158(5):426-428.

[60] Fisher RS, Espeleta HC, Baskin LS, et al. Decisional regret about surgical and non-surgical issues after genitoplasty among caregivers of female infants with CAH. *J Pediatr Urol*. 2022;18(1):27-33; Vavilov S, Smith G, Starkey M, Pockney P, Deshpande AV. Parental decision regret in childhood hypospadias surgery: A systematic review. *J Paediatr Child Health*. 2020;56(10):1514-1520.

[61] Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in prevalence, treatment, and regrets. *J Sex Med*. 2018;15(4):582-590.

diabetes.[62] These changes are a justification for further research on gender-affirming medical care rather than prohibiting these treatments and thereby preventing further research on them.

Treatment Protocols in Europe Do Not Support a Ban

59. The legislative findings also point to the actions of health authorities in Sweden, Finland, and the United Kingdom as support for the state's decision to ban gender-affirming medical care.[63] It is difficult to evalu-

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[62] Christensen DL, Maenner MJ, Bilder D, et al. Prevalence and characteristics of autism spectrum disorder among children aged 4 years—Early Autism and Developmental Disabilities Monitoring Network, seven sites, United States, 2010, 2012, and 2014. *MMWR Surveill Summ*. 2019;68(2):1-19; The DIAMOND Project Group. Incidence and trends of childhood Type 1 diabetes worldwide 1990-1999. *Diabet Med*. M 2006;23(8):857-866.

[63] The relevant documents include the following: Socialstyrelsen. God vård av barn och ungdomar med könsdysfori. March 2021. Accessed November 23, 2022. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskap sstod/2015-4-6.pdf; Socialstyrelsen. Stöd, utredning och hormonbehandling vid könsinkongruens hos barn och ungdomar. February 2022. Accessed November 23, 2022. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-2-7774.pdf; Socialstyrelsen: The National Board of Health and Welfare. Care of children and adolescents with gender dysphoria: Summary. Accessed November 23, 2022. Available at https://www.socialstyrelsen.se/globalassets/sharepointdokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf; Palveluvalikoima. Medical treatment methods for dysphoria associated with variations in gender identity in minors—recommendations. June 16, 2020. Accessed November 23, 2022. Available at https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en+(1).pdf/fa2054c5-8c35-8492-59d6-b3de1c00de49/Summary_minors_en+(1).pdf?t=1631773838474; The Cass Review. Independent review of gender identity services for children

ate the actions of the Swedish and Finnish health authorities because all of the relevant material is not available in official English translations. The legislative findings characterize the authorities as conducting systematic reviews of the evidence and finding no evidence that the benefits of these procedures outweigh the risks. 68-33-101(e). This claim confuses systematic reviews of the literature and clinical practice guidelines. While both ideally grade the quality of the evidence, only clinical practice guidelines make recommendations and grade their strength. Of the documents by European health authorities that do make treatment recommendations, none rate the quality of the evidence and the strength of the recommendations.

60. Critically, none of the European health authorities has prohibited gender-affirming medical care as does Tennessee. The authorities instead emphasize the importance of multidisciplinary evaluation and treatment, including psychological care, and the need for additional research. Even though Sweden has called for the provision of gender-affirming medical care within the research context, the Swedish National Board of Health and Welfare states that doing so "does not necessarily imply the use of randomized controlled trials,"[64] acknowledging that other study designs are appropriate to evaluate gender-affirming medical care. The Eu-

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and young people: Interim report. February 2022. Accessed November 23, 2022. Available at https://cass.independent-review.uk/publications/ interim-report/.

[64] Socialstyrelsen. Stöd, utredning och hormonbehandling vid könsinkongruens hos barn och ungdomar. February 2022. Accessed November 23, 2022. Available at https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskap sstod/2022-2-7774.pdf.

ropean documents do not support the claims that gender-affirming medical care should be banned.

THE MEDICAL CARE BAN UNDERMINES THE INTEGRITY OF THE MEDICAL PROFESSION

61. The legislative findings state, "[t]his state has a legitimate, substantial, and compelling interest in protecting the integrity of the medical profession," 68-33-101(m), when in fact the ban violates the integrity of the medical profession and coerces medical professionals to violate their integrity and ethical duties.

62. The medical profession has processes by which it evaluates treatments and determines whether they are safe and effective. The ban intervenes in these processes replacing medical professionals judgement with the judgment of the legislature. The ban itself violates the integrity of the medical profession by defining a disease, gender dysphoria, as not a disease. 68-33-103(b)(2). Gender-affirming medical care is in fact "consistent with professional medical standards," 68-33-101(c), and, as described above, it is endorsed by many medical professional associations.

63. Healthcare providers have an ethical obligation to promote their patients' well-being and to protect them from harm. When providers believe that the potential benefits of gender-affirming medical care outweigh the potential risks for a particular patient, prohibiting them from providing this treatment forces them to violate their ethical obligations to their patients or risk losing their licenses and incurring financial penalties.

CONCLUSION

64. Treating adolescents with gender dysphoria with gender-affirming medical care under clinical practice guidelines, like the Endocrine Society's, is evidence-based; its potential benefits outweigh its potential risks for many patients; and these risks are well within the range of other medical decisions that adolescents and their parents or guardians have the discretion to make in consultation with their healthcare professionals.

65. Based on my research and experience as a pediatrician and bioethicist, there is no sound medical or ethical basis to prohibit healthcare professionals from providing gender-affirming medical care to minors. Doing so puts clinicians in the untenable position of having to harm their patients and violate their integrity and ethical obligations due to the threat of losing their licenses and incurring economic penalties.

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

Executed on: Apr. 13, 2023

/s/ ARMAND H. MATHENY ANTOMMARIA
ARMAND H. MATHENY ANTOMMARIA, MD, PhD

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

Case No. 3:23-cv-00376

L.W., BY AND THROUGH HER PARENTS AND NEXT FRIENDS, SAMANTHA WILLIAMS AND BRIAN WILLIAMS, ET AL., PLAINTIFFS

v.

JONATHAN SKRMETTI, IN HIS OFFICIAL CAPACITY AS THE TENNESSEE ATTORNEY GENERAL AND REPORTER, ET AL., DEFENDANTS

EXPERT DECLARATION OF JACK TURBAN, M.D.

I, Jack Turban, 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 have actual knowledge of the matters stated herein.

3. In preparing this declaration, I reviewed Tennessee Senate Bill 1 (hereafter "ban"). In addition to that legislation and the materials cited herein, I have also relied on my years of research and other experience, as set out in my curriculum vitae (Exhibit A) in forming my opinions. The materials I have relied upon in preparing this declaration are the same types of materials that experts in my field of study 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

4. I am currently an Assistant Professor of Child & Adolescent Psychiatry at the University of California, San Francisco School (UCSF) of Medicine, where I am also Affiliate Faculty at the Philip R. Lee Institute for Health Policy Studies. As a member of the faculty at UCSF, I serve as director of the Gender Psychiatry Program in the Division of Child & Adolescent Psychiatry. I also serve as an attending psychiatrist in the adult LGBT psychiatry clinic, and in the eating disorders program. I conduct research focusing on the determinants of mental health among transgender youth and teach medical students, psychology trainees, psychiatry residents, and child and adolescent psychiatry fellows.

5. I received my undergraduate degree in neuroscience from Harvard College. I received both my MD and Master of Health Science degrees from Yale University School of Medicine. I completed residency training in general psychiatry in the combined Massachusetts General Hospital / McLean Hospital residency training program (Harvard Medical School) and fellowship training in child and adolescent psychiatry at Stanford University. I am board certified in psychiatry by The American Board of Psychiatry and Neurology.

6. My research focuses on the mental health of transgender youth and gender dysphoria. While at Yale, I was awarded the Ferris Prize for my thesis entitled "Evolving Treatment Paradigms for Transgender

Youth." In 2017, I received the United States Preventative Health Services Award for Excellence in Public Health based on my work related to the mental health of transgender youth. I have lectured on the mental health of transgender youth at Yale School of Medicine, The University of California San Francisco, Stanford University, and The Massachusetts General Hospital (a teaching hospital of Harvard Medical School). I have given grand rounds presentations around the country and have presented nationally and internationally on topics related to the mental health of transgender people and people experiencing gender dysphoria.

7. I have served as a manuscript reviewer for numerous professional publications, including *The Journal of The American Medical Association (JAMA)*, *JAMA Pediatrics*, *JAMA Psychiatry*, *The Journal of The American Academy of Child & Adolescent Psychiatry*, *Pediatrics*, *The Journal of Adolescent Health*, and *The American Journal of Public Health*. I have served as lead author for textbook chapters on the mental health of transgender youth, including for *Lewis's Child & Adolescent Psychiatry: A Comprehensive Textbook* and the textbook of The International Academy for Child & Adolescent Psychiatry and Allied Professionals. I am co-editor of the textbook *Pediatric Gender Identity: Gender-Affirming Care for Transgender and Gender Diverse Youth.*

8. I have published extensively on the topic of transgender youth, including ten articles in peer-reviewed journals within the past two years.

9. I was deposed and testified at trial in *Brandt et al. v. Rutledge, et al.*, No. 21-CV-450 (D. Ark. 2021).

10. 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.

SUMMARY OF OPINIONS

11. In this declaration, I cite relevant literature to support my opinions that: (1) gender-affirming medical interventions improve mental health outcomes for adolescents with gender dysphoria when medically indicated; (2) adolescents who experience gender dysphoria at the onset of puberty rarely come to identify with their assigned sex at birth, and (3) de-transition and regret among individuals receiving medical treatment for gender dysphoria are uncommon.

GENDER-AFFIRMING MEDICAL INTERVENTIONS IMPROVE MENTAL HEALTH OUTCOMES FOR ADOLESCENTS WITH GENDER DYSPHORIA WHEN MEDICALLY INDICATED

12. The claims made by the legislature in support of the ban are not supported by data and are counter to the widely accepted views of the mainstream medical community. Existing research shows gender-affirming medical treatments for adolescents with gender dysphoria are consistently linked to improved mental health, and denial of such care is expected to lead to adverse mental health outcomes, including, in some instances, worsening suicidality.

13. The ban's assertion that gender-affirming medical care for adolescents with gender dysphoria is "not consistent with professional medical standards" is false.

All relevant major medical organizations have highlighted the importance of this care and have issued explicit statements opposing bans on gender-affirming medical care for adolescents with gender dysphoria. These organizations include The American Medical Association, The American Academy of Pediatrics, The American Psychiatric Association, The American College of Physicians, The American Academy of Family Physicians, The American Academy of Child & Adolescent Psychiatry, The Endocrine Society, The Pediatric Endocrine Society, The World Professional Association for Transgender Health, and the United States Professional Association for Transgender Health.[1]

14. The ban's assertion that gender-affirming medical care is "experimental in nature" is also incorrect. In ascribing this term to gender-affirming medical interventions, it presumably is alluding to the fact that pubertal suppression and gender-affirming hormones do not have FDA indications for gender dysphoria specifically, but rather for other conditions. Prescribing FDA-approved medications without specific FDA indications for the condition being treated is common in medicine generally and particularly in pediatrics. It is referred to as "off-label" prescribing.[2] The American Academy of Pediatrics has explained, "it is important to note that the term 'off-label' does not imply an improper, illegal, contraindicated, or investigational use."[3] The Academy

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[1] For a list of statements, please see Turban, J. L., Kraschel, K. L., & Cohen, I. G. (2021). Legislation to criminalize gender-affirming medical care for transgender youth. *JAMA*, *325*(22), 2251-2252.

[2] American Academy of Pediatrics Committee on Drugs. (2014). Policy Statement: Off-label use of drugs in children. *Pediatrics*, *133*(3), 563-567.

[3] *Id.*

goes on to explain that "off-label use of medications is neither experimentation nor research." A substantial body of evidence links gender-affirming medical interventions to improved mental health outcomes for adolescents 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.

15. Peer-reviewed cross-sectional and longitudinal studies[4] have found that pubertal suppression is associated with a range of improved mental health outcomes for adolescents with gender dysphoria, including statistically significant improvements in internalizing psychopathology (*i.e.*, anxiety and depression), externalizing psychopathology (*e.g.*, disruptive behaviors), global functioning, and suicidality.[5] For example, in the realm

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[4] A note on methodology: cross-sectional studies examine mental health at a single point in time. For example, van der Miesen et al. 2020 *Journal of Adolescent Health* compared, at a single time point, those who accessed pubertal suppression with those who desired but had not accessed it. Longitudinal studies examine multiple time points (e.g., looking at levels of suicidality before and after gender-affirming medical care).

[5] See for example, de Vries, A.L., Steensma, T.D., Doreleijers, T.A., & Cohen-Kettenis, P.T. (2011). Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study. *The Journal of Sexual Medicine*, 8(8), 2276-2283., Turban, J.L., King, D., Carswell, J.M., & Keuroghlian, A.S. (2020). Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. *Pediatrics*, 145(2):e20191725., van der Miesen, A.I., Steensma, T.D., de Vries, A.L., *et al.* (2020). Psychological Func-

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.[6] 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.[7] 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.[8]

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tioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared with Cisgender General Population Peers. *Journal of Adolescent Health*, 66(6), 699-704., and Achille, C., Taggart, T., Eaton, N.R., *et al.* (2020). Longitudinal Impact of Gender-Affirming Endocrine Intervention on the Mental Health and Well-Being of Transgender Youths: Preliminary Results. *International Journal of Pediatric Endocrinology*, 2020(8), 1-5.

[6] Turban, J.L., King, D., Carswell, J.M., & Keuroghlian, A.S. (2020). Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. *Pediatrics*, 145(2):e20191725.

[7] van der Miesen, A.I., Steensma, T.D., de Vries, A.L., *et al.* (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.

[8] See for example, de Vries, A.L., McGuire, J.K., Steensma, T.D., *et al.* (2014). Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment. *Pediatrics*, 134(4), 696-704 and Costa, R., Dunsford, M., Skagerberg, E., Holt, V., Carmichael, P., & Colizzi, M. (2015). Psychological support, puberty suppression, and psychosocial functioning in adolescents

16. Peer-reviewed research studies have likewise found improved mental health outcomes following gender-affirming hormone treatment (*e.g.,* estrogen or testosterone) for individuals with gender dysphoria, including adolescents. These include statistically significant improvements in internalizing psychopathology (*e.g.*, anxiety and depression), general well-being, and suicidality.[9] For example, Chen et al. followed a cohort of 315 transgender youth receiving gender-affirming hormone treatment and found improvements in anxiety, depression, and life satisfaction.[10] Similarly, 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

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with gender dysphoria. *Journal of Sexual Medicine*, *12*(11), 2206-2214.

[9] See for example, Chen, D., Berona, J., Chan, Y. M., Ehrensaft, D., Garofalo, R., Hidalgo, M. A., . . . & Olson-Kennedy, J. (2023). Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. *New England Journal of Medicine*, *388*(3), 240-250., Allen, L.R., Watson, L.B., Egan, A.M., & Moser, C.N. (2019). Well-Being and Suicidality Among Transgender Youth After Gender-Affirming Hormones. *Clinical Practice in Pediatric Psychology*, 7(3), 302-311., Achille, C., Taggart, T., Eaton, N.R., *et al.* (2020). Longitudinal Impact of Gender-Affirming Endocrine Intervention on the Mental Health and Well-Being of Transgender Youths: Preliminary Results. *International Journal of Pediatric Endocrinology*, 2020(8), 1-5., and de Lara, D.L., Rodríguez, O.P., Flores, I.C., *et al.* (2020). Psychosocial Assessment in Transgender Adolescents. *Anales de Pediatría (English Edition)*, 93(1), 41-48..

[10] Chen, D., Berona, J., Chan, Y. M., Ehrensaft, D., Garofalo, R., Hidalgo, M. A., . . . & Olson-Kennedy, J. (2023). Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. *New England Journal of Medicine*, *388*(3), 240-250.

Questions" instrument.[11] Cross-sectional studies comparing those who accessed gender-affirming hormones during adolescence to those who did not access these interventions have similarly linked access to gender-affirming hormone treatment during adolescence to lower odds of suicidality.[12]

17. Peer-reviewed research has also shown improvements in mental health following gender-affirming chest surgery[13] for transmasculine adolescents with gender dysphoria, where medically indicated.[14] A study

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[11] Allen, L.R., Watson, L.B., Egan, A.M., & Moser, C.N. (2019). Well-Being and Suicidality Among Transgender Youth After Gender-Affirming Hormones. *Clinical Practice in Pediatric Psychology*, 7(3), 302-311.

[12] See for example, Turban, J. L., King, D., Kobe, J., Reisner, S. L., & Keuroghlian, A. S. (2022). Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults. *PLoS One*, *17*(1), e0261039 and Green, A. E., DeChants, J. P., Price, M. N., & Davis, C. K. (2022). Association of gender-affirming hormone therapy with depression, thoughts of suicide, and attempted suicide among transgender and nonbinary youth. *Journal of Adolescent Health*, *70*(4), 643-649.

[13] Of note, all surgical interventions in pediatrics (for gender dysphoria or otherwise) are approached with substantial caution, given the risks inherit with any kind of surgery. Gender-affirming chest surgery is only considered for adolescents with gender dysphoria when an interdisciplinary team, including medical providers, surgical providers, mental health providers, the adolescent, and their legal guardians are in agreement that the benefits of such an intervention would outweigh the risks.

[14] Olson-Kennedy, J., Warus, J., Okonta, V., *et al.* (2018). Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. *JAMA Pediatrics*, 172(5), 431-436; Mehringer, J.E., Harrison, J.B., Quain, K.M., *et al.* (2021). Experience of Chest Dysphoria and Masculinizing Chest Surgery in Transmasculine

by Tang et al. examined 209 adolescents who had undergone gender-affirming chest surgery between 2013 and 2020 and found an extremely low rate of postoperative regret (0.95%).[15]

18. Overall, as summarized above, existing peer-reviewed published research studies consistently link gender-affirming medical interventions to improved mental health for individuals with gender dysphoria, including adolescents.

19. The ban asserts that adolescent gender dysphoria "can be resolved by less invasive approaches that are likely to result in better outcomes for the minor." It is notable that the medical ban does not list any specific evidence-based interventions, other than gender-affirming medical care, that treat adolescent gender dysphoria. That is because none exist. There are no evidence-based psychotherapy protocols that effectively treat gender dysphoria. Under this law, medical and mental health providers would be left with no evidence-based treatment approaches to support their adolescent patients with gender dysphoria. This would

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Youth. *Pediatrics*, 147(3):e2020013300. Large studies of primarily adults have also shown high rates of satisfaction with gender-affirming chest surgery; for example, a recent systematic review that included data from 1,052 transmasculine patients found that pooled overall postoperative satisfaction was 92%. Bustos, V.P., Bustos, S.S., Mascaro, A., *et al.* (2021). Transgender and Gender-Nonbinary Patient Satisfaction After Transmasculine Chest Surgery. *Plastic and Reconstructive Surgery Global Open*, 9(3):e3479.

[15] Tang, A., Hojilla, J. C., Jackson, J. E., Rothenberg, K. A., Gologorsky, R. C., Stram, D. A., . . . & Yokoo, K. M. (2022). Gender-affirming mastectomy trends and surgical outcomes in adolescents. *Annals of Plastic Surgery*, *88*(4), S325-S331

be a devastating situation for adolescents and their parents, physicians, and other mental health providers who care for them.

20. In the past, some clinicians have described psychotherapeutic strategies that aimed to result in youth with gender dysphoria identifying with their sex assigned at birth.[16] Such practices, termed "gender identity conversion efforts" have subsequently been linked to adverse mental health outcomes, including suicide attempts.[17] In addition to being harmful, there is no peer-reviewed research to suggest that these gender identity conversion efforts are successful in changing a person's gender identity from transgender to cisgender. Gender identity conversion efforts have been labelled unethical by major medical organizations including The American Medical Association[18] and The American Academy of Child & Adolescent Psychiatry.[19]

21. The ban asserts that gender-affirming medical care is not supported by "long-term medical studies."

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[16] Meyer-Bahlburg, H.F. (2002). Gender Identity Disorder in Young Boys: A Parent-and Peer-Based Treatment Protocol. *Clinical Child Psychology and Psychiatry*, 7(3), 360-376.

[17] Turban, J.L., Beckwith, N., Reisner, S.L., & Keuroghlian, A.S. (2020). Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults. *JAMA Psychiatry*, 77(1), 68-76.

[18] American Medical Association. (2017). Health Care Needs of Lesbian, Gay, Bisexual and Transgender Populations. H-160.991. *Available at* https://policysearch.ama-assn.org/policyfinder/detail/gender%20identity?uri=%2FAMADoc%2FHOD.xml-0-805.xml.

[19] The American Academy of Child & Adolescent Psychiatry. (2018). Conversion Therapy. *Available at* https://www.aacap.org/AACAP/Policy_Statements/2018/Conversion_Therapy.aspx.

However, it does not state what period of longitudinal follow-up would be considered adequate. One study by deVries et al. in the journal *Pediatrics* examined mental health outcomes a mean 5.9 years after starting pubertal suppression.[20] Turban et al. 2022 *PLoS One*, which found associations between access to gender-affirming hormone treatment during adolescence and better mental health outcomes, similarly examined mental health outcomes a mean six to seven years after starting gender-affirming hormones.[21] To put this into context, a major study used by the FDA to approve the medication lurasidone for bipolar depression in children and adolescents followed study participants for six weeks.[22] If the state were to ban all medications that lack at least a decade of long-term follow up studies, that would require banning a substantial proportion of FDA-approved and relied-upon medications.

22. Given the well-documented benefits of gender-affirming medical care outlined above, and the known harms of untreated adolescent gender dysphoria, banning this care is expected to lead to substantial deterioration of mental health for adolescents diagnosed with

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[20] de Vries, A.L., McGuire, J.K., Steensma, T.D., *et al.* (2014). Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment. *Pediatrics*, 134(4), 696-704.

[21] Turban J.L., King D., Kobe J., Reisner S.L., Keuroghlian A.S. (2022) Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults. *PLoS One*. 17(1): e0261039.

[22] DelBello, M. P., Goldman, R., Phillips, D., Deng, L., Cucchiaro, J., & Loebel, A. (2017). Efficacy and safety of lurasidone in children and adolescents with bipolar I depression: a double-blind, placebo-controlled study. *Journal of the American Academy of Child & Adolescent Psychiatry*, *56*(12), 1015-1025.

gender dysphoria. For many of these patients, this is likely to include worsening suicidality.[23] A recent qualitative study of 273 parents of transgender youth identified that bans on gender-affirming care led to substantial concerns that their children would have worsening mental health and be at an increased risk of death from suicide.[24] These parents implored lawmakers to leave critical decisions about gender-affirming medical interventions to families and their medical providers.[25] Another qualitative study of 103 healthcare providers who care for transgender youth similarly identified substantial concerns that such bans would lead to worsening mental health and increased risk of suicide for adolescents with gender dysphoria.[26]

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[23] See, for example, Green, A. E., DeChants, J. P., Price, M. N., & Davis, C. K. (2022). Association of gender-affirming hormone therapy with depression, thoughts of suicide, and attempted suicide among transgender and nonbinary youth. *Journal of Adolescent Health*, *70*(4), 643-649 and other studies cited above.

[24] Kidd, K. M., Sequeira, G. M., Paglisotti, T., Katz-Wise, S. L., Kazmerski, T. M., Hillier, A., . . . & Dowshen, N. (2021). "This could mean death for my child": Parent perspectives on laws banning gender-affirming care for transgender adolescents. *Journal of Adolescent Health*, *68*(6), 1082-1088.

[25] Kidd, K. M., Sequeira, G. M., Paglisotti, T., Katz-Wise, S. L., Kazmerski, T. M., Hillier, A., . . . & Dowshen, N. (2021). "This could mean death for my child": Parent perspectives on laws banning gender-affirming care for transgender adolescents. *Journal of Adolescent Health*, *68*(6), 1082-1088.

[26] Hughes, L. D., Kidd, K. M., Gamarel, K. E., Operario, D., & Dowshen, N. (2021). "These laws will be devastating": Provider perspectives on legislation banning gender-affirming care for transgender adolescents. *Journal of Adolescent Health*, *69*(6), 976-982.

ADOLESCENTS WHO EXPERIENCE GENDER DYSPHORIA AT THE ONSET OF PUBERTY RARELY COME TO IDENTIFY WITH THEIR ASSIGNED SEX AT BIRTH

23. Though the terms "children" and "adolescents" are sometimes used synonymously in common parlance, these terms have specific and distinct meanings in the context of child and adolescent psychiatric research. In this field, "child" and "children" refer to minors who have not yet reached the earliest stages of puberty. The terms "adolescent" and "adolescents" refer to minors who have begun puberty. Studies of prepubertal children (who are not candidates for gender-affirming medical interventions under any existing clinical guidelines) cannot be conflated with studies of adolescents (who, depending on several factors, may be candidates for various forms of gender-affirming medical interventions).

24. This distinction is vital in the realm of "desistence" studies (*i.e.*, studies that aim to assess how many young people who identify as transgender will later identify as cisgender). The suggestion that a majority of transgender minors affected by this law will come to identify with their assigned sex at birth inappropriately relies on studies of gender diverse *prepubertal* children, which have, in the past, shown that many of these children will not grow up to be transgender. These studies do not apply to transgender minors who have reached puberty (*i.e.*, "adolescents"). Once a transgender youth begins puberty, it is rare for them to later identify as cisgender.[27] Furthermore, physicians and families must

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[27] See for example de Vries, A.L., McGuire, J.K., Steensma, T.D., *et al.* (2014). Young Adult Psychological Outcome After Puberty

weigh the low risk of a future cisgender identification against the often substantial risk of deteriorating mental health due to active gender dysphoria. Under existing medical guidelines, any minor who is considering gender-affirming medical or surgical interventions must first work with a mental health professional to conduct a complete biopsychosocial evaluation, which includes ensuring that an adolescent and their parents understand the complexity of this decision. Such evaluations are designed to minimize regret rates.

25. Any study regarding prepubertal children and their likelihood of ultimately identifying as transgender should not be used to assess the interventions targeted by the ban, namely, pubertal suppression, hormone therapy, and gender-affirming surgery, since none of these interventions are provided to prepubertal patients under current medical guidelines.[28]

26. Further, the utility of "desistence" studies even for assessing the likelihood that prepubertal children will persist in a transgender identity has been questioned due to their reliance on an outdated diagnosis of "gender identity disorder in children," which did not require a child to identify as a sex different than their sex

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Suppression and Gender Reassignment. *Pediatrics*, 134(4), 696-704., Turban, J.L., de Vries, A.L.C., & Zucker, K. (2018). Gender Incongruence & Gender Dysphoria. In Martin A., Bloch M.H., & Volkmar F.R. (Editors): *Lewis's Child and Adolescent Psychiatry: A Comprehensive Textbook, Fifth Edition*. Philadelphia: Wolters Kluwer.

[28] Hembree, W.C., Cohen-Kettenis, P.T., Gooren, L., *et al.* (2017). Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*, 102(11), 3869-3903.

assigned at birth. This diagnosis likely captured many cisgender "tomboys" or cisgender boys with feminine interests like dresses or dolls who never identified as transgender and, thus, unsurprisingly did not identify as transgender when followed up with later in life. In contrast, the diagnosis of "gender dysphoria in children" requires one to not merely have gender atypical interests and behaviors; one must identify as a gender different than one's sex assigned at birth. This is a vital distinction. While the diagnostic category of "gender identity disorder" would capture many cisgender children, the diagnostic category of "gender dysphoria," by definition, does not.[29] Of note, a recent study by Kristina Olson et al. found that the vast majority of prepubertal transgender children continued to identify as transgender over a five-year follow-up period.[30]

DE-TRANSITION AND REGRET AMONG INDIVIDUALS RECEIVING MEDICAL TREATMENT FOR GENDER DYSPHORIA ARE UNCOMMON

27. The legislative findings in the ban and the legislative testimony concerning the ban focused on the risk of "de-transition" and the possibility of regret following gender-affirming medical care. De-transition and transition regret are distinct concepts and neither is common.

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[29] The desistance have also been criticized for a range of methodological limitations. Olson, K.R. (2016). Prepubescent Transgender Children: What We Do and Do Not Know. *Journal of the American Academy of Child & Adolescent Psychiatry*, 3(55), 155-156.

[30] Olson, K. R., Durwood, L., Horton, R., Gallagher, N. M., & Devor, A. (2022). Gender identity 5 years after social transition. Pediatrics.

28. The term "de-transition" is used inconsistently in literature and may sometimes refer to simply the stopping of medical interventions. But discontinuation of gender-affirming medical interventions does not always coincide with a change in understanding of one's gender identity or with transition-related regret. Rather, transgender adolescent patients who discontinue gender-affirming medical interventions may do so because of external factors (*e.g.*, pressure from family, societal rejection, harassment by peers). For example, a substantial number of currently identified transgender people (13.1%) have "de-transitioned" at some point in their life, with the majority (82.5%) citing external factors like family rejection, societal stigma, or harassment.[31] Given that these people *currently* identify as transgender, it highlights that many people who "de-transition" choose to transition again in the future.

29. Studies focused specifically on regret, as opposed to the broad heterogeneous category of "de-transition," indicate that regret is extremely rare. In 2018, Amsterdam's VUMC Center of Expertise on Gender Dysphoria published the rates of regret among their cohort of 6,793 transgender patients who had undergone gender-affirming medical and/or surgical interventions.[32] Among transgender women with gender

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[31] Turban, J. L., Loo, S. S., Almazan, A. N., & Keuroghlian, A. S. (2021). Factors Leading to "Detransition" Among Transgender and Gender Diverse People in the United States: A Mixed-Methods Analysis. *LGBT Health,* 8(4), 273-280.

[32] Wiepjes, C. M., Nota, N. M., de Blok, C. J., Klaver, M., de Vries, A. L., Wensing-Kruger, S. A., . . . & den Heijer, M. (2018). The Amsterdam cohort of gender dysphoria study (1972-2015): trends in prevalence, treatment, and regrets. *The Journal of Sexual Medicine*, *15*(4), 582-590.

dysphoria who underwent gender-affirming surgery, 0.6% experienced regret. Among transgender men with gender dysphoria who underwent gender-affirming surgery, 0.3% experienced regret. Several of those who experienced regret were classified as having "social regret" rather than "true regret," defined in the study as still identifying as transgender but deciding to reverse their gender-affirming surgery due to factors like "the loss of relatives [being] a large sacrifice." The study also reported that only 1.9% of adolescents who started pubertal suppression did not choose to go onto gender-affirming hormones. In a second study of 143 transgender adolescents who started pubertal suppression, five adolescents (3.5%) decided not to proceed with further gender-affirming medical treatments.[33] One of these adolescents noted that pubertal suppression helped them to better understand their gender identity, and they ultimately identified with their sex assigned at birth. One birth-assigned female had ongoing chest dysphoria but chose to live with a female gender expression regardless, though was dreading further breast development and menstruation. One stopped due to unspecified "psychosocial reasons" but continued to identify as transgender. One identified as gender nonbinary and felt they no longer needed treatment. One came to identify with his sex assigned at birth. There was no indication that any of these adolescents *regretted* pubertal suppression; rather, this study shows that the treatment served its goal of allowing adolescents more time to better understand their gender identity before being

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[33] Brik, T., Vrouenraets, L. J., de Vries, M. C., & Hannema, S. E. (2020). Trajectories of adolescents treated with gonadotropin-releasing hormone analogues for gender dysphoria. *Archives of Sexual Behavior*, 49(7), 2611-2618.

assessed for additional treatment. Cases of initiating then discontinuing gender-affirming hormones like estrogen or testosterone appear to be uncommon, largely at the case report level.[34] In one of these case reports, a patient similarly noted that a trial of estrogen helped them to better understand their gender identity, which had evolved to non-binary, and they did not regret initiating estrogen therapy.[35] Though there have been scattered and difficult-to-confirm social media reports of people regretting gender-affirming medical care, this must be considered in the context of the 1.4 million transgender people in the United States alone.[36]

30. All treatments in medicine carry risks, benefits, and side effects. It is essential that parents, adolescents, and their doctors be able to work together to weigh these factors and choose a path forward that is *most likely* to improve a young person's health, including their mental health. If the government were to ban all medical treatments with potential adverse side effects or the possibility of regret, it would ban essentially of all medicine. As one example, the vast majority of people who take the antibiotic penicillin find that their infections resolve; however, a small number of people will experience Stevens-Johnson syndrome (SJS) or toxic epidermal necroylysis (TEN) from the medication —rare potentially fatal conditions in which the person's

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[34] A case report is a publication in which clinicians report on what occurred with a single patient.

[35] Turban, J. L., Carswell, J., & Keuroghlian, A. S. (2018). Understanding pediatric patients who discontinue gender-affirming hormonal interventions. *JAMA Pediatrics*, *172*(10), 903-904.

[36] Flores, A.R., Herman, J.L., Gates, G.J., & Brown, T.N.T. (2016). How Many Adults Identify as Transgender in the United States? Los Angeles: The Williams Institute.

skin detaches.[37] Morality rates from SJS/TEN are as high as 50%. The cholesterol-lowering medication atorvastatin (known to many under the brand name Lipitor) is one of the most commonly prescribed medications in the U.S., given its potential to lower cholesterol and subsequently reduce the risk of a heart attack. However, a small number of people will experience rhabdomyolysis as a side effect—a potentially fatal form of muscle breakdown that can cause kidney damage. Though both these medications carry a serious risk of adverse side effects, they help the vast majority of people, and thus should not be—and are not—banned. The responsibility of the provider of care is to inform patients about these risks, benefits, and potential side effects, and work with patients and families to identify the best course of action. Gender-affirming care is not unique in carrying risks, side effects, or the possibility of regret.

31. While there is undoubtedly a small number of people who start gender-affirming medical interventions and later stop them, only a minority of this small number appear to regret the treatment, and existing research suggests that regret following gender-affirming medical interventions is rare. As with all medical interventions, gender-affirming medical interventions cannot claim a 100% success rate. However, for the vast majority of adolescents, these interventions improve mental health. Accordingly, it is dangerous to take the only evidence-based treatment option away from fami-

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[37] Lee, E. Y., Knox, C., & Phillips, E. J. (2023). Worldwide Prevalence of Antibiotic-Associated Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis: A Systematic Review and Meta-analysis. *JAMA Dermatology.*

lies and physicians as they work together to examine existing evidence and their individual case to determine what pathway is most likely to result in favorable mental health outcomes for an adolescent.

CONCLUSION

32. In summary, gender-affirming medical care for adolescent gender dysphoria, when medically indicated, is supported by a substantial body of peer-reviewed scientific evidence that has been collected over more than a decade. Though these treatments, like all medical treatments, carry potential risks and side effects, these potential risks must be weighed against the benefits of treatment. It is essential that physicians be able to work with adolescents and their families to weigh benefits against potential risks and side effects and provide the care that is appropriate for a given adolescent and their family. Banning these medical interventions would leave physicians without any evidence-based treatments for adolescent gender dysphoria, which, when left untreated, has been linked to dramatic adverse mental health outcomes, including suicidality. For these reasons, all relevant major medical organizations (The American Medical Association, The American Academy of Pediatrics, The American Psychiatric Association, The American Academy of Child & Adolescent Psychiatry, The Endocrine Society, and The Pediatric Endocrine Society, to name a few) oppose bans on gender-affirming medical care for adolescents with gender dysphoria.

Executed on: Apr. 14, 2023

/s/ JACK L. TURBAN
JACK L. TURBAN, MD, MHS

Materials Relating to
Vanderbilt University Medical Center

EXHIBIT 1

EXHIBIT 1-A

AP AP News

Social media posts spark calls to investigate Tenn.'s VUMC

By KIMBERLEE KRUESI September 21, 2022

NASHVILLE, Tenn. (AP)—Tennessee Gov. Bill Lee has called for an investigation into a pediatric transgender health clinic after videos surfaced on social media of a doctor touting that gender-affirming procedures are "huge money makers" for hospitals and a staffer saying anyone with a religious objection should quit.

Vanderbilt University Medical Center came under fierce scrutiny Tuesday after conservative political commentator Matt Walsh posted a series of tweets accusing the private hospital of opening its transgender health clinic because it was profitable, as well as criti-

cizing some of the treatments VUMC provides to minors.

The posts included a video of one VUMC doctor in 2018 saying these "types of surgeries bring in a lot of money" and later saying that female-to-male bottom surgeries are "huge money makers." A separate video shows another staffer warning that if employees do not want to participate in transgender treatments then they "probably shouldn't work at Vanderbilt," and warned that objections should be met with "consequences."

"We should not allow permanent, life-altering decisions that hurt children or policies that suppress religious liberties, all for the purpose of financial gain," Lee, a Republican running for reelection this year, said in a late Tuesday statement. "We have to protect Tennessee children, and this warrants a thorough investigation."

The governor did not specify what laws the Nashville-based hospital may have violated, but his spokesperson told The Associated Press that they had passed along concerns to Attorney General Jonathan Skrmetti.

Skrmetti's office did not rule out an investigation when reached by the AP on Wednesday.

"We are aware of allegations of illegal conduct at the Clinic for Transgender Health at Vanderbilt University Medical Center," said spokesperson Samantha Fisher

in an email. "General Skrmetti will use the full scope of his authority to ensure compliance with Tennessee law."

Fisher did not immediately respond to questions seeking clarity on what law specifically VUMC may have violated.

In a statement, VUMC said it started its transgender health clinic in 2018 because transgender people face higher risks for mental and physical health issues.

"VUMC requires parental consent to treat a minor patient who is to be seen for issues related to transgender care and never refuses parental involvement in the care of transgender youth who are under age 18," said spokesperson Craig Boerner in a statement.

Boerner added that VUMC employees are allowed to decline to participate in any treatment they find morally objectionable and prohibits discrimination against employees who do so.

"We have been and will continue to be committed to providing family-centered care to all adolescents in compliance with state law and in line with professional practice standards and guidance established by medical specialty societies," he said.

Boerner declined to answer any additional questions, including how many treatments the clinic has provided to minors and what types. The websites for VUMC's transgender health clinic and LGBTQ health programs were down Wednesday.

The social media posts have attracted the attention of key Tennessee Republican lawmakers—many of whom are also running for reelection—vowing to further limit gender-affirming treatments when the General Assembly reconvenes in January. Meanwhile, Tennessee's

U.S. Sen. Marsha Blackburn praised Gov. Lee's call for an investigation.

Nationally, Republicans have increasingly pushed to restrict LGBTQ rights in their effort to drive the party's base and push the bounds in already GOP-strongholds.

Tennessee over the years has been on the front lines among Republican-dominated statehouses advancing anti-LGBTQ legislation. Just last year, Republican lawmakers and Gov. Lee banned doctors from providing gender-confirming hormone treatment to prepubescent minors even though advocates maintain that no doctor in Tennessee was doing so.

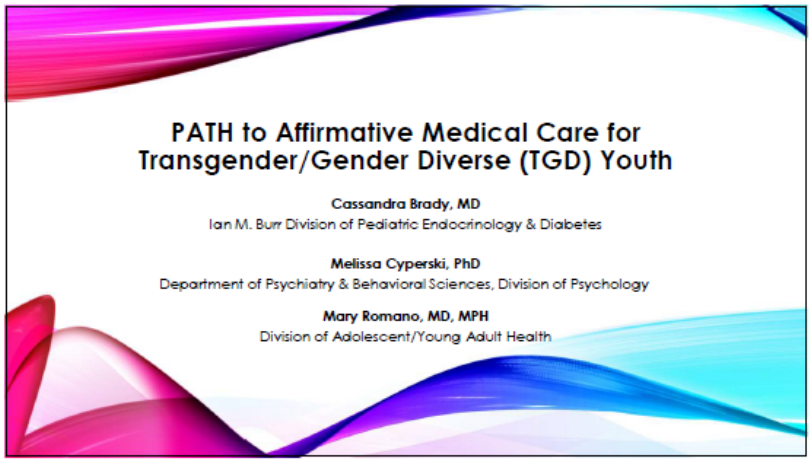
Lee also approved banning transgender athletes from playing girls' public high school sports or middle school sports after declaring that allowing transgender girls to participate would "destroy women's sports."

Such transgender-focused legislation is commonly challenged in court. While Tennessee's youth transgender ban remains in effect, Arkansas is currently blocked from enforcing a similar version. A federal judge in May blocked a similar law in Alabama.

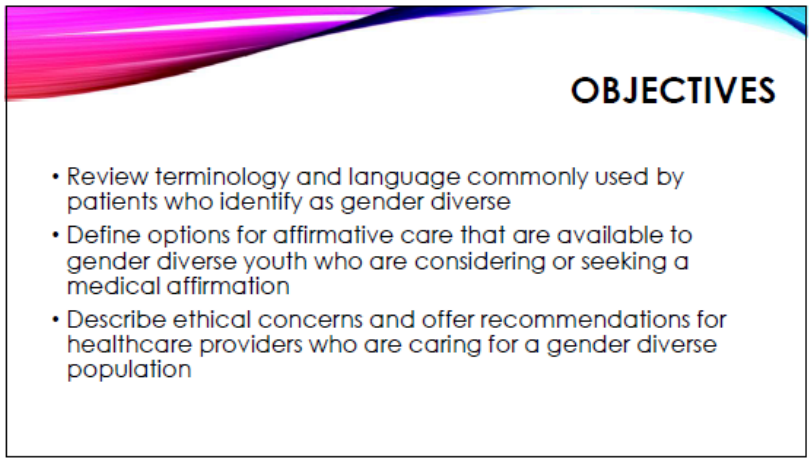
In Texas, child welfare officials have been blocked from investigating three families of transgender youth over gender-confirming care the minors have received.

EXHIBIT 1-B
(Conventionally Filed)

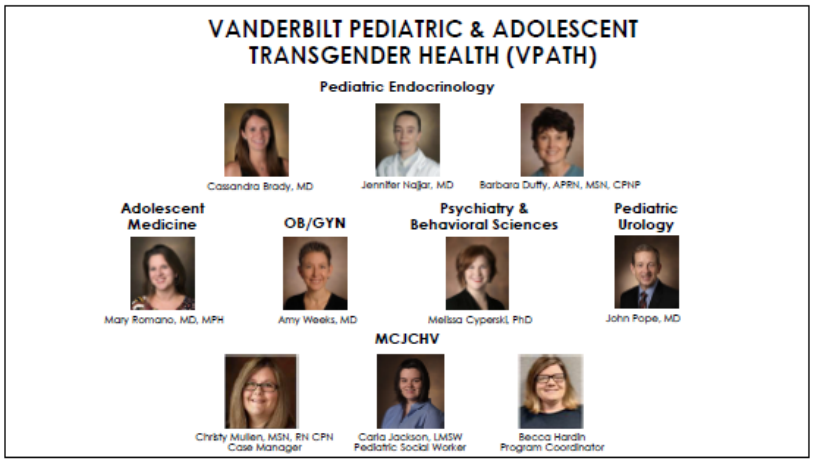
EXHIBIT 1-C


PATH to Affirmative Medical Care for Transgender/Gender Diverse (TGD) Youth
Cassandra Brady, MD
Ian M. Burr Division of Pediatric Endocrinology & Diabetes
Melissa Cyperski, PhD
Department of Psychiatry & Behavioral Sciences, Division of Psychology
Mary Romano, MD, MPH
Division of Adolescent/Young Adult Health

1


OBJECTIVES
• Review terminology and language commonly used by patients who identify as gender diverse
• Define options for affirmative care that are available to gender diverse youth who are considering or seeking a medical affirmation
• Describe ethical concerns and offer recommendations for healthcare providers who are caring for a gender diverse population

2



3

DEFINITIONS

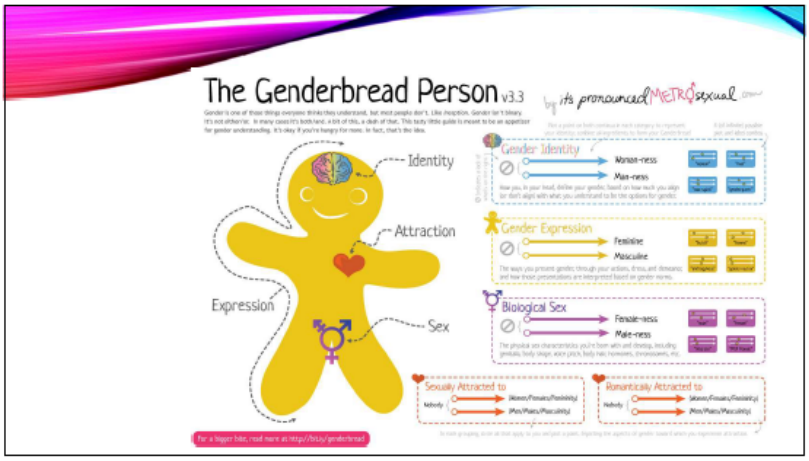
- **Natal sex** - sex assigned at birth, typically based on genitalia
- **Gender identity** - sense of male/female/both/neither
- **Gender expression** – presentation of identity such as through appearance, dress, or behavior
- **Sexual orientation** - direction of an individual's sexuality, classifiable according to the sex or gender of the persons whom the individual finds sexually attractive

4

DEFINITIONS

- **Gender dysphoria** - distress with natal sex assignment and gender identity
- **Transgender** - adjective to describe individuals whose gender identity and sex assigned at birth do not correspond
- **Gender nonconformity** - variation from cultural norm in gender expression
- **Gender nonbinary** - assigned either sex at birth and identify as neither, both, or fluid gender

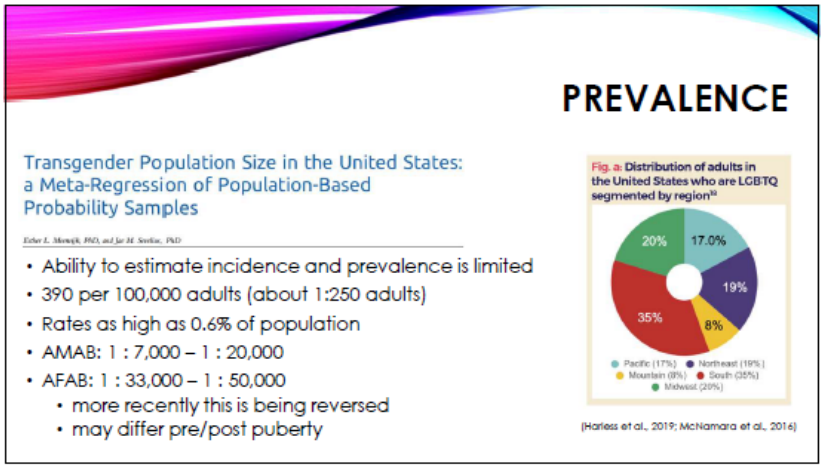
5



6


NATIONAL LGBTQIA+ HEALTH EDUCATION CENTER
A PROGRAM OF THE FENWAY INSTITUTE
Learning Resources
What We Offer
About Us
My Learning
LGBTQIA+ Glossary of Terms for Health Care Teams
Publication
Originally published on 3 February, 2020
Becoming familiar with terms used by lesbian, gay, bisexual, transgender, queer, intersex, asexual, and other sexual and gender minorities (LGBTQIA+) can help you provide patients with the highest quality care. In this glossary, you will find terms relevant to the health care and identities of LGBTQIA+ people.
Download this Publication
Filed under Introduction to LGBTQIA+ Health
https://www.lgbtqiahealtheducation.org/publication/lgbtqia-glossary-of-terms-for-health-care-teams/

7


PREVALENCE
Transgender Population Size in the United States: a Meta-Regression of Population-Based Probability Samples
Ability to estimate incidence and prevalence is limited
390 per 100,000 adults (about 1:250 adults)
Rates as high as 0.6% of population
AMAB: 1 : 7,000 – 1 : 20,000
AFAB: 1 : 33,000 – 1 : 50,000
more recently this is being reversed
may differ pre/post puberty
Fig. a: Distribution of adults in the United States who are LGBTQ segmented by region
20%
17.0%
19%
35%
8%
Pacific (17%)
Northeast (19%)
Mountain (8%)
South (35%)
Midwest (20%)
(Harless et al., 2019; McNamara et al., 2016)

8

- Gen Z (1997 – 2012)
  - **1 in 6** (15.9%) said they are queer or transgender
  - 50% believe traditional gender norms outdated
  - 1 in 3 open to dating different genders
  - 1 in 5 open to polyamory
- Millennials (1981- 1997)
  - **1 in 10** said they are LGBTQ+ with a high percentage (8.1%) declining to answer
- In 2012, just 3.5% of American adults said they were LGBTQ+

them.

(Clifton, 2021; Lang, 2021; Sonoma, 2020)

9

GENDER DIVERSE (TGD) YOUTH

(de Vries et al., 2010; Drummond et al., 2008; Littman, 2018; Strang et al., 2018; Wallien & Cohen-Kettenis, 2008)

- Timing can be variable
  - May present early in childhood or with onset of puberty
  - Late onset may surprise parents
- Fluidity in prepubertal children vs. adolescents
  - Children persist 12-27%
  - Adolescents near 100% persistence
- Gender ratio 3:1 AMAB/AFAB in children; 1:1 in adolescents
- Commonly comorbid with other conditions, such as ASD

10

GENDER DEVELOPMENT

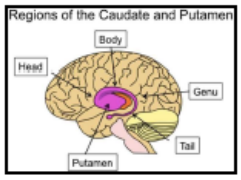
- Across lifespan
  - 2 – 3 yo: basic gender identity
  - 3 – 5 yo: gender stability
  - 5 – 7 yo: gender consistency
  - 10 yo+: identity, expression, role continue to develop and flex over time
- Influenced by nature and nurture
  - Early experiences
  - Social learning
  - Biology

(Ron-Li Liaw & Janssen, 2014)

11

BIOLOGY OF GENDER IDENTITY

- Pre and postnatal exposure to androgens
  - Data is from DSD population
- Gender dysphoria as high as 39% in monozygotic twin pairs (Heylens et al., 2012)
  - Several studies suggest this but date back to early 2000s
- Brain studies



12

13

TGD MENTAL HEALTH RISKS

Higher risk than sexually diverse (LGB) peers for experiencing negative health outcomes, substance use, trauma victimization, homelessness, stigma, and/or minority stress.

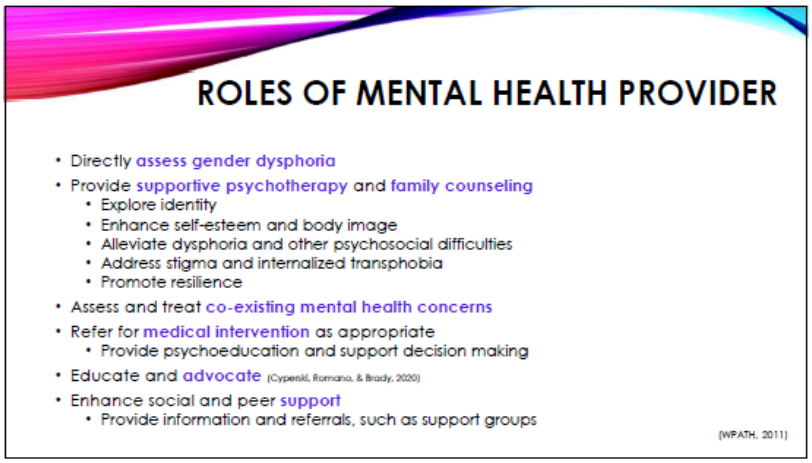
- 53% of TGD youth felt sad or hopeless
- 43.9% considered suicide vs. 11 - 20.3% of cisgender peers
- 34.6% of transgender students attempted suicide vs. 5.5 – 9.1% cisgender peers

(Cohen et al., 2018; Johns et al., 2019; National Resource Center for Mental Health Promotion and Youth Violence Prevention, n.d.)

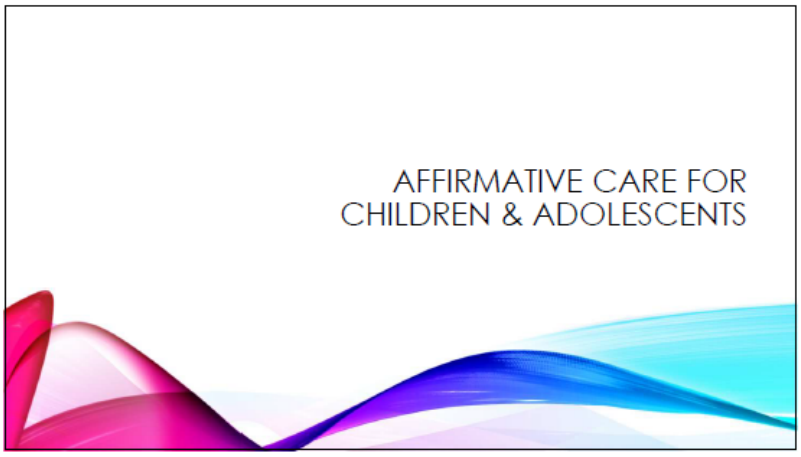
14


DSM-5
GENDER DYSPHORIA
"A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration. . .
The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning"

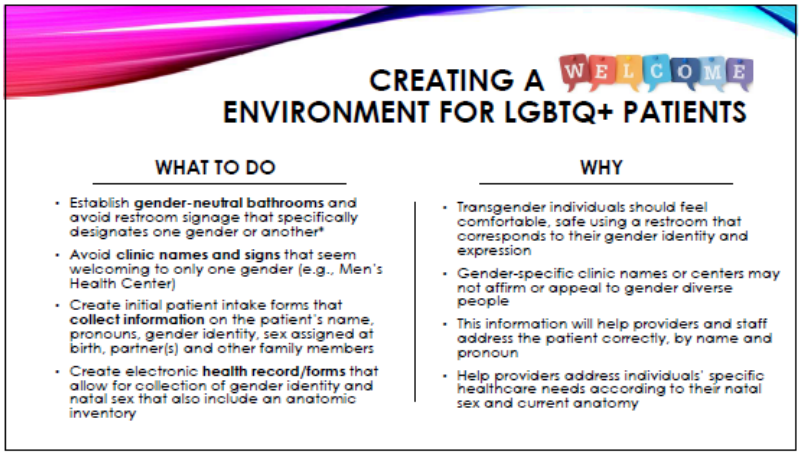
15


ROLES OF MENTAL HEALTH PROVIDER
Directly assess gender dysphoria
Provide supportive psychotherapy and family counseling
Explore identity
Enhance self-esteem and body image
Alleviate dysphoria and other psychosocial difficulties
Address stigma and internalized transphobia
Promote resilience
Assess and treat co-existing mental health concerns
Refer for medical intervention as appropriate
Provide psychoeducation and support decision making
Educate and advocate (Cyrenkl, Romano, & Brady, 2020)
Enhance social and peer support
Provide information and referrals, such as support groups
(WPATH, 2011)

16


AFFIRMATIVE CARE FOR
CHILDREN & ADOLESCENTS

17


CREATING A WELCOME ENVIRONMENT FOR LGBTQ+ PATIENTS
WHAT TO DO
Establish gender-neutral bathrooms and avoid restroom signage that specifically designates one gender or another*
Avoid clinic names and signs that seem welcoming to only one gender (e.g., Men's Health Center)
Create initial patient intake forms that collect information on the patient's name, pronouns, gender identity, sex assigned at birth, partner(s) and other family members
Create electronic health record/forms that allow for collection of gender identity and natal sex that also include an anatomic inventory
WHY
Transgender individuals should feel comfortable, safe using a restroom that corresponds to their gender identity and expression
Gender-specific clinic names or centers may not affirm or appeal to gender diverse people
This information will help providers and staff address the patient correctly, by name and pronoun
Help providers address individuals' specific healthcare needs according to their natal sex and current anatomy

18

INITIAL HEALTHCARE ENCOUNTER

- Ask open ended questions about identity for all
- Defer to your patient on language, name, pronouns
- Be aware of confidentiality issues—particularly as they pertain to adolescents
- Assess for safety at home, in school
- Review risk-taking behaviors (e.g., sexual activity, substance use)
- Assess mood (e.g., depression, self-harm behaviors, suicide)
- Keep open mind and don't make assumptions about individual path to affirmation

19

OPTIONS FOR AFFIRMATION

- Goal: to help people feel more confident and comfortable
- Individualized approach to alleviating GD
  - Psychotherapy
  - Peer support (e.g., GSA)
  - Parental resources (e.g., PFLAG)
  - Social transition (e.g., school, legal name)
  - Resources for affirmative clothing (e.g., binders, gaff, swimwear)
  - Gender affirming hormones (i.e., pubertal blockers and/or hormone therapy)
  - Surgery

20

REAL-LIFE EXPERIENCE (RLE)

- "The act of fully adopting a new or evolving gender role or gender presentation in everyday life"
- Previous guidelines recommended living **12 months** full-time in the desired gender role prior to medical intervention
  - Consider the person and individual needs (e.g., may be challenging to transition as a "female with a beard")

(Hembree et al., 2017)

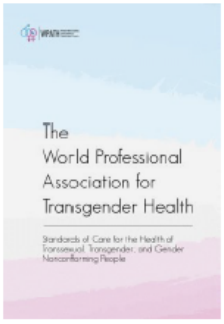
21

BEST PRACTICE GUIDELINES


CLINICAL PRACTICE GUIDELINE

Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline

Wylie C. Hembree,[1] Peggy T. Cohen-Kettenis,[2] Louis Gooren,[3] Sabine E. Hannema,[4] Walter J. Meyer,[5] M. Hassan Murad,[6] Stephen M. Rosenthal,[7] Joshua D. Safer,[8] Vin Tangpricha,[9] and Guy G. T'Sjoen[10]


The World Professional Association for Transgender Health

Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People

22

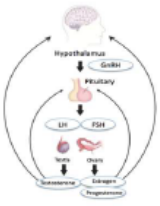
CASE EXAMPLE

Ryan (12)

23

"PUBERTAL BLOCKERS"

- GnRH agonists
  - Leuprolide (Lupron), Supprelin (Histrelin/Vantas)
  - Fully reversible
  - Tanner stage 2/3
  - Significant increase GD with puberty
  - Effects on bone?
  - Fertility
  - Expense
    - ~$1500/month Lupron
    - ~$15,000 for Histrelin



24

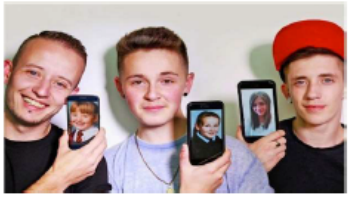
ALTERNATE BLOCKING AGENTS

- Medroxyprogesterone acetate PO or IM (MTF or FTM)
  - Inhibits the HPG axis and inhibits gonadal steroidogenesis
  - Menstrual suppression
- Spironolactone PO (MTF)
  - Inhibits T synthesis and action
- Finasteride PO (MTF)
  - Inhibits 5 a-reductase, blocking conversion of T to DHT

25

GENDER AFFIRMING HORMONES

- Previously recommended start at age 16, but consider as early as 14 yo
- Continue pubertal blockers
- Fertility preservation and consent prior to initiation



26

RESULTS

Masculinizing
- Cessation of menses
- Increased libido
- Increased facial and body hair
- Increased oiliness to skin
- Increased muscle/redistribution of fat mass
- Deeper voice

Feminizing
- Decreased libido
- Decreased facial and body hair
- Decreased oiliness of skin
- Breast tissue growth
- Redistribution of fat mass

27

ESTRADIOL RISKS

Likely increased risk
- Venous thromboembolic disease (blood clot or stroke)
- Gallstones
- Elevated liver enzymes
- Weight gain
- Elevated triglycerides
- Severe migraine headaches
- Cardiovascular disease

Possible increased risk
- High blood pressure
- Elevated prolactin level or benign brain tumor (prolactinoma)
- Infertility
- Type 2 Diabetes

No increased risk or inconclusive risk
- Breast cancer

28

TESTOSTERONE RISKS

Likely increased risk
- Polycythemia (increased number of red blood cells)
- Weight gain
- Acne
- Male pattern balding
- Sleep apnea

Possible increased risk
- Elevated liver enzymes
- Hyperlipidemia (elevated cholesterol)
- Thromboembolism
- Infertility
- Worsening of certain psychiatric problems
- Cardiovascular disease
- Hypertension
- Type 2 Diabetes

No increased risk or inconclusive risk
- Loss of bone density
- Breast cancer
- Cervical cancer
- Ovarian cancer
- Uterine cancer

29

SURGERY

For minors:
- Top surgery
  - Hormone therapy for 12 mo+
  - Completed chest development
  - Support of both parents
  - Followed and cleared by MHP
- Bottom surgery not available

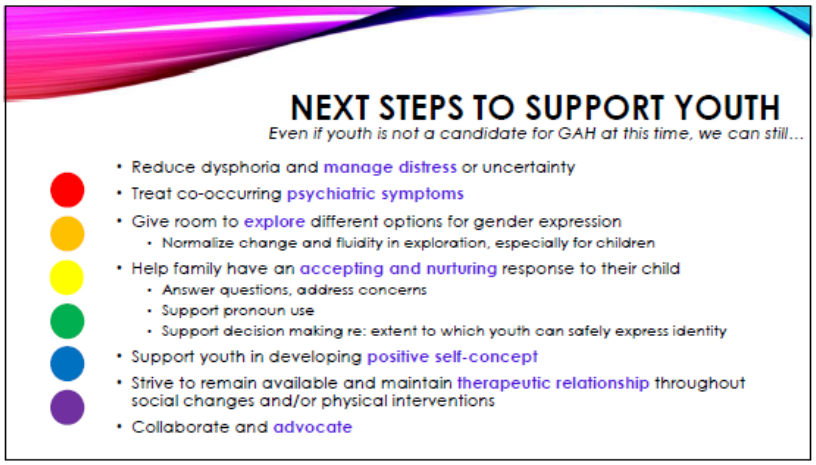
For adults:
- Top surgery
  - Hormone therapy recommended for 6 mo+
  - Letter from MHP
- Bottom surgery
  - Hormone therapy for 12 mo+
  - Two letters of recommendation
    - Community MHP
    - Evaluation at VUMC

Note: May vary by MCO

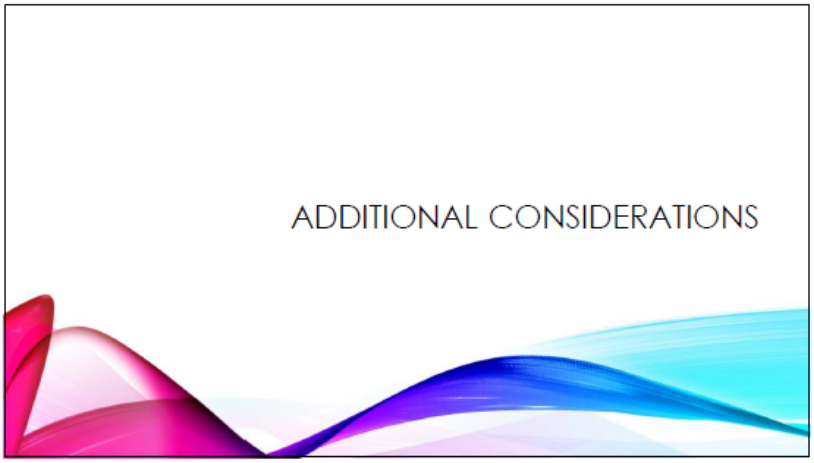
30


CASE EXAMPLE
Dylan (16)

31


NEXT STEPS TO SUPPORT YOUTH
Even if youth is not a candidate for GAH at this time, we can still…
• Reduce dysphoria and manage distress or uncertainty
• Treat co-occurring psychiatric symptoms
• Give room to explore different options for gender expression
  • Normalize change and fluidity in exploration, especially for children
• Help family have an accepting and nurturing response to their child
  • Answer questions, address concerns
  • Support pronoun use
  • Support decision making re: extent to which youth can safely express identity
• Support youth in developing positive self-concept
• Strive to remain available and maintain therapeutic relationship throughout social changes and/or physical interventions
• Collaborate and advocate

32



33

ETHICAL CONSIDERATIONS

- Confidentiality and consent
  - Coming out
  - Diagnosis
  - Documentation
- Gatekeeping (Budge, 2015)
  - Discriminatory
  - Impact on working alliance and engagement
- Risk of withholding letter of support and/or affirmative care
  - Prolong gender dysphoria
  - Suicidal ideation and attempt
  - Contribute to appearance that may elicit abuse or stigmatization
  - Health and safety (e.g., black market; binding)

34

FAMILY ENGAGEMENT

LGBT young people who are **HIGHLY REJECTED** by their parents...

3x more likely to use **illegal drugs**
3x more likely to be at high risk for **HIV and STIs**
6x more likely to report high levels of **depression**
8x more likely to attempt **suicide**

...compared to those who are only **SLIGHTLY REJECTED** by family.

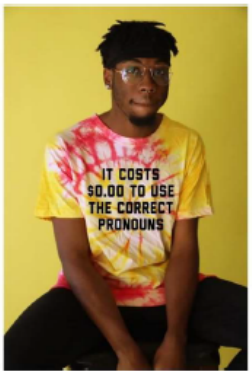
(Ryan, 2009)

35

USE CORRECT PRONOUNS AND CHOSEN NAME.

An increase of one context (e.g., home, school, friends) where children are able to use their chosen name is associated with 5 unit decrease in depressive symptoms, 29% decrease in suicidal ideation, and 56% decrease in suicidal behavior.

(Russell et al., 2018)



36

CLOSING

- Provide a safe and affirming space for patients to share their gender identity
- Be aware of various options for treating gender dysphoria
- Understand best practices in assessment and treatment of youth
  - Affirming and supportive
  - Comprehensive assessment
  - Suicide risk and frequent screening
  - Family, family, family
- Collaboration with patient and caregivers
- Consultation with colleagues, experts

(GLSEN)

37

RESOURCES

38

39

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42

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43

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44

EXHIBIT 1-D
(Conventionally Filed)

EXHIBIT 1-E
(Conventionally Filed)

EXHIBIT 1-F

A Primer for Transgender Health

Southeast/TN AIDS Education and Training Center

Shayne Sebold Taylor, MD
Assistant Professor
Departments of Internal Medicine and Pediatrics

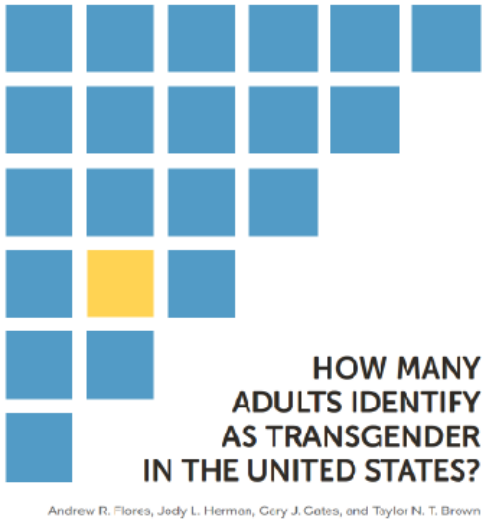
1.30.2019

VANDERBILT HEALTH

Disclosures

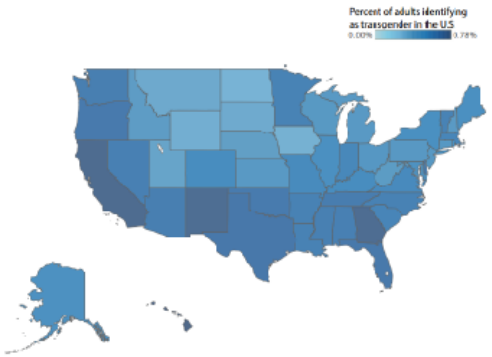
- Unfortunately, no financial disclosures.
- I am a cis-gender, white, heterosexual female from an upper middle class background.

Number of Adults Who Identify as Transgender



~0.6% of adults – 1.4 million Americans – identify as transgender

Figure 1 Percent of Adults Who Identify as Transgender in the United States



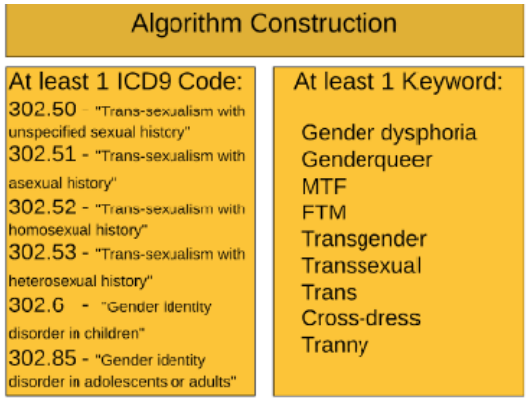


Table 1: Demographics of VUMC Transgender Cohort

	N	Percent
Race		
White	162	70%
Black	39	17%
Other	13	6%
Unknown	41	18%
Gender Identity		
MTF	23	10%
FTM	18	8%
Gender non-binary	0	0%
Transgender Unspecified	191	82%
Sex Changed in EMR		
Yes	43	19%

Beach, L & Ehrenfeld, J et al. "Development of a natural language processing algorithm to identify transgender patients in the Vanderbilt University Medical Center electronic health records system" 2016.[1]

A Growing Population

- According to Williams Institute Survey, approximately 262,000 adults identify as transgender in the Southeast (TN, AL, MS, LA, FL, KY, GA)
- By the year 2020, estimated 1,077 transgender individuals in the Vanderbilt system[2]

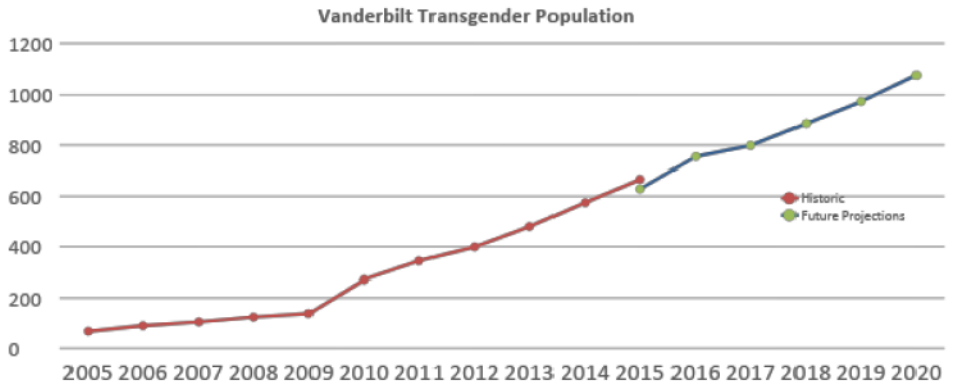
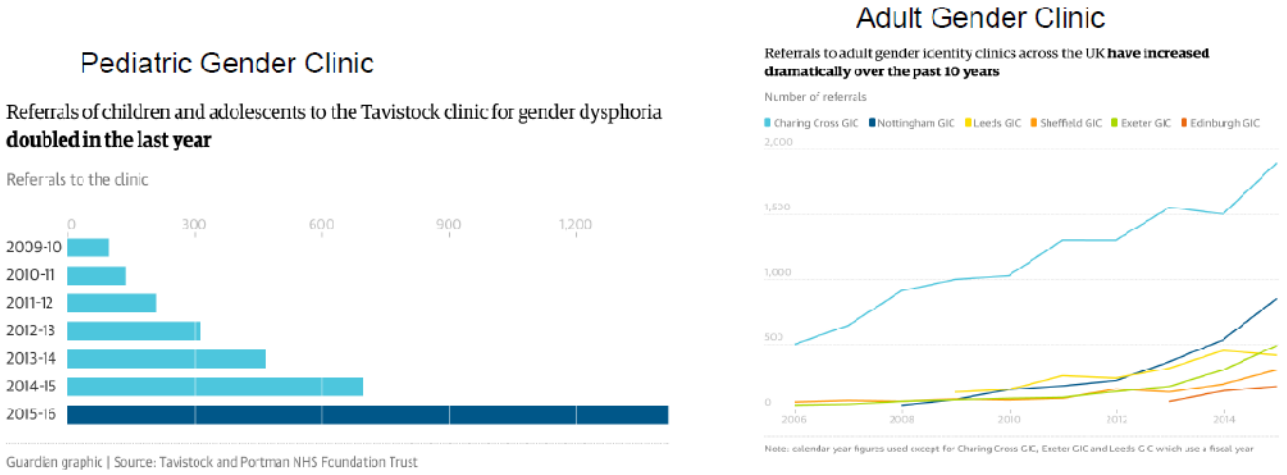


Figure Courtesy of Lea Davis, PhD 2016.

[2] Data derived from VUMC Synthetic Derivative, number of new individuals with ICD codes/ keywords added to EHR within the last year, linear extrapolation over the next 5 years.

Leads to an (Exponentially) Growing Need

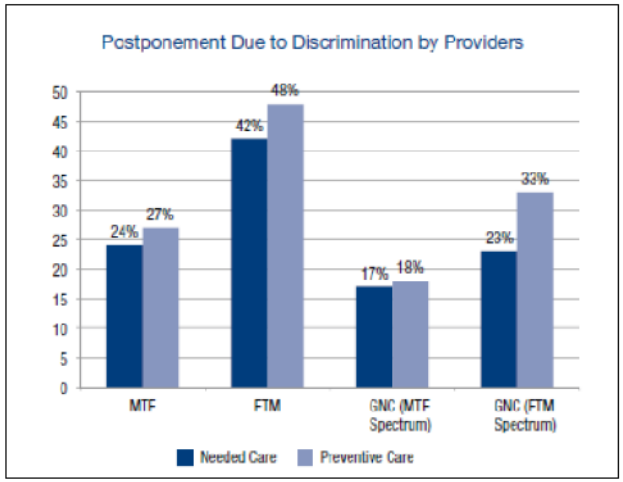


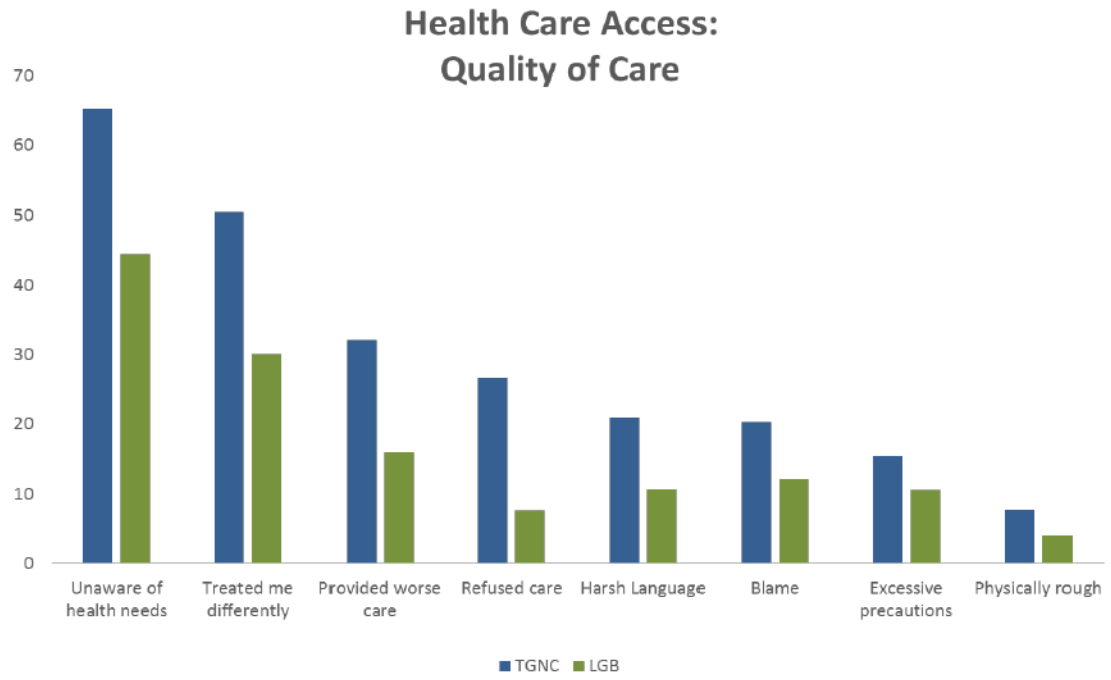
Lyons, K. The Guardian, Travistock and Portman NHS Foundation, 2016.

Health Concerns for Transgender People

Transgender communities:

- are currently underserved
- are more likely to delay care due to fear of discrimination or past negative experiences
- face challenges in finding friendly and knowledgeable providers
- higher rates of depression, anxiety, and suicide
- higher incidence of HIV/AIDs





Source: Lambda Legal
"When Health Care Isn't Caring" study, 2010

HEALTH DISPARITIES AMONG TRANSGENDER PEOPLE

- One in four (25%) respondents experienced a problem in the past year with their insurance related to being transgender, such as being denied coverage for care related to gender transition or being denied coverage for routine care because they were transgender.
- More than half (55%) of those who sought coverage for transition-related surgery in the past year were denied, and 25% of those who sought coverage for hormones in the past year were denied.

Source: The 2015 U.S. Transgender Survey

HEALTH DISPARITIES AMONG TRANSGENDER PEOPLE

- One-third (33%) of those who saw a health care provider in the past year reported having at least one negative experience related to being transgender, with higher rates for people of color and people with disabilities. This included being refused treatment, verbally harassed, or physically or sexually assaulted, or having to teach the provider about transgender people in order to get appropriate care.
- In the past year, 23% of respondents did not see a doctor when they needed to because of fear of being mistreated as a transgender person, and 33% did not see a doctor when needed because they could not afford it.

Source: The 2015 U.S. Transgender Survey

Caring for the Transgender Patient

A quick review of terms and nomenclature

What do these terms mean to You?

Sex

Sexual Orientation

Gender

Sex

A medically assigned identity based on physical packaging – our chromosomes, hormones, and genitalia.

female, male, intersex

Gender Identity

Our inner sense of being a man, woman, or another gender; "how the mind and the heart regard the body."

woman, man, trans woman, trans man, nonbinary

Gender Expression

The ways in which we externally communicate our gender identity to others, such as through mannerisms, clothing, body language, roles, hairstyles, etc.

feminine, masculine, androgynous, butch, femme

Sexual Orientation

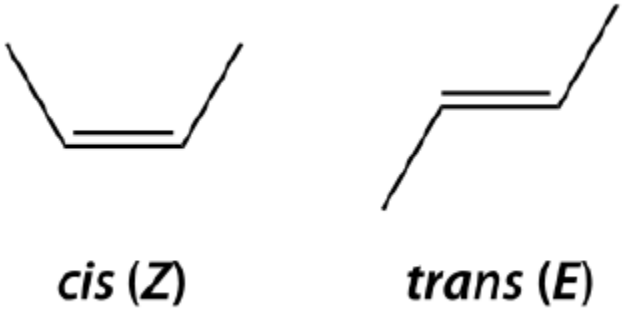
An enduring emotional, romantic, sexual, affectional, & relational attraction to other people.

Determined by the personally significant sexual or romantic attractions one has, and the way in which someone self-identifies.

lesbian, gay, bisexual, MSM, WSW, queer, asexual, pansexual, straight

“Definitions”

- Transgender
  - Describes people whose gender identity differs from their sex assigned at birth
- Cisgender
  - A person who is not transgender



cis (*Z*) *trans* (*E*)

"Definitions" Continued

Transgender people are very diverse and use many different terms to describe themselves. These terms tend to change over time. Some of the more common terms in 2018 include:

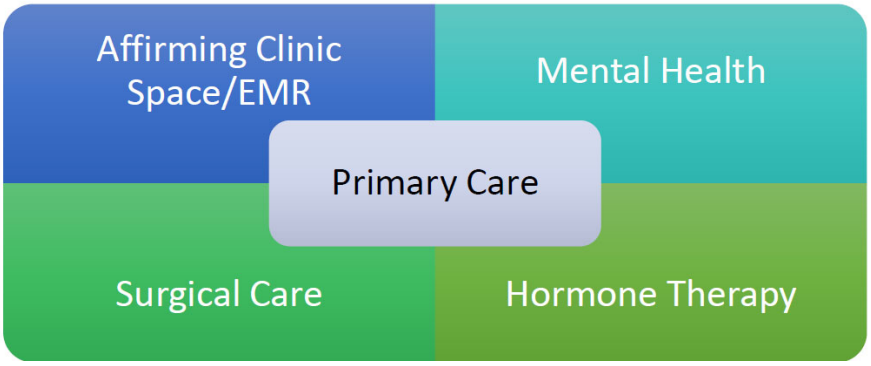
- Transgender woman, trans woman, male-to-female (MTF)
    - A person assigned male at birth who identifies as a woman
- Transgender man, trans man, female-to-male (FTM)
    - A person assigned female at birth who identifies as a man

Gender identity ≠ sexual orientation

- Sexual orientation
  - How a person identifies their physical and emotional attraction to others
  - Dimensions include: desire/attraction, behavior, and identity
- All people have a sexual orientation and a gender identity
- Transgender people can be any sexual orientation

- James S.E. HJL, Rankin, S., Keisling, M., Mottet, L., & Anafil, M.: **The Report of the 2015 U.S. Transgender Survey**. In. Washington, D.C.: National Center for Transgender Equality; 2016.

Shayne Taylor's 5 pronged approach to caring for Transgender Patients



Primary Care: Screen the parts they have. Assign no value or meaning to these parts.

Primary Care Case Example

- 40yo male to female transgender patient here to establish care. Has been on hormone therapy (spironolactone and estradiol) for the last 10 years prescribed by an endocrinologist in town who has just retired. Hopeful to have you take over hormone therapy. Has had top surgery (breast augmentation, 2003), but has not had any bottom surgery. Not currently sexually active, but interested in men. Other medical problems include HTN, treated with lisinopril.

What parts does this patient have?

- Breasts, prostate, testes, penis
- Assign no value or meaning to these parts.
- Your goal is just to keep them healthy

Screen according to Parts and Practices

- Screen according to the parts (and sexual practices)!
    - No good research on mammography in MTF trans patients, UCSF recs mammograms in patients >50 who have been on HRT >5 years
    - Prostate Cancer (and cervical cancer screen per guidelines)
        - Interpretation within the right context (PSA values may be off on hormone therapy, cervical atrophy on testosterone therapy)
    - Depression/anxiety/substance use/tobacco use
    - Suicidality
- Vaccines per ACIP guidelines, HepA/HepB if engages in sex with men

Mental Health Case Presentation

- 65yo male to female transgender veteran here to establish care. Served in Vietnam and has PTSD. Smokes 1ppd, has uncontrolled DM (last A1c 11%), history of CVA with residual right sided weakness, and CAD s/p NSTEMI. Came out as transgender 5 years ago. Has not yet found a doctor willing to do hormone therapy given her medical history. Came out to wife who is entirely unsupportive. Can't divorce her due to her veteran benefits. They live in separate parts of the house, and go weeks without talking. Kids don't want her around their children.

Specific Mental Health Concerns

Mental Health Concerns

- Suicide
- Mood Disorders
- Anxiety Disorders
- PTSD
- Body Image / Eating Disorders
- Substance Use Disorders
- Personality Disorders

Suicide

- Rates of suicide attempts among gender and sexuality minorities ranging from 1.5-7x rate of heterosexual, cis-gendered peers
- Transgender adults suffer the greatest suicide risk
  - Sparse data available; estimates range between 10%-45% of transgender and gender variant individuals attempt suicide

- *Haas A, al. e. Suicide and suicide risk in lesbian, gay, bisexual, and transgender populations: Review and recommendations. Journal of Homosexuality. 2011; 58: p. 10-51.*
- *King M, al. e. A systematic review of mental disorder, suicide, and deliberate self harm in lesbian, gay and bisexual people. BMC Psychiatry. 2008; 8(70): ps. e1-17.*

Mood Disorders

- Elevated depression risk in transgender pts (44.1%)
- Social stigma was positively associated with psychological distress, but is moderated by peer support from other transgender people
- Strong evidence that depression symptoms improve dramatically with the initiation of gender affirmation treatments, including hormones
- *Gorin-Lazard A, et al. Hormonal therapy is associated with better self-esteem, mood, and quality of life in transsexuals. Journal of Nervous and Mental Disorders. 2013; 201: p. 996-1000.*
- *Bockting W, Miner M, Swinburne Romine R, Hamilton A, Coleman E. Stigma, mental health, and resilience in an online sample of the US transgender population. Am J. of Public Health. 2013 May; 103(5): p. 943-951.*
- *Hoffmann B. An overview of depression among transgender women. Depression Research & Treatment. 2014: p. 1-9.*

Gender Affirming Care

What are your transition goals, and how can I help you get there?

Treatment Considerations: Female to Male

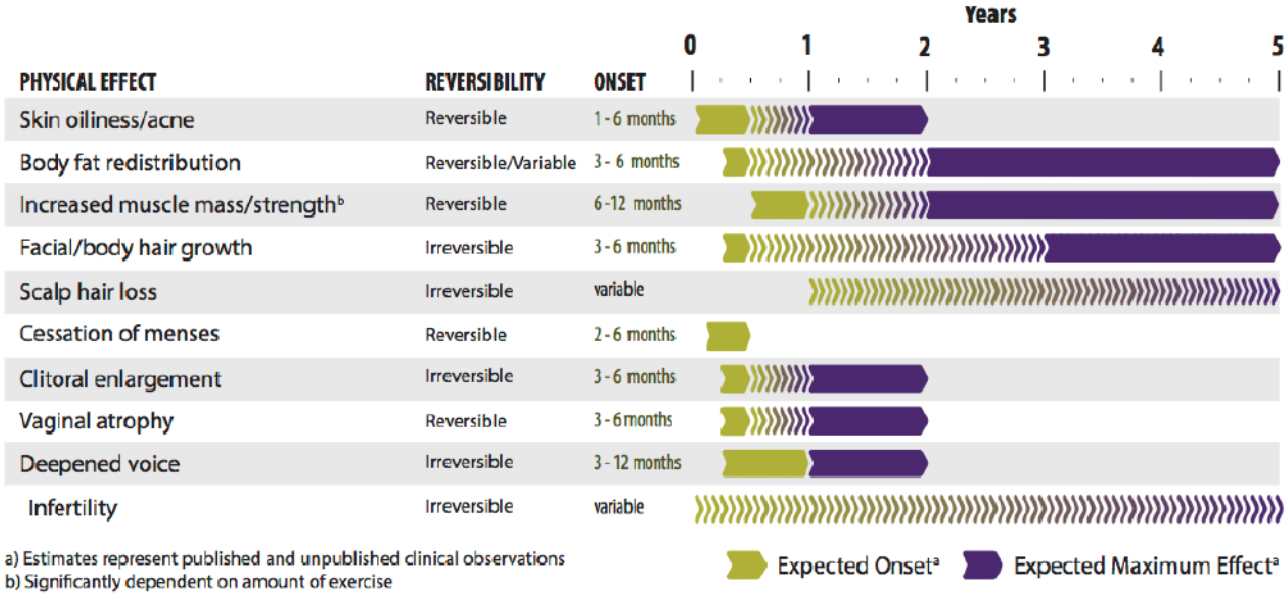
Hormone Therapy: Female to Male

- 1 drug: Testosterone
- Can do injections or transdermal
- Injections are cheaper, can do subQ or IM.
- Weekly or every 2 weeks
- Transdermal: daily, more expensive, dermal absorption is variable. Have to be cautious about gel not touching partners/kids/pets
- Monitor levels for a trough testosterone level between 400-700

Testosterone therapy (my practice)

- Start 25mg SubQ testosterone weekly (depends on which guidelines you read!)
- Dose adjust every 6-8 weeks with a goal of mid-dose injection total testosterone levels of 400-700ng/dL
- Usual dose is between 50-100mg weekly (some do injections every 2 weeks, with double the dose)
- Prior to starting: CBC, CMP, A1c, Lipid panel (+/- estradiol, testosterone baseline)
- Lab monitoring: ALT, HCT, Total testosterone
- Once on stable regimen, can space labs to q6months, and then q12months

Timeline of expected changes



a) Estimates represent published and unpublished clinical observations
b) Significantly dependent on amount of exercise

Surgical Therapy: Female to Male

- Mastectomy with chest reconstruction
- Metoidioplasty (uses current tissue from clitoral enlargement to make a neo-phallus)
- Phalloplasty (uses graft tissue, usually radial/forearm to make a neophallus)
- More on this in a future webcast by Dr. Julian Winocour

Treatment considerations Male to Female

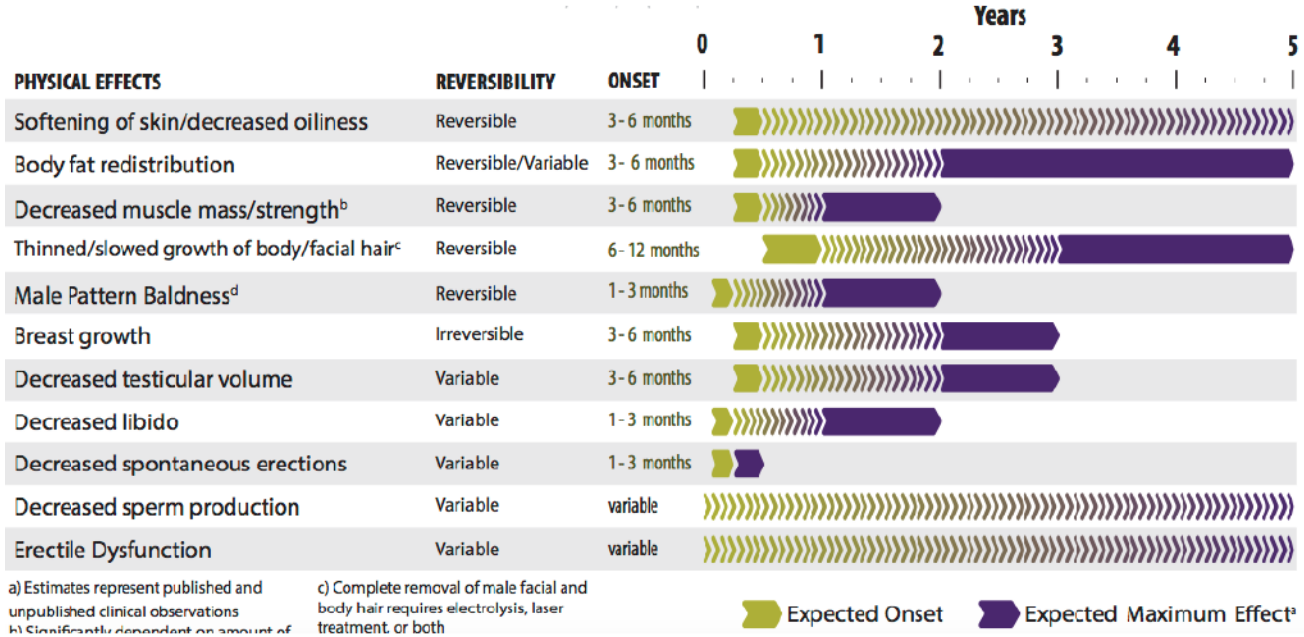
Hormone Therapy: Male to Female

- Goal: suppress testosterone, add estrogen
- Androgen blockers: sprinolactone used most frequently
- Monitor BMP, BP
- Estrogen: pills, patches, injections each with risks and benefits
- Pills are easy and CHEAP ($4 generic list at Wal-Mart, but highest risk of VTE)
- Injections can be subQ, usually weekly (dosing is different for estradiol cypionate vs estradiol valerate)
- Progesterone: data isn't great, may have some use with breast/nipple contour when first beginning treatment, increases VTE risk. Short term use only

The controversy of Estradiol levels.

- No real consensus
- Endocrine guidelines: goal for estradiol level between 100-200pg/dl
- Many others smart people aim goal of 300-500pg/dl
- Planned Parenthood approach: based on symptomatic response without lab monitoring
- My practice: still figuring it out! If patient's are unhappy a level between 100-200, can consider targeting higher levels

Timeline of Expected Changes



PHYSICAL EFFECTS	REVERSIBILITY	ONSET
Softening of skin/decreased oiliness	Reversible	3-6 months
Body fat redistribution	Reversible/Variable	3- 6 months
Decreased muscle mass/strength[b]	Reversible	3-6 months
Thinned/slowed growth of body/facial hair[c]	Reversible	6-12 months
Male Pattern Baldness[d]	Reversible	1-3 months
Breast growth	Irreversible	3-6 months
Decreased testicular volume	Variable	3-6 months
Decreased libido	Variable	1-3 months
Decreased spontaneous erections	Variable	1-3 months
Decreased sperm production	Variable	variable
Erectile Dysfunction	Variable	variable

a) Estimates represent published and unpublished clinical observations

b) Significantly dependent on amount of

c) Complete removal of male facial and body hair requires electrolysis, laser treatment, or both

Expected Onset

Expected Maximum Effect[a]

Ancillary considerations

- Voice therapy
- Hair removal- laser vs electrolysis
- Hair transplant for bald/balding transwomen

Surgical Therapy: Male to Female

- Electrolysis/laser hair removal
- Facial feminisation surgery
- Tracheal shave
- Breast augmentation, chest reconstruction
- Orchiectomy
- Penectomy
- Vaginoplasty

Non-binary patients

- Patients that may not identify with either sex, or identify with features of both sexes
- Often prefer they/them pronouns
- THE SAME RULES APPLY!
- "What are your transition goals and how can I help you get there?"
- Low doses of HRT, chest surgery are often desired.

Peds Case #1

4yo caucasian female presents to PCP for WCC. Mother is concerned that the patient only wants to wear her brother's clothes. She tells people she wants to be a man when she grows up, and corrects everyone who calls her pretty to tell her that she's handsome. The mom has even caught the child stuffing a pair of socks in her underwear to make it look like she had a penis. The mother is very concerned and wants to know if this is just a phase or something more serious.

What do you do for this patient? What do you tell mom?

Social transitioning

- Reversible
- Child lives as their identified gender by adopting hairstyle, clothing, pronouns, possibly new name
- Requires plan for disclosure to friends and family, cooperation with school

Peds Case #2

Now your patient is 11 years old and is here for WCC. She has a short haircut, is wearing boy's clothes and remains persistent that she identifies as male. On exam she has tanner stage 2 breast and pubic hair development. She has not had her first menstrual period. HEADSS assessment is positive for bullying and feelings of isolation. She has tried smoking cigarettes with some older kids at school. She is active in athletics, specifically soccer and basketball.

Now, how is this case different? What do you tell mom?

Gender dysphoria that intensifies with puberty, will rarely subside.

Persistent. Insistent. Consistent.

Puberty suppression: GNRH agonists

- Prevents the development of secondary sexual characteristics that may result in increased body dysmorphia and comorbid anxiety and depression
- Prevents secondary sexual traits would require multiple surgeries to reverse if patient were to fully transition (i.e. breast removal, electrolysis)
- Allows the patient and family more time to fully explore the patient's gender identity
- Completely reversible

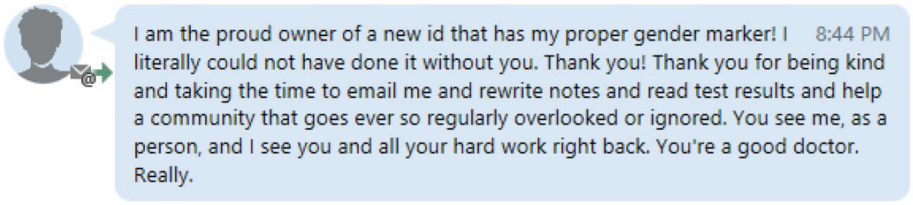
Cross Gender Hormone Therapy

- Requires good psychosocial support, stable mental health, responsible medication compliance, informed consent of risks etc.
- If the patient underwent pubertal suppression, some benefit to starting at the time when age matched peers would also be going through puberty, other guidelines recommend to start at 16
- Patient will be infertile if previously underwent pubertal suppression
- If patient underwent natural puberty, can start hormones at any time

Some meaningful stories/quotes

- "I've known I was a woman all of my life. The first time I tried coming out as trans to my parents I was 17, they scheduled the exorcism for that night. And then three more after that."
- "I came out as trans in the 1990s. I got a breast augmentation and was living as a woman. My dad died in the early 2000s. My mom said to me, you can either continue to do this or you can choose your family. I was scared. I missed my dad. I didn't want to lose my mom too. She gave me the money to get my implants taken out. I went back to the surgeon, and he just looked at me- like what are you doing here? I said, don't ask. Just take them out. Now 15 years later, I'm finally ready to live my authentic true self."

And the #1 reason why I do this.



RECAP Final points

- Be nice, compassionate physicians, nurses, providers. These patients often have negative interactions with healthcare providers
- Ask your TG patients what transitioning means to them, individual decisions different for each pt. Ask them how you can help them reach their goals.
- Screen your TG patients based on the anatomy/ organs/tissue that they have
- Ask about pronouns, use them. Apologize if you mess up (you will) and move on.
- Like my patients, my clinic is always in transition! We are learning to be patient and enjoy the journey. We have learned so so much.

Resources

- UCSF Guidelines
- Endocrine Society
- WPATH/USPATH (World/US Professional Association of Transgender Health)
- Rainbow Health Ontario
- Fenway Health
- University of British Columbia
- Facebook! (seriously)

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EXHIBIT 1-G
(Conventionally Filed)

EXHIBIT 1-H

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

Case No. 3:23-cv-00490

BONGO PRODUCTIONS, LLC, ROBERT BERNSTEIN, SANCTUARY PERFORMING ARTS LLC, AND KYE SAYERS, PLAINTIFFS

v.

CARTER LAWRENCE, TENNESSEE STATE FIRE MARSHAL, IN HIS OFFICIAL CAPACITY, CHRISTOPHER BAINBRIDGE, DIRECTOR OF CODES ENFORCEMENT, IN HIS OFFICIAL CAPACITY, GLENN R. FUNK, DISTRICT ATTORNEY GENERAL FOR THE 20TH JUDICIAL DISTRICT, IN HIS OFFICIAL CAPACITY, AND NEAL PINKSTON, DISTRICT ATTORNEY GENERAL FOR 11TH JUDICIAL DISTRICT, IN HIS OFFICIAL CAPACITY, DEFENDANTS

DECLARATION OF SHAYNE SEBOLD TAYLOR, MD

Preliminary statement

1. My name is Shayne Sebold Taylor, MD. I have been retained by counsel for Plaintiffs as an expert in connection with the above-mentioned litigation. I have actual knowledge of the matters stated herein.

2. I am an Assistant Professor of Internal Medicine and Pediatrics at Vanderbilt University Medical Center and the Monroe Carrell Jr. Children's Hospital at Vanderbilt in Nashville, Tennessee.

3. I am licensed in the state of Tennessee to practice medicine (TN License #55151).

4. I am board certified in both Internal Medicine and Pediatrics by the American Board of Internal Medicine and the American Board of Pediatrics, respectively.

5. I obtained my undergraduate degree at Emory University with a BS in Biology and a BA in Women and Gender Studies. I received my medical degree from Drexel University College of Medicine and completed my Internal Medicine and Pediatrics residencies at Vanderbilt University Medical Center.

6. I have lived and practiced medicine in the state of Tennessee since 2014.

7. Additional information about my professional background and experience is outlined in my curriculum vitae, a true and accurate copy of which is attached as Exhibit A to this report. In conjunction with serving as an Assistant Professor of Internal Medicine and Pediatrics at Vanderbilt, I am the creator and Lead Clinician of the Vanderbilt Clinic for Transgender Health, a multi-disciplinary patient-centered medical home for transgender adults. My clinical duties include providing primary care and transition-related care (particularly hormone therapy), as well as providing care navigation with specialists across the Vanderbilt medical community. I have over 700 transgender patients under my care with a 3-6 month waitlist to be seen for services. The majority of my patients reside in Middle TN, however I have patients traveling 3-4 hours to

come to the clinic spanning from Memphis to the west and Kingsport to the east.

8. In addition to my clinical work, I provide guidance to physicians throughout Vanderbilt and Middle Tennessee who care for transgender patients. I do this by giving grand rounds, presentations to medical students and residents, and training to various community providers on the importance of culturally competent care for the transgender patient.

9. As part of my practice, I stay current on medical research and literature relating to the care of transgender persons and patient's suffering with gender dysphoria.

10. I am a member of the World Professional Association of Transgender Health (WPATH), American Academy of Pediatrics (AAP), American College of Physicians (ACP), Alpha Omega Alpha (AOA) medical honor's society, and the Gay and Lesbian Medical Association (GLMA).

11. I am being compensated $350/hour for my time preparing this testimony. My compensation does not depend on the outcome of the litigation, the opinions I express, or the testimony I provide.

Sex, Gender, and Gender Identity

12. The sex of a child is most often determined after delivery based on the visual appearance of an infant's external genitals.

13. Research has identified that determination of sex is far more complex than what is seen on genital exam. Instead, sex is a complex compilation of multiple factors including one's chromosomal

make up (XX for those assigned female at birth, XY for those assigned male at birth), gonadal sex (presence of ovaries or testes), fetal hormonal sex (production of sex hormones *by* the fetus or exogenous exposure of sex hormones *to* the developing fetus), pubertal hormonal sex (the change in hormonal milieu that results in the development of secondary sexual characteristics-facial hair and deep voice for those assigned male at birth, breasts and menstrual cycles for those assigned female), hypothalamic sex (variations in brain structure and function as a result of embryonal exposure of sex hormones), and gender identity.

14. For each of the above factors that contribute to the development of sex, there can be variations. Sex related characteristics do not always align as either completely male or completely female. For example, many children are born with ambiguous genitalia, and as a result it is difficult to assign these infants as either male or female at birth. These patients are often identified as intersex, which is one of many disorders of sexual development (DSD). These children often see multiple specialists throughout their lifespan. Other examples of DSDs are those of chromosomal differences. The typical human chromosomal make up includes 46XY for males and 46XX for females. However, in male patients with Kleinfelter's syndrome their chromosomal make-up is 47XXY. These chromosomal male individuals have an extra X chromosome. The results include breast development and small testes, in addition to other physical findings. Patients with

Turner Syndrome are 45XO. These female individuals are missing an X chromosome, and as such many of them do not develop normal female puberty and are often infertile. These variations are common. The Monroe Carrell Children's Hospital at Vanderbilt has an entire clinic to cater to the medical needs of this patient population.

15. Gender identity is a person's inner sense of belonging to a particular gender. Identifying as male or female is a core component of one's overall identity. Every person has a gender identity. Research has shown that children begin to develop and express their gender identity during their toddler years, at around the age of 3 years old. It has a strong biological basis and cannot be changed.

16. Scientific research has discovered many biological reasons for how an individual develops a gender identity. Complex interactions between hormones, chromosomes, and the developing embryo in utero are at the center of these theories.

17. From a medical perspective, in the event that one's gender identity does not match their sex assigned at birth, i.e. in transgender people, one's gender identity should be the determining factor of their sex. The medical consensus recognizes that when one's sex related-characteristics are not in alignment, a person's gender identity is the determining factor, more important than the presence of their genitals, their chromosomal analysis, or their hormone levels.

Gender Dysphoria and its Treatment

18. Transgender people have a gender identity that differs from the sex that was assigned to them at birth.

19. This lack of alignment of assigned sex and gender identity can result in severe distress, depression, anxiety. This constellation of symptoms is termed gender dysphoria.

20. Treating gender dysphoria results in significant improvement in the quality of life, mental and physical health of transgender persons. Transgender people undergoing treatment for their gender dysphoria can live long, happy, productive and meaningful lives.

21. Gender transition for those that suffer from Gender Dysphoria is a lengthy process with multiple components. These components may include social transition, medical transition, and surgical transition. Each transgender individual approaches transition differently, as the decision to undergo any aspect of transition is deeply personal and depends on the degree and type of dysphoria the patient is experiencing.

22. The social transition is a formative aspect of a transgender person's experience. Social transition can include going by a different name, using different pronouns, or changing one's haircut, or clothing to match one's gender identity.

23. As part of the social transition, a transgender individual will make changes that will allow them to seamlessly incorporate into their communities with a presentation that matches with their gen-

der identity. This may mean using a restroom facility that matches their gender identity, in the same way that a non-transgender person uses the bathroom that matches their gender identity.

24. In addition to social transition, transgender individuals often interface with a healthcare setting for medical or surgical intervention. Medical transition often includes the prescription of hormones so that the transgender person can develop secondary sexual characteristics of the sex with which they identify. This may mean that a transgender man (or someone who was assigned female at birth) may grow facial hair and develop a much deeper voice as a result of testosterone treatment. Alternatively, transgender women (assigned male at birth), may develop breast tissue and a more feminine body fat distribution as a result of estrogen that may be prescribed by a clinician.

25. Some transgender patients seek surgical transition. These surgical procedures further change the patient's anatomy so that their outward appearance matches more closely with their gender identity.

26. Given the medical and surgical treatments that transgender patients may encounter, they are often no longer presenting as their sex assigned at birth. This will further create stress and anxiety for bathroom users, both transgender and otherwise. An example is as follows: a transgender man has been on testosterone therapy for many years. As a result, he has a full-grown beard. He has also had surgical removal of his breast tissue.

He wears men's clothing and speaks in a deep voice. It is harmful for that man to have to use a woman's restroom.

Transgender in Tennessee

27. According to a Williams Institute study in 2016, there are approximately 1.6 million people in the United States that identify as transgender. In this same study, it was revealed that an estimated 31,000 transgender people (or 0.6% of the state's population) live in the state of Tennessee. Tennessee is ranked 10th in the nation for its percentage of transgender individuals (Hawaii being the highest and North Dakota with the lowest).

28. H.B. 1182 requires a sign that specifically mentions the term "biological sex." This term has no place or meaning in either science or medicine, because experts who study sex and gender understand that the biology and identity of a human being is far more complex than what can be identified on an individual's genital anatomy or chromosomal evaluation. Having this controversial political term, one that has no value or meaning in medicine or science, posted on every public bathroom in the state of Tennessee is dangerous and distressing, further running the risk of worsening gender dysphoria for those that suffer from the condition.

29. The 31,000 transgender individuals in Tennessee work in Tennessee businesses, go to Tennessee schools and are active members of their families, communities and churches to name a few. Transgender Tennesseans deserve privacy when they

use the restroom. Using the restroom at a business is often necessary and should be routine. A transgender patron should not have to effectively disclose their transgender status by using the designated restroom that matches their sex assigned at birth. A transgender person should be able to use the restroom that matches with their gender identity. A large posted sign referencing "biological sex" on every business is stigmatizing and isolating for transgender Tennesseans. The Act that goes into law on July 1, 2021 is harmful and dangerous for these members of our community.

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

Dated: June [24], 2021

/s/ SHAYE SEBOLD TAYLOR, MD
SHAYNE SEBOLD TAYLOR, MD

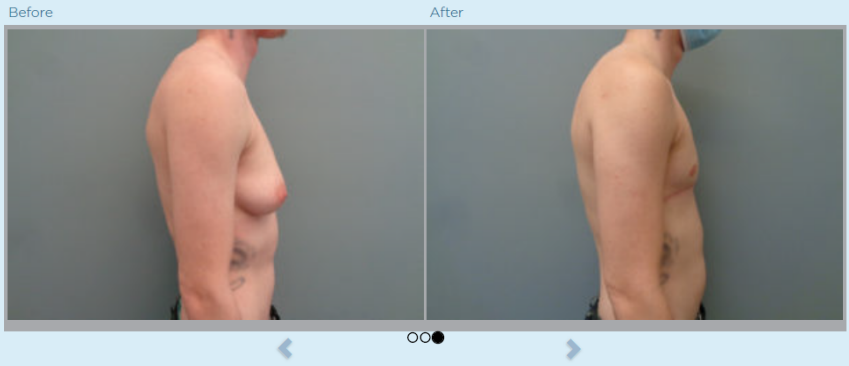
EXHIBIT-I

Home—Plastic Surgery Before and After Pictures in Nashville, TN—Transgender-Female to Male

Before & After Pictures In Nashville, TN

TRANSGENDER-FEMALE TO MALE BEFORE & AFTER PICTURES IN NASHVILLE, TN

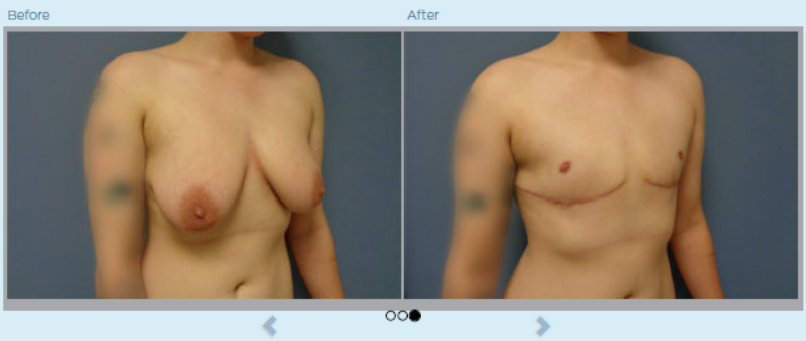
Patient 7437: 28 year old female who underwent removal of breast tissue as well as liposuction.



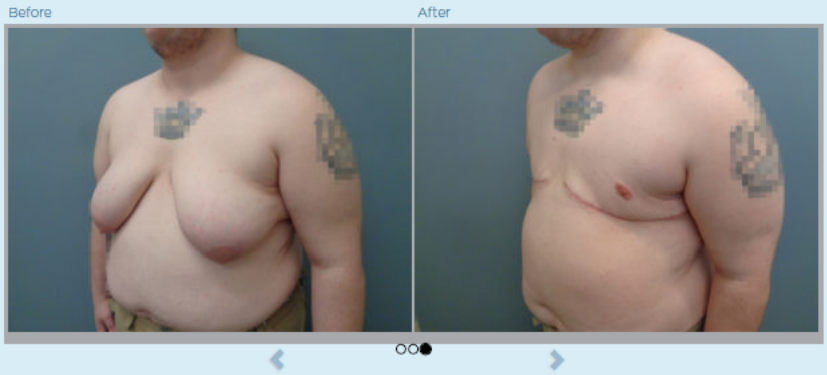
Patient 10237: 15 year old female to male who underwent removal of breast tissue.

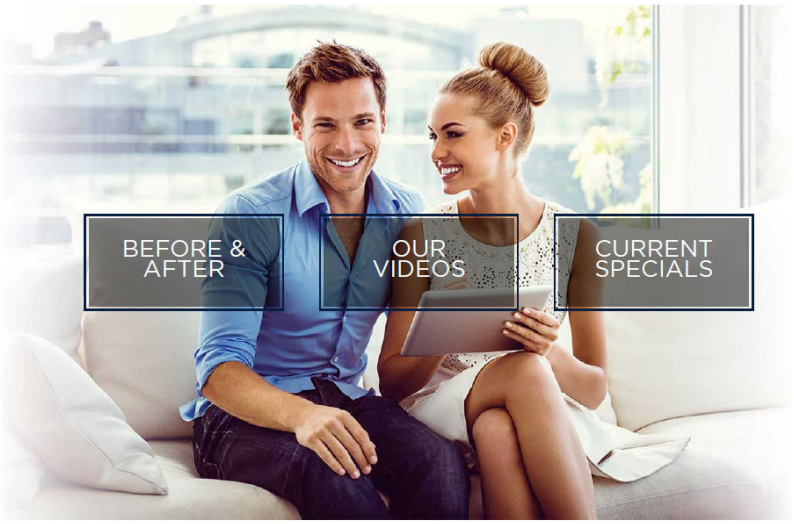
Patient ST486819: 29 year old female to male who underwent removal of breast tissue as well as liposuction.

Patient 5869: 20 year old female to male who underwent removal of breast tissue as well as liposuction.



Patient 6635: 24 year old female to male who underwent removal of breast tissues as well as liposuction.





SOCIAL

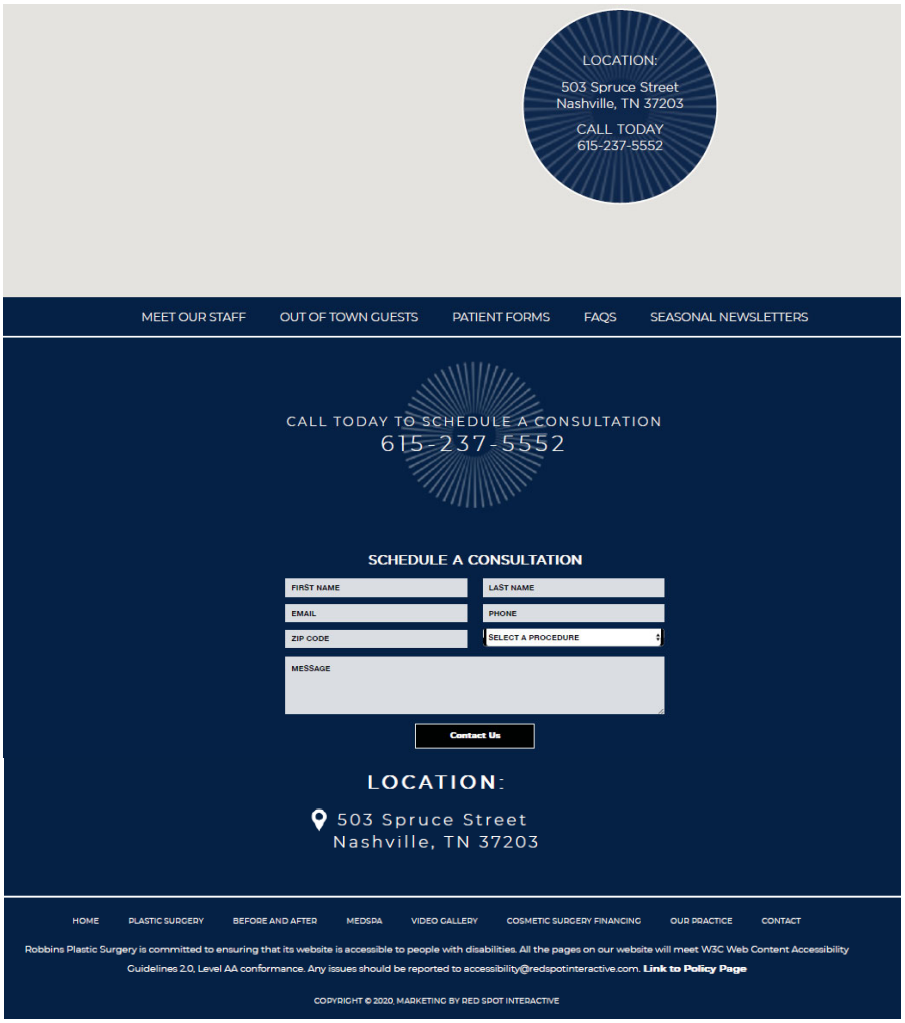

LOCATION:
503 Spruce Street
Nashville, TN 37203
CALL TODAY
615-237-5552
MEET OUR STAFF
OUT OF TOWN GUESTS
PATIENT FORMS
FAQS
SEASONAL NEWSLETTERS
CALL TODAY TO SCHEDULE A CONSULTATION
615-237-5552
SCHEDULE A CONSULTATION
FIRST NAME
LAST NAME
EMAIL
PHONE
ZIP CODE
SELECT A PROCEDURE
MESSAGE
Contact Us
LOCATION:
503 Spruce Street
Nashville, TN 37203
HOME
PLASTIC SURGERY
BEFORE AND AFTER
MEDSPA
VIDEO GALLERY
COSMETIC SURGERY FINANCING
OUR PRACTICE
CONTACT
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EXHIBIT 1-J

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

Civil Action No. 3:23-cv-00376

L.W., ET AL., PLAINTIFF

v.

JONATHAN SKRMETTI, DEFENDANT

DECLARATION OF C. WRIGHT PINSON, MBA, MD

I, C. Wright Pinson, MBA, MD, hereby state as follows:

1. My name is C. Wright Pinson, MBA, MD. I am over the age of eighteen and have personal knowledge of the facts set forth herein.

2. I am the Deputy CEO and Chief Health System Officer of Vanderbilt University Medical Center ("VUMC"), an academic medical center with its principal offices in Nashville, Tennessee. I have served in this capacity from April 30, 2016 to the present. In this role I have senior management responsibility for all aspects of the health care business and operations of VUMC.

3. I am submitting this Declaration in connection with the lawsuit captioned above.

4. I am familiar with the provisions of 2023 Public Chapter 1, codified at Tenn. Public Acts §§ 68-33-101, *et seq.* (hereafter, the "Act").

5. The Act prohibits a healthcare provider on and after July 1, 2023 (the "Effective Date") from knowingly

performing or administering any "medical procedure" (as defined in § 68-33-102(5) of the Act) to a minor, if the performance or administration of that medical procedure (as defined in the Act) is for the purpose of enabling a minor to identify with or live as a gender other than their sex at birth, *or* treating discomfort or distress from discordance between a minor's assigned sex and their asserted identity. As defined in the Act, "medical procedure" includes, but is not limited to, prescribing, administering or dispensing any puberty blocker (as further defined in the Act) or hormone (as further defined in the Act) (collectively referred to herein as "Hormone Therapy").

6. Notwithstanding the prohibition discussed immediately above, the Act provides that a medical procedure (as defined in the Act) which commences before the Effective Date may continue to be performed or administered to a minor patient through March 31, 2024, if the minor's treating physician determines that ending the medical procedure would be harmful to that specific patient. Pursuant to Section 68-33-103(b)(3) of the Act, this determination must be certified by the treating physician, must include specific findings by the treating physician which support such determination, and must be documented in the individual minor patient's medical record (the "Continued Care Exception").

7. After the Act was signed into law, VUMC reviewed the Act and determined that on and after the Effective Date it could no longer offer any Hormone Therapy to minor patients. VUMC has communicated this determination to its patients through communications distributed through various media (including the US Mail, and electronically to existing patients sent

through MyHealth@Vanderbilt®, VUMC's digital patient health information portal).

8. As of the date of this Declaration, no minor patient of VUMC has been identified who will continue to receive Hormone Therapy at VUMC following the Effective Date in reliance on the Continued Care Exception.

9. Should enforcement of the Act's provisions prohibiting Hormone Therapy be deferred, delayed or enjoined, VUMC would continue to provide Hormone Therapy consistent with prevailing standards of care for persons with gender dysphoria to those minor patients of VUMC for whom such care is clinically appropriate, given the assessment of the patient's condition.

I, C. Wright Pinson, MBA, MD, hereby declare under the penalty of perjury that the foregoing is true and accurate.

/s/ C. WRIGHT PINSON
C. WRIGHT PINSON, MBA, MD

[5/11/23]
DATE

EXHIBIT 1-K

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

Civil Action No. 3:23-cv-00376

L.W., ET AL., PLAINTIFF

v.

JONATHAN SKRMETTI, DEFENDANTS

DECLARATION OF CASSANDRA C. BRADY, MD

I, Cassandra C. Brady, MD, hereby state as follows:

1. My name is Cassandra C. Brady, MD. I am over the age of eighteen and have personal knowledge of the facts set forth herein.

2. I am an Assistant Professor of Clinical Pediatrics at Vanderbilt University Medical Center ("VUMC"), an academic medical center with its principal offices in Nashville, Tennessee.

3. I received my medical degree from Indiana University School of Medicine and completed my residency in General Pediatrics at Monroe Carrell Jr. Children's Hospital at Vanderbilt. I then completed a fellowship in Pediatric Endocrinology at Cincinnati Children's Hospital Medical Center.

4. I have been licensed to practice medicine in the State of Tennessee since 2015. I am board certified in both General Pediatrics and Pediatric Endocrinology by the American Board of Pediatrics.

5. I am a member of the American Academy of Pediatrics, the Endocrine Society, and the Pediatric Endocrine Society. I am also a member of the World Professional Association for Transgender Health ("WPATH").

6. I have been treating patients with gender dysphoria since 2012, and I have extensive experience in the treatment of adolescents with gender dysphoria. My clinical duties at VUMC have included providing gender-affirming care such as puberty blocking and hormone treatments to transgender/gender diverse youth with gender dysphoria.

7. I believe 2023 Public Chapter 1, codified at Tenn. Public Acts §§ 68-33-101, *et seq.* (hereafter, the "Act"), is harming my transgender/gender diverse patients by interfering with their ability to receive necessary medical care in accordance with recognized standards of care for transgender persons, including WPATH Standards of Care Version 8.

8. Prior to the passage of the Act, I had over 200 transgender/gender diverse patients under my care. After the Act was signed into law, VUMC reviewed the Act and determined that on and after July 1, 2023, when the Act takes effect (the "Effective Date"), it would no longer offer Hormone Therapy (as defined in Dr. C. Wright Pinson's Declaration of May 11, 2023) to minor patients. VUMC has communicated this determination to patients.

9. As of the date of this Declaration, I have not identified minor patients who will continue to receive Hormone Therapy at VUMC following the Effective Date in reliance on § 68-33-103(b)(3) (the "Continued Care Exception") for several reasons, including that some of my

minor patients have not returned to clinic since the Act was passed and many are already seeking care out of state. For those who are unable to seek care out of state, weaning from Hormone Therapy has begun, but it is too soon to determine whether they can be weaned from their medications by the Effective Date without harm.

10. Additionally, I am concerned that my determination that a patient meets the Continued Care Exception could subsequently be deemed by non-medical third parties to violate the Act, which could expose me to punitive consequences.

I, Cassandra C. Brady, MD, hereby declare under the penalty of perjury that the foregoing is true and accurate.

/s/ CASSANDRA C. BRADY
CASSANDRA C. BRADY MD

[5/18/23]
DATE

EXHIBIT 1-L

October 7, 2022

Representative Zachary,

I write in response to your letter of September 28, 2022 on behalf of Vanderbilt University Medical Center ("VUMC") and its Board of Directors regarding the concerns about surgical care provided through the transgender clinic for those under age 18.

VUMC began its Transgender Health Clinic in 2018 because transgender individuals are at high risk for mental and physical health issues, and have been consistently underserved by our nation's healthcare systems. Among those patients under 18 receiving transgender care, an average of 5 per year have received gender-affirming surgical procedures. Contrary to some media reports, all were at least 16 years of age, none have received genital procedures and parental consent to these surgeries was obtained in all cases. None of these surgeries have been paid for by state or federal funds; the revenues from this limited number of surgeries represent an immaterial percentage of VUMC's net operating revenue.

VUMC approaches its responsibility to care for patients by following the most widely recognized national and international standards of care, while at all times doing so in accordance with state and federal laws. Our clinical

teams provide transgender care that is informed by the professional practice standards and guidance established by leading medical specialty societies, such as the Endocrine Society and the World Professional Association of Transgender Health (WPATH). We fully comply with the requirements of legislation passed by the General Assembly in 2021, now codified at Tenn. Code Ann. § 63-1-169, which prohibits providing hormone therapy to prepuberal children.

VUMC serves as the employment home for over 40,000 people and our people express their views in many forums, including hundreds of open conferences on our campus facilities each year. Comments from videos posted on social media that are obtained at these kinds of events should not be construed as statements of VUMC policy. VUMC's policies and practices allow employees to request an accommodation to be excused from participating in surgeries or procedures they believe are morally objectionable. We do not condone discrimination against employees who choose to request accommodations.

You have asked that VUMC halt permanent gender affirmation surgeries being performed on minor children. On September 6, 2022, WPATH published a new version of its recommendations to health care professionals for treatment of transgender persons, known as SOC-8. In light of these new recommendations, and as part of completing our internal clinical review of the SOC-8 guidance in patients under 18, we will be seeking advice from local and national clinical experts. We are pausing gender affirmation surgeries on patients under age 18 while we complete this review, which may take several months.

In addition, we understand this issue is likely to be taken up by the General Assembly in its next legislative session. As always, we will assure that VUMC's programs comply with any new requirements which may be established as a part of Tennessee law.

1161 21st Avenue South
D3300 Medical Center North
Nashville, TN 37232-2104

tel 615.343.9324
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I trust this letter has been responsive to the concerns which have been surfaced to you and your colleagues.

Sincerely yours,

/s/ C. Wright Pinson
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EXHIBIT 2

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ACTA PÆDIATRICA NURTURING THE CHILD WILEY

REVIEW ARTICLE

A systematic review of hormone treatment for children with gender dysphoria and recommendations for research

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Abstract

Aim: The aim of this systematic review was to assess the effects on psychosocial and mental health, cognition, body composition, and metabolic markers of hormone treatment in children with gender dysphoria.

Methods: Systematic review essentially follows PRISMA. We searched PubMed, EMBASE and thirteen other databases until 9 November 2021 for English-language studies of hormone therapy in children with gender dysphoria. Of 9934 potential studies identified with abstracts reviewed, 195 were assessed in full text, and 24 were relevant.

Results: In 21 studies, adolescents were given gonadotropin-releasing hormone analogues (GnRHa) treatment. In three studies, cross-sex hormone treatment (CSHT) was given without previous GnRHa treatment. No randomised controlled trials were identified. The few longitudinal observational studies were ham-

pered by small numbers and high attrition rates. Hence, the long-term effects of hormone therapy on psychosocial health could not be evaluated. Concerning bone health, GnRHa treatment delays bone maturation and bone mineral density gain, which, however, was found to partially recover during CSHT when studied at age 22 years.

Conclusion: Evidence to assess the effects of hormone treatment on the above fields in children with gender dysphoria is insufficient. To improve future research, we present the GENDHOR checklist, a checklist for studies in gender dysphoria.

KEYWORDS

adolescent, bone density, gender dysphoria, gonadotropin-releasing hormone agonist, psychosocial functioning

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Abbreviations: BMD, bone mineral density; CSHT, cross-sex hormone treatment; DXA, dual-energy X-ray absorptiometry; GnRHa, gonadotropin-releasing hormone agonist (analogues); GRADE, grades of recommendation, assessment, development and evaluation; ICD, International Classification of Diseases; MRI, magnetic resonance imaging; SBU, Swedish Agency for Health Technology Assessment and Assessment of Social Services.

Berit Kriström and Mikael Landén have equal contrbution.

[†]Part of the original study group but deceased in December 2021.

Key Notes

- This systematic review assessed psychosocial effects, bone health, body composition and metabolism, and therapy persistence in children (<18 years of age) with gender dysphoria undergoing treatment with gonadotropin-releasing hormone analogues (GnRHa).
- Long-term effects of hormone therapy on psychosocial health are unknown. GnRHa treatment delays bone maturation and gain in bone mineral density.
- GnRHa treatment in children with gender dysphoria should be considered experimental treatment of individual cases rather than standard procedure.

1 | INTRODUCTION

Gender incongruence refers to a mismatch between the biological sex and perceived gender identity. When gender incongruence causes significant discomfort, it is called gender dysphoria. When gender dysphoria causes clinically significant distress, the condition might meet the diagnostic criteria for transsexualism according to

the (international classification of disease) ICD-10 guidelines,[1] or gender dysphoria according to the DSM-5.[2] Gender identity-affirming health care is provided to ease gender dysphoria.[3] The treatment aims to align bodily characteristics with the individual's gender identity, and usually includes cross-sex hormone treatment (CSHT), as well as chest and genital surgery.

In youth with gender dysphoria, gonadotropin-releasing hormone analogues (GnRHa) have been used to inhibit spontaneous puberty development. The rationale is to prevent irreversible bodily changes and give young individuals time to explore their gender identity. Following the first case report in which a GnRHa was used to suppress puberty in a female-to-male transsexual individual,[4] the "Dutch protocol" was developed.[5] According to this protocol, young pubertal people presenting with gender dysphoria should first undergo a thorough psychological evaluation. If the diagnosis gender dysphoria is confirmed, GnRHa treatment is recommended to start during the early stages of puberty (Tanner stages 2-3). If gender dysphoria subsides, the individual may discontinue GnRHa treatment, at which point spontaneous puberty will restart. If gender dysphoria persists, CSHT might start at age 16 years and sex-reassignment surgery at 18 years. Gender dysphoria in youth was a rare phenomenon when the Dutch multidisciplinary protocol for the treatment of gender dysphoria was introduced. Seeking care for gender dysphoria has since become increasingly common in younger people in many parts of the western world,[6,7] with an exponential rise among children born female.[8] Although not all children with gender dysphoria receive gender identity affirming treatment, there has been an ensuing increase in hormones to treat chil-

dren with gender dysphoria, of which data on the effects and side effects are limited. There is no previous systematic review or meta-analysis of hormone treatment for children with gender dysphoria.

This systematic review aimed at assessing (a) psychosocial effects, (b) effects on bone health, (c) effects on body composition and metabolism, and (d) satisfaction and therapy persistence in children aged <18 years with gender dysphoria undergoing hormone therapy. In this review, trans women are referred to as male-to-female and trans men as female-to-male.

2 | METHODS

2.1 | Preregistration

This systematic review originated from a 2-year commissioned work from the governmental body the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU). Ongoing SBU reviews are registered on the SBU website (https://www.sbu.se/en/ongoing-projects/) but not recorded in external databases.

2.2 | Selection criteria

The search was restricted to children aged <18 years with reported gender dysphoria. We included observational studies, randomized controlled trials, and systematic reviews according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[9] Case reports, editorials, and non-human studies were excluded from further review. The search was limited to English-language publications.

2.3 | Search strategy

Two professional information specialists at the Swedish Agency for Health Technology Assessment and Assessment for Social Services (SBU) performed a comprehensive search of the following medical databases up until 9 November 2021: CINAHL (EBSCO), Cochrane Library (Wiley), EMBASE (Embase.com), PsycINFO (EBSCO), PubMed (NLM), Scopus (Elsevier), and SocINDEX (EBSCO). They also searched the Campbell Library, Epistemonikos, Evidence Search, International HTA database, as well as three NIHR Centre for Reviews and Dissemination (CRD) databases: Database of Abstracts of Reviews of Effects (DARE), Health, and Technology Assessment (HTA), and NHS Economic Evaluation Database (EED). Finally, we searched PROSPERO, an international prospective register for systematic reviews, to identify any relevant ongoing systematic reviews but found none. The search, selection, and assessment were conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[9] The search and selection processes are outlined in Figure 1. Only studies of low or moderate bias were eligible for this review. Full literature search strategy is provided at the SBU web page (https://www.sbu.se/contentassets/4062b596a35c4e1383405766b7365076/bilaga-1-litteratursokning.pdf).

2.4 | Relevance, risk of bias, and quality of evidence

Two independent experts checked all hits for relevance. Relevant studies (based on a pre-defined PICO) were then evaluated for risk of bias, also by two independent experts, according to ROBINS-I (Risk of bias in non-randomised studies of interventions).[10,11] Robins-I as-

sesses possible bias in seven domains: confounding; bias due to selection, measurement classification of interventions, deviations from intended interventions, missing data, measurement of outcomes, and selection of the reported result.

If the two reviewers did not agree on content or quality, the paper was discussed in the larger research team of four experts (JFL, PR, BK, ML). Randomised controlled trials were planned to be assessed by RoB-2.[10,11] To rate the quality of evidence for specific outcomes, we used the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) system.[12] GRADE has four levels of evidence (very low, low, moderate, high) and considers five domains that can decrease the level of certainty one or two levels (risk of bias, imprecision, inconsistency, indirectness (similar to 'external validity'), and publication bias).

2.5 | Data extraction

Two reviewers (MH, JA) retrieved data from the included studies. The data extracted included the outcomes mental and psychosocial health including suicidality, anthropometric measures and metabolism, bone health, adverse events, and the characteristics of each study including age at referral or intake, age at start of GnRHa treatment, age at start of CSHT, number of participants enrolled in study, number of transgender participants, number of hormone treated transgender participants, number of non-transgender participants, number of participants evaluated, treatment type (drugs, dosages, type of administration, treatment frequency), total treatment duration, and total follow-up time. The full data extraction of included studies is provided at the SBU web page (https://www.sbu.se/content

assets/4062b596a35c4e1383405766b7365076/bilaga-3-tabellverk-over-inkluderade-studier.pdf).

2.6 | Statistics

No statistical analyses were performed.

2.7 | Ethics

Ethical approval is not applicable for this systematic review.

3 | RESULTS

3.1 | Identified studies

After duplicate removal, the search yielded 9934 potential studies (Figure 1). Of these, 195 were selected for thorough reading. Of these, 36 were relevant and assessed for risk of bias. Twelve studies were excluded because of high risk for bias, leaving 24 studies with low to moderate, moderate, or moderate to high risk of bias reviewed in this paper. A list of excluded studies is provided at the SBU web page (https://www.sbu.se/contentassets/4062b596a35c4e1383405766b7365076/bilaga-2-exkluderade-studier-med-hog-risk-for-bias.pdf).

3.2 | Characteristics of the 24 studies

All 24 relevant studies had been published since 2014 (Table 1). Study participant age at the start of GnRHa therapy was typically between 11 and 15 years (range 9-18.6 years), with CSHT rarely being introduced before age 15. Except for the Hisle-Gorman et al.[6] (n = 3 754 participants) and Mullins et al.13 (n = 611) papers, few studies included >200 individuals. GnRHa treatment often continued for around 2 years, sometimes up to 4 years, and similar treatment durations were observed or reported for CSHT as observations were usually not reported after age 18 years. Full details of in-

cluded studies are given at the SBU web page. Overall, there were eight studies on GnRH alone, 13 studies on GnRH+CSHT, and three studies on CSHT alone.

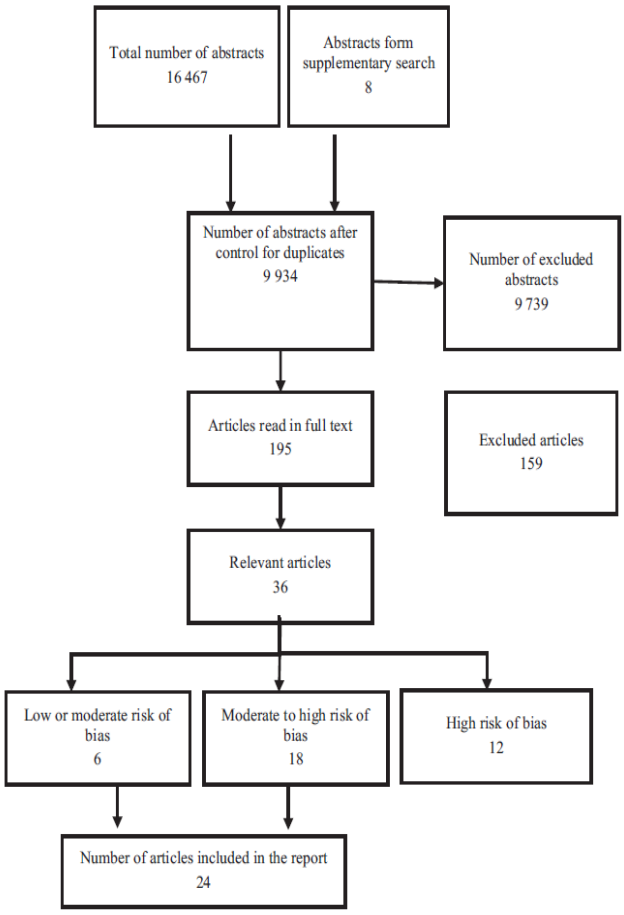

FIGURE 1 PRISMA flow diagram.

3.3 | Psychosocial and mental health

Table 2 outlines the six studies that examined psychosocial outcomes and cognitive effects.[14-19] Three of these studies found significantly improved overall psychosocial function after GnRHa treatment as measured by the Children's Global Assessment Scale (CGAS).[14-16] Two of these studies observed no statistically significant change in gender dysphoria.[15,16] Two of these studies reported significantly improved self-rated quality of life after treatment measured through Kidscreen-27, Short Form-8 (SF-8), Child Behaviour Checklist (CBCL) (parent report), and Youth Self Report (YSR),[16,17] while another study reported no statistically significant differences in anxiety and depression between those who started and not started hormone therapy.[18]

Because these studies were hampered by small number of participants and substantial risk of selection bias, the long-term effects of hormone treatment on psychosocial health could not be evaluated. Of note, the above studies do not allow separation of potential effects of psychological intervention independent of hormonal effects.

3.4 | Cognitive outcomes

We could only identify one study of low-moderate bias on cognitive outcomes in children with gender dysphoria receiving GnRHa therapy.[19] This cross-sectional study from the USA comprised 20 treated (8 male-to-female and 12 female-to-male) and 20 untreated (10 male-to-female and 10 female-to-male) young transgender persons and a control group (n=45). Controls were identified from age-matched family members and friends. The Tower of London task was administered to

assess executive functioning. The study neither found differences in cognitive function between treated and untreated transgender persons, nor between treated transgender persons and controls. However, because no before-after GnRHa therapy analyses were performed, the study could not investigate potential cognitive effects of hormone therapy.

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TABLE 2 Summary of findings on psychosocial outcomes of puberty-blocking treatment (GnRHa) treatment in children with gender dysphoria.[14–19]

Outcome measures	Number of study participants, description of studies	Main result	"Certainty of evidence"	Deduction in GRADE[a]
Global function	*n* on hormones = 251 *n* evaluated = 113 Four observational cohort studies: one prospective and three retrospective studies[14–17]	Improved global function as assessed with the CGAS	Cannot be assessed	−2 risk of overall bias[b] −2 precision[c]
Suicide ideation	*n* on hormones = 42 *n* evaluated = 28 One prospective observational cohort study with mixed treatment (38 subjects with no pharmacological treatment)[18]	No change in suicide ideation	Cannot be assessed	−2 risk of overall bias[b] −2 precision[c]
Gender dysphoria	*n* on hormones = 145 *n* evaluated = 49 Two prospective observational cohort studies[15,16]	No change in gender dysphoria	Cannot be assessed	−2 risk of overall bias[b] −2 precision[c]
Depression	*n* on hormones = 97 *n* evaluated = 60 Two prospective observational cohort studies of which one included mixed treatment[15,18]	No change in depression	Cannot be assessed	−2 risk of overall bias[b] −2 precision[c]
Anxiety	*n* on hormones = 97 *n* evaluated = 60 Two prospective observational cohort studies[14,18]	No change in anxiety	Cannot be assessed	−2 risk of overall bias[b] −2 precision[c]
Cognition	*n* on hormones = 20 *n* evaluated = 20 One study[19]	No change in cognition compared with matched controls	Cannot be assessed	−2 risk of overall bias[b] −2 precision[c]
Quality of life	*n* on hormones = 98 *n* evaluated = 46 Two observational cohort studies, whereof one retrospective[16,17]	1. Improvement in quality of life most pronounced in subjects receiving puberty-blocking hormones, followed by gender-affirming hormone treatment[17] 2. Some improvement[16]	Cannot be assessed	−2 risk of overall bias[b] −2 precision[c]

Abbreviation: CGAS, Children's Global Assessment Scale.

[a]Starting at 4 for optimal studies in each study type.

[b]Selection of study participants is difficult to assess, analysis not based on stage in puberty development.

[c]Few study subjects in each study, heterogeneity in outcome and analyses.

3.5 | Bone health outcomes

Six longitudinal studies used dual-energy X-ray absorptiometry (DXA) scan technology to explore bone health before and again after some time with GnRHa treatment (Table 3). The second DXA scan usually coincided with CSHT initiation leading to different follow-up durations. The third DXA scan was performed after variable time with CSHT, performed with variable dosing and administration. The lumbar spine and hip were most often examined. One study investigated bone geometry.[20] Six studies were retrospective[21-26] and one study was prospective.[20] An additional study was cross-sectional where study participants in early puberty (Tanner stages 2-3) were examined only once, before the start of GnRHa therapy.[27]

Three studies reported a lower bone mineral density (BMD) in patients before or at start of GnRHa treatment compared with the general population of the same biological sex and age.[21,23,27] During GnRHa treatment, BMD estimated through area or volume, and expressed in z-scores increased less compared with general population reference values. However, the mean absolute BMD remained unchanged up to 2-3 years of GnRHa treatment.[20,23] The initiation of CSHT stimulated bone maturation and mineral accrual, increasing BMD.[21,22] After a median CSHT duration of 5.4 years in in female-to-male and 5.8 years in male-to-female, the lumbar spine mean areal BMD z-score was still significantly lower than at the start of GnRH therapy, while the other volume BMD and femoral neck estimates had normalised.[21] In another study, female-to-male receiving testosterone replacement therapy for 1-2 years had not regained their group mean BMD z-score registered at the start of GnRHa therapy.[24]

Bone geometry, estimated as subperiosteal width and endocortical diameter, was studied on DXA scans before start of GnRHa treatment and after at least two years on CSHT and compared with reference values of the general population: the bone geometry resembled the reference curve for the experienced sex only when GnRHa was started during early puberty. Bone geometry estimates in those who started GnRHa treatment during mid and late puberty remained within the reference curve of the biological sex.[26]

TABLE 3 Summary of effects on bone development by puberty-blocking treatment (GnRHa) followed by CSHT in children with gender dysphoria.[20-25]

Outcome measures	Number of study participants, description of studies	Main Result	"Certainty of Evidence"	Deduction in GRADE[a]
Bone density during puberty-blocking hormonal treatment (g/cm^2, g/cm^3)	*n* on hormones = 363 *n* evaluated = 297 Five observational cohort studies (four retrospective and one prospective)[20-24]	Unchanged bone density (DXA measurement)	⊕⊕◯◯ Low certainty	-1 risk of overall bias[b] -1 precision
Bone density during puberty blocking hormonal treatment in relation to reference data in the literature (z-score)	*n* on hormones = 408 *n* evaluated = 292 Five observational cohort studies (four retrospective, and one prospective)[21-25]	Decreased increase in bone density over time	⊕⊕◯◯ Low certainty	-1 risk of overall bias[b] -1 precision
Bone density after 1–3 years (up to 22 years of age) of CSHT, which had been preceded by puberty-blocking hormonal treatment in relation to reference data in the literature	*n* on hormones = 268 *n* evaluated = 165 Three observational cohort studies (two retrospective and one prospective)[21,24,25]	After group median five years with CSHT, bone density recovered in hip but not in lumbar spine compared to data at start of treatment (z-score)	⊕⊕◯◯ Low certainty	-1 risk of overall bias[b] -1 precision

Abbreviations: CSHT, Cross-sex hormone treatment; DXA, Dual-Energy X-ray Absorptiometry.

[a]Starting at 4 for optimal studies in each study type.

[b]Analysis not based on stage in puberty development.

3.6 | Body composition and metabolic markers

GnRHa treatment effectively reduced endogenous sex hormone serum levels (Table 4). DXA scans after 1 year of GnRHa treatment revealed increased fat mass and reduced lean body mass.[28] Longitudinal growth depends on bone maturity (bone age) of those in the study group. Ongoing pubertal growth spurt will be arrested when GnRHa therapy is started, reducing the growth velocity to the prepubertal rate.[29]

Nokoff et al studied body composition and insulin sensitivity during 1 year of GnRHa therapy.[30] In addition to body composition, metabolic effects as insulin sensitivity during CSHT, and changes in blood pressure during testosterone therapy were examined.[31-33] Of these studies, three originated from Amsterdam.[29,32,33] The Amsterdam studies included observations during GnRHa therapy,[28] 1 year after starting CSHT,[32] as well as after a group median >5 years with CSHT in a cohort of 22-year-old adolescents.[31,33] The studies from Amsterdam were generally larger than the other studies. CSHT changed body composition towards the affirmed sex.[31,32] Obesity (defined as BMI >30 at age 22 years) was more prevalent in the transgender population[33] (Table 4).

3.7 | CSHT in children without prior GnRHa treatment

We were able to identify three studies of low-to-moderate bias examining CSHT in children without prior GnRHa treatment.[13,34,35] All were retrospective longitudinal studies. Because the number of study participants was small, studies were deemed to have low external validity, and because the studies examined different outcomes (e.g., lipid serum levels, Hb, blood pressure, metrorrhagia), it was not possible to draw any overall

conclusions from these studies. Although the Mullins et al. paper[13] included several individuals at elevated risk of arterial or venous thrombosis, no cases of thrombosis were reported.

4 | DISCUSSION

We performed an extensive literature search to examine psychosocial and cognitive outcomes as well as metabolic and bone health in children with gender dysphoria taking hormone therapy. No randomised controlled trials were found, but we could identify 24 relevant observational studies. However, these were limited by methodological weaknesses, for instance lack of or inappropriate control group, lack of intra-individual analyses, high attrition rates that precluded conclusion to be drawn. The exception being that children with gender dysphoria often had lower group mean values for BMD already prior to GnRHa treatment, and that GnRHa treatment delays the physiologically occurring BMD gain during pubertal sex hormone stimulation. However, this GnRHa-induced delay in BMD gain is almost fully compensated for by later ensuing CSHT. Although study participants were followed up to 22 years of age, the observed remaining deficit may depend on the limited study group size or on too short observation time.[21]

Our review highlights several specific knowledge gaps in gender dysphoria that are important to bridge not least given the recent increased incidence in many countries.[6,7] First, randomised controlled trials are lacking in gender dysphoria research. We call for such studies, which may be the only way to address biases that we have noted in the field. Given the current lack of evidence for hormonal therapy improving gender

dysphoria, another ethically feasible option would be to randomise individuals to hormone therapy with all study participants, independent of intervention status, receiving psychological and psychosocial support. However, controlled trials do not necessarily require placebo treatment, but could for example build on the date or time of starting hormonal therapy to generate comparison groups. However, it should also be noted that this is a highly vulnerable population.

A second limitation concerns the statistical management of data. In the reviewed studies, observational data have frequently been analysed at a group level where intra-individual changes would have been more appropriate. Intra-individual analyses would allow for a better understanding of how subgroups of individuals respond (both positively and negatively) to hormone therapy. Group-level analyses are sensitive to selection bias because of high drop-out rates: The group studied at the end of the study is a selection of the group studied at baseline, which increases indirectness (reduces external validity). Moreover, it is important to analyse the distribution of individual data to be able to identify outliers who may be at risk for severe consequences of treatment.

Third, many studies only present data on chronological age but fail to account for puberty stage and biological age. This is a concern because the main purpose of GnRHa treatment is to suppress puberty and, with that, biological ageing.

Fourth, long-term studies are lacking. The duration of GnRHa treatment and CSHT was rarely >4 years. The absence of long-term studies is worrying because many individuals start treatment as minors (<18 years)

and CSHT is lifelong. Fifth, individuals who stop GnRHa treatment before the start of CSHT need to be described and followed up. Sixth, some of the findings underlying this review are old, and studies reflecting the changing demographics of individuals seeking care for gender dysphoria are warranted.

TABLE 4 Summary of findings of puberty-blocking (GnRHa) hormone treatment on anthropometric measures, body composition, and metabolism in children with gender dysphoria.[28–33]

Outcome measures	Number of study participants, description of studies	Main result	"Certainty of Evidence"	Deduction in GRADE[a]
Anthropometric measures	*n* on hormones = 192 *n* evaluated = 192 One retrospective observational cohort study[31]	Increased weight and body mass index	Cannot be assessed	-2 risk for overall bias[b] -1 precision[c] -1 indirectness[d]
Body composition	*n* on hormones = 325 *n* evaluated = 286 Two prospective observational cohort studies and one controlled cross-sectional study[28,30,31]	Decreased lean body mass	Cannot be assessed	-2 risk for overall bias[b] -1 precision[c] -1 indirectness[d]
Metabolic measures	*n* on hormones = 209 *n* evaluated = 209 One retrospective observational cohort study and one controlled cross-sectional study[30,32]	No change in serum lipids or blood pressure Increased insulin level in MtF Decreased insulin sensitivity	Cannot be assessed	-2 risk for overall bias[b] -1 precision[c] -1 indirectness[d]
Blood pressure	*n* on hormones = 15 *n* evaluated = 15 One retrospective observational cohort study[33]	Change in blood pressure	Cannot be assessed	-2 risk for overall bias[b] 1 precision[c] -1 indirectness[d]
Growth (cm/year)	*n* on hormones = 55 *n* evaluated = 55 One prospective multicentre observational GnRHa treatment cohort study[29]	Reduced growth velocity	Cannot be assessed	-2 risk for overall bias[b] -1 precision[c] -1 indirectness[d]

[a]Starting at 4 for optimal studies in each study type.
[b]Selection of study participants is difficult to assess. Analysis not based on stage in puberty development.
[c]Few study subjects in each study, hence there is heterogeneity in outcome and analyses.
[d]Single study. In this context, 'indirectness' is similar to 'external validity'.

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Finally, we could not evaluate the frequency of individuals who drop out from GnRHa treatment and no longer wish to continue with gender transition. However, a follow up study was published after our literature search.[36] Of 720 children (31% born male and 69% born female) who started GnRHa treatment in adolescence, 98% continued to use hormone treatment into adulthood, which suggests that children generally continue with gender transition once they have started GnRHa treatment. We know from internet-based surveys that detransitioning exists,[37] but such studies cannot provide reliable estimates of detransitioning frequency because of selection bias. Studies that closely follow individuals who start GnRHa therapy and/or CSHT until at least age 30 are urgently needed. We also acknowledge there are other potential side effects from GnRHa therapy or CSHT that were not included in our review such as alopecia and abscesses from injections.[38]

Due to limitations in reporting of data, previous published studies in this field repeatedly contain insufficient details on drug administration and dosages, treatment duration, and the type of surgery performed. Some of these limitations will be partly remedied by the introduction of the new ICD version 11, and the Utrecht criteria,[39] but the field also urgently needs high quality longitudinal studies that not only assess medical outcomes but also those outcomes that matter most for affected individuals. Building on the identified limitations in previous research, we compiled a checklist to improve gender dysphoria research ("GENDHOR", Table 5). The aim of this checklist is not to replace existing research guidelines, but using it together with existing

guidelines might support researchers and peer reviewers, and ultimately benefit patients and their families.

Last, there have been studies in this field published after the date of our literature search (9 November 2021). These have not been added to this study in order to not depart from the systematic approach. We nevertheless wish to comment on some of the publications. First, the National Institute for Health and Care Excellence in England (NICE) conducted evidence reviews of GnRHa[40] as well as CSHT[41] for children with gender dysphoria, which were independent from our work. The conclusions generally align with our findings. Second, Chien et al.[42] recently published a prospective study of psychosocial functioning during 2 years after initiation of CSHT in youths (12-20 years of age) with gender dysphoria. Of 315 participants, 162 completed that study. Life satisfaction increased, and depression and anxiety scores decreased, among biological females but not biological males. The strongest finding was a moderately improved appearance congruence. No information on concomitant psychological or psychopharmacological therapy was provided.

5 | CONCLUSION

This systematic review of almost 10000 screened abstracts suggests that long-term effects of hormone therapy on psychosocial and somatic health are unknown, except that GnRHa treatment seems to delay bone maturation and gain in bone mineral density.

AUTHOR CONTRIBUTIONS

Study concept and design: All authors. Acquisition of data: Malin Höistad, Jan Adolfsson. Drafting of the manuscript: All authors. Interpretation of data and

critical revision of the manuscript for important intellectual content: All authors. Administrative, technical, or material support: Jan Adolfsson, Malin Höistad. Funding acquisition: the Swedish agency for technology assessment and assessment for social services.

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Information specialists Klas Moberg and Hanna Olofsson designed and performed the literature search.

FUNDING INFORMATION

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CONFLICT OF INTEREST STATEMENT

JFL coordinated an unrelated study on behalf of the Swedish inflammatory bowel disease quality register (SWIBREG) that received funding from the Janssen Corporation. JFL has also received financial support from Merck Sharp & Dohme developing a paper reviewing national healthcare registers in China. JFL is currently discussing potential research collaboration with Takeda. ML has received lecture honoraria for Lundbeck pharmaceuticals and served as consultant for AstraZeneca. The other authors report no conflict of interest.

The data collection of this study was funded by the Swedish agency for technology assessment and assessment for social services. JA and MH are employees at this agency.

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EXHIBIT 3

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

Civil Action No. 3:23-cv-00376

L.W., BY AND THROUGH HER PARENTS AND NEXT FRIENDS, SAMANTHA WILLIAMS AND BRIAN WILLIAMS, ET AL., PLAINTIFFS

v.

JONATHAN SKRMETTI, IN HIS OFFICIAL CAPACITY AS THE TENNESSEE ATTORNEY GENERAL AND REPORTER, ET AL., DEFENDANTS

EXPERT DECLARATION OF JAMES CANTOR, PhD

Table of Contents

I. Credentials and Qualifications

A. Education and professional background

1. I am a sexual behavior scientist, with an internationally recognized record studying the development of human sexualities, and an expert in research methodology of sexuality. My curriculum vitae is attached as Appendix 1 to this report. My publication record includes both biological and non-biological influences on sexuality, ranging from pre-natal brain development, through adulthood, to senescence. The primary, but not exclusive, focus of my own research studies has been the development of atypical sexualities. In addition to the studies I myself have conducted, I am regularly consulted to evaluate the research methods, analyses, and proposals from sexual behavior scientists throughout the world. The methodologies I am qualified to assess span the neurochemical and neuroanatomic level, individual behavioral level, and social and interpersonal levels.

2. I am trained as a clinical psychologist and neuroscientist, and I am the author of over 50 peer-reviewed articles in my field, spanning the development of sexual orientation, gender identity, hypersexuality, and atypical sexualities collectively referred to as *paraphilias*. Although I have studied many atypical sexualities, the most impactful of my work has been MRI and other biological studies of the origins of pedophilia. That work has revolutionized several aspects of the sex offender field, both with regard to the treatment of offenders and to the prevention of sexual abuse of children. In 2022, I received the Distinguished Contribution Award from the Association for the Treatment and Prevention of Sexual Abuse in recognition of my research and its in-

tegration into public policy. My efforts in this regard have been the subject of several documentary films.

3. Over my academic career, my posts have included Senior Scientist and Psychologist at the Centre for Addiction and Mental Health (CAMH), and Head of Research for CAMH's Sexual Behaviour Clinic. I was on the Faculty of Medicine of the University of Toronto for 15 years and have served as Editor-in-Chief of the peer reviewed journal, *Sexual Abuse*. That journal is one of the top-impact, peer-reviewed journals in sexual behavior science and is the official journal of the Association for the Treatment and Prevention of Sexual Abuse. In that appointment, I was charged to be the final arbiter for impartially deciding which contributions from other scientists in my field merited publication. I believe that appointment indicates not only my extensive experience evaluating scientific claims and methods, but also the faith put in me by the other scientists in my field. I have also served on the Editorial Boards of *The Journal of Sex Research*, the *Archives of Sexual Behavior*, and *Journal of Sexual Aggression*. I am currently the Director of the Toronto Sexuality Centre in Canada. Thus, although I cannot speak for other scientists, I regularly interact with and am routinely exposed to the views and opinions of most of the scientists active in our field today, within the United States and throughout the world.

4. For my education and training, I received my Bachelor of Science degree from Rensselaer Polytechnic Institute, where I studied mathematics, physics, and computer science. I received my Master of Arts degree in psychology from Boston University, where I studied neuropsychology. I earned my doctoral degree in psychology from McGill University, which included suc-

cessfully defending my doctoral dissertation studying the effects of psychiatric medication and neurochemical changes on sexual behavior, and included a clinical internship assessing and treating people with a wide range of sexual and gender identity issues.

5. I have a decades-long, international, and award-winning history of advocacy for destigmatizing people with atypical sexualities. While still a trainee in psychology, I founded the American Psychological Association's (APA) Committee for Lesbian, Gay, and Bisexual Graduate Students. Subsequently, I have served as the Chair for the Committee on Science Issues for APA's Division for the Psychology of Sexual Orientation and Gender Diversity and was appointed to its Task Force on Transgender Issues. Throughout my career, my writings and public statements have consistently supported rights for transgender populations and the application of science to help policy-makers best meet their diverse needs. Because my professional background also includes neurobiological research on the development of other atypical sexualities, I have become recognized as an international leader also in the destigmatizing of the broader range of human sexuality patterns.

6. I am highly experienced in the application of sex research to forensic proceedings: I have served as the Head of Research for the Law and Mental Health Program of the University of Toronto's psychiatric teaching hospital, the Centre for Addiction and Mental Health, where I was appointed to the Faculty of Medicine.

7. I have served as an expert witness in 21 cases in the past four years, as listed on my *curriculum vitae*.

These cases included criminal, civil, and custody proceedings, preliminary injunction and Frye hearings, as well as trials. I have testified in courts in Canada and throughout the U.S., including Alabama, Arizona, Florida, Illinois, Indiana, Kansas, Kentucky, Massachusetts, New York, Texas, Utah, and West Virginia. I have provided expert testimony concerning the nature and origins of atypical sexualities, as well as concerning gender dysphoria and gender identity in children.

8. For my work in this case, I am being compensated at the hourly rate of $400 per hour. My compensation does not change based on the conclusions and opinions that I provide here or later in this case or on the outcome of this lawsuit.

B. Clinical expertise vs. scientific expertise

9. In clinical science, there are two kinds of expertise: Clinicians' expertise regards applying general principles to the care of an individual patient and the unique features of that case. A scientist's expertise is the reverse, accumulating information about many individual cases and identifying the generalizable principles that may be applied to all cases. Thus, different types of decisions may require different kinds of experts, such that questions about whether a specific patient represents an exception to the general rule might be better posed to a physician's expertise, whereas questions about establishing the general rules themselves might be better posed to a scientist's.

10. In legal matters, the most familiar situation pertains to whether a given clinician correctly employed relevant clinical standards. Often, it is other clinicians who practice in that field who will be best equipped to speak to that question. When it is the clinical standards

that are themselves in question, however, it is the experts in the assessment of scientific studies who are the relevant experts.

C. The professional standard to evaluate treatment models is to rely on objective assessors, not treatment model users in a conflict of interest with its results.

11. I describe in a later section the well-recognized procedures for conducting reviews of literature in medical and scientific fields to evaluate the strength of evidence for particular procedures or treatments. Importantly, the standard procedure is for such evaluations to be conducted by objective assessors with expertise in the science of assessment, and not by those with an investment in the procedure being assessed. Because the people engaged in providing clinical services are necessarily in a conflict of interest when claiming that their services are effective, formal evaluations of evidence are routinely conducted by those *without* direct professional involvement and thus without financial or other personal interest in whether services are deemed to be safe or effective. This routine practice standard is exemplified by all of the only three systematic, comprehensive research reviews that have been conducted concerning the safety and efficacy of puberty blockers and cross-sex hormones as treatments for gender dysphoria in children.

12. In 2020, England's National Health Service (NHS) commissioned a major review of the use of puberty blockers and cross-sex hormones in children and young people and appointed prominent pediatrician Dr. Hilary Cass to lead that review, explicating that "Given the increasingly evident polarization among clinical

professionals, Dr. Cass was asked to chair the group as a senior clinician with *no prior involvement* or fixed views in this area." (Cass 2022 at 35, italics added.) Dr. Cass's committee in turn commissioned formal systematic reviews of evidence from the England National Institute for Health & Care Excellence (NICE), a government entity of England's Department of Health and Social Care, established to provide guidance to health care policy, such as by conducting systematic reviews of clinical research, but without direct involvement in providing treatment to gender dysphoric individuals. (https://www.nice.org.uk/.) Similarly, the Finnish health care council commissioned its systematic review to an external firm, Summaryx Oy. (Pasternack 2019.) Summaryx Oy is a "social enterprise" (a Finnish organization analogous to a non-profit think-tank) that conducts systematic research reviews and other analyses for supporting that nation's medical and social systems. Its reviews are conducted by assessment professionals, not by clinicians providing services. (www.summaryx.eu/en/.) The systematic review by Sweden's National Board of Health and Welfare (NBHW) included four experts. (SBU Scoping Review 2019.) In addition to their own research fields, they provided clinical services in areas adjacent to but apart from gender dysphoric children, such as physical disorders of sexual development (Dr. Berit Kriström) or gender dysphoria in adults (Dr. Mikael Landén).

13. My own most-cited peer-reviewed paper relating to gender dysphoria in minors illustrates the expertise in the evaluation of scientific evidence that I have and am recognized for. That is, that paper provided not clinical advice or a clinical study, but rather a review and interpretation of the available evidence concerning de-

sistance in children who suffer from gender dysphoria, as well as of evidence (and lack of evidence) concerning the safety and efficacy of medical transition to treat gender dysphoria in minors. (Cantor 2019.)

14. My extensive background in the assessment of sexuality research and in the development of human sexuality places me in exactly the position of objectivity and freedom from conflict-of-interest required by the universal standards of medical research science.

15. I do not offer opinions about the best public policy. Multiple jurisdictions have attempted multiple different means of implementing that science into various public policies. Although I accept as an axiom that good public policy must be consistent with the scientific evidence, science cannot objectively assess societal values and priorities. Therefore, my opinions summarize and assess the science on which public policy is based, but I can offer no opinion regarding which public policy mechanisms would be best in light of that science.

II. Multiple international health care systems that had initially expanded medicalized transition to include minors have reversed that policy, as research on safety and effectiveness accumulated, in a growing international trend against the medicalized transition of minors.

16. Medicalized interventions for minors originated in European clinics (most prominently in the Netherlands and Sweden), and these precedents (and in particular the so-called "Dutch Protocol") are frequently cited by American clinicians. However, growing concerns about safety together with the continuing absence of reliable evidence of benefit even after more than 20 years of experience have led respected and far-from "con-

servative" European health care ministries to step back and discourage or even cease providing medicalized transition of minors, other than in exceptional and carefully limited circumstances, such as within registered and approved research trials. Instead, these authorities now endorse psychotherapy as the treatment of choice for minors, with medical interventions representing a method of last resort, if permitted at all. These range from medical advisories to outright bans on the medical transition of minors. I provide details concerning these policy changes below, and provide additional details regarding the underlying systematic reviews in Section II and VI below.

A. England

17. The National Health Service (NHS) of the United Kingdom centralized gender counselling and transitioning services into a single clinic, the Gender Identity Development Service (GIDS) of the Tavistock and Portman NHS Foundation Trust. Between 2008 and 2018, the number of referrals to the clinic had increased by a factor of 40, leading to a government inquiry into the causes. (Rayner 2018.) The GIDS was repeatedly accused of approving and endorsing medical transition in minors without adequate justification, including by 35 members of the GIDS own staff, who resigned by 2019. (BBC News 2021; Donnelly 2019). An ex-governor and psychotherapist of the Trust who resigned, Marcus Evans, said staff feared being called transphobic, which was impacting their objectivity in their work. (Doward 2019).

18. In 2020, a former patient of the GIDS, Keira Bell, brought a lawsuit alleging that the GIDS practices with respect to prescribing puberty blockers for minors were

unproven and potentially harmful in ways that meant that it was impossible for minors to give meaningful informed consent. After taking extensive expert evidence, the trial court concluded that puberty blockers might have "potentially irreversible" and "life-changing" effects on a young person (*Bell v. Tavistock*, [2020] EWHC 3274 (Admin), ¶ 148, 151), that there was "very limited evidence as to its efficacy" (¶ 134) such that "it is right to call the treatment experimental" (¶ 148), and that use of puberty blockers almost always led to use of cross-sex hormones that "may well lead to a loss of fertility" (¶¶ 137-138). While an appeals court later concluded that the trial court had exceeded the proper role of the court in making factual findings on these questions, the appeals court acknowledged that "Medical opinion is far from unanimous about the wisdom of embarking on treatment before adulthood. The question raises not only clinical medical issues but also moral and ethical issues, all of which are the subject of intense professional and public debate." (Bell v. Tavistock 2021 at ¶ 3.)

19. Perhaps prompted by the Kiera Bell litigation, also in 2020 the English National Health Service ("NHS") commissioned the thorough independent review of the use of puberty blockers and cross-sex hormones to be chaired by Dr. Cass that I have described above. After an extensive process that included obtaining the systematic reviews of all published studies bearing on safety or efficacy of these hormonal interventions in minors as well as "extensive" listening sessions with clinicians, patients, and families, in February 2022 Dr. Cass issued an extensive "Interim Report" summarizing the state of the relevant medical science and in particular highlighting the presence of serious but unstud-

ied risks, and the lack of strong evidence of efficacy. I will quote specific items from Dr. Cass's Report as relevant to specific topics below. At a high level, Dr. Cass concluded that to date there has been "very limited research on the sexual, cognitive, or broader developmental outcomes" from the use of puberty blockers for gender dysphoria (Cass 2022 at 19), that it is an unanswered question "whether the evidence for the use and safety of [puberty blockers] is strong enough as judged by reasonable clinical standards" (at 37), and that "the available evidence was not strong enough to form the basis of a policy position" with regard to use of both puberty blockers and cross-sex hormones in minors (at 35).

20. Following issuance of Dr. Cass's Interim Report, the English NHS has published a consultation document concerning a proposed revised service specification under which "NHS England will only commission [puberty blockers] in the context of a formal research protocol." (NHS Interim Service Specification at 12.)

B. Finland

21. In Finland, minors were made eligible for medicalized transition in 2011 by that country's health care service, the Council for Choices in Health Care in Finland (COHERE). Assessments of mental health and preparedness were centralized by law into two research clinics, Helsinki University Central Hospital and Tampere University Hospital.

22. In 2019, the Service Selection Council (Palko) of the Finnish Ministry of Social Affairs and Health commissioned a systematic review of the effectiveness and safety of medicalized transition (Pasternack 2019), and in 2020, Finnish researchers published an analysis of the outcomes of adolescents diagnosed with transsexu-

alism and receiving cross-sex hormone treatment in Finland's Tampere University Hospital. (Kaltiala 2020.) Despite the purpose of medical transition being to improve mental health, the study showed:

> Medical gender reassignment is not enough to improve functioning and relieve psychiatric comorbidities among adolescents with gender dysphoria. Appropriate interventions are warranted for psychiatric comorbidities and problems in adolescent development. (Kaltiala 2020 at 213.)

They concluded that the youth who were functioning well after transition were those who were already functioning well before transition, and those who were functioning poorly before transition continued to function poorly after transition.

23. Importantly, the results of this study exemplify why correlations reported from surveys cannot be interpreted as evidence of causality. Mental health assessment would exclude the most poorly functioning youth from among those permitted to transition, but transition itself did not improve the functioning of those who were permitted to transition.

24. Consistent with the results of the independent evidence review by Summaryx Oy and analysis of the ethical issues involved, Finland's health care service ended the surgical transition of minors, ruling in 2020 that "Surgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors." (COHERE Summary 2020.) The review of the research concluded that "[N]o conclusions can be drawn on the stability of gender identity during the period of disorder caused by a psychiatric illness with symptoms that hamper development." (COHERE

Summary 2020.) COHERE also greatly restricted access to puberty-blocking and cross-sex hormonal treatments, explicating that they may be considered for minors "only if it can be ascertained that their identity as the other sex is of a permanent nature and causes severe dysphoria," and only "if the need for it continues *after* [any] other psychiatric symptoms have *ceased* and adolescent development is progressing normally." (COHERE Summary 2020, italics added.) They restricted the procedures to their centralized research clinics. The council was explicit in noting the lack of research needed for decision-making, "There is also a need for more information on the disadvantages of procedures and on people who regret them." (COHERE Summary 2020.) In light of the special developmental and ethical considerations surrounding minors, COHERE recommended that "no decisions should be made that can permanently alter a still-maturing minor's mental and physical development." (COHERE Recommendation 2020 at 7.)

C. Sweden

25. Sweden's national health care policy regarding trans issues has developed quite similarly to that of the UK. Already in place 20 years ago, Swedish health care policy permitted otherwise eligible minors to receive puberty-blockers beginning at age 14 and cross-sex hormones at age 16. At that time, only small numbers of minors sought medical transition services. An explosion of referrals ensued in 2013-2014. Sweden's Board of Health and Welfare ("Socialstyrelsen") reported that, in 2018, the number of diagnoses of gender dysphoria was 15 times higher than 2008 among girls ages 13-17. (Swedish Socialstyrelsen Support 2022 at 15.)

26. Sweden has long been very accepting with regard to sexual and gender diversity. In 2018, a law was proposed to lower the age of eligibility for surgical care from age 18 to 15, remove the requirement for parental consent, and lower the legal age for change of gender to age 12. A series of cases of regret and suicide following medical transition were reported in the Swedish media. (Orange 2020.) In 2019, the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) therefore initiated its own systematic review of the research. The SBU released English-language results first as a summary and then published as a peer reviewed article. (Ludvigsson et al., 2023.) Like the UK, the Swedish investigation employed standardized review methods to ensure the encapsulation of the all the relevant evidence and came to the same conclusions: "This systematic review of almost 10,000 screened abstracts suggests that long-term effects of hormone therapy on psychosocial and somatic health are unknown, except that GnRHa treatment seems to delay bone maturation and gain in bone mineral density." (Ludvigsson 2023 at 12.) They emphasized, "The absence of long-term studies is worrying because many individuals start treatment as minors (<18 years) and CSHT is lifelong." (Ludvigsson 2023 at 10.) Regarding the full set of studies, "No randomised controlled trials were found, but we could identify 24 relevant observational studies. However, these were limited by methodological weaknesses, for instance lack of or inappropriate control group, lack of intraindividual analyses, high attrition rates that precluded conclusion to be drawn." (Ludvigsson 2023 at 9-10.)

27. In 2021, the leading Swedish pediatric gender clinic, at the Karolinska Institute, issued a new policy

statement in which it stated that the Swedish evidence review "showed a lack of evidence for both the long-term consequences of the treatments, and the reasons for the large influx of patients in recent years." (Karolinska 2021.) The Karolinska Institute further stated that "These treatments are potentially fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis." In a dramatic reversal of its policy, the Institute announced that "In light of the above, and based on the precautionary principle, which should always be applied, it has been decided that hormonal treatments (i.e., puberty blocking and cross-sex hormones) will not be initiated in gender dysphoric patients under the age of 16." Further, the Karolinska clinic announced that patients ages 16-18 would receive such treatments *only* within research settings (clinical trials monitored by the appropriate Swedish research ethics board). (Karolinska 2021.)

28. In 2022, the Swedish National Board of Health and Welfare published a major new national policy document concerning "Support, investigation and hormone therapy in gender incongruence in children and youth," including an English-language summary. (Swedish Socialstyrelsen Support 2022.) The National Board of Health noted "the continued lack of reliable scientific evidence concerning the efficacy and the safety of both [puberty blockers and cross-sex hormones]," and concluded (based on the commissioned evidence reviews) that "the evidence on treatment efficacy and safety is still insufficient and inconclusive for all reported outcomes. Further, it is not possible to determine how common it is for adolescents who undergo gender-affirming treatment to later change their perception of

their gender identity or interrupt an ongoing treatment." As a result, the Board of Health concluded that, "[f]or adolescents with gender incongruence, the . . . risks of puberty suppressing treatment with GnRH-analogues and gender-affirming hormonal treatment currently outweigh the possible benefits." (Swedish Socialstyrelsen Support 2022 at 10-12.) Accordingly, the Swedish Board of Health and Welfare "recommends restraint when it comes to hormone treatment." (Swedish Socialstyrelsen Updated Recommendations 2/22/22.)

D. France

29. While medical authorities in France have not issued any actual restriction, in 2022, the Académie Nationale de Médecine of France issued a strongly worded statement, citing the Swedish ban on hormone treatments:

> [A] great medical caution must be taken in children and adolescents, given the vulnerability, particularly psychological, of this population and the many undesirable effects, and even serious complications, that some of the available therapies can cause . . . such as impact on growth, bone fragility, risk of sterility, emotional and intellectual consequences and, for girls, symptoms reminiscent of menopause." (Académie Nationale de Médecine 2022.)

For hormones, the Académie concluded "the greatest reserve is required in their use," and for surgical treatments, "[T]heir irreversible nature must be emphasized." The Académie warned "the risk of over-diagnosis is real, as shown by the increasing number of transgender young adults wishing to 'detransition'." Rather than medical interventions, it advised health care pro-

viders "to extend as much as possible the psychological support phase." The Académie reviewed and emphasized the evidence indicating the very large and very sudden increase in youth requesting medical transition. It attributed the change, not to society now being more accepting of sexual diversity, but to social media, "underlining the addictive character of excessive consultation of social networks which is both harmful to the psychological development of young people and responsible, for a very important part, of the growing sense of gender incongruence." (Académie Nationale de Médecine 2022.)

E. Norway

30. In 2022, Norway's Healthcare Investigation Board (Ukom) began a review of that country's guidelines for the medicalized transition of minors. (Block, Norway's Guidance, 2023.) In 2023, it released its report, which concluded that the evidence for the use of puberty blockers and cross-sex hormone treatments in youth was insufficient, and acknowledged the international recognition of the dearth of evidence of safety and effectiveness. The report deemed medicalized transition to be experimental. (Ukom 2023, Summary and Section 11.) The report faulted the existing Norwegian guidelines, published in 2020, for concentrating on "equality and rights" while "deviating from the requirements for the development of knowledge-based guidelines." (Ukom 2023, Summary.)

31. The Norwegian report concluded that "The knowledge base, especially research-based knowledge for gender-affirming treatment (hormonal and surgical), is insufficient and the long-term effects are little known" and that "This applies particularly to the teen-

age population, which accounts for a large part of the increase in referrals to the specialist health service in the last decade." (Ukom 2023, Summary and Section 7.)

32. In an interview about the report with the *British Medical Journal,* the Ukom Medical Director, Stine Marit Moen, said, "We're concerned that there may be undertreatment, overtreatment, and the wrong treatment" and added:

> We've seen a marked increase in referrals to specialised healthcare services in Norway for teenagers, as seen in many other western countries, and nobody knows the reason. The stability of the gender dysphoria of these teenagers is not known, and the evidence of long term effects of gender affirming treatments for this young population is insufficient. (Block, Norway's Guidance, 2023.)

33. Ukom noted that referrals to its national treatment service increased by a factor of eight between 2007 and 2018, and that this increase was largely from young biological females. Seventy-five percent of the referrals to its National Treatment Service had other co-morbid psychiatric diagnoses, including not only depression and anxiety but also autism spectrum disorders, ADHD, and Tourette's Syndrome. (Ukom 2023, Summary and Section 7.)

F. Assertions by U.S. organizations and officials that there is 'no debate' over medicalized transition are false.

34. The international consensus is clearly demonstrated by the multiple recent analyses, statements, and policy decisions from the health care service systems around the world. These include England's National

Health Service, which noted the "Scarce and inconclusive evidence to support clinical decision making [which] has led to a lack of clinical consensus on what the best model of care for children and young people experiencing gender incongruence and dysphoria should be." (NHS 2022 at 5.)

35. As these several recent national policy reviews, statements, and recommendations make very clear, there is a great deal of doubt and debate among the sophisticated international medical and mental health community as to whether the administration of puberty blockers and cross-sex hormones to children and young people is the best clinical practice, and as to whether these treatments have been shown to be safe and effective. Indeed, the lack of scientifically reliable data concerning safety and efficacy highlighted by the systematic evidence reviews commissioned by the English National Health Service, by the Swedish National Board of Health and Welfare, and by the Finnish Council for Choices in Health Care in Finland have caused those national health authorities and others to move sharply away from approving puberty blockers, cross-sex hormones, or surgery for minors.

36. In this report, I explain the evidence and lack of evidence behind that doubt, that debate, and the emerging international consensus of caution reflected in the several recent European policy statements or changes.

III. Clinical research has a standard *Pyramid of Evidence* that summarizes the relative strength of potential sources of information.

37. The widely accepted starting point in evidence-based medicine is the recognition that clinical experiences and recollections of individual practitioners (often

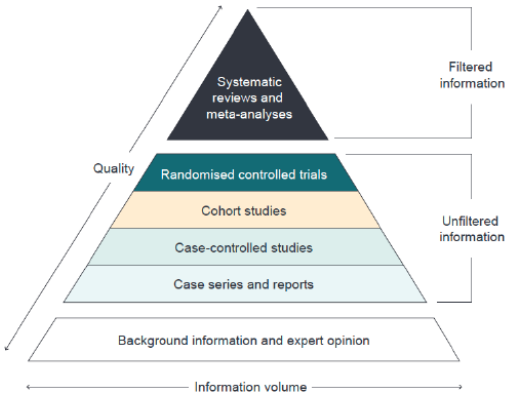
called "expert opinion" or "clinical anecdote") do not and cannot provide a reliable, scientific basis for treatment decisions. Rather, in evidence-based medicine, clinical decision-making is based on objectively demonstrated evidence of outcomes from the treatment options. An essential first step in evidence-based medicine is identifying the relevant findings from among the immense flood of clinical journal articles published each year. Those studies and the evidence they report are then assessed according to the strength offered by the research methods used in each study. The research methods used in a study determine its reliability and generalizability, meaning the confidence one may have that using the same treatment again will have the same result again on other people. In this section, I explain the well-accepted criteria for evaluating the evidentiary value of clinical studies.

A. Clinical research comprises a standard *Pyramid of Evidence*, wherein studies from higher levels of evidence outrank even more numerous studies from lower levels of research.

38. The accepted hierarchy of reliability for assessing clinical outcomes research is routinely represented as a "Pyramid of Evidence" (Figure 1). Scientific questions are not resolved by the number of studies coming to one versus another conclusion. Studies representing higher levels of evidence outrank studies from lower levels. Even large numbers of lower-level studies cannot overcome a study representing a higher level of evidence. Indeed, because lower-level studies are generally faster and less expensive to conduct, it is typical for them to outnumber higher level studies. This is the property meant to be reflected by the pyramid's

shape, which is larger at the base and smaller at the apex.

Figure 1: Pyramid of Standards of Evidence



Source: OpenMD. Retrieved from https://openmd.com/guide/levels-of-evidence.

B. The highest level of evidence for safety and effectiveness research is the systematic review of clinical experiments.

39. The most reliable and conclusive method of determining what is actually known or not known with respect to a particular treatment is the *systematic review.* Systematic reviews employ standardized procedures to assess comprehensively all available evidence on an issue, minimizing opportunities for bias in gathering and evaluating research evidence. As described by Dr. Gordon Guyatt, the internationally recognized pioneer in medical research who invented the term *evidence-based medicine,* "A fundamental principle to the hierarchy of evidence [is] that optimal clinical decision making requires systematic summaries of the best available evidence." (Guyatt 2015 at xxvi.)

40. I note that Dr. Antommaria's report for the plaintiffs correctly indicated that "It is best practice to

ascertain the studies via systematic reviews of the literature." (Antommaria Report at 6.) Missing from Dr. Antommaria's report is that none of the systematic reviews he cited were systematic reviews of safety and efficacy, both of which are necessary for assessing the risk:benefit ratio of a treatment. Moreover, I note that none of the plaintiffs' other experts cited any systematic reviews at all, failing to meet the standard Dr. Antommaria and I indicated.

1. Systematic reviews prevent the 'cherry-picking' of studies that favor a particular result.

41. Because systematic reviews are designed to prevent researchers from including only the studies they favor and other biases, systematic reviews are the routine starting point for developing clinical practice guidelines. (Moher 2009.) The methods of a systematic review include:

- Define the scope, including the "PICO": Population/Patient, Intervention, Comparison/ Control, and Outcome(s);
- Select and disclose the keywords used to search the (massive) available clinical research database(s) for potentially relevant articles, identify the databases they were applied to, and the date(s) of the searches, including any subsequent updates;
- Select and disclose the inclusion/exclusion criteria to be used to filter the "hits" from the keyword searches to identify research studies to be included in the detailed review;
- Review abstracts to select the final set of studies, using at least two independent re-

viewers to allow for measuring inter-rater reliability on the criteria;

- Code each study's results impacting the research question(s), disclosing the list of all studies and the results coded from each;
- Evaluate the reliability of the results [risk of bias] of each included study, applying uniform criteria across them all.

42. As detailed in Section V, several systematic reviews have been conducted of the outcomes of medicalized transition of gender in minors. Their conclusions are highly consistent with each other. Much of the expert testimony offered by plaintiffs' experts, however, depends on levels of evidence far lower on the pyramid of evidence (e.g., "expert opinion") or beneath the pyramid entirely (e.g., survey studies) while ignoring the thorough, high-quality systematic reviews available in the research literature. Doing so is in direct conflict with foundational principles of evidence-based medicine.

2. Systematic reviews prevent biased assessment of individual studies by uniformly applying standard criteria to each study reviewed. The most widely used criteria set is "GRADE."

43. In order to produce unbiased assessment of the studies within the systematic review, all the studies must be evaluated using the same evaluation criteria. Without such criteria, assessments can become influenced by researchers who, intentionally or not, hold the evaluative bar higher or lower for studies according to whether the studies' conclusions support or challenge that researcher's perspective. Several such systems

have been developed. The most widely used system is the "Grading of Recommendations, Assessment, Development and Evaluations" (GRADE). (Goldet & Howick 2013.) In the GRADE system, studies' findings are downgraded for:

- Risk of bias:[1]
  - Lack of clearly randomized allocation sequence,
  - Lack of blinding,
  - Lack of allocation concealment,
  - Failure to adhere to intention-to-treat analysis,
  - Trial is cut short,
  - Large losses to follow-up;
- Inconsistency;
- Indirectness of evidence;
- Imprecision; and
- Publication bias (when studies with 'negative' findings remain unpublished). Studies' ratings are upgraded if their findings identify:
- A large effect of the treatment;

[1] In science, including in the GRADE system, the term "bias" refers to any external influence leading to a systematic over- or underreporting of the outcome being measured. That is, in this context "bias" is not used in the sociopolitical sense of personal values.

- A dose-response relationship (the size of the effect has a systematic association with the dose of the treatment given); or

- That all plausible biases only *reduce* the apparent effect of the treatment (necessarily making the estimated effect sizes conservative estimates).

44. GRADE assessments yield a four-point score representing the certainty that a reported treatment effect is true. These certainty scores are (GRADE Handbook, Section 5):

Certainty	**Meaning**
High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very Low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

C. The highest level experimental study of clinical safety and effectiveness is the Randomized Controlled Trial (RCT). RCTs can demonstrate that a given treatment causes (rather than only correlates with) a given outcome.

45. Randomized Controlled Trials are the gold standard method of assessing the effects caused by an experimental treatment. The great scientific weight of RCTs follows from the randomization: People do not pick which research group they are in—a treatment group or a control group. Without random group assignment, it is not possible to identify which, if any, changes are due to the treatment itself or to the factors that led to who did and did not receive treatment.

46. Levels of evidence lower than RCTs are unable to distinguish when changes are caused by the experimental treatment, or by factors that can mimic treatment effects, such as 'regression to the mean' and the placebo effect.

47. In the absence of evidence that X causes Y, it is a scientific error to use language indicating there is causal relationship. In the absence of evidence of causality, it is scientifically unsupportable to describe a correlation with terms such as: increases, improves, benefits, elevates, leads to, alters, influences, results in, is effective for, causes, changes, contributes to, leads to, yields, impacts, decreases, harms, and depresses. Scientifically valid terms for correlations include: relates to, is associated with, predicts, and varies with.

48. I note that the plaintiffs' experts repeatedly misrepresent studies using causal language to describe studies that are unable to demonstrate causality. Such

language incorrectly asserts that the evidence is stronger than it actually is.

1. RCTs, but not lower levels of evidence, overcome biases representing 'regression to the mean' and other factors that can mimic clinical improvement.

49. 'Regression to the mean' arises when researching issues, such as mood, depression, or levels of emotional distress that typically fluctuate over time. People are more likely to seek out treatment during low points rather than high points in their emotional lives. Thus, when tracking emotional states over time, the average of a group of people in a treatment group may often show an increase; however, without an untreated control group to which to compare them, researchers cannot know whether the group average would have increased anyway, with only the passage of time.

50. Blinding or masking participants in an RCT from which group they are in has been described as a preferred strategy since the 1950s, in order to exclude the possibility that a person's expectations of change caused any changes observed (the "placebo effect"). In practice, however, it has often made little or no significant difference. For example, a study using very high quality methods—meta-analysis of meta-analysis research—has revealed no statistical difference in the sizes of the effects detected by blinded/placebo-controlled studies from non-blinded/non-placebo-controlled studies of depression. (Moustgaard 2019.) That is, the pre-/post- treatment differences found in placebo groups are not as attributable to participants' expectations of improvement as they are to expectable regression to the mean. (Hengartner 2020.)

2. When a 'no treatment control group' is untenable, RCTs use an 'active comparator' group instead.

51. It is not always possible to compare a group receiving a treatment to a group receiving only an inactive procedure, such as a placebo treatment or no treatment at all. In such situations, the standard, ethical, clinical research method is to compare two active treatments with each other.

52. The systematic reviews from England explicitly called for 'active comparator' studies to test whether medicalized transition of minors shows mental health benefits superior to those obtained from psychotherapy. (NICE 2020a at 40; NICE 2020b at 47.) Risk:benefit analysis cannot justify the greater risks associated with medicalization without evidence of correspondingly greater benefit.

D. Cohort studies are the highest level of evidence about medicalized transition currently available.

53. The highest-level study of medicalized transition of minors conducted thus far are cohort studies: gathering a sample of individuals who chose to undergo treatment and tracking them over time. Cohort studies are able to answer some questions that lower-level studies cannot, such as whether a high-functioning group improved over time versus having been composed of people who were already high-functioning. Cohort studies are, however, unable to demonstrate causality, to identify how much of any change was due to regression to the mean, or to detect any placebo effects.

E. Expert opinion represents the least reliable evidence.

54. As Figure 1 illustrates, evidence-based medicine opinion based on clinical experience is identified as the *least* reliable source of medical knowledge. Among other reasons, this is because non-systematic recollections of unstructured clinical experiences with self-selected clientele in an uncontrolled setting is the most subject to bias. Indeed, mere "clinical experience" was long the basis of most medical and mental health clinical decisions, and it was precisely the scientific and clinical inadequacy of this type of "knowledge" that led to the development and widespread acceptance of the importance of evidence-based medicine. As Dr. Guyatt has written, "EBM places the unsystematic observations of individual clinicians lowest on the hierarchy," both because EBM "requires awareness of the best available evidence," and because "clinicians fall prey to muddled clinical reasoning and to neglect or misunderstanding of research findings." (Guyatt 2015 at 10, 15.)

F. Surveys and cross-sectional studies cannot demonstrate treatment effectiveness.

55. Surveys represent observational research rather than experimental research. (In science, experiments are studies involving a manipulation, not merely observation, by the researcher.) Surveys and cross-sectional studies can provide only correlational data and cannot demonstrate causality. (See Section IV below.) It is not possible for a survey to yield evidence that a treatment is effective. No number of surveys can test a treatment, advancing it from 'experimental' to 'established' status.

56. Survey studies do not even appear on the *pyramid of evidence.* In accordance with the routine stand-

ards, systematic reviews of treatment studies exclude surveys.

57. I note that the plaintiffs' experts' reports rely largely on survey studies.

IV. Methodological defects limit or negate the evidentiary value of many studies of treatments for gender dysphoria in minors.

A. In science, to be valid, a claim must be objective, testable, and falsifiable.

58. In behavioral science, people's self-reports do not represent objective evidence. It is when emotional and other pressures are strongest that the distinction between and need for objective over subjective evidence is greatest. Surveys do not represent objective evidence. This is especially true of non-random surveys and polls, recruited through online social networks of the like-minded.

B. Correlation does not imply causation.

59. Studies representing lower levels of evidence are often used because they are faster and less expensive than studies representing higher levels. A disadvantage, however, is that they are often limited to identifying which features are *associated* with which other features, but they cannot show which ones are *causing* which. It is a standard property of statistical science that when a study reports a correlation, there are necessarily three possible explanations. Assuming the correlation actually exists (rather than represents a statistical fluke or bias), it is possible that X causes Y, that Y causes X, or that there is some other variable, Z, that causes both X and Y. (More than one of these can be

true at the same time.) To be complete, a research analysis of a correlation must explore all three possibilities.

60. For example, assuming a correlation between treatment of gender dysphoria in minors and mental health actually exists (rather than is a fluke): (1) It is *possible* that treatment causes improvement in mental health. (2) Yet, it is also possible that having good mental health is (part of) what enabled transition to occur in the first place. That is, because of gate-keeping procedures in the clinical studies, those with the poorest mental health are typically not permitted to transition, causing the higher mental health scores to be sorted into the transitioned group. (See Section IV.E on *Selection Bias*.) (3) It is also possible that a third factor, such as wealth or socioeconomic status, causes both the higher likelihood of transitioning (by being better able to afford it) and the likelihood of mental health (such as by avoiding the stresses of poverty or affording psychotherapy).

61. This principle of scientific evidence is why surveys do not (cannot) represent evidence of treatment effectiveness: Surveys are limited to correlations. (See Section III.F. on *Surveys*.)

C. When two or more treatments are provided at the same time, one cannot know which treatment caused observed changes (i.e., 'confounding').

62. Confounding is a well-known issue in clinical research design. As detailed in the present report, it applies throughout treatment studies of gender dysphoria. Patients who undergo medical transition procedures in research clinics routinely undergo mental health treatment (psychotherapy) at the same time. Without explicit procedures to distinguish them, it can-

not be known which treatment produced which outcome (or in what proportions). Indeed, that mental health improvement came from mental health treatment is a more parsimonious (and therefore, scientifically superior) conclusion than is medicalized treatment causing mental health improvement.

D. Extrapolation to dissimilar populations and dissimilar conditions.

63. The purpose of clinical science is to establish from a finite sample of study participants information about the effectiveness and safety, or other variables, of a treatment that can be generalized to other people. Such extrapolation is only scientifically justified with populations matched on all relevant variables. The identification of those variables can itself be a complicated question, but when an experimental sample differs from another group on variables already known to be related, extrapolation cannot be assumed but must be demonstrated directly and explicitly.

64. Each of the systematic reviews from the UK, Sweden, and Finland emphasized that the recently observed, greatly increased numbers of youth coming to clinical attention are a population different in important respects from the subjects of often-cited research studies. Conclusions from studies of adult-onset gender dysphoria and from childhood-onset gender dysphoria cannot be assumed to apply to the current patient populations of adolescent-onset gender dysphoria. The Cass Report correctly advised:

> It is also important to note that any data that are available do not relate to the current predominant cohort of later-presenting birth-registered female teenagers. This is because the rapid increase in this

> subgroup only began from around 2014-15. Since young people may not reach a settled gender expression until their mid-20s, it is too early to assess the longer-term outcomes of this group. (Cass 2022 at 36.)

The report also indicated:

> [I]t is important that it is not assumed that outcomes for, and side effects in, children treated for precocious puberty will necessarily be the same in children or young people with gender dysphoria. (Cass 2022 at 63.)

65. Finland's review repeated the observation of greatly (20 times) increased numbers, an entirely different demographic of cases, and increased proportions of psychiatric co-morbidities. (Finnish Palko Preparation Memo at 4-6.) The Swedish review highlighted "the uncertainty that follows from the yet unexplained increase in the number of care seekers, an increase particularly large among adolescents registered as females at birth." (Swedish Socialstyrelsen Support 2022 at 11.)

66. It is well known that males and females differ dramatically in the incidence of many mental health conditions and in their responses to treatments for mental health conditions. Thus, research from male-to-female transitioners (the predominant population until recent years) cannot be extrapolated to female-to-male transitioners (the predominant population presenting at clinics today). Outcomes from patients who experienced clear pre-pubertal childhood gender dysphoria cannot be extrapolated to patients who first manifest diagnosable gender dysphoria well into puberty. Outcomes from clinics employing rigorous and openly reported gate-keeping procedures cannot be extrapolated

to clinics or clinicians employing only minimal or perfunctory assessments without external review. Developmental trajectories and outcomes from before the social media era cannot be assumed to apply to those of the current era or the future. Research from youth with formal diagnoses and attending clinics cannot be extrapolated to self-identifying youth and those responding to surveys advertised on social media sites.

67. Further, treatment of gender dysphoria in children and adolescents presents novel-use cases very dissimilar to the contexts in which puberty blockers and cross-sex hormones have previously been studied. Whereas use of puberty blockers to treat precocious puberty *avoids* the medical risks caused by undergoing puberty growth before the body is ready (thus outweighing other risks), use of blockers to treat gender dysphoria in patients already at their natural puberty pushes them *away* from the mean age of the healthy population. Instead of avoiding an objective problem, one is created: Among other things, patients become subject to the issues and risks associated with being late-bloomers, *very* late-bloomers. This transforms the risk:benefit balance, where the offsetting benefit is primarily (however validly) cosmetic.

68. Similarly, administering testosterone to an adult male to treat testosterone deficiency addresses both a different condition and a different population than administration of that same drug to an adolescent female to treat gender dysphoria; the benefits and harms observed in the first case cannot be extrapolated to the second.

E. Mental health assessment used for gate-keeping medicalized transition establishes a *selection bias*, creating a statistical illusion of mental health improvement among the selected.

69. Importantly, clinics are expected to conduct mental health assessments of applicants seeking medicalized transition, disqualifying from medical services patients with poor mental health. (The adequacy of the assessment procedures of specific clinics and clinicians remains under debate, however.) Such gate-keeping—which was also part of the original "Dutch Protocol" studies—can lead to misinterpretation of data unless care is explicitly taken. A side-effect of excluding those with significant mental health issues from medical transition is that when a researcher compares the average mental health of the gender dysphoric individuals first presenting to a clinic with the average mental health of those who completed medical transition, then the post-transition group would show better mental health—but only because of the *selection bias*, (Larzelere 2004; Tripepi 2010) even when the transition had no effect at all.

V. Systematic reviews of safety and effectiveness have been conducted by the health care ministries/departments of several governments. They *unanimously* concluded the evidence on medicalized transition in minors to be of poor quality.

A. Understanding safety and efficacy.

70. Plaintiffs' experts assert that use of puberty blockers and cross-sex hormones on adolescents is "safe." This claim is unsupported by any substantial scientific evidence, depreciates widely recognized risks of serious harm to minors so medicalized, and ignores

both the many unknowns and the growing international doubts about their use.

71. At the outset, it is important to understand the meaning of "safety" in the clinical context. The criteria for assessing safety involve two independent components, and discussion of the safety of hormonal interventions on the natural development of children requires consideration of both of them. The term *safety* in the clinical context represents a "risk:benefit ratio," not an absolute statement that can be extrapolated across applications. In clinical research, assessing safety requires simultaneous consideration of both components of the risk:benefit ratio. That is, treatments are not deemed simply "safe" or "unsafe," as the plaintiffs' experts repeatedly use those words. These dual components are reflected in FDA regulation:

> There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that *the probable benefits* to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh *any probable risks*. (Code of Federal Regulations Title 21 Sec. 860.7, italics added.)

72. Thus, for example, as I explain in further detail below, because the Endocrine Society did not undertake (or rely on) any systematic review of the efficacy of hormonal interventions to relieve gender dysphoria in minors (i.e., their benefits), and WPATH did not undertake (or rely on) any systematic review of the safety of hormonal interventions in minors (i.e., their risks), neither gathered the evidence necessary to assess the risk:benefit ratio of medicalized transition in minors.

73. In fact, as I also review below, after conducting systematic reviews, the English, Finnish, and Swedish national health care institutions all concluded that there is insufficient evidence to determine that hormonal interventions as treatments for gender dysphoria in minors are safe. Reasons for these consistent conclusions include lack of research, insufficient research quality among the existing investigations, and insufficient investigation of long-term safety.

74. To understand the uniform conclusions of these national health care bodies, it is important to understand that—at least where there is *prima facie* reason to be concerned that certain harms may result—when the research has not been done, the absence of evidence cannot be taken as evidence of the absence of such harms. "We don't know" does not permit the conclusion "It is safe." Plaintiffs' experts and many advocates in the field of transgender medicine make this error.

B. The McMaster University systematic review of systematic reviews.

75. McMaster University is recognized as a center of expertise in the performance of methodologically sound systematic reviews. In 2022, authors associated with that McMaster University team (Dr. Romina Brignardello-Petersen and Dr. Wojtek Wiercioch) conducted a systematic review, "Effects of gender affirming therapies in people with gender dysphoria: evaluation of the best available evidence," spanning all the available systematic reviews in this area, including their methodological strength, the evidence they cited, and the conclusions they reached. (Brignardello-Petersen & Wiercioch 2022.) Applying carefully disclosed criteria and methods, they identified on-point systematic reviews, and

graded the methodological quality of each on-point review as high, moderate, low, or critically low. With regard to systematic reviews relating to the effects of puberty blockers or cross-sex hormones, the authors included in their analysis all reviews that achieved at least a "low" rating of methodological quality, while excluding those rated as "very low." No systematic reviews earned a "high" methodological rating, except a review performed by the highly respected Cochrane Library of the effects of cross-sex hormones on transitioning natal males (Haupt 2020), but that most careful review in turn found *no* published studies on this topic of sufficient methodological soundness to satisfy its inclusion criteria and thus merit review. After this careful review of the data and analysis contained in available systematic reviews, the McMaster authors concluded:

> Due to important limitations in the body of evidence, there is great uncertainty about the effects of puberty blockers, cross-sex hormones, and surgeries in young people with gender dysphoria. This evidence alone is not sufficient to support whether using or not using these treatments. (Brignardello-Petersen & Wiercioch 2022 at 5.)

C. The quality of the systematic reviews from governmental bodies and professional associations.

76. To ensure consideration of all available evidence, I compiled into a single table all the cohort studies of safety and effectiveness included by any of the systematic reviews from the international health care systems and (although they were incomplete) by the U.S.-based clinical associations issuing guidelines or standards. I discuss their specific findings in the following sections.

77. New studies continue to be conducted and published. I have identified two additional studies that were published after these reviews were released, but that meet their inclusion criteria: Tordoff, *et al.*, 2022, and Chen, *et al.*, 2023. The findings from both these studies are consistent with those already included and are noted here for completeness.

Table 1. Cohort studies of effectiveness and safety of puberty-blockers and cross-sex hormones in minors.

	Finland (2019)	NICE (2020a,b)	Sweden (2022)	E.S. (2017)	AAP (2018)	Baker (2021) (WPATH)
Effectiveness GnRHa	Costa et al. 2015 de Vries et al. 2011	Costa et al. 2015 de Vries et al. 2011	Becker-Hebly et al. 2020 Carmichael et al. 2021 Costa et al. 2015 *** Eisle-Gorman et al. 2021			de Vries et al. 2011
Effectiveness Sex Hormones	de Vries et al. 2014*	Achille et al. 2020 Allen et al. 2019 Kaltiala et al. 2020 Lopez de Lara et al. 2020	*** *** Ciantu et al. 2020* de Vries et al. 2014* ***			Achille et al. 2020 de Vries et al. 2014* Lopez de Lara et al. 2020
Safety (Bones) GnRHa		Brik et al., 2020 Joseph et al. 2019 Khatchadourian et al. 2014 Klink et al. 2015 Vlot et al., 2017	Joseph et al. 2019 Klink et al. 2015 Navabi et al. 2021 Schagen et al. 2020 Stoffers et al. 2019 Vlot et al. 2017 Lee et al. 2020 van der Loos et al., 2021			
Safety (Bloods) GnRHa		Klaver et al. 2020 Schagen et al. 2016	Klaver et al. 2018 Klaver et al. 2020 Nokoff et al. 2020 Perl et al. 2020 Schagen et al. 2016 Schulmeister et al., 2021			
Safety (Bones) Sex Hormones	****	Khatchadourian et al. 2014 Klaver et al. 2020 Klink et al. 2015 Kuper et al. 2020 Stoffers et al. 2019 Vlot et al., 2017		Klink et al. 2015		
Safety (Bloods) Sex Hormones			Jarin, 2017 Mullins et al. 2021 Tack et al. 2016			

* Included both puberty-blockers and cross-sex hormones.

** The Endocrine Society review included bone/skeletal health, but did not explicate whether the scope included minors.

*** Sweden explicitly excluded due to high risk of bias: Achille, *et al.,* (2020), Allen, *et al.* (2019), de Vries, *et al.,* (2011), and López de Lara, *et al.,* (2020).

**** The Finnish review adopted the Endocrine Society review, but did not indicate whether minors were included.

D. United Kingdom

78. The National Health Service (NHS) of the United Kingdom conducted an independent review of its services for minors with gender dysphoria. (Cass 2022.) Included in that process were two systematic, comprehensive reviews of the research literature, conducted by England's National Institute for Health Care Excellence (NICE) in 2020. One regarded the efficacy, safety, and cost-effectiveness of Gonadotrophin-Releasing Hormone (GnRH) analogs (or "puberty blockers") in minors. (NICE 2020a.) The other regarded the efficacy, safety, and cost-effectiveness of cross-sex hormones, or "gender-affirming hormones," in minors. (NICE 2020b.) (Only efficacy and safety are relevant to the present report.)

79. The puberty-blocker review was tasked with reviewing the research on two relevant questions. For one:

> *In children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with GnRH analogues compared with one or a combina-*

> *tion of psychological support, social transitioning to the desired gender or no intervention?* (NICE 2020a at 4.)

Clinical effectiveness of puberty-blockers was composed of three factors deemed "critical outcomes": impact on gender dysphoria, impact on mental health, and impact on quality of life. The second question addressed in the review was:

> *In children and adolescents with gender dysphoria, what is the short-term and long-term safety of GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?* (NICE 2020a at 6.)

Puberty-blocker safety was assessed as its effect on three categories of health: bone density, cognitive development or functioning, and "other."

80. The second review, for cross-sex hormone treatment, was tasked with the corresponding questions. For one:

> *In children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with gender-affirming hormones compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?* (NICE 2020b at 4.)

The critical outcomes were again deemed to be impact on gender dysphoria, on mental health, and on quality of life. The impact on mental health was composed of indicators of depression, anxiety, and suicidality and self-injury. The second question was:

> *In children and adolescents with gender dysphoria, what is the short-term and long-term safety of gender-affirming hormones compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?* (NICE 2020b at 7.)

Cross-sex hormone treatment safety was assessed as its effect on bone density and on "clinical parameters," which included insulin, cholesterol, and blood pressure levels.

81. These two reviews included a systematic consolidation of all the research evidence, following established procedures for preventing the "cherry-picking" or selective citation favouring or down-playing any one conclusion, carefully setting out the criteria for including or excluding specific studies from the review, and providing detailed analyses of each included study. The whole was made publicly available, consistent with good practice.

82. The reviews' results were unambiguous: For both puberty blockers and cross-sex hormones, "The critical outcomes for decision making are the impact on gender dysphoria, mental health and quality of life." The quality of evidence for these outcomes was assessed as "very low" using the established GRADE procedures for assessing clinical research evidence. (NICE 2020a at 4; NICE 2020b at 4.) The reviews also assessed as "very low" the quality of evidence regarding "body image, psychosocial impact, engagement with health care services, impact on extent of satisfaction with surgery and stopping treatment" or (in the case of cross-sex hormones) of "detransition." (NICE 2020a at 5; NICE 2020b at 6.) The review of puberty blockers concluded

that of the existing research, "The studies included in this evidence review are all small, uncontrolled observational studies, which are subject to bias and confounding," "They suggest little change with GnRH analogues [puberty blockers] from baseline to follow-up." (NICE 2020a at 13.) The cross-sex hormone review likewise reported a lengthy list of methodological defects or limitations affecting all available studies. (NICE 2020b at 13-14.)

83. The NHS changed the language on its website describing puberty blockers and cross sex hormones. It removed the statement that "The effects of treatment with GnRH analogues are considered to be fully reversible,"[2] replacing that text with:[3]

> Little is known about the long-term side effects of hormone or puberty blockers in children with gender dysphoria. . . . [I]t is not known what the psychological effects may be. It's also not known whether hormone blockers affect the development of the teenage brain or children's bones.

84. As mentioned in the McMaster review, the highly respected Cochrane Library, based in England, undertook a systematic review of studies of the safety and efficacy of the administration of cross-sex hormones to natal males. That review focused primarily on adults (age 16 and older). The results, including a detailed explanation of methodology and inclusion criteria, were

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[2] BBC. Retrieved from https://www.bbc.co.uk/sounds/play/m000kgsj; Kurkup, J. (2020, June 4). *The Spectator.* Available from https://www.spectator.co.uk/article/the-nhs-has-quietly-changed-its-trans-guidance-to-reflect-reality/

[3] NHS. Retrieved from https://www.nhs.uk/conditions/gender-dysphoria/treatment/

published in 2020. Unfortunately, but importantly, the Cochrane review found *zero* studies, globally, that were sufficiently reliable to meet the inclusion criteria even at a "very low" level of evidentiary quality. The authors reported:

> Despite more than four decades of ongoing efforts to improve the quality of hormone therapy for women in transition, we found that no RCTs or suitable cohort studies have yet been conducted to investigate the efficacy and safety of hormonal treatment approaches for transgender women in transition. . . . We found insufficient evidence to determine the efficacy or safety of hormonal treatment approaches . . . for transgender women in transition. The evidence is very incomplete, demonstrating a gap between current clinical practice and clinical research. (Haupt 2020 at 10-11.)

The authors' frustration at the total lack of reliable research was evident: "The lack of reliable data on hormone therapy for transitioning transgender women should encourage the development of well-planned RCTs and cohort studies to evaluate widespread empirical practice in the treatment of gender dysphoria." (Haupt 2020 at 10.)

E. Sweden

85. Sweden similarly commissioned a systematic review, published in 2022 and charged with addressing these three questions:

> *Are there any scientific studies explaining the increase in numbers seeking for gender dysphoria?*
>
> *Are there any scientific studies on long-term effects of treatment for gender dysphoria?*

> *What scientific papers on diagnosis and treatment of gender dysphoria has been published after the National Board of Health and Welfare in Sweden issued its national support for managing children and adolescents with gender dysphoria in 2015?* (SBU Scoping Review Summary 2019.)

The databases searched included CINAHL (EBSCO), Cochrane Library (Wiley), EMBASE (Embase.com), PsychINFO (EBASCO), PubMed (NLM), Scopus (Elsevier), and SocINDEX (EBSCO). A total of 8,867 abstracts were identified, from which 315 full text articles were assessed for eligibility. The review concluded that "literature on management and long-term effects in children and adolescents is sparse," that no RCTs have been conducted, and that there remains no explanation for the recent and dramatic increases in numbers of minors presenting with gender dysphoria. (SBU Scoping Review Summary 2019.) I have quoted other conclusions from the Swedish systematic review in Section II above.

F. Finland

86. Finland's Ministry of Social Affairs and Health commissioned a systematic review, completed in 2019, of the effectiveness and safety of medicalized transition. (COHERE Recommendation 2020.) The review spanned both minors and adults and included both puberty blockers and cross-sex hormones (Pasternack 2019). Three reviewers tabulated the results. In total, 38 studies were identified, of which two pertained to minors: de Vries (2011) and Costa (2015). The report noted that, because the methodological quality of the studies was already "weak" (no study including any control groups), the assessors declined detailed quality assessment of

the existing studies. (Pasternack 2019 at 3.) I have quoted other conclusions from the Finnish systematic review in Section II above.

G. Norway

87. Norway's investigation of its health care policy for gender dysphoric minors also revealed substantial safety concerns:

> There are unsettled questions related to puberty blockers in young people. A published study shows that puberty-inducing hormones cause slower height growth and a slower increase in bone density. It is also noted that the effects on cognitive development have not been mapped. Unexplained side effects and long-term effects of both puberty blockers (hormone treatment) and gender-affirming hormone treatments are increasingly being questioned. However, experience with other patient groups shows that long-term use of sex hormones can affect disease risk. When people with gender incongruence are treated, it is with significantly longer duration and intensity of hormone treatment than hormone treatments for other conditions. (Ukom 2023.)

VI. The Endocrine Society, WPATH, and the American Academy of Pediatrics did not conduct systematic reviews of safety and efficacy in establishing clinical guidelines, despite systematic reviews being the foundation and gold standard of evidence-based care.

88. I have also examined the reviews conducted by the U.S.-based professional associations that have published standards and guidelines for the treatment of gender dysphoric youth. As detailed herein, and unlike the European reviews, none of the U.S.-based profes-

sional associations conducted a systematic review of both effectiveness and safety, without which they are unable to assess the risk:benefit ratio posed by medicalized transition of minors.

A. The Endocrine Society reviewed cross-sex hormones, but not puberty blockers. They reviewed safety, but did not review effectiveness research.

89. The Endocrine Society appointed a task force which commissioned two systematic reviews as part of updating their 2009 recommendations. (Hembree 2017.) The scopes of the two reviews were limited to physiological effects of cross-sex hormones, narrowly defined: "The first one aimed to summarize the available evidence on the effect of sex steroid use in transgender individuals on lipids and cardiovascular outcomes. . . . The second review summarized the available evidence regarding the effect of sex steroids on bone health in transgender individuals." (Hembree 2017 at 3873.) As described in the Endocrine Society Guidelines, those reviews did not, however, include the effectiveness of any treatment on mental health (quality of life, suicidality, rates of detransition, cosmetic or functional outcomes, or improvements in feelings of gender dysphoria). What appears to be the referenced review of lipids and cardiovascular outcomes (Maraka 2017) did not identity any study of adolescents, noting "literature addressing this clinical question in the pediatric/adolescent population is completely lacking." (Maraka at 3921.) What appears to be the referenced review of bone health (Singh-Ospina 2017) identified only one small study on adolescents, involving 15 male-to-female and 19 female-to-male cases. (Klink 2015.) Notably, the median duration of puberty-blocker administration was 1.2 years, leaving unknown the effects on children receiving

blockers from puberty onset (usually age 9-10) to age 14 or 16.

90. Further, the Endocrine Society does not claim to have conducted or consulted any systematic review of the efficacy of puberty blockers or cross-sex hormones to reduce gender dysphoria or increase mental health or well-being by any metric. Nor does it claim to have conducted or consulted any systematic review of safety of any of these treatments for minors with respect to brain development, future fertility, actual reversibility, or any other factor of safety or adverse event other than cardiovascular disease and bone strength.

91. For all these reasons, I concur with the opinion of Dr. Guyatt, who has said that he finds "serious problems" with the Endocrine Society guidelines, among other reasons because the only systematic reviews those guidelines refer to did not look at the efficacy of the recommended hormonal interventions to improve gender dysphoria, which he termed "the most important outcome." (Block, Gender Dysphoria 2023 at 4.)

92. The current Endocrine Society guidelines, released in 2017, include this disclaimer:

> The Endocrine Society makes no warranty, express or implied, regarding the guidelines and specifically excludes any warranties of merchantability and fitness for a particular use or purpose. The Society shall not be liable for direct, indirect, special, incidental, or consequential damages related to the use of the information contained herein. (Hembree 2017 at 3895.)

The previous, 2009, version included no disclaimers. (Hembree 2009.)

B. WPATH reviewed effectiveness, but not the safety of medicalized transition of minors.

93. WPATH engaged in a multi-step process in updating its Standards of Care from version 7 to version 8. That process included commissioning a systematic review, which was published as Baker, *et al.* (2021) which included the disclaimer "The authors are responsible for its content. Statements in this report do not necessarily reflect the official views of or imply endorsement by WPATH." (Baker 2021 at 14.)

94. The literature search was completed in June 2020, and spanned 13 questions. Two questions related to the effectiveness of medicalized transition of minors: Question #10 was "[W]hat are the effects of suppressing puberty with GnRH agonists on quality of life?", and question #11 was "[W]hat are the psychological effects (including quality of life) associated with hormone therapy?" (Sharma 2018; Baker 2021.) That is, the review included studies of the effectiveness of puberty blockers and cross-sex hormones, but, remarkably did not include any effort to determine the *safety* of either.

95. Baker (2021) identified that among all experimental evidence published on medicalized transition, a total of "Three studies focused on adolescents." (Baker 2021 at 1.) These were Achille, *et al.* (2020), López de Lara, *et al.* (2020), and de Vries, *et al.* (2011, 2014). (Baker 2021 considered the two de Vries articles as a single study, because the later one included the subset of patients from the earlier one who continued in treatment. I will refer to this set as four studies, however, to be consistent with the other reviews.) Notably, in contrast with WPATH's review, the Swedish review entirely excluded Achille *et al.* (2020), López de Lara *et al.*

(2020), and de Vries *et al.* (2011) due to their high risks of bias. (SBU Scoping Review Appendix 2.) The Baker team did not used the GRADE system for assessing the quality of evidence, instead using the Methods Guide for Conducting Comparative Effectiveness Reviews.

96. The Baker team noted "no study reported separate results by gender identity for transgender youth." (Baker 2021 at 3.) They also found that "No study reported on hormone therapy among nonbinary people." (at 3.) (Despite this finding, WPATH SOC-8 now includes recommendations for people who identify as nonbinary.)

97. My assessment of the Baker review revealed that there were substantial discrepancies and misleading ambiguities in their reporting: Baker, *et al.* indicated in the abstract that "Hormone therapy was associated with increased QOL [quality of life], decreased depression, and decreased anxiety" (Baker 2021 at 1,) and that "Associations were similar across gender identity and age" (Baker 2021 at 12). This is not what its actual data tables showed, however. Table 2 presented the only study of QOL specifically among adolescents included in the review and indicated that "Mean QOL scores did *not* change." (Baker 2021 at 7, italics added.)

98. The review, however, did not rate the quality of the studies of adolescents on their own, instead combining them with the studies of adults. (at 10, italics added.) Table 4 of that study presented three analyses of anxiety: One showed a decrease, and on the other two, "Mean anxiety score did *not* change." (at 11, italics added.) Finally, the review also concluded, "It was impossible to draw conclusions about the effects of hormone therapy on death by suicide." (at 12.) Even for

the combined set, the review read the strength of evidence to be "low" for each of QOL, depression, and anxiety, and to be "insufficient" for death by suicide. (Baker 2021 at 13, Table 6.) Specifically, the review indicated, "There is insufficient evidence to draw a conclusion about the effect of hormone therapy on death by suicide among transgender people." (at 13, Table 6.) Overall, "The strength of evidence for these conclusions is low due to methodological limitations." (at 12.) Of particular concern was that "Uncontrolled confounding was a major limitation in this literature." (at 12.)

99. Additionally, although WPATH commissioned the Baker review, WPATH did not follow its results. Baker 2021 indicated the use of two systematic quality assessment methods, called RoB 2 and ROBINS-I (Baker 2021 at 3); however, WPATH modified the conclusions that that process yielded. WPATH SOC-8 states, "This evidence is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion."

(Coleman 2022 at S8.) Moreover:

> Recommendations in the SOC-8 are based on available evidence supporting interventions, a discussion of risks and harms, as well as feasibility and acceptability within different contexts and country settings. Consensus on the final recommendations was attained using the Delphi process that included all members of the guidelines committee and required that recommendation statements were approved by at least 75% of members. (Coleman 2022 at S8.)

100. By allowing "consensus-based expert opinion" to modify or overrule conclusions supported by systematic reviews that apply accepted criteria of evidentiary

strength, WPATH has explicitly abandoned evidence-based medicine. As indicated already by the Pyramid of Evidence, "expert opinion" represents the *lowest* level of evidence in science, whereas systematic review, the highest. (Also, it is unclear what the authors mean by "background evidence.") To modify systematic results according to committee opinion is to re-introduce the very biases that the systematic process is meant to overcome. The WPATH document attempts to claim the authority of a systematic review, while reserving the ability to "overrule" results that WPATH members did not like.

101. As to evidence supporting hormonal interventions in minors, WPATH asserted that "a systematic review regarding outcomes of [hormonal] treatment in adolescents is not possible" due to the lack of "outcome studies that follow youth into adulthood." (Coleman 2022 at S46.) WPATH is correct that essential outcome studies have not been done, but incorrect that this authorizes issuance of guidelines or standards in the absence of a systematic review. As Dr. Guyatt has stated, "systematic reviews are always possible"—and indeed an important conclusion from such a review may be (as here) that insufficient evidence exists to support any evidence-based guideline. As Dr. Guyatt further elaborated, if an organization issues recommendations without performing an on-point systematic review, "they'd be violating standards of trustworthy guidelines." (Block, Dysphoria Rising, 2023 at 3.)

102. Finally, the WPATH SOC-8 were revised immediately after their release, removing all age minimums to all recommendations. None of these studies and none of these reviews support such a change, and

WPATH cites no studies or other document in support of the change.

103. In sum, the WPATH SOC8 cannot be called evidence-based guidelines under any accepted meaning of that term.

C. The American Academy of Pediatrics did not conduct a systematic review either of safety or effectiveness.

104. While the AAP policy statement is often referenced, the AAP did not report conducting any systematic review of any aspect of transgender care in producing its policy statement on gender-diverse children and adolescents. (Rafferty 2018.) Further, the AAP policy statement on its face is the work of a single author rather than of any committee or the membership more broadly (Dr. Rafferty "conceptualized," "drafted," "reviewed," "revised," and "approved" the statement), and the statement explicitly states that it does not "indicate an exclusive course of treatment" nor "serve as a standard of medical care." (Rafferty 2018 at 1.)

VII. Definitions of sex, gender identity, and gender dysphoria.

A. Sex and sex-assigned-at-birth represent objective features.

105. Sex is an *objective* feature: It can be ascertained regardless of any declaration by a person, such as by chromosomal analysis or visual inspection. Gender identity, however, is *subjective:* There exists no means of either falsifying or verifying people's declarations of their gender identities. In science, it is the objective factors—and only the objective factors—that matter to a valid definition. Objectively, sex can be as-

certained, not only in humans or only in the modern age, but throughout the animal kingdom and throughout its long history in natural evolution.

106. I use the term "sex" in this report with this objective meaning, which is consistent with definitions articulated by multiple medical organizations:

Endocrine Society (Bhargava 2021 at 220.)

> "Sex is dichotomous, with sex determination in the fertilized zygote stemming from unequal expression of sex chromosomal genes."

American Academy of Pediatrics (Rafferty 2018 at 2 Table 1.):

> "An assignment that is made at birth, usually male or female, typically on the basis of external genital anatomy but sometimes on the basis of internal gonads, chromosomes, or hormone levels."

American Psychological Association (APA Answers 2014):

> "Sex is assigned at birth, refers to one's biological status as either male or female, and is associated primarily with physical attributes such as chromosomes, hormone prevalence, and external and internal anatomy."

American Psychological Association (APA Resolution 2021 at 1):

> "While gender refers to the trait characteristics and behaviors culturally associated with one's sex assigned at birth, in some cases, gender may be distinct from the physical markers of biological sex (e.g., genitals, chromosomes)."

American Psychiatric Association (Am. Psychiatric Ass'n Guide):

> "Sex is often described as a biological construct defined on an anatomical, hormonal, or genetic basis. In the U.S., individuals are assigned a sex at birth based on external genitalia."

107. The phrases "assigned male at birth" and "assigned female at birth" are increasingly popular, but they lack any scientific merit. Science is the systematic study of natural phenomena, and nothing objective changes upon humans' labelling or re-labelling it. That is, the objective sex of a newborn was the same on the day before as the day after the birth. Indeed, the sex of a fetus is typically known by sonogram or amniocentesis many months before birth. The use of the term "assign" insinuates that the label is arbitrary and that it was possible to have been assigned a different label that is equally objective and verifiable, which is untrue. Infants were born male or female before humans invented language at all. Indeed, it is exactly because an expected child's sex is known before birth that there can exist the increasingly popular "gender reveal" events. Biologically, the sex of an individual (for humans and almost all animal species) as male or female is irrevocably determined at the moment it is conceived. Terms such as "assign" obfuscate rather than clarify the objective evidence.

B. Gender identity refers to subjective feelings that cannot be defined, measured, or verified by science.

108. It is increasingly popular to define gender identity as a person's "inner sense," however, neither "inner sense" nor any similar phrase is scientifically meaning-

ful. In science, a valid construct must be both objectively measurable and falsifiable with objective testing. The concept of an "inner sense" fits none of these requirements.

VIII. Gender Dysphoria is a mental health diagnosis.

109. Gender Dysphoria is a mental health condition defined by diagnostic criteria set out in the *Diagnostic and Statistical Manual of Mental Disorders* ("DSM") 5-TR. (American Psychiatric Ass'n 2022.) While the definitions contain multiple components and vary modestly for children, adolescents, and adults, all cases are characterized by a strong and lasting desire to be the opposite sex, and "clinically significant" distress of sufficient severity to impair the individuals' ability to function in their daily life setting. Gender dysphoria is nowhere defined as a medical (as opposed to mental health) condition, and it is not characterized by any disability or impairment or ill health affecting any part of the physical body.

IX. Distinct mental health phenomena must not be—but frequently are—confused or conflated.

110. One of the most widespread public misunderstandings about transsexualism and people with gender dysphoria is that all cases of gender dysphoria represent the same phenomenon; however, the clinical science has long and consistently demonstrated that prepubescent children expressing gender dysphoria represent a phenomenon distinct from that of adults starting to experience it. That is, gender dysphoric children are not simply younger versions of gender dysphoric adults. They differ in virtually every objective variable measured, including in their responses to treatments. A third presentation has recently become increasingly ob-

served among people presenting to gender clinics: these cases appear to have an onset in adolescence—after the onset of puberty and before adulthood—and occur in the absence of any childhood history of gender dysphoria. Such cases have been called adolescent-onset or "rapid-onset" gender dysphoria (ROGD). Despite having only recently been observed, they have quickly and greatly outnumbered the better characterized types. Moreover, large numbers of adolescents are today self-identifying in surveys as "gender fluid" and "non-binary." These are not recognized mental health diagnoses, and do not relate in any known way to gender dysphoric groups that have been the subject of previous treatment outcome studies. Because each of these phenomena differ in multiple objective features, it is scientifically invalid to extrapolate findings from one type to the others.

A. Adult-Onset Gender Dysphoria consists predominantly of males sexually attracted to females.

111. Whereas Childhood-Onset Gender Dysphoria occurs in biological males and females and is strongly associated with later homosexuality (next section), Adult-Onset Gender Dysphoria consists primarily of biological males sexually attracted to females. (Lawrence 2010.) They typically report being sexually attracted to women and rarely showed gender atypical (effeminate) behavior or interests in childhood (or adulthood). Some individuals express being sexually attracted to both men and women, and some profess asexuality, but very few indicate having a primary sexual interest only in men. (Blanchard 1998.) Cases of adult-onset gender dysphoria are typically associated with a sexual interest pattern involving themselves in female form (a para-

philia called autogynephilia). (Blanchard 1989a, 1989b, 1991.)

112. Because of the numerous objective differences between adult-, childhood-, and adolescent-onset gender dysphoria, it is not possible to extrapolate from these results to juvenile populations, which responsible authors are careful not to do.

B. Childhood-onset gender dysphoria (prepubertal-onset) is a distinct phenomenon characterized by high rates of desistance in the absence of social or medical transition.

113. For many decades, small numbers of prepubescent children have been brought to mental health professionals for help with their unhappiness with their sex and in the belief they would be happier living as the other sex. The large majority of childhood onset cases of gender dysphoria occur in biological males, with clinics reporting 2-6 biological male children to each female. (Cohen-Kettenis 2003; Steensma Evidence 2018; Wood 2013.)

1. Eleven cohort studies followed children not permitted social transition, all showing the majority to desist feeling gender dysphoric upon follow-up after puberty.

114. Currently, the studies of outcomes among children who experience gender dysphoria before puberty that provide the most evidentiary strength available are only "cohort studies," which follow people over time, recording the outcomes of the treatments they have undergone. Such studies supersede (i.e., overrule) the outcomes of surveys, which are much more prone to substantial error. As I have explained above, however,

cohort studies can describe developmental pathways, but cannot provide evidence of causation.

115. In total, there have been 11 cohort studies showing the outcomes for these children, listed in Table 2. I first published this comprehensive list of studies in my own peer-reviewed article on the topic. (Cantor 2019.)

Table 2. Cohort studies of gender dysphoric, prepubescent children.

Count	Group	Study
2/16 4/16 10/16	gay trans-/crossdress straight/uncertain	Lebovitz, P. S. (1972). Feminine behavior in boys: Aspects of its outcome. *American Journal of Psychiatry, 128,* 1283–1289.
2/16 2/16 12/16	trans- uncertain gay	Zuger, B. (1978). Effeminate behavior present in boys from childhood: Ten additional years of follow-up. *Comprehensive Psychiatry, 19,* 363–369.
0/9 9/9	trans- gay	Money, J., & Russo, A. J. (1979). Homosexual outcome of discordant gender identity/role: Longitudinal follow-up. *Journal of Pediatric Psychology, 4,* 29–41.
2/45 10/45 33/45	trans-/crossdress uncertain gay	Zuger, B. (1984). Early effeminate behavior in boys: Outcome and significance for homosexuality. *Journal of Nervous and Mental Disease, 172,* 90–97.
1/10 2/10 3/10 4/10	trans- gay uncertain straight	Davenport, C. W. (1986). A follow-up study of 10 feminine boys. *Archives of Sexual Behavior, 15,* 511–517.
1/44 43/44	trans- cis-	Green, R. (1987). The "sissy boy syndrome" and the development of homosexuality. New Haven, CT: Yale University Press.
0/8 8/8	trans- cis-	Kosky, R. J. (1987). Gender-disordered children: Does inpatient treatment help? *Medical Journal of Australia, 146,* 565–569.
21/54 33/54	trans- cis-	Wallien, M. S. C., & Cohen-Kettenis, P. T. (2008). Psychosexual outcome of gender-dysphoric children. *Journal of the American Academy of Child and Adolescent Psychiatry, 47,* 1413–1423.
3/25 6/25 16/25	trans- lesbian/bi- straight	Drummond, K. D., Bradley, S. J., Badali-Peterson, M., & Zucker, K. J. (2008). A follow-up study of girls with gender identity disorder. *Developmental Psychology, 44,* 34–45.
47/127 80/127	trans- cis-	Steensma, T. D., McGuire, J. K., Kreukels, B. P. C., Beekman, A. J., & Cohen-Kettenis, P. T. (2013). Factors associated with desistence and persistence of childhood gender dysphoria: A quantitative follow-up study. *Journal of the American Academy of Child and Adolescent Psychiatry, 52,* 582–590.

17/139 122/139	trans- cis-	Singh, D., Bradley, S. J., Zucker, K. J. (2021). A follow-up study of boys with Gender Identity Disorder. *Frontiers in Psychiatry*, 12:632784.

*For brevity, the list uses "gay" for "gay and cis-", "straight" for "straight and cis-", etc.

116. The children in these studies were receiving professional mental health support during the study period, but did not "socially transition." In sum, despite coming from a variety of countries, conducted by a variety of labs, using a variety of methods, at various times across four decades, every study without exception has come to the identical conclusion: among prepubescent children who feel gender dysphoric, the majority cease to want to be the other gender over the course of puberty—ranging from 61-88% desistance across the large, prospective studies. Such cases are often referred to as "desisters," whereas children who continue to feel gender dysphoric are often called "persisters."

117. This interpretation of these studies is widely accepted, including by the Endocrine Society, which concluded:

> In most children diagnosed with GD/gender incongruence, it did not persist into adolescence. . . . [T]he large majority (about 85%) of prepubertal children with a childhood diagnosis did not remain GD/gender incongruent in adolescence. (Hembree 2017 at 3879.)

The developers of the Dutch Protocol, at the Vrije University gender clinic, likewise concluded based on these studies that "Although the persistence rates differed between the various studies . . . the results unequivocally showed that the gender dysphoria remitted after

puberty in the vast majority of children." (Steensma & Cohen-Kettenis 2011 at 2.)

118. The consistent observation of high rates of desistance among pre-pubertal children who present with gender dysphoria demonstrates a pivotally important—yet often overlooked—feature: because gender dysphoria so often desists on its own, clinical researchers cannot assume that therapeutic intervention cannot facilitate or speed desistance for at least some patients. That is, it cannot be assumed that gender identity is immune to influence such as from psychotherapy. Such is an empirical question, and there has not yet been any such research.

119. These same studies are often vaguely cited to assert that the high desistance rates uniformly reported in these 11 studies do not apply to children who have persisted until "the start of puberty" (which is taken to mean Tanner Stage 2), or in an alternative phrasing, that children "who persist until the start of puberty" are likely to continue to persist into adulthood. But these studies taken together do not support that degree of precision. Rather, the studies do not specify at exactly what developmental stage the reported desistance occurred—what they report is that the subjects had desisted by late adolescence or early adulthood. I am aware of no systematic study that establishes that—in the absence of social and/or medical transition—children who experience gender dysphoria are unlikely to desist if they have not desisted by the start of Tanner Stage 2.

2. One cohort study followed children who were permitted social transition. In contrast with children not permitted to transition socially, most persisted in expressing gender dysphoria.

120. In contrast, Olson et al. have now published a single cohort study of prepubescent children, ages 3-12 (average of 8), who had already made a complete, binary (rather than intermediate) social transition, including a change of pronouns. (Olson 2022.) The study did not employ DSM-5 diagnosis, as "Many parents in this study did not believe that such diagnoses were either ethical or useful and some children did not experience the required distress criterion." (Olson 2022.) Unlike the prior research studies, only 7.3% of these (socially transitioned) children ceased to feel gender dysphoric.

121. Although the team publishing this cohort study did not discuss it, their finding matches the prediction of other researchers, that social transition itself represents an active intervention, such that social transition may *cause* the persistence of gender dysphoria when it would have otherwise resolved, avoiding any need for subsequent medicalization and its attendant risks. Conversely stated, social transition seems to prevent desistance. (Singh 2021; Zucker 2018, 2020.)

122. As recognized by multiple authors, the potential impact of social transition on rates of desistance is pivotal. The Endocrine Society cautions that "social transition . . . has been found to contribute to the likelihood of persistence." (Hembree 2017 at 3879.) WPATH has stated that after social transition, "A change back to the original gender role can be highly distressing and [social transition can] even result in

postponement of this second transition on the child's part." (Coleman 2012 at 176.) In 2013, prominent Vrije University researchers observed:

> Childhood social transitions were important predictors of persistence, especially among natal boys. Social transitions were associated with more intense GD in childhood, but have never been independently studied regarding the possible impact of the social transition itself on cognitive representation of gender identity or persistence. [Social transition] may, with the hypothesized link between social transitioning and the cognitive representation of the self, influence the future rates of persistence. (Steensma 2013 at 588-589.)

3. There is no reliable method for predicting for which children who present with gender dysphoria will persist versus desist.

123. The Endocrine Society Guidelines stated in 2017 that "With current knowledge, we cannot predict the psychosexual outcome for any specific child" (Hembree 2017 at 3876), and this remains true today. Research has not yet identified any reliable procedure for discerning which children who present with gender dysphoria will persist, as against the large majority who will desist, absent transition and "affirmation." Such a method would be valuable, as the more accurately that potential persisters can be distinguished from desisters, the better the risks and benefits of options can be weighted. Such "risk prediction" and "test construction" are standard components of applied statistics in the behavioral sciences. Multiple research teams have reported that, on average, groups of persisters are somewhat more gender non-conforming than desisters,

but not so different as to usefully predict the course of any particular child. (Singh 2021; Steensma 2013.)

124. In contrast, one research team (the aforementioned Olson group) claimed the opposite, asserting that they developed a method of distinguishing persisters from desisters, using a single composite score representing a combination of children's "peer preference, toy preference, clothing preference, gender similarity, and gender identity." (Rae 2019 at 671.) They reported a statistical association (mathematically equivalent to a correlation) between that composite score and the probability of persistence. As they indicated, "Our model predicted that a child with a gender-nonconformity score of .50 would have roughly a .30 probability . . . of socially transitioning. By contrast, a child with gender-nonconformity score of .75 would have roughly a .48 probability." (Rae 2019 at 673.) Although the Olson team declared that "social transitions may be predictable from gender identification and preferences" (Rae 2019 at 669), their actual results suggest the opposite: the gender-nonconforming group who went on to transition (socially) had a mean composite score of .73 (which is less than .75), and the gender-nonconforming group who did not transition had a mean composite score of .61, also less than .75. (Rae 2019, Supplemental material at 6, Table S1.) Both of those are lower than the value of .75, so both of those would be more likely than not to desist, rather than to proceed to transition. That is, Olson's model does not distinguish likely from unlikely to transition; rather, it distinguishes unlikely from even less likely to transition.

125. Further, in the absence of long-term follow-up, it cannot be known what proportion of those who transition and persist through the early stages of puberty

will later (for example as young adults) come to regret having transitioned and then *de*transition. Because only a minority of gender dysphoric children persist in feeling gender dysphoric in the first place, "transition-on-demand" increases the probability of unnecessary transition and unnecessary medical risks.

4. Temple Newhook's attempts to dismiss evidence of high rates of desistance from childhood gender dysphoria are invalid.

126. The unanimous consistency across all 11 cohort studies of (non-transitioned) gender dysphoric children offers high confidence in the conclusion that most childhood-onset cases desist during the course of puberty. In 2018, however, a commentary was published, contesting that conclusion, criticizing four studies. (Temple Newhook 2018.) Multiple accomplished international researchers studying outcomes of gender dysphoric children responded (Zucker 2018; Steensma & Cohen-Kettenis 2018), to which the Temple Newhook team wrote a rejoinder. (Winters 2018.) I have reviewed each of these arguments, finding that the Temple Newhook comments rely on demonstrable falsehoods, whereas the responses remain consistent with the peer-reviewed evidence. The Temple Newhook commentary has not altered the consensus of the international medical community, which continues to cite and rely upon these cohort studies.

127. Before delineating each of their arguments, it should be noted that the Temple Newhook team based their analysis on the wrong research reports, attacking only a straw-person version of the contents of the research literature. Table 3 repeats the 11 cohort studies

(on the left left) and the four studies Temple Newhook criticized (right):

Table 3.

• Lebovitz (1972)	
• Zuger (1978)	
• Money & Russo (1979)	
• Zuger (1984)	
• Davenport (1986)	
• Green (1987)	
• Kosky (1987)	
• Wallien & Cohen-Kettenis (2008)	• Wallien & Cohen-Kettenis (2008)
• Drummond, *et al.* (2008)	• Drummond, *et al.* (2008)
• Steensma, *et al.* (2013)	• Steensma, *et al.* (2011, 2013)
• Singh, 2012/Singh, *et al.* (2021)[4]	

128. It should be noted that the Temple Newhook 2018 commentary does not represent a systematic review. Temple Newhook did not indicate search strategies, inclusion/exclusion criteria, coding methods, reliability checks, or other standard procedures used for ensuring objective and unbiased assessment of all relevant studies. Rather, the Temple Newhook analysis targeted a small and selective subset of the research available—a scientifically invalid endeavor, which the

[4] At the time of the 2018 Temple Newhook commentary, the Singh *et al.,* 2021 study was available as Singh, 2012.

systematic review process is meant to prevent. Not only did Temple Newhook skip most of the relevant science, but conversely, Temple Newhook inserted the Steensma 2011 study, which should have been rejected. (The data it reported was already included in Wallien & Cohen-Kettenis 2008.) The Temple Newhook commentary claimed it was "systematically engaging scholarly literature" (Temple Newhook 2018 at 2); however, as the above reference lists demonstrate, that commentary involved no such systematic procedures.

129. Temple Newhook does not report any research evidence of its own. Rather, the commentary hypothesizes issues they assert could, theoretically, have affected the rates of desistance consistently detected. Scientifically, such a criticism is vacuous: In science, it is always possible for additional, external factors to have affected what was observed.

130. Also, as already detailed herein, the currently available level of evidence for outcomes of medicalized transition is the cohort study. The methodological issues highlighted by Temple Newhook are exactly why randomized, controlled trials (RCTs) need to be conducted, as such studies would be capable of resolving exactly those questions (in whichever direction). In the absence of randomized, controlled studies, however, the correct scientific process is to follow the results of the cohort studies (that is, the systematic reviews of the cohort studies).

131. In the science process, one cannot merely continue to retain a desired hypothesis, rejecting all counter-evidence until a perfect study emerges. This is especially important in clinical science, when the hypothesis relates to physical interventions, in children,

with the potential to affect them for their entire lives. Rather, the scientific process proceeds by successive approximation, with results from the best available research replacing lesser quality research, increasing in confidence, but always with the possibility of changes imposed by future evidence.

132. By involving only a few of the full set of cohort studies, the Temple Newhook commentary removes one of the most compelling implications of the existing (cohort) studies: Their results are unanimous. However unlikely it might be for four studies to produce the same result randomly, it is even more unlikely for eleven studies all to come to the same result randomly.

133. Temple Newhook emphasized that gender identity issues differ across times and contexts/political environments, hypothesizing that children attending her clinic might differ from children attending the Toronto and the Amsterdam clinics. Returning once again to the full set of all studies, however, the evidence shows the very opposite: All studies yielded the same result, whether from the 1970s, 80s, 90s, 2000s, 2010s, and wherever in the world any clinic was. Acknowledging the possibility that future studies may lead to a different conclusion, the existing evidence shows majority desistance, constantly and across all time periods.

134. Consideration of the full set of studies also indicates that the contrast is not Toronto and Amsterdam versus whatever "reality" Temple Newhook perceives. Rather, they show the contrast is between Temple Newhook and every facility in every country ever reporting desistance data on childhood-onset gender dysphoria. Moreover, despite Temple Newhook's mention of influences of political cultures, that commentary does

not point out that Canada and the Netherlands are much more politically liberal than the U.S. Although the commentary offers the hypothesis that the Canadian and Dutch contexts might decrease persistence, the commentary does not include the inverse possibility: that these liberal environments might be "*iatrogenic*"—that is, causing dysphoria to continue when it might otherwise remit.

135. Also, the very evidence suggesting that gender dysphoria can be influenced by local environmental factors is itself evidence that gender identity is not, in fact, an innate and immutable feature, potentially amenable to change.

C. Adolescent-Onset Gender Dysphoria, the predominant clinical population today, is a distinct and largely unstudied phenomenon.

136. Concurrent with the advent of social media, a third profile began appearing clinically and socially, characteristically distinct from the two previously identified profiles. (Kaltiala-Heino 2015; Littman 2018.) Despite lacking any history before the current generation, this profile has now numerically overwhelmed the previously known and better characterized types in clinics and on Internet surveys. Unlike adult-onset or childhood-onset gender dysphoria, this group is predominately biologically female. This group typically presents in adolescence, but lacks the history of cross-gender behavior in childhood like the childhood-onset cases have. It is that feature which led to the term Rapid Onset Gender Dysphoria (ROGD). (Littman

2018.)[5] Cases commonly appear to occur within clusters of peers in association with increased social media use (Littman 2018), and among people with autism or other mental health issues. (Kaltiala-Heino 2015; Littman 2018; Warrier 2020.) (See section XI on Mental Health.) The patterns reported by Littman have now been independently replicated by another study which also found it to be a predominantly female phenomenon, associated with very high rates of social media use, among youth with other mental health issues, and in association with peers expressing gender dysphoria issues. (Diaz 2023.) Due to the multiple differences across the epidemiological and other objective variables, there is no justification for extrapolating findings from adult-onset or childhood-onset gender dysphoria to this new presentation.

137. There do not yet exist any cohort studies of people with adolescent-onset gender dysphoria undergoing medicalized transition. Current studies are limited to surveys typically of volunteers from activist and support groups on the Internet.

138. Moreover, no study has yet been organized in such a way as to allow for a distinct analysis of the adolescent-onset group, as distinct from childhood-onset or adult-onset cases. Many published studies fail to distinguish between people who had childhood-onset gender dysphoria and have aged into adolescence versus people whose onset was not until adolescence. (Analogously, there are reports failing to distinguish

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[5] After initial criticism, the publishing journal conducted a reassessment of the article. The article was expanded with additional detail and republished. The relevant results were unchanged. Littman's paper as revised has been widely cited.

people who had adolescent-onset gender dysphoria and aged into adulthood from adult-onset gender dysphoria.) Studies selecting groups according to their current age instead of their ages of onset produces confounded results, representing unclear mixes according to how many of each type of case wound up in the final sample.

X. Suicide and suicidality are distinct phenomena representing different mental health issues and indicating different clinical needs.

139. *Suicide* refers to completed suicides and the sincere intent to die. It is substantially associated with impulsivity, using more lethal means, and being a biological male. (Freeman 2017.) *Suicidality* refers to *para*-suicidal behaviors, including suicidal ideation, threats, and gestures.

A. Rates of suicidality among all adolescents have skyrocketed with the advent of social media.

140. The CDC's 2019 Youth Risk Behavior Survey found that 24.1% of female and 13.3% of male high school students reported "seriously considering attempting suicide." (Ivey-Stephenson 2019 at 48.)

141. The CDC survey reported not only that these already alarming rates of suicide attempt were still increasing (by 8.1%-11.0% per year), but also that this increase was occurring only among female students. No such trend was observed among male students. That is, the demographic increasingly reporting suicidality is the same demographic increasingly reporting gender dysphoria. (Ivey-Stephenson at 51.)

142. The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) produces a series of evidence-based resource guides which includes their

Treatment for Suicidal Ideation, Self-Harm, and Suicide Attempts Among Youth. It noted (italics added):

> [F]rom 1999 through 2018, the suicide death rate doubled for females aged 15 to 19 and 20 to 24. For youth aged 10 to 14, the suicide death rate more than tripled from 2001 to 2018. Explanations for the increase in suicide may include bullying, social isolation, increase in technology and *social media*, increase in *mental illnesses*, and economic recession. (SAMHSA 2020 at 5.)

The danger potentially posed by social media follows from suicidality spreading as a social contagion, as suicidality increases after media reports, occurs in clusters of social groups, and in adolescents after the death of a peer. (Gould & Lake 2013.)

143. Social media voices today loudly advocate "hormones-on-demand" while issuing hyperbolic warnings that teens will commit suicide unless this is not granted. Both adolescents and parents are exposed to the widely circulated slogan that "I'd rather have a living son than a dead daughter," and such baseless threats or fears are treated as a justification for referring to affirming gender transitions as 'life-saving' or 'medically necessary'. Such claims grossly misrepresent the research literature, however. Indeed, they are unethical: Suicide prevention research and public health campaigns repeatedly warn against circulating messages that can be taken to publicize or even glorify suicide, due to the risk of copy-cat behavior they encourage. (Gould & Lake 2013.)

144. Systematic review of 44 studies of suicidal thoughts and behaviors in LGBTQ youth and suicidality found only a small association between suicidality and

sexual minority stress. (Hatchel 2021.) The quantitative summary of the studies (an especially powerful type of systematic review called *meta-analysis*) found no statistically significant association between suicidality and any of having an unsupportive school climate, stigma and discrimination, or outness/openness. There were, however, significant associations between suicidality and indicators of social functioning problems, including violence from intimate partners, victimization from LGBT peers and from non-LGBT peers, and sexual risk taking.

B. *Suicidality* is substantially more common among females, and *suicide,* among males. Sexual orientation is strongly associated with suicidality, but much less associated with suicide.

145. Notwithstanding public misconceptions about the frequency of suicide and related behaviors, the highest rates of death by suicide are among middle-aged and elderly men in high income countries. (Turecki & Brent 2016 at 3.) Males are at three times greater risk of death by suicide than are females, whereas suicidal ideation, plans, and attempts are three times more common among females. (Klonsky 2016; Turecki & Brent 2016.) In contrast with completed suicides, the frequency of suicidal ideation, plans, and attempts is highest during adolescence and young adulthood, with reported ideation rates spanning 12.1-33%. (Borges 2010; Nock 2008.) Relative to other countries, Americans report elevated rates of each of suicidal ideation (15.6%), plans (5.4%), and attempts (5.0%). (Klonsky 2016.) Suicide attempts occur up to 30 times more frequently than completed suicides. (Bachmann 2018.) The rate of completed suicides in the U.S. population is 14.5 per 100,000 people. (WHO 2022.)

146. There is substantial research associating sexual orientation with suicidality, but much less so with completed suicide. (Haas 2014.) More specifically, there is some evidence suggesting gay adult men are more likely to die by suicide than are heterosexual men, but there is less evidence of an analogous pattern among lesbian women. Regarding suicidality, surveys of self-identified LGB Americans repeatedly report rates of suicidal ideation and suicide attempts 2-7 times higher than their heterosexual counterparts. Because of this association of suicidality with sexual orientation, one must apply caution in interpreting findings allegedly about gender identity: because of the overlap between people who self-identify as non-heterosexual and as transgender or gender diverse, correlations detected between suicidality and gender dysphoria may instead reflect (be confounded by) sexual orientation. Indeed, other authors have made explicit their surprise that so many studies, purportedly of gender identity, entirely omitted measurement or consideration of sexual orientation, creating the situation where features that seem to be associated with gender identity instead reflect the sexual orientation of the members of the sample. (McNeil 2017.)

C. There is no evidence that medicalized transition reduces rates of suicide or suicidality.

147. It is repeatedly asserted that despite the known risks, despite the lack of research into the reality or severity of unquantified risks, it is essential and "the only ethical response" to provide medical transition to minors because medical transition is known to reduce the likelihood of suicide among minors who suffer from gender dysphoria. This is simply untrue. *No studies* have documented any reduction in suicide rates in mi-

nors (or any population) as a result of medical transition. No methodologically sound studies have provided meaningful evidence that medical transition reduces suicidality in minors. Instead, multiple studies show tragically high rates of suicide after medical transition, with that rate beginning to spike several years after medical transition.

148. Among post-transition adults, completed suicide rates remain elevated. (Wiepjes 2020.) Among post-operative transsexual adults in Sweden's highly tolerant society, death by suicide is 19 times higher than among the cisgendered. (Dhejne 2011.) Systematic review of 17 studies of suicidality in transsexual adults confirmed suicide rates remain elevated even after complete transition. (McNeil 2017.) Among post-operative patients in the Netherlands, long-term suicide rates of six times to eight times that of the general population were observed depending on age group. (Asscheman 2011 at 638.) Also studying patients in the Netherlands, Wiepjes et al. (2020) reported the "important finding" that "suicide occurs similarly" before and after medical transition. (Wiepjes 2020 at 490.) In other words, *transition did not reduce suicide*. A very large dataset from the U.K. GIDS clinic showed that those referred to the GIDS clinic for evaluation and treatment for gender dysphoria committed suicide at a rate five times that of the general population, both before and after commencement of medical transition (Biggs 2022). Finally, in a still-ongoing longitudinal study of U.S. patients, Chen *et al.* have reported a shockingly high rate of completed suicide among adolescent subjects in the first two years *after* hormonal transition, although they provide no pre-treatment data for this population to compare against. (Chen 2023 at 245.)

149. WPATH's systematic review of the effectiveness of puberty blockers and cross-sex hormones on suicide in minors concluded that "It was impossible to draw conclusions about the effects of [either] hormone therapy on death by suicide." (Baker 2021 at 12.) In short, I am aware of no respected voice that asserts that medical transition reduces suicide among minors who suffer from gender dysphoria.

150. As to the separate and far more common phenomenon of suicidality, of course, that claim is widely made. McNeil's systematic review revealed, however, a complicated set of interrelated factors rather than supporting the common hypothesis that rates of suicidal ideation and suicidal attempts would decrease upon transition. Rates of suicidal ideation did not show the same pattern as suicide attempts, male-to-female transitioners did not show the same patterns as female-to-male transitioners, and social transition did not show the same patterns as medical transition. Importantly, the review included one study that reported "a positive relationship between higher levels of social support from leaders (e.g., employers or teachers) and increased suicide attempt, which they suggested may be due to attempts instigating increased support from those around the person, rather than causing it." (McNeil 2017 at 348.)

151. Moreover, the 2020 Kuper, *et al.* cohort study of minors receiving hormone treatment found *increases* in each of suicidal ideation (from 25% to 38%), attempts (from 2% to 5%), and non-suicidal self-injury (10% to 17%). (Kuper 2020 at Table 5.) Research has found social support to be associated with *increased* suicide attempts, suggesting the reported suicidality may repre-

sent attempts to evoke more support. (Bauer 2015; Canetto 2021.)

152. Overall, the research evidence is only minimally consistent with the hypothesis that an absence of transition causes mental health issues and suicide, but very strongly consistent with the hypothesis that mental health issues, such as *Borderline Personality Disorder* (BPD), cause both suicidality and unstable identity formation (including gender identity confusion). (See section XI.) BPD is repeatedly documented to be greatly elevated among sexuality minorities (Reuter 2016; Rodriguez-Seiljas 2021; Zanarini 2021), and both suicidality and identity confusion are symptoms of that disorder. Thus, diverting distressed youth towards transition necessarily diverts youth away from receiving the psychotherapies designed for treating the issues actually causing their distress.

153. Despite that mental health issues, including suicidality, are repeatedly required by clinical standards of care to be resolved before transition, threats of suicide are instead oftentimes used as the very justification for labelling transition a "medical necessity". However plausible it might seem that failing to affirm transition causes suicidality, the epidemiological evidence does not support that hypothesis.

XI. Mental health profiles differ across adult-, adolescent-, and childhood-onset gender dysphoria.

A. Mental health issues in Adult-Onset Gender Dysphoria.

154. Systematic review of all studies examining mental health issues in transgender adults identified 38 such studies. (Dhejne 2016.) The review indicated that

many studies were methodologically weak, but nonetheless consistently found (1) that the average rate of mental health issues among adults is highly elevated both before *and after* transition, (2) but that the average was less elevated among adults who completed transition. It could not be concluded that transition improves mental health, however. Patients were commonly receiving concurrent psychotherapy, introducing a confound (meaning, again, that it cannot be determined whether the change was caused by the transitioning or the mental health treatment). Further, several studies showed more than 40% of patients to become "lost to follow-up." It remains unknowable to what extent the information from the remaining participants accurately reflects the whole population.

B. Mental health issues in Childhood-Onset Gender Dysphoria.

155. Elevated rates of multiple mental health issues among gender dysphoric children are reported throughout the research literature. A formal analysis of children (ages 4-11) undergoing assessment at the Dutch child gender clinic showed that 52% fulfilled criteria for a formal DSM diagnosis of a clinical mental health condition other than Gender Dysphoria. (Wallien 2007 at 1307.) A comparison of the children attending the Canadian versus Dutch child gender dysphoria clinic showed only few differences between them, and a large proportion in both groups were diagnosable with clinically significant mental health issues. Results of standard assessment instruments (Child Behavior Check List, or CBCL) demonstrated that among 6-11-year-olds, 61.7% of the Canadian and 62.1% of the Dutch sample satisfied the diagnostic criteria for one or more men-

tal health conditions other than gender dysphoria. (Cohen-Kettenis 2003 at 46-47.)

156. A systematic review of all studies of Autism Spectrum Disorders (ASDs) and Attention-Deficit Hyperactivity Disorder (ADHD) among children diagnosed with gender dysphoria was recently conducted. (Thrower 2020.) It was able to identify a total of 22 studies examining the prevalence of ASD or ADHD youth with gender dysphoria. Studies reviewing medical records of children and adolescents referred to gender clinics showed 6-26% to have been diagnosed with ASD. (Thrower 2020 at 695.) Moreover, those authors gave specific caution on the "considerable overlap between symptoms of ASD and symptoms of gender variance, exemplified by the subthreshold group which may display symptoms which could be interpreted as either ASD or gender variance. Overlap between symptoms of ASD and symptoms of GD may well confound results." (Thrower 2020 at 703.) The rate of ADHD among children with GD was 8.3-11%. Conversely, data from children (ages 6-18) with Autism Spectrum Disorders (ASDs) show they are more than seven times more likely to have parent-reported "gender variance." (Janssen 2016 at 63.)

157. As shown by the outcomes studies (see Section XIII), there is little reliable evidence that transition improves the mental well-being of children. As shown repeatedly by clinical guidelines from multiple professional associations, mental health issues are expected or required to be resolved *before* undergoing transition. The reasoning behind these conclusions is that children may be expressing gender dysphoria, not because they are experiencing what gender dysphoric adults report, but because they mistake what their experiences indi-

cate or to what they might lead. For example, a child experiencing depression from social isolation might develop the hope—and the unrealistic expectation—that transition will help them fit in, as a member of the other sex.

158. In cases where gender dysphoria is secondary to a different issue, efforts at transition are aiming at the wrong target and leave the primary issue(s) unaddressed. Given the highly reliable, repeatedly replicated finding that childhood-onset gender dysphoria resolves with puberty for the large majority of children, the evidence indicates that blocking a child's puberty blocks the child's natural maturation that itself would resolve the dysphoria.

C. Mental health issues in Adolescent-Onset Gender Dysphoria (ROGD).

159. The literature varies in the range of gender dysphoric adolescents with co-occurring disorders. In addition to self-reported rates of suicidality (see Section X), clinical assessments reveal elevated rates not only of depression (Holt 2016; Skagerberg 2013; Wallien 2007), but also anxiety disorders, disruptive behavior difficulties, Attention Deficit/Hyperactivity Disorder, Autism Spectrum Disorder, and personality disorders, especially Borderline Personality Disorder (BPD). (Anzani 2020; de Vries 2010; Jacobs 2014; Janssen 2016; May 2016; Strang 2014, 2016; Swedish Socialstyrelsen, Evolution 2020.)

160. Of particular concern in the context of adolescent-onset gender dysphoria is Borderline Personality Disorder (BPD; diagnostic criteria in Table X below). Symptoms of BPD overlap in important respects with symptoms commonly interpreted as signs of gender

dysphoria, and it is increasingly hypothesized that very many cases appearing to be adolescent-onset gender dysphoria actually represent cases of BPD. (E.g. Anzani 2020; Zucker 2019.) That is, some people may be misinterpreting their experiencing of the broader "identity disturbance" of symptom Criterion 3 to represent a gender identity issue specifically. Like adolescent-onset gender dysphoria, BPD begins to manifest in adolescence, is three times more common in biological females than males, and occurs in 2-3% of the population, rather than 1-in-5,000 people. (Thus, if even only a portion of people with BPD experienced an identity disturbance, and focused that disturbance on gender identity resulting in transgender identification, they could easily overwhelm the number of genuine cases of gender dysphoria.)

Table 4. DSM-5-TR Diagnostic Criteria for Borderline Personality Disorder.

A pervasive pattern of instability of interpersonal relationships, self-image, and affects, and marked impulsivity beginning by early adulthood and present in a variety of contexts, as indicated by five (or more) of the following:

1. Frantic efforts to avoid real or imagined abandonment. (Note: Do not include suicidal or self-mutilating behaviour covered in Criterion 5.)
2. A pattern of unstable and intense interpersonal relationship characterized by alternating between extremes of idealization and devaluation.
3. *Identity disturbance: markedly and persistently unstable self-image or sense of self.*

4. Impulsivity in at least two areas that are potentially self-damaging (e.g., spending, sex, substance abuse, reckless driving, binge eating). (Note: Do not include suicidal or self-mutilating behavior covered in Criterion 5.)

5. *Recurrent suicidal behaviour, gestures, or threats, or self-mutilating behavior.*

6. Affective instability due to a marked reactivity of mood (e.g., intense episodic dysphoria, irritability, or anxiety usually lasting a few hours and only rarely more than a few days).

7. Chronic feelings of emptiness.

8. Inappropriate, intense anger or difficulty controlling anger (e.g., frequent displays of temper, constant anger, recurrent physical fights).

9. Transient, stress-related paranoid ideation or severe dissociative symptoms. (Italics added.)

(American Psychiatric Association 2022 at 752-753.)

161. Mistaking cases of BPD for cases of Gender Dysphoria may prevent such youth from receiving the correct mental health services for their condition. A primary cause for concern is symptom Criterion 5: *recurrent suicidality.* (See Section X on suicide and suicidality.) Regarding the provision of mental health care, the distinction between these conditions is crucial: A person with BPD going undiagnosed will not receive the appropriate treatments (the currently most effective of which is Dialectical Behavior Therapy). The problem was not about *gender* identity, but about having an *unstable* identity.

162. Regarding research, there have now been several attempts to document rates of suicidality among gender dysphoric adolescents. The scientific concern presented by BPD is that it poses a potential confound: samples of gender dysphoric adolescents could appear to have elevated rates of suicidality, not because of the gender dysphoria (or transphobia in society), but because of the number of people with BPD in the sample.

D. Neuroimaging studies have associated brain features with sex and with sexual orientation, but not gender identity.

163. Claims that transgender identity is an innate property resulting from brain structure remain unproven. Neuroimaging and other studies of brain anatomy repeatedly identify patterns distinguishing male from female brains, but when analyses search for those patterns among transgender individuals, "gender identity and gender incongruence could not be reliably identified." (Baldinger-Melich 2020 at 1345.) Although much smaller than male/female differences, statistically significant neurological differences are repeatedly associated with sexual orientation (termed "homosexual" vs "nonhomosexual" in the research literature). Importantly, despite the powerful associations between transsexuality and homosexuality, as explicated by Blanchard, many studies analyzing gender identity failed to control for sexual orientation, representing a problematic and centrally important confound. I myself pointed this out in the research literature, noting that neuroanatomical differences attributed to gender dysphoria should instead be attributed to sexual orientation. (Cantor 2011, Cantor 2012.) A more recent review of the science, by Guillamon, et al. (2016), agreed, stating:

> Following this line of thought, Cantor (2011, 2012, but also see Italiano, 2012) has recently suggested that Blanchard's predictions have been fulfilled in two independent structural neuroimaging studies. Specifically, Savic and Arver (2011) using VBM on the cortex of untreated nonhomosexual MtFs and another study using DTI in homosexual MtFs (Rametti et al., 2011b) illustrate the predictions. *Cantor seems to be right*". (Guillamon 2016 at 1634, italics added; see also Italiano 2012.)

In addition to this confound, because snapshot neurobiological studies can provide only correlational data, it would not be not possible for such studies to distinguish whether brain differences cause gender identity or if gender atypical behavior modifies the brain over time, such as through neuroplasticity. As noted by one team of neuroscientists, "[I]t remains unclear if the differences in brain phenotype of transgender people may be the result of a sex-atypical neural development or of a lifelong experience of gender non-conformity." (Fisher 2020 at 1731.) In sum, at present assertions that transgender identity is caused by neurology represent faith, not science.

XII. Medicalized transition of gender remains *experimental,* lacking causal evidence of mental health improvement.

A. Criteria distinguishing *'experimental'* from *'established'.*

164. In science, the term "experimental" has a specific technical meaning. Within the scientific method, research studies can be *observational* or *experimental.* Among observational studies, such as surveys, the researchers do not administer any treatment and instead

only describe the features of the group observed. Among experimental studies, treatments are actively administered by the researchers, who then compare the treated and untreated groups (or compare a group to itself, before versus after treatment). Also, within a given treatment study, the term "experimental treatment" would be used to distinguish it from the "control treatment" or "treatment-as-usual" being provided to the control group.

165. Outside research studies and within public and legal contexts, the term 'experimental' typically denotes '*unverified by experimental evidence*'. A treatment would continue to be experimental until the demonstration of (1) reliable, clinically meaningful improvement and (2) the reliable estimation of safety risks in randomized, controlled trials (RCTs) or research of equivalent level of evidence. A treatment would remain experimental while its effects, including side effects, remain uninvestigated.

166. Being long-standing, popular, or familiar do not, of themselves, impact whether a treatment is experimental—they suggest opportunities for the experiments to have been done. Clinicians' feelings of self-confidence do not impact status as experimental.

B. International consensus explicitly regards gender transition to be experimental.

167. In England, after a thorough review of the literature and the current practice, Dr. Cass stated that the critical and currently unanswered question "is whether the evidence for the use and safety of the medication is strong enough as judged by reasonable clinical standards." She recognized that these treatments cannot formally be called "experimental" not because they

are proven, but because the experiments needed to test their efficacy and safety have not only not been done, but are not even being attempted. (Cass 2022 at 37.) To address this, Dr. Cass called for "the rapid establishment of the necessary research infrastructure to prospectively enrol young people being considered for hormone treatment into a formal research programme." (Cass Review Letter 2022). In response, in its interim service specification NHS England states that it "will only commission GnRHa [i.e., puberty blockers] in the context of a formal research protocol." (NHS 2022 at 12.)

168. Finland, by law, restricts all assessment and treatment activities for gender dysphoric minors to its two research clinics, Helsinki University Central Hospital and Tampere University Hospital. (COHERE Summary.) Further, after conducting a systematic review of the research, the council responsible for the assessment of public health care services in Finland (COHERE Finland) concluded, "In light of available evidence, gender reassignment of minors is *an experimental practice.*" (COHERE Summary, italics added.)

169. Sweden's research on gender transition is conducted at the Karolinska Institutet in Stockholm. In 2015, that facility registered its research on medicalized transition with the U.S. National Institutes for Health (NIH), noting "[H]ormonal treatment includes inhibition of one's own sex hormone production followed by treatment with testosterone or estrogen levels that are normal for the opposite sex. *Seen as experimental model,* this is a process that provides an opportunity to study the sex hormone dependent influences." (Clinicaltrials.gov.) In its policy updates in 2021, Sweden limited medicalized treatments for gender dysphoria in mi-

nors to clinical research studies approved by the Swedish national research ethics board ("EPM"). (Medscape Psychiatry 2021.)

170. Norway reviewed its own national policy on transition in minors in 2023, explicitly concluding such medical procedures to be experimental. (Ukom 2023.)

171. The widely cited Dutch studies were co-conducted by Dr. Thomas Steensma. Despite being an originator and international leader of medicalized transition of gender dysphoric minors, Dr. Steensma stated in an interview in 2021 that he still considers it to be experimental: "Little research has yet been done on the treatment with puberty inhibitors and hormones in young people. That is why it is also *seen as experimental*." Dr. Steensma decried other clinics for "blindly adopting our research" despite the indications that those results may not actually apply: "We don't know whether studies we have done in the past are still applicable to today. Many more children are registering, and also a different type." Steensma opined that "every doctor or psychologist who is involved in transgender care should feel the obligation to do a good pre- and post-test." (Tetelepta 2021.) But few if any are doing so.

C. Claims that medical transition is "medically necessary" are undefined, unsupported, and self-interested.

172. While European health authorities have examined the science and concluded that medical transition for minors remains "experimental" and of unproven benefit, terminology has been distorted in the U.S. because the U.S. lacks a public health care system and the terms "medically necessary" and "experimental" im-

pact health insurance coverage. "Medically necessary" justifies coverage for these procedures; advocates know or fear that the term "experimental" will preclude coverage.

173. WPATH's 2016 statement asserting "medical necessity" was explicitly made in order to facilitate insurance claims, as is clear in their document entitled, "Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A." (WPATH Position Statement.) The AMA released a similar statement supporting insurance coverage for medical transition as a result of being assertedly medically necessary.[6] U.S. medical associations' advocacy corresponds to the financial interests of their members.

174. Moreover, there do not exist a scientific definition or objective criteria of "medically necessary." An analysis published in the *Canadian Medical Association Journal,* however (not pertaining to gender dysphoria or transition), attempted to define 'medically necessary.' (Caulfield 2012.) The article quoted Timothy Caulfield, Research Chair in Health, Law, and Policy at the University of Alberta (Edmonton), Canada: "As for putting great effort into coming up with a tidy, all-encompassing definition of 'medically necessary'—it's probably a waste of time . . . Given the history of the concept of 'medically necessary' and the numerous failed attempts to define it, a practical, operational and meaningful definition is likely unattainable." (Caulfield at 1771-1772.) According to Mark Stabile, director of the School of Public Policy and Governance and profes-

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[6] Available from https://www.ama-assn.org/system/files/2019-03/transgender-coverage-talking-points.pdf

sor of economics and public policy at the Rotman School of Management at the University of Toronto, "Providers of those services will naturally be critical of the decision if they feel that the demand for their services will decline as a result." (Caulfield at 1772.)

D. WPATH repeatedly warns of untested hypotheses, continuing unknowns, and lack of research.

175. The latest (2022) WPATH Standards of Care v8 document avoided the word "experimental" in its guidelines, but instead repeatedly deployed terms and phrases that are synonymous with being experimental: "The criteria in this chapter [on assessment of adults] have been significantly revised from SOC-7 to reduce requirements and unnecessary barriers to care. *It is hoped that future research will explore the effectiveness* of this model." (Coleman 2022 at S33, italics added.)

176. The WPATH Standards of Care v8 (Coleman 2022.) indicates the lack of experimental evidence available again and again (italics added):

- "It primarily includes an assessment approach that uses specific criteria that are examined by [a Health Care Provider, or] HCP in close cooperation with a TGD adult and does not include randomized controlled trials or long-term longitudinal research" (at S33.)
- "While there was *limited supportive research,* this recommendation was considered to be good clinical practice as it allows a more reversible experience prior to the irreversible experience of surgery" (at S40.)
- "Due to *the limited research in this area,* clinical guidance is based primarily on individual

case studies and the expert opinion of HCPs" (at S41.)

- "While available research shows consistent positive outcomes for the majority of TGD adults who choose to transition . . . some TGD adults may decompensate or experience a worsened condition following transition. *Little research has been conducted to systematically examine variables that correlate with poor or worsened biological, psychological, or social conditions following transition"* (at S42.)
- "Future research would shed more light on gender identity development if conducted over long periods of time with diverse cohort groups" (at S45.)
- "In addition, elevated scrotal temperatures can be associated with poor sperm characteristics, and genital tucking could theoretically affect spermatogenesis and fertility (Marsh 2019) although *there are no definitive studies evaluating these adverse outcomes.* Further *research is needed to determine the specific benefits and risks* of tucking in youth" (at S54.)
- *"There is no formal research evaluating* how menstrual suppression may impact gender incongruence and/or dysphoria" (at S54-55.)
- "Currently, there are only preliminary results from retrospective studies evaluating transgender adults and the decisions they made when they were young regarding the consequences of medical-affirming treatment on reproductive capacity. It is important not to make assump-

tions about what future adult goals an adolescent may have" (at S57.)

- *"Only limited empirical research exists* to evaluate such interventions" (at S75.)
- *"Research has not been conclusive* about when in the life span such detransition is most likely to occur, or what percentage of youth will eventually experience gender fluidity and/or a desire to detransition" (at S77.)
- "Research on pitch-lowering surgeries is limited" (at S139.)
- "The number and quality of research studies evaluating pitch-lowering surgeries are currently insufficient" (at S141.)
- "To date, *research on the long-term impact of [Gender Affirming Hormone Treatment or] GAHT on cancer risk is limited* . . . We have *insufficient evidence* to estimate the prevalence of cancer of the breast or reproductive organs among TGD populations (Joint et al., 2018.)" (at S144.)
- "Contraceptive *research gaps within this population are profound. No studies have examined* how the use of exogenous androgens (e.g., testosterone) may modify the efficacy or safety profile of hormonal contraceptive methods (e.g., combined estrogen and progestin hormonal contraceptives, progestin-only based contraceptives) or nonhormonal and barrier contraceptive methods" (at S162.)

- "TGD individuals AFAB undergoing abortion still represents a critical gap in research" (at S162.)
- "The effects of current TGD-related medical treatments on sexuality are heterogeneous (Ozer et al., 2022; T'Sjoen et al., 2020), and *there has been little research on the sexuality of TGD adolescents"* (at S163.)
- "While sex-positive approaches to counseling and treatment for sexual difficulties experienced by TGD individuals have been proposed (Fielding, 2021; Jacobson et al., 2019; Richards, 2021), to date *there is insufficient research on the effectiveness of such interventions"* (at S163.)

XIII. There have been 11 cohort studies of puberty blockers and cross-sex hormones in minors. They provide no reliable evidence of effectiveness for improving mental health relative to mental health treatments that lack medical risk.

177. Several studies are cited by plaintiffs' experts and in the media as purporting to show that medical transition in minors brings important improvements in mental health beyond the issues of suicide and suicidality that I have already addressed. In fact, there is no reliable evidence of any such benefit.

178. In this section, I summarize the results of all cohort studies investigating the mental health outcomes of puberty blockers and cross-sex hormones on minors. These include all such studies identified by any of the systematic reviews of effectiveness from England, Sweden, Finland, and WPATH. (Listed in Table 1, *Cohort*

studies of effectiveness and safety of puberty blockers and cross-sex hormones in minors.)

179. As enumerated in the following section, all of these studies that reported improved mental health among transitioners were also providing psychotherapy at the same time. (See Section VI on confounding.) None of these studies was able to differentiate which of them was contributing to the improvement.

180. The problem imposed by confounding medicalized transition with psychotherapy is widely recognized. As explicated in the NICE review from England:

> [V]ery little data are reported on how many children and adolescents needed additional mental health support, and for what reasons, or whether additional interventions, and what form and duration (for example drug treatment or counselling) that took. This is a possible confounder for the treatment outcomes in the studies because *changes in critical and important outcomes may be attributable to external care rather than the psychological support or GnRH analogues used in the studies.* (NICE 2020a at 41, italics added.)

Similarly, WPATH's own systematic review noted that "[T]his conclusion is limited by high risk of bias in study designs, small sample sizes, and *confounding with other interventions.*" (Baker 2021 at 1, italics added.)

181. The need to disentangle the roles of these two treatments has been largely ignored despite that several issues depend upon them. If medicalized transition does not show mental health improvement superior to that of mental health treatment, it cannot readily be called "medically necessary" for insurance purposes or

other institutional needs. Clinicians may be subjecting minors to known and potential (but unstudied) harms without any scientific justification.

182. Moreover, without a control group for comparison (i.e., another group of similar age, sex, and mental health status), these studies are also unable to identify when and if any changes are due to regression to the mean or maturation over time.

A. Of the cohort studies, four found little to no improvement in mental health.

183. Kaltiala, *et al.* (2020) similarly reported that after cross-sex hormone treatment, "Those who had psychiatric treatment needs or problems in school, peer relationships and managing everyday matters outside of home continued to have problems during real-life." (Kaltiala 2020 at 213.) They concluded:

> Medical gender reassignment is not enough to improve functioning and relieve psychiatric comorbidities among adolescents with gender dysphoria. Appropriate interventions are warranted for psychiatric comorbidities and problems in adolescent development. (Kaltiala 2020 at 213.)

184. Cantu, *et al.* (2020) studied 80 youth, 11-18 years of age (average of 15.1 years), measuring patients' levels of anxiety, depression, and suicidality. This sample was 18.75% male-to-female, 72.5% female-to-male, and 8.75% nonbinary, but the report did not include the patients' ages of onset. The study authors compared youth according to those receiving puberty blockers only, cross-sex hormones only, both treatments, or neither. No significant differences in mental health were detected on any of these variables. Of the 27 youth re-

porting suicidality before medicalized treatment, 81% continued to report suicidality after medicalized treatment. Remarkably, although the authors reported that "the results of this study suggest that no clinically significant changes in mood symptoms occur" (Cantu 2020 at 199), they did not convey the logical interpretation that transition failed to help these youth. Instead, they emphasized that "findings suggest changes may actually take longer to occur." (Cantu 2020 at 196.)

185. Carmichael, *et al.* (2021) released their findings from the Tavistock and Portman clinic in the U.K. (Carmichael 2021.) Study participants were ages 12-15 (Tanner stage 3 and above for natal males, Tanner stage 2 and above for natal females) and were repeatedly tested before beginning puberty-blocking medications and then every six months thereafter. Cases exhibiting serious mental illnesses (*e.g.*, psychosis, bipolar disorder, anorexia nervosa, severe body-dysmorphic disorder unrelated to gender dysphoria) were excluded. Relative to the time point before beginning puberty suppression, there were *no* significant changes in any psychological measure, from either the patients' or their parents' perspective.

186. Hisle-Gorman, *et al.* (2021) analyzed military families' healthcare data to compare 963 transgender and gender-diverse youth before versus after hormonal treatment, using their non-gender dysphoric siblings as a control group. The study participants included youth undergoing puberty-blocking as well as those undergoing cross-sex hormone treatment, but these subgroups did not differ from each other. Study participants had a mean age of 18 years when beginning hormonal treatments, but their initial clinical contacts and diagnoses occurred at a mean age of 10 years. According to the

study, "mental health care visits overall did not significantly change following gender-affirming pharmaceutical care" (Hisle-Gorman 2021 at 1448), yet, "psychotropic medication use *increased*," (Hisle-Gorman 2021 at 1448, italics added.) indicating *deteriorating* mental health.

B. Six of the cohort studies confounded medical treatment with psychotherapy.

187. The initial enthusiasm for medical blocking of puberty followed largely from early reports from the Dutch clinical research team suggesting at least some mental health improvement. (de Vries 2011, 2014.)

188. The Dutch clinical research team followed up a cohort of youth at their clinic undergoing puberty suppression (de Vries 2011), and later cross-sex hormone treatment and surgical sex reassignment (de Vries 2014). The youth improved on several variables upon follow-up as compared to pre-suppression measurement, including depressive symptoms and general functioning. No changes were detected in feelings of anxiety, or anger, or in gender dysphoria itself as a result of puberty suppression. Moreover, natal females suffered *increased* body dissatisfaction both with their secondary sex characteristics and with nonsexual characteristics. (Biggs 2020.)

189. The reports' own authors noted that while it remains possible that the improvement on some variables was due to the puberty blockers, it was also possible that the improvement was due to the mental health support or to natural maturation. The study authors noted this explicitly: "All these factors may have contributed to the psychological well-being of these gender dysphoric adolescents." (de Vries 2011 at 2281.)

190. van der Miesen, et al. (2020) provided an update of the Dutch clinic's sample, reporting continued improvement in transitioners' psychological functioning, but the medical and psychological treatments remained confounded. Also, the authors indicate that the changing demographic and other features among gender dysphoric youth might have caused the treated group to differ from the control group in unknown ways. The study authors expressly noted, "The present study can, therefore, not provide evidence about the direct benefits of puberty suppression over time and long-term mental health outcomes." (van der Miesen 2020 at 703.)

191. Allen, *et al.* (2019) reported on a sample of 47 youth, ages 13-20, undergoing cross-sex hormone treatment. They reported observing increases in measures of well-being and decreases in measures of suicidality; however, as the authors also noted, "whether a patient is actively receiving psychotherapy" may have been a confounding variable. (Allen 2019.)

192. Becker-Hebley, *et al.* (2021) assessed the quality of life and overall functioning of a sample of German youth both before and after undergoing treatment with GnRHa, CSHT, or both. Excluded from participating were youth with severe psychiatric issues, including suicidality. Of the sample, 79% of the sample participated in psychotherapy at the same time. As the study authors were careful to indicate, "Because this study did not test for statistically significant differences between the four intervention groups or before and after treatment, the findings cannot be generalized to other samples of transgender adolescents." (Becker-Hebly 2021 at 1755.)

193. In Kuper, *et al.* (2020), a multidisciplinary team from Dallas used a battery of mental health tests to assess 148 youth undergoing either puberty-blocking or cross-sex hormone treatment. The tests revealed highly inconsistent results: Most revealed no significant change, some indicated improvement, and some indicated deterioration. Because 144 of the 148 participants were also in treatment with a therapist or counselor (Kuper at 7, Table 4), no conclusions can be drawn regarding the cause of the improvements. Similarly, 47% of the sample were receiving psychiatric medication at the time of their initial assessments, but it was 61% of the sample at the follow-up time: It cannot be known to what extent mental health improvement was associated with transition-related or with psychiatric medication. Importantly, the variables demonstrating deterioration included each of the ones indicating suicidality and self-harm: At follow-up time, the sample showed *higher* levels of suicidal ideation (from 25% to 38%), suicide attempts (from 2% to 5%), and "non-suicidal self-injury" (from 10% to 17%) (Kuper at 8, Table 5).

194. This evidence of worsening mental health was highly obscured in the Kuper report, however. Rather than provide the standard comparison of pre- and post-treatment rates, Kuper instead listed the post-treatment rates along side the full *lifetime* rates: "Lifetime and follow-up rates were 81% and 39% for suicidal ideation, 16% and 4% for suicide attempt, and 52% and 18% for NSSI, respectively" (p. 1). Rates from over a lifetime are necessarily higher numbers, and putting them where pre-treatment rates normally appear conveys the statistical illusion of a decrease, exactly opposite to the actual pattern.

C. Two found no advantage of medicalization over psychotherapy.

195. Costa, *et al.* (2015) provided preliminary outcomes from a small study conducted with patients of the GIDS clinic in the UK. They compared the psychological functioning of one group of youth receiving psychological support with a second group receiving both psychological support as well as puberty blocking medication (representing an "active comparator" group. See Section III.C.2). The "untreated" group, however, was different from the treated group in another important respect, in that these were the patients who began with such severe psychiatric comorbidities that they were deemed ineligible to begin puberty blockers until mental health improved. Further, the study suffered a dramatic loss-to-follow-up, with almost two thirds of participants dropping out across just 18 months. (Biggs 2019.) In this preliminary report, both groups improved in psychological functioning over the course of the study, but no statistically significant difference between the groups was detected at any point. (Costa 2015 at 2212, Table 2.) In any event, all these findings have been superseded, however, and are moot. The final outcomes report for this cohort was subsequently published (as Carmichael 2021, above), finding that neither group actually had experienced any significant improvement at all. (Carmichael 2021.)

196. Achille, *et al.* (2020) at Stony Brook Children's Hospital in New York studied a sample of 95 youth with gender dysphoria, but 45 were lost-to-follow-up within just 12 months, failing to complete follow-up surveys at 6 month and or 1 year. That is, outcomes were available only for the 50 who remained in the study. As well as receiving puberty blocking medications, "Most subjects

were followed by mental health professionals. Those that were not were encouraged to see a mental health professional." (Achille 2020 at 2.) Upon follow-up, some incremental improvements were noted; however, after statistically adjusting for psychiatric medication and engagement in counselling, "*most predictors did not reach statistical significance*." (Achille 2020 at 3, italics added.) That is, puberty blockers did not improve mental health any more than did mental health care on its own. More specifically, only one of the 12 predictors reached statistical significance. (Achille 2020 at Table 4.) That is, medicalized transition was not associated with improved mental health beyond improvement associated with the mental health care received. Moreover, the single predictor reaching the threshold for statistical significance is not reliable: the study authors made a methodological error by failing to account for the multiple comparisons it conducted. Had the study applied the standard adjustment for correcting for multiple comparisons, that remaining predictor would also have ceased to be statistically significant.

197. Tordoff, et al. (2022) reported on the mental health of youth (mean age 15.8) as they underwent their first year of puberty blocker or cross-sex hormone treatment. Of the initial 104, 62.5% were receiving psychotherapy at the same time. (Tordoff 2022 at 5 Table 1.) An unknown number of participants were also receiving psychiatric medications, which the report acknowledged as a potential confounding factor. There were 104 participants at the beginning of the study, but by the end, only 65 remained. Importantly, the report failed to indicate its procedures for assessing the mental health readiness of prospective transitioners, and the results are highly susceptible to selection bias be-

tween those deemed eligible for hormones or puberty blockers, and those who were not.

D. One failed to report whether psychotherapy was provided.

198. Chen, *et al.* (2023) reported finding some improvement in some mental health variables associated with the cosmetic changes after two years of cross-sex hormone treatment in a sample of 315 youth (mean age, 16 years). Unlike the other studies, Chen et al. did not report how many participants were receiving psychotherapy or psychiatric medication at the same time as the hormone treatments. It is therefore not possible to assess to what extent any changes were due to hormone treatment versus the potential confounds. Because the study did not include a control group, it is not possible to assert that changes were due to hormone treatment rather than representing regression to the mean. Potential conclusions are also hampered by the large proportion of mental health data that were missing: Of the 315 youth in the sample, analyses could be conducted with only 208-217 (Chen 2023, supp. Material at 12, Table S5). The purported changes in mental health variables were statistically significant, but not clinically meaningful. The depression test used by Chen et al consisted of 21 items, with each item contributing up to 3-points to the total score. For example:

0 I do not feel sad.

1 I feel sad.

2 I am sad all the time and I can't snap out of it.

3 I am so sad and unhappy that I can't stand it.

Thus, the total scores range from 0 to 63. Scores 0-13 represent minimal difficulty; 14-19 represent mild de-

pression; 20-28, moderate; and 29–63, severe. The change that Chen et al. found after two years of hormone treatment was from 16.39 to 13.95 (at Table S5). Changes of this size are unlikely to be associated with patients reporting they feel better. Such scores are below the "minimum clinically important difference". (Button 2015.) Although the report did not include data on co-morbid mental health diagnoses, it noted that two patients receiving cross-hormone treatment died by suicide (representing 0.6% mortality within just two years). (Chen 2023 at 240.)

199. In addition to the incomplete reporting of key aspects of the project and large proportion of missing data, Chen et al appears to have provided only a selected subportion of the information it collected. A knowledgeable journalist investigating transgender issues, Jesse Singal, identified documentation representing the full set of information the Chen et al team planned to collect. I have verified that documentation and have come to the same conclusion. As described by Singal:

> In their study protocol, including a version that they submitted into a preregistration database, the researchers hypothesized that members of this cohort would experience improvement on eight measures, including ones that are just about universally recognized by youth gender researchers as important outcomes, such as gender dysphoria, suicidality, and self-harm. Then, in the published *NEJM* paper, the researchers changed their hypothesis and six of those variables were nowhere to be found. The two remaining—anxiety and depression—moved in a positive direction for trans boys (natal females) but not trans girls (natal males). The researchers re-

ported on three other variables, too, without explaining how they picked them (two improved for trans girls and boys, and one just for trans boys). (Singal 2023.)

200. This appears to represent "cherry-picking" of the findings being reported, rather than a comprehensive reporting on the complete set of evidence. Further, Chen et al. failed to balance the concrete and strikingly high rate of *completed* suicide among their sample against the very incremental mental health changes they claim, even though the ethical and clinical importance of those suicides is obvious.

XIV. Known and potential harms associated with administration of puberty blockers and cross-sex hormones to children and adolescents.

201. As I have explained, any conclusion about safety requires knowledge about and balancing of both risks and benefits.

202. In concluding that safety has not been established (see Section V above), national health authorities, authors of systematic reviews, and researchers have identified a number of harms which are either known to result from administration of puberty blockers and cross-sex hormones to children and adolescents, or can be reasonably anticipated but have not been sufficiently studied to reach any conclusion as to the likelihood or severity of harm.

203. When applying research regarding harms to clinical policy, several considerations need to be included: (1) The harms of medicalized transition of gender does or may differ between male-to-female and female-to-male cases, differ between ages of transition,

and differ according to age-of-onset of the gender dysphoria. Evidence and conclusions about harms (and safety) cannot be generalized or extrapolated across such cases. (2) The evidence has strongly shown that after social transition of gender, minors are much more likely than otherwise to undergo medicalized transition of gender. Thus, the appropriate assessment of the risk:benefit ratio for social transition must include the increased risks posed by the medicalized path to which it is likely to lead. (3) The evidence has shown strongly that youth who undergo puberty blocking are highly likely to undergo cross-sex hormone treatment. Thus, the appropriate risk:benefit evaluation must also consider its potential implications over the full lifespan.

204. Systematic reviews of the evidence have identified fewer than 10 studies investigating potential harms of medicalized transition of minors at all, (NICE 2020a at 6.) and most of these have been limited to bone and skeletal health. As concluded by the NICE systematic review, "A key limitation to identifying the effectiveness and safety of GnRH analogues for children and adolescents with gender dysphoria is the lack of reliable comparative studies." (NICE 2020a at 40.) With that said, numerous harms are either known, or reasonably anticipated by respected health authorities but thus far unmeasured.

A. Sterilization without proven fertility preservation options.

205. Clinical guidelines for the medical transition of gender among children include the need to caution and counsel patients and parents about what are euphemistically called "options for fertility preservation." (e.g., Endocrine Society Guidelines, Hembree 2017 at 3872.)

For children who are placed on puberty blockers at Tanner Stage 2, however, because most continue onto cross-sex hormones once they begin a medicalized approach to their dysphoria, no viable fertility preservation options exist. The decision to undergo medicalized transition also represents the decision never to have biological children of one's own.

206. For the large new population of young people who are first being put on puberty blockers and/or cross-sex hormones at a somewhat later stage of puberty, no studies at all have been done of when, whether, or with what probability either males or females can achieve healthy fertility if they later regret their transition decision and cease taking puberty blockers and/or cross-sex hormones. Much less has this been studied as a function of the stage of development at which they began puberty blockers and/or cross-sex hormones, and how long their gonads were subjected to cross-sex hormones.

B. Permanent loss of capacity for breast-feeding in adulthood.

207. While the removal of the breasts of a biological female adolescent or young adult may be cosmetically revised, it is functionally irreversible; even if the person later regrets and detransitions before or during adulthood, breast-feeding a child will never be possible. To the adolescent determined to transition, this may seem no cost at all. To the future adult mother, it may be a very severe harm indeed.

C. Lifetime lack of orgasm and sexual function.

208. There has not been systematic investigation of the effects on adult sexuality among people medically

transitioned at an early stage of puberty. Notably, Dr. Marci Bowers, current President of WPATH, and surgeon with substantial experience conducting penis-to-vagina operations, opined, "If you've never had an orgasm pre-surgery, and then your puberty's blocked, it's very difficult to achieve that afterwards . . . I consider that a big problem, actually. It's kind of an overlooked problem that in our 'informed consent' of children undergoing puberty blockers, we've in some respects overlooked that a little bit." (Shrier 2021.) In my opinion as a psychologist and sex and couple's therapist, this represents a large potential harm to future relationships and mental health to "overlook," and must be taken into consideration in any serious risk:benefit analysis of "safety."

D. Hormonal treatments during puberty interfere with neurodevelopment and cognitive development.

209. It is well known that pubertal hormone levels drive important stages of neural development and resulting capabilities, although the mechanisms are not yet well understood. Dr. John Strang (Research Director of the Gender Development Program at Children's National Hospital in Washington, D.C.) (Terhune 2022), the Cass Report from the U.K., and the systematic review from Finland all reiterated the central importance and unknown effects of GnRH-agonists on windows, or "sensitive periods," in brain development, notably including adolescence. As Dr. Cass put it:

> A further concern is that adolescent sex hormone surges may trigger the opening of a critical period for experience-dependent rewiring of neural circuits underlying executive function (i.e. maturation of the

> part of the brain concerned with planning, decision making and judgement). If this is the case, brain maturation may be temporarily or permanently disrupted by puberty blockers, which could have significant impact on the ability to make complex risk-laden decisions, as well as possible longer-term neuropsychological consequences. To date, there has been very limited research on the short-, medium- or longer-term impact of puberty blockers on neurocognitive development. (Cass Review Letter 2022 at 6.)

210. In a meta-analysis (a highly rigorous type of systematic review) of studies of neuropsychological performance, non-transsexual males undergoing puberty earlier show a different cognitive profile than those underdoing puberty later. The association of brain development with age of pubertal onset exists in humans as well as non-human animals. (Shirazi 2022.)

211. Even in adults, neuroscience studies employing MRI and other methods have shown that the blockade of normal levels of hormones associated with puberty and adulthood degrade brain performance. Thus, when GnRH-agonists are administered to adult biological women, several brain networks decrease in activity and cognitive performance, such as in working memory, declines. (Craig 2007; Grigorova 2006.)

212. In light of this science, multiple voices have expressed concern that blocking the process of puberty during its natural time could have a negative and potentially permanent impact on brain development (Cass 2022 at 38-39; Chen 2020; Hembree 2017 at 3874.) As Chen *et al.* (2020) observed:

> [I]t is possible these effects are temporary, with youth 'catching up' . . . However, pubertal suppres-

> sion may prevent key aspects of development during a sensitive period of brain organization. Neurodevelopmental impacts might emerge over time, akin to the 'late effects' cognitive findings associated with certain [other] oncology treatments. (Chen 2020 at 249.)

Chen et al. (2020) noted that no substantial studies have been conducted to identify such impacts outside "two small studies" (at 248) with conflicting results. I have not identified any systematic review of neurodevelopment or cognitive capacity.

213. A related concern is that by slowing or preventing stages of neural development, puberty blockers may impair precisely the mature cognitive capabilities that would be necessary to evaluation of, and meaningful informed consent to, the type of life-changing impacts that accompany cross-sex hormones. (See Section XV.)

E. Substantially delayed puberty is associated with medical harms.

214. The research cited by the WPATH Standards of Care includes the evidence that children whose natural puberty started very late (top 2.3% in age) have elevated risks of multiple health issues in adulthood. (Zhu & Chan 2017.) These include elevations in metabolic and cardiovascular disease, lower height, and decreased bone mineral density. It has not been studied whether these correlations also occur in children whose puberty is chemically delayed. Undergoing puberty much later than one's peers is also associated with poorer psychosocial functioning and lesser educational achievement. (Koerselman & Pekkarinen 2018.)

F. Elevated risk of Parkinsonism in adult females.

215. Epidemiological research has shown adult, non-transsexual women who undergo surgical removal of both ovaries to have substantially elevated odds of developing parkinsonism, including Parkinson's Disease, relative to age-matched women randomly selected from the local population in an on-going epidemiological study. (Rocca 2022.) The effect was greater among younger women, showing 7-8 times greater odds among women under 43. The observed delay between removal of ovaries and the onset of parkinsonism was 26.5 years. Whether chemically suppressing the ovaries of a biological female via puberty blockers during adolescence followed by cross-sex hormones will cause a similar increase in parkinsonism, or when, remains unknown.

G. Reduced bone density.

216. The systematic reviews by Sweden, Finland, and England all included bone health as an outcome. *The New York Times* also recently commissioned its own independent review of the available studies. (Twohey & Jewett 2022.) These reviews all identified subsets of the same group of eight studies of bone health. (Carmichael 2021; Joseph 2019; Klink 2015; Navabi 2021; Schagen 2020; Stoffers 2019; van der Loos 2021; Vlot 2017.) These studies repeatedly arrived at the same conclusion. As described by *The New York Times* review:

> [I]t's increasingly clear that the drugs are associated with deficits in bone development. During the teen years, bone density typically surges by about 8 to 12 percent a year. The analysis commissioned by *The Times* examined seven studies from the Netherlands, Canada and England involving about 500 trans-

gender teens from 1998 through 2021. Researchers observed that while on blockers, the teens did not gain any bone density, on average—and lost significant ground compared to their peers.[7] (Twohey & Jewett 2022.)

217. There is some evidence that some of these losses of bone health are regained in some of these youth when cross-sex hormones are later administered. The rebounding appears to be limited to female-to-male cases, while bone development remains deficient among male-to-female cases.

218. The long-term effects of the deficient bone growth of people who undergo hormonal interventions at puberty remain unstudied. The trajectory of bone quality over the human lifetime includes decreases during aging in later adulthood. Because these individuals may enter their senior years with already deficient bone health, greater risks of fracture and other issues are expectable in the long term. As the *New York Times'* analysts summarized, "That could lead to heightened risk of debilitating fractures earlier than would be expected from normal aging—in their 50s instead of 60s." Such harms, should they occur, would not be manifest during the youth and younger adulthood of these individuals. This distinction also represents one of the differences between adult transitioners and childhood transitioners and why their experiences cannot be extrapolated between them.

219. There does not exist an evidence-based method demonstrated to prevent these outcomes. The recom-

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[7] The eighth study was Lee, *et al.*, 2020, which reported the same deficient bone development.

mendations offered by groups endorsing puberty blockers are quite limited. As summarized by *The Times:*

> A full accounting of blockers' risk to bones is not possible. While the Endocrine Society recommends baseline bone scans and then repeat scans every one to two years for trans youths, WPATH and the American Academy of Pediatrics provide little guidance about whether to do so. Some doctors require regular scans and recommend calcium and exercise to help to protect bones; others do not. Because most treatment is provided outside of research studies, there's little public documentation of outcomes. (Twohey & Jewett 2022.)

H. Short-term/Immediate side-effects of puberty blockers include sterile abscesses, leg pain, headache, mood swings, and weight gain.

220. The Cass Report summarized that "In the short-term, puberty blockers may have a range of side effects such as headaches, hot flushes, weight gain, tiredness, low mood and anxiety, all of which may make day-to-day functioning more difficult for a child or young person who is already experiencing distress." (Cass 2022 at 38.)

221. In 2016, the U.S. FDA began requiring drug manufacturers to add a warning about the psychiatric side effects, after reports of suicidal ideation and a suicide attempt began to emerge among children prescribed GnRH-agonists (for precocious puberty).[8] The warning label on Lupron reads that "Psychiatric events

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[8] Reuters Special Report; 2022, Oct. 6. Retrieved from https://www.reuters.com/investigates/special-report/usa-transyouth-care/

have been reported in patients . . . such as crying, irritability, impatience, anger and aggression."

222. Other than the suicide attempt, such adverse effects may seem minor relative to the major health and developmental risks I have reviewed above, and they may be dismissed by children and by parents confronted by fears of suicidality and an urgent hope that transition will resolve the child's unhappiness and mental health issues. However, when assessing risk:benefit ratio for "safety" against the undemonstrated benefits claimed for hormonal interventions, these observed harms should not be ignored.

I. Long-term use of cross-sex hormones in adult transsexuals is associated with unfavorable lipid profiles (cholesterol and triglycerides) and other issues.

223. As the Cass Report correctly and succinctly indicated, "Sex hormones have been prescribed for transgender adults for several decades, and the long-term risks and side effects are well understood. These include increased cardiovascular risk, osteoporosis, and hormone-dependent cancers." (Cass 2022 at 36.)

224. Minors who begin puberty blockers and proceed to cross-sex hormones—as almost all do—will require continuing treatment with cross-sex hormones for life, unless they go through the very difficult process of detransition. Because a lifetime dependence on cross-sex hormones is the expected course, the known adverse effects of cross-sex hormones on adults must also be part of the risk:benefit analysis of the "safety" of putting a minor on cross-sex hormones (and indeed, of the initial decision to put a child on puberty blockers).

225. Systematic review identified 29 studies of the effects of cross-sex hormone treatment on cardiovascular health in adults. (Maraka 2017.) By the two-year follow-up mark among female-to-male transitioners, hormone administration was associated with increased serum triglycerides (indicating poorer health), increased low-density-lipid (LDL) cholesterol (indicating poorer health), and decreased high-density-lipid (HDL) cholesterol (indicating poorer health). Among male-to-female transitioners at the two-year mark, cross-sex hormone treatment was associated with increased serum triglycerides (indicating poorer health).

XV. Assertions that puberty blockers act only as a "fully reversible" "pause button" are not supported by scientific evidence.

226. Plaintiffs' experts, along with many advocates and organizations, have boldly asserted that the administration of puberty blockers to adolescents is "fully reversible." The assertion is not consistent with or supported by any objective assessment of the existing science. Although withdrawal of the medication will allow the pubertal process to resume, that is very far from establishing that the impact of that interruption of natural development is "fully reversible." The evidence is not that the person's life will proceed as if the medical intervention never happened, as the popularized phrase suggests. Rather, the evidence repeatedly indicates that stopping a healthy child's natural onset of puberty imposes multiple substantial harms, risks, or opportunity costs.

227. First, as I have previously mentioned (Section IV.D), it is scientifically invalid to extrapolate results from using puberty blockers to prevent precocious pu-

berty by delaying the pubertal process to its normal age range, to using them to *prevent* normally occurring healthy puberty, merely assuming the effects and side-effects will be the same. The two are very different populations and very different uses.

228. Second, not all the effects of GnRHa's in otherwise healthy children are known: It is therefore not possible to assess whether all effects are reversed or to what extent. Indeed, within the scientific method, it is never possible to demonstrate that any intervention is "fully reversible." In science, it always remains possible for future evidence to identify an effect that does not reverse. To assert that all the effects of GnRHa's are fully reversible is to assert that all its effects have been investigated and checked for reversibility, which is false.

229. Third, and more concretely, I have reviewed above a large number of medical and developmental risks which multiple responsible voices have associated with administration of puberty blockers to adolescents, and which are either established by studies or have not been shown not to exist. In the face of this knowledge and lack of knowledge, it is scientifically unsupported and irresponsible to assert that this use of puberty blockers is "fully reversible" and "just a pause."

230. Here, I identify additional psycho-social developmental impacts of delaying healthy, naturally-occurring puberty which are likely to be irreversible, but have not been meaningfully studied.

A. Stopping puberty does not stop time: Patients' peers continue to develop and mature, with patients falling increasingly behind.

231. Initiating puberty blockers at Tanner Stage 2 (at the very first signs of puberty, typically ages 9 or 10) holds the child in a prepubescent state, while their peer group and classmates continue to grow. By the time many patients begin cross-sex hormone treatment, their peers will have completed puberty and progressed far into adolescence. Puberty may become unblocked, but these children have irreversibly lost the opportunity and experience of developing with their peers and must instead do so alone.

232. Being a "late bloomer," indeed among the latest possible bloomers, has psychological consequences of its own. Having the body and mind of a prepubescent child while one's friends have grown into physically mature sixteen-year-olds is extreme. Despite being a teenager chronologically, remaining prepubescent both physically and mentally while the lives of one's peers have advanced to teenagers' interests only increases the isolation of children already reporting social distress. There does not exist a means of distinguishing how much of any improvement in mental health that might be observed across these years in a particular study is simply the result of finally undergoing at least some pubertal development and finally catching up with one's peers in at least some parameters.

233. Concretely, undergoing puberty much later than one's peers (as a result of naturally occurring rather than medically induced conditions) has been associated with poorer psychosocial functioning and lesser educational achievement. (Koerselman & Pekkarinen

2018.) Whether this holds true when the late puberty is the result of puberty blockers has not been studied.

B. Blocking puberty blocks the awareness of sexuality and sexual orientation that can play an important role in the individual's understanding of gender identity.

234. As demonstrated unanimously by the cohort studies of prepubescent children with gender dysphoria, the great majority cease to feel gender dysphoric during the course of puberty. (Section IX.B.) Studies also find that many such children subsequently identify as gay or lesbian, providing a potential alternative source and understanding of their atypical childhood gender interests. But for all children, blocking puberty necessarily blocks the onset of adult sexual interest, sexual arousal, and sexual response which are part of "the usual process of sexual orientation and gender identity development." (Cass 2022 at 38.) That is, blocking the experience of sexual feelings and development blocks normal phenomena that enable the young person to understand sexuality and sexual orientation, as distinct from gender identity. As Dr. Cass summarized:

> We do not fully understand the role of adolescent sex hormones in driving the development of both sexuality and gender identity through the early teen years, so by extension we cannot be sure about the impact of stopping these hormone surges on psychosexual and gender maturation. We therefore have no way of knowing whether, rather than buying time to make a decision, puberty blockers may disrupt that decision-making process. (Cass Review Letter 2022 at 5.)

Thus, contrary to the hypothesis that providing time might permit more considered understanding and decision-making, the prevention of puberty blocks the awareness of a central factor that may well influence that understanding.

235. Because puberty blockers prevent prepubescent children from developing any understanding of sexual arousal and sexual relationships, such children are necessarily incapable of providing informed consent. There does not exist—indeed, there cannot exist—an age-appropriate way to equip a child who has not gone through puberty to make an informed decision about age-inappropriate issues, such as their future sex life, choices of sexual partners, sex-bonded relationships including marriage, and sacrificing ever experiencing orgasm.

C. Blocking puberty may block development of adult decision-making capacity.

236. As I have explained above, there are reasons to fear that use of puberty blockers may have permanent negative effects on brain development. That long-term risk aside, blocking puberty nevertheless threatens to prevent the child from growing towards adult decision-making capability during precisely the years in which he or she is being asked to make life-altering decisions about gender identity, gender presentation and cross-sex hormones. Pubertal brain development includes pervasive change in structural and functional connectivity (Chen 2020), rebalancing its capabilities between the acquisition of skills and knowledge and their application. Foremost among these are acquiring the abilities to control impulsivity and engage in rational and long-term decision-making (Crone & Steinbeis 2017), in as-

sociation with development of a brain region called the "prefrontal cortex," and similarly acquiring the capacity to process adult social interaction, in association with the development of a network of brain areas (Kilford 2016), collectively called the "social brain." To understand medicalized transition of gender and its known and unknown consequences is one of the most complicated questions that a young person today could face, and a prepubescent brain is not equipped to process that information rationally, objectively, and with a whole lifetime rather than immediate desires and social pressures in mind.

D. Time spent on puberty blockers poses significant opportunity costs.

237. One of the primary, if not the foremost, justifications for medically transitioning children and adolescents is to reduce the psychological distress they report. That hypothesis interprets these children's psychological concerns (e.g., anxiety and depression) to gender dysphoria and/or external sources (e.g., transphobia). As I have noted here previously, however, many gender dysphoric children and adolescents suffer from multiple other mental health issues. In several studies of minors on puberty blockers, a substantial portion of the subjects do not report ongoing psychological care. If years spent on puberty blockers in the hopes that that will relieve distress distract from systematic efforts to directly address comorbidities through psychotherapy, then it diverts the minors from treatment which exhibits substantial evidence of effectiveness for improving mental health and lacks the multiple and significant side-effects of puberty blockers.

XVI. Assessments of clinical guidelines, standards, and position statements.

238. Several sets of recommendations have been offered regarding the clinical treatment of people with gender dysphoria. In this section, I comment on these protocols or recommendations individually.

A. The Dutch Protocol (aka Dutch Approach).

239. The Netherlands' child gender identity clinic in Amsterdam associated with the Vrije University (VU) was one of the international leaders in the use of hormonal interventions to treat gender dysphoria in minors. Researchers associated with that clinic have generated a large portion of the seminal research literature in the field. Key early publications from that group spelled out criteria and procedures that are collectively referred to as the "Dutch Protocol," and this approach has been widely influential internationally.

240. The purpose of the protocol was to compromise conflicting desires and considerations including: clients' initial wishes upon assessment; the long-established and repeated observation that those wishes will change in the majority of (but not in all) childhood cases; and that cosmetic aspects of medical transition are perceived to be better when they occur earlier rather than later in pubertal development.

241. The VU team summarized and explicated their approach in their paper, *Clinical management of gender dysphoria in children and adolescents: The Dutch Approach*. (de Vries & Cohen-Kettenis 2012.) Key components of the Dutch Approach are:

- no social transition at all considered before age 12 (watchful waiting period),

- no puberty blockers considered before age 12,
- cross-sex hormones considered only after age 16, and
- resolution of mental health issues before any transition.

242. For youth under age 12, "the general recommendation is watchful waiting and carefully observing how gender dysphoria develops in the first stages of puberty." (de Vries & Cohen-Kettenis 2012 at 301.)

243. The age cut-offs of the Dutch Approach were not based on any research demonstrating their superiority over other potential age cut-offs. Rather, they were chosen to correspond to the ages of consent to medical procedures under Dutch law. Nevertheless, whatever the original rationale, the data from this clinic simply contain no information about the safety or efficacy of employing these measures at younger ages.

244. The authors of the Dutch Approach repeatedly and consistently emphasize the need for extensive mental health assessment, including clinical interviews, formal psychological testing with validated psychometric instruments, and multiple sessions with the child and the child's parents.

245. Within the Dutch Approach, there is no social transition before age twelve. That is, social affirmation of the new gender may not begin until age 12—as desistance is less likely to occur past that age. "Watchful Waiting" refers to a child's developmental period up to that age. Watchful waiting does not mean do nothing but passively observe the child. Rather, such children and families typically present with substantial distress involving both gender and non-gender issues, and it is

during the watchful waiting period that a child (and other family members as appropriate) would undergo therapy, resolving other issues which may be exacerbating psychological stress or dysphoria. As noted by the Dutch clinic, "[T]he adolescents in this study received extensive family or other social support [and they] were all regularly seen by one of the clinic's psychologists or psychiatrists." (de Vries 2011 at 2281.) One is actively treating the person, while carefully "watching" the dysphoria.

246. The use of hormonal interventions described in the Dutch Protocol, while markedly more conservative than today's practice in many U.S. clinics, has recently been criticized in detail in a peer-reviewed article as unjustified by reliable evidence (Biggs 2022; Levine 2023; Levine 2022). Certainly, the published research evidence base concerning safety and efficacy available to the VU clinicians is and was no greater than the global evidence base that the NICE review recently labelled as uniformly of "very low quality."

247. Because clinical practices are often justified by alluding to the Dutch Protocol, however, it is important to be aware of the limitations on the use of hormones and puberty blockers specified by the Dutch Protocol and listed above (and thus the limits of the clinical evidence published out of the VU clinic) which are regularly ignored by clinicians in the U.S.

B. World Professional Association for Transgender Health (WPATH).

248. The WPATH standards of care have been lauded as long-established and high quality procedures. This does not reflect any objective assessment, however. The previous WPATH standards (version 7) were

subjected to standardized evaluation, the Appraisal of Guidelines for Research and Evaluation ("AGREE II") method. (Dahlen 2021.) That assessment concluded "[t]ransition-related [clinical practice guidelines] tended to lack methodological rigour and rely on patchier, lower-quality primary research." (Dahlen 2021 at 6.) The WPATH guidelines were not merely given low scores, but received unanimous ratings of "Do not recommend." (Dahlen 2021 at 7.)

249. Immediately after the release of the current (2023) version of WPATH's standards (version 8), WPATH fundamentally altered it by removing from it minimum ages previously required for undergoing social or medical transition of gender. (WPATH Correction 2022.) This is despite the fact that age is the central component to young people's emerging understanding of their sexual identities through social identity formation, pubertal development, and the onset of sexual interest. The removal of age restrictions was not based on any research evidence at all—WPATH provided no reference to any study as justification, and the WPATH leadership have been explicit in indicating that the change was intended to prevent clinical care providers from legal liability for physicians rejecting those minimums. The implementation of such fundamental and dramatic changes, in the complete absence of any supporting science whatsoever, negates entirely any claim that WPATH represents evidence-based or empirically-supported treatment. As explicated herein, on Table 1, the systematic review on which WPATH based its standards for minors included exactly one study on puberty blockers and three studies on cross-sex hormones. All other references represent cherry-picked citations of studies rejected by its own systematic pro-

cess. Moreover, even among the four studies in WPATH's review, three were rejected by the Swedish review, due to the low quality of the science they contained.

C. Endocrine Society (ES).

250. As I have noted, in preparing its guidelines the Endocrine Society did not conduct systematic reviews of evidence relating to efficacy of any hormonal intervention in children or adolescents, and instead conducted reviews on only two safety-related endpoints.

251. Although outside the professional expertise of endocrinologists, mental health issues were also addressed by the Endocrine Society, repeating the need to handle such issues before engaging in transition, "In cases in which severe psychopathology, circumstances, or both seriously interfere with the diagnostic work or make satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues." (Hembree 2017 at 3877.) This ordering—to address mental health issues before embarking on transition—avoids relying on the unproven belief that transition will solve such issues.

252. The Endocrine Society did not endorse any affirmation-only approach. The guidelines were neutral with regard to social transitions before puberty, instead advising that such decisions be made only under clinical supervision: "We advise that decisions regarding the social transition of prepubertal youth are made with the assistance of a mental health professional or similarly experienced professional." (Hembree 2017 at 3870.)

253. The Endocrine Society guidelines make explicit that, after gathering information from adolescent cli-

ents seeking medical interventions and their parents, the clinician "provides correct information to prevent unrealistically high expectations [and] assesses whether medical interventions may result in unfavorable psychological and social outcomes." (Hembree 2017 at 3877.)

254. The 2017 update of the Endocrine Society's guidelines added a disclaimer not previous appearing:

> The guidelines cannot guarantee any specific outcome, nor do they establish a standard of care. . . . The Endocrine Society makes no warranty, express or implied, regarding the guidelines and specifically excludes any warranties of merchantability and fitness for a particular use or purpose. The Society shall not be liable for direct, indirect, special, incidental, or consequential damages related to the use of the information contained herein. (Hembree 2017 at 3895-3896.)

255. The Endocrine Society guidelines do not rely on any systematic review of evidence of *efficacy* of any form of treatment for gender dysphoria. The Dahlen et al. team also subjected these guidelines to review according to the AGREE II criteria, and two out of three independent reviewers concluded that they should *not* be used clinically. (Dahlen 2021 at 7.)

D. American Academy of Pediatrics (AAP).

256. A "Policy Statement" issued by the American Academy of Pediatrics (AAP) in 2018, but on its face declared to represent exclusively the work of one author who alone is "accountable for all aspects of the work," is unique among the major medical associations in being the only one to endorse an affirmation-on-demand pol-

icy, including social transition before puberty without any watchful waiting period. (Rafferty 2018.) Although changes in recommendations can obviously be appropriate in response to new research evidence, the AAP identified no such new evidence to justify a radical departure from the "therapy first" approach of the Dutch Protocol. Rather, the research studies AAP cited in support of its policy simply did not say what AAP claimed they did. In fact, the references that AAP cited as the basis of their policy instead outright contradicted that policy, repeatedly endorsing watchful waiting. (Cantor 2019.) Moreover, of all the outcomes research published, the AAP policy cited *one*, and that without mentioning the outcome data it contained. (Cantor 2019.)

257. Immediately following the publication of the AAP policy, I conducted a point-by-point fact-check of the claims it asserted and the references it cited in support. I submitted that to the *Journal of Sex & Marital Therapy*, a well-known research journal of my field, where it underwent blind peer review and was published. I append that article as part of this report. *See* Appendix 2. A great deal of published attention ensued; however, the AAP has yet to respond to the errors I demonstrated its policy contained. Writing for *The Economist* about the use of puberty blockers, Helen Joyce asked AAP directly, "Has the AAP responded to Dr Cantor? If not, have you any response now?" The AAP Media Relations Manager, Lisa Black, responded: "We do not have anyone available for comment."

XVII. Assessment of plaintiffs' experts' reports.

258. In the body of my report above I have addressed the nature and strength of the scientific evidence con-

cerning the primary scientific issues raised in the expert reports of Plaintiffs' experts. Here, I add a few remarks directed to specific evidentiary or logical defects in the opinions offered by specific experts.

A. Adkins

259. Dr. Adkins indicated she was an expert witness for the plaintiffs in B.P.J. v West Virginia Board of Education et al. I am an expert witness for the defense in that case, which is currently in process.

260. Dr. Adkins' employment in programs and centers for gender care represents a significant conflict of interest: The income she derives from her medical treatment of these children would be directly affected by the outcome of this case. Individuals who stand to lose income on the basis of research findings cannot be objective in their assessment of those findings. (See Section I.B. on *Clinical vs. Scientific Expertise* and Section I.C. on the *Professional Standard on Conflict of Interest.)*

261. Dr. Adkins reported training in pediatric endocrinology, not mental health. She is not qualified to assess the mental health of her patients. Patients undergoing medicalized transition requires screening for mental health issues before entering her care at all.

262. Dr. Adkins' declaration made explicit that her opinions repeatedly derived from her personal experiences rather than on the contents of the peer reviewed literature. Because Dr. Adkins is not qualified to assess mental health status, she is not able to offer reliable opinions about changes in mental health status. However qualified she is to assess physical health, she is not qualified to evaluate the mental health outcomes of the

physical interventions she provides, not qualified to predict effects on mental health of withdrawing the treatments she provides, and not qualified to opine on whether or when mental health treatments such as psychotherapies can provide an equally (or superior) effective alternative lacking the risks of physical interventions.

263. Dr. Adkins claimed "a person's gender identity . . . cannot be changed voluntarily or by external forces" citing page 3874 of the Endocrinology Society guidelines (Adkins, paragraph 20). Regarding "external forces," the Endocrine Society guidelines claim the very opposite of what Dr. Adkins attributed to them: That document actually says, "Results of studies from a variety of biomedical disciplines—genetic, endocrine, and neuroanatomic—support the concept that gender identity and/or gender expression (20) likely reflect a complex interplay of biological, environmental, and cultural factors." (Hembree 2017 at 3874.) The Endocrine Society explicitly included the influence of exactly the factors Dr. Adkins claimed it excluded.

264. Regarding gender identity being "changed voluntarily," Dr. Adkins mistakes the pertinent issue: The central issue is youth who are *mistaken* about their gender identity. These youth are *misinterpreting* their experiences to indicate they are transgender, or are exaggerating descriptions of their experiences in service of attention-seeking, calls for help, or other psychological needs. Finally, Dr. Adkins' claim is not merely lacking any science to support it; the claim itself defies the scientific method itself. In science, it is not possible to know that gender identity cannot be changed: We can know only that we lack evidence of such a procedure. In science, it remains eternally possible for evidence of

such a treatment to emerge, and unlike sexual orientation's long history with conversion therapy, there have not been systematic attempts to change gender identity.

265. Dr. Adkins claimed that "untreated" gender dysphoria can result in mental health issues including suicidality, citing two sources, Spack et al. (2012) and Olson et al. (2016) (Adkins ¶22.) Her claim does not at all reflect the contents of the research on suicidality, however. (See Section X. *Suicide and Suicidality.)* Dr. Adkins's claim directly contradicts the contents of Spack et al. (2012). Whereas Adkins cites Spack in support of her medicalized treatment of gender dysphoria, Spack instead repeatedly and unambiguously indicated that "Gender dysphoric children who do not receive *counseling* have a high risk of behavioural and emotional problems and psychiatric diagnoses." (Spack 2012 at 422, italics added.) In direct opposition to Adkins' claims that medical transition is needed to treat this medical condition, Spack has instead written that "*mental health intervention* should persist for the long term, even after surgery, as patients *continue to be* at mental health risk, *including for suicide.* While the causes of suicide are multifactorial, the possibility cannot be ruled out that some patients unrealistically believe that surgery(ies) solves their psychological distress." (Spack 2013 at 484 italics added.) Whereas Adkins cited Spack to support her insinuations that transition relieves distress, Spack instead explicitly warned against drawing exactly the conclusion that Adkins presented to the court.

266. While Spack notes the mental health issues of these youth require mental health treatments (which Adkins is not qualified to provide), Adkins cites him to

claim the reverse: that the mental health issues instead require the *medical* interventions (which she can provide). It is situations likes these that the aforementioned conflict of interest policies are meant to prevent.

267. Dr. Adkins' declaration also misleads the court in citing Olson et al. (2016). First, that study did not report on medical interventions at all: It compared the mental health of children who had *socially* transitioned (not medically transitioned) with a non-transgender control group, finding no significant differences between them. Second, the Olson report turned out to be have been incorrectly analyzed. After correcting for the statistical errors, the data instead showed that the socially transitioned children in the Olson clinic showed significantly *lower* mental health than the controls. (Schumm 2019; Schumm & Crawford 2020.)

268. I conducted an electronic search of the research literature to identify any responses from the Olson team regarding the Schumm and Crawford re-analysis of the Olson data and was not able to locate any. I contacted Professor Schumm by email on August 22, 2021 to verify that conclusion, to which he wrote there has been: "No response [from Olson]." (Schumm, email communication, 22 Aug 2021, on file with author.[9])

269. In her deposition, Adkins claims to have achieved a level of success in her medical practice unlike

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[9] The date of these emails precedes the filing of the present case. As indicated already, Dr. Adkins and I previously were expert witnesses in BPJ v West Virginia. In her declaration in that case, Dr. Adkins made the same claims as here using these same citations. It was in preparing my response for that case, in 2021, that I contacted Dr. Schumm. Despite having been alerted to her factual errors, however, Dr. Adkins knowingly repeats them here.

that reported by any other anywhere in the world: "I currently treat hundreds of transgender patients. All of my patients who have received medical treatment for gender dysphoria have benefitted from clinically appropriate treatment." (Adkins ¶24.) No clinic has published success rates even approximating this. (See Section XIII. *Studies of Puberty Blockers and Cross-Sex Hormones.*) By contrast, the peer-reviewed research literature repeatedly indicates that clients misrepresent themselves to their care-providers, engaging in "image management" so as to appear as having better mental health than they actually do. (Anzani et al. 2020; Lehmann et al. 2021.)

270. Dr. Adkins did not describe engaging any systematic file review, tabulation of cases who dropped out and whose outcomes became invisible to her, no consideration of patients receiving mental health treatment as the same time as medical treatment, and no use of validated methods to assess (or define) "benefit." In the absence of any structured method, it is not possible to evaluate to what extent Dr. Adkins' conclusion reflects human recall bias, the aforementioned impression management efforts of clients, or just general maturation during which patients would have improved regardless of medical intervention. Indeed, the very purpose of engaging in systematic, peer-reviewed outcomes research instead of anecdotal recollection is to rule out exactly these biases. (See Section III. *Pyramid of Evidence.*) As already noted, Dr. Adkins is not qualified to assess mental health status or changes to it. In the absence of objective evidence, it is not possible to differentiate Adkins' claims of the unbridled success of her own work from the simpler explanation that she and her patients

are telling each other what they want and expect to hear.

271. Instead of any systematic reviews of the science, the Adkins declaration repeatedly cited the guidelines from the Endocrine Society (aka Hembree et al. 2017, the World Professional Association for Transgender Health (WPATH SOC 8; aka Coleman et al. 2022), the American Association of Pediatrics (AAP; aka Rafferty et al. 2018). As already detailed herein, those documents did not include systematic reviews of the research on the safety or effectiveness medicalized transition. (See Section VI. *Endocrine Society, WPATH, and AAP.*) Adkins' declaration did not include, or mention the existence of, any of the systematic reviews that have been conducted. (See Section V. *Systematic Reviews.*)

B. Antommaria

272. Dr. Antommaria's declaration included his participation as an expert witness for the plaintiffs in three cases for which I am an expert witness for the defense: Dekker v Weida (Florida), Doe v Abbot (Texas), and Boe v Marshal (Alabama).

273. Dr. Antommaria repeatedly argued against professional standards by noting conditions for which exceptions are made, but failed to indicate that any of those conditions are met in the present case.

274. Dr. Antommaria cited the AAP to assert "Clinical practice guidelines are developed using systematic processes to select and review scientific evidence" (Antommaria ¶ 16). Missing from Dr. Antommaria's report is that the AAP failed to engage in exactly that process

for their policy on medical transition of minors. (See XVI. *American Academy of Pediatrics.*)

275. Dr. Antommaria noted that even when a patient did not qualify for a given research study "a clinician *may,* however, recommend a treatment to a patient . . . because the clinician believes the treatment will benefit the patient." (Antommaria ¶17.) Missing from Dr. Antommaria's reasoning is that this does not excuse clinicians from assessing the risk:benefit ratio, ignoring evidence of risk, or overconfidently treating their beliefs as superior to objective evidence.

276. In his ¶18, Dr. Antommaria insinuates that one may ignore the conclusion of the international medical community on the medical transition of minors because "'low' does *not necessarily* mean poor or inadequate," (italics added) but he provides no evidence that the present situation represents such an exception. Dr. Antommaria similarly noted "The labels 'high" and "low" quality evidence *can be misleading* if the latter is used in the colloquial sense of poor or inadequate" (Antommaria ¶ 21). He provided no evidence that the terms are misleading as used here. Moreover, the fulsome descriptions within each of the systematic reviews of the topic make clear that the research is indeed inadequate for justifying the medical procedure they are being used to support.

277. Dr. Antommaria indicates his belief that "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" (Antommaria ¶ 19). That belief ignores the much more important benefit that the RCT design is what permits us to conclude that the treatment *caused* whatever

changes. RCTs are required to distinguish cause from correlation, which is, in turn, required to assessing whether the attendant risks are worth the potential benefits. Because there does not exist evidence that the potential benefits *sometimes* reported on *some* variables in *some* cohort studies (Section XIII. *Cohort Studies*) are caused by medical interventions instead of by the psychotherapy that accompanies it, the medical risks cannot be justified. (See IV. *Methodological Defects.*)

278. In ¶ 20, Dr. Antommaria cites a survey as an example of a cross-sectional study which "permits investigators to examine *potential* associations between factors" (italics added). Surveys are limited to showing correlational results, for which there are multiple potential interpretations. (See IV.B. *Correlation Does Not Imply Causation.*) Of the multiple possibilities, Dr. Antommaria's language insinuates only the one suggesting that puberty blockers caused decreases in suicidal ideation, but ignores the others, including for example that only the mentally healthier children were permitted to receive the blockers in the first place, especially because the clinical assessment procedures are meant to do exactly that.

279. Dr. Antommaria claimed "randomized controlled trials *may* not be feasible or ethical, *may* have intrinsic methodological limitations, or *may* be unavailable in some contexts" (Antommaria ¶ 21); however, his declaration provided no evidence that any of these hypothetical situations applied in the present case. The routine and ethical alternative procedure in clinical science is to use what is called an "active comparator," such as comparing youth receiving both psychotherapy and medicalized transition with youth receiving psycho-

therapy only, as spelled out in the systematic review by NICE in the U.K. (NICE 2020a at 40; NICE 2020b at 47.)

280. The public cannot be confident in medicine when doctors can claim to be performing evidence-based medicine but get out of producing any evidence by relying only on their own self-confidence. This appears to be the same illogic as Dr. Adkins' positive assertions of her own success.

281. Dr. Antommaria's next justification for foregoing the standard methods of testing medical procedures before using them on children was that "there must be uncertainty about whether the efficacy of the intervention or the control is greater" (¶ 22), referring to an ethical principle called *clinical equipoise.* Dr. Antommaria did not, however, spell out uncertainty *among whom:* Physicians avoiding the need to demonstrate their effectiveness simply by declaring certainty about their own performance is exactly the situation evidence-based medicine is designed to prevent. According to bioethicist Benjamin Freedman, the originator of the concept of clinical equipoise, "The requirement is satisfied if there is genuine uncertainty within *the expert medical community*—not necessarily on the part of the individual investigator—about the preferred treatment." (Freedman 1987.) The international expert medical community is indeed highly uncertain, as thoroughly documented throughout the present report (Section II.F. *There Is 'No Debate'*) and in the international medical press, such as the British Medical Journal's recent article: *Gender Dysphoria in young people is rising and so is professional disagreement.* (Block 2023.) The peer reviewed studies that have attempted to do so have been unable to demonstrate differences in efficacy

between medicalized and psychotherapeutic treatment of gender dysphoria in minors. (See Section XIII. *Cohort Studies of Puberty Blockers and Cross-Sex Hormones.*)

282. Dr. Antommaria declared "Gender-affirming medical care is not experimental" (¶ 27-28). Every institution conducting systematic reviews of the safety and efficacy of those procedures, however, came to the opposite conclusion. (See Section XII. *Experimental.*) Ignoring the international conclusion, Dr. Antommaria instead cites claims by groups that did *not* conduct systematic reviews of effectiveness and safety (Antommaria ¶¶ 29-30). These have been reviewed in their own section. (Section VI. *Endocrine Society, WPATH, and AAP.*)

283. Dr. Antommaria is incorrect to compare the use of puberty blocking medication for gender dysphoria with its use for precocious puberty (Antommaria ¶¶ 31, 33, 45). Precocious puberty can be diagnosed with much greater accuracy and upon the basis of objective findings, unlike gender dysphoria, which is based entirely on subjective self-report. With precocious puberty, treatment ends upon attaining typical pubertal age, whereas youth with gender dysphoria instead go on to receive cross-sex hormones, for life, sterilizing them upon its initiation. Because the risks are higher in this situation, the standards for its ethical use is higher in this situation. Pediatric obesity and congenital adrenal hyperplasia, again unlike gender dysphoria, are diagnosable with high accuracy using objective findings, without entailing the destruction of healthy, functioning tissue.

284. Dr. Antommaria claimed the legislative findings "overstate the potential effects of gender-affirming care on fertility" because "puberty blockers do not, by themselves, permanently impair fertility" (¶ 45). Dr. Antommaria does not provide the whole truth: As already noted, gender-affirming care includes both puberty blockers and cross-sex hormones, and it is their *combination* that causes infertility. Dr. Antommaria's verbal slight-of-hand, claiming relative safety when using only one and not the other, is to hide the actual risks in question. Any consent provided after receiving only this select sub-portion of the relevant information would not constitute *informed* consent, and withholding this information would be a terrible violation of medical ethics.

285. Dr. Antommaria cited a (cherry-picked) set of studies seeming to suggest that medicalized transition benefits its patients (¶¶ 34, 51) and that doing any further research would therefore be unethical (¶ 35). The systematic reviews comprising the full set of all such studies came to the opposite conclusion as Dr. Antommaria, as reviewed herein (Section XIII *Cohort Studies of Puberty Blockers and Cross-Sex Hormones.*)

286. Dr. Antommaria also asserted an RCT would be unlikely to enroll a sufficient number of participants because few people would volunteer for a study in which they might not get the medicalized treatment they want (¶ 35). However, several *entire countries* have banned medicalized transition *except* for research studies. Directly opposite to Dr. Antommaria's scenario, it is *only* by such participation that minors could receive medicalized treatment, so one should actually predict *high* participation rates.

287. In ¶ 49, Dr. Antommaria indicates that the associations between medicalized transition and various health and mental health issue are not established to be causally related. He applies his ethical logic incorrectly. Under the medical ethics principle of *primum no nocere*, evidence of the *possibility* of doing harm has the higher priority. It is the evidence of *benefit* that must be *causal,* in order to outweigh the potential harm, whereas evidence of harm may be only correlational. The potential harm must be ruled out, whereas benefits must be causally demonstrated.

288. Dr. Antommaria is incorrect to compare gender dysphoria with DSD's (¶ 54): Such disorders are diagnosed with very high accuracy on the basis of objective features, unlike the subjective basis of diagnosing gender dysphoria.

289. Dr. Antommaria is incorrect to compare hormone therapy of gender dysphoria with chemotherapy (¶ 54). Gender dysphoria involves objectively healthy and functioning tissue, whereas cancers involve the very opposite (and, again, are diagnosed on the basis of objective features).

290. Standards for clinical practice comprise multiple, mutually reinforcing principles and procedures. This overlap can sometimes permit some flexibility in some circumstances where the other principles with high reliability can compensate, such as allowing some reports of pain and sensation when diagnosing a physical disease before prescribing a short-acting and low-risk medication. Dr. Antommaria's advocacy for medicalized transition, however, entails the simultaneous removal of multiple overlapping protections, leaving no meaningful protection at all. Dr. Antommaria is accept-

ing, at face-value only, purely subjective reports, of a diagnosis with no objective evidence of validity, requiring long-term and life-long physical intervention, on the basis of the lowest possible quality evidence, despite all objective counterevidence, and without first exhausting the safer and less invasive alternatives.

C. Janssen

291. Dr. Janssen's declaration indicated he was deposed as an expert witness by the plaintiffs in *BPJ v WV Board of Education.* I testified as an expert witness for the defense in that case. Although he did not include it, Dr. Janssen has also submitted an expert witness declaration for the plaintiffs in *Boe v Alabama.* I have submitted an expert witness declaration for the defense in that case, for which I am scheduled to be deposed and to testify at trial.

292. Dr. Janssen's declaration that 90% of the patients in his clinical practice are transgender children and adolescents represents a significant conflict of interest: The income he derives from his medical treatment of these children would be directly affected by the outcome of this case. Individuals who stand to lose income on the basis of research findings cannot be objective in their assessment of those findings. (See Section I.B. *Clinical vs. Scientific Expertise* and Section I.C. *Professional Standard on Conflict of Interest.)*

293. Dr. Janssen cites de Vries et al. (2014) as the basis of his claim that puberty-blocking medication is responsible for "forestalling increased distress and dysphoria" (Janssen ¶ 48) and that the benefits "increase over the long term" (Janssen ¶ 48). Dr. Janssen's claim contradicts that study's own authors, who instead acknowledged "the positive results may also be attributa-

ble to supportive parents, open-minded peers, and the social and financial support (treatment is covered by health insurance) that gender dysphoric individuals can receive in the Netherlands." (de Vries 2014.) Also, as noted herein, the participants in this study were receiving not only medicalized services, but also psychotherapy, which may instead have caused the mental health improvements. (See Section XIII.B. *Studies Confounded Medical Treatment.*) It is not scientifically possible for Dr. Janssen (or anyone else) to know whether mental health improvement came from the medical interventions, from mental health treatment, or from any of the other possibilities noted by that study's authors.

294. Moreover, Dr. de Vries continues to express the very opposite of what Dr. Janssen attributed to her: Writing in 2023, she repeated that "rigorous longitudinal outcomes studies that provide evidence about whether this approach [hormonal interventions in minors] is effective and safe are needed" and that "Future studies that compare outcomes with different care models are needed." (de Vries 2023 at 276.)

295. SB-1 found that "many of these types procedures, *when performed on a minor* for such purposes, are experimental in nature and not supported by high-quality, long-term medical studies" (SB-1, Section 1, 68-33-101 *Findings.* Paragraph (b), italics added.) Dr. Janssen's declaration quoted only the final part of that sentence, excluding the text indicating it referred only to minors. Dr. Janssen then claimed of the legislative finding "This statement is false." (Janssen ¶ 52.) To justify his assessment, Dr. Janssen wrote "There have been scores of studies *in adult transgender patients* from prospective data collection among this population over decades." (Janssen ¶ 52, italics added.) This rep-

resents highly manipulative and misleading wordplay. Regarding research on minors, Dr. Janssen cited only a single study, Chen et al., 2023, which is *not* a high quality one, as per the widely accepted standards of clinical research, and entirely consistent with the legislative finding. (See Section XIII *No Reliable Evidence*.)

D. Turban

296. Although it was not included in his declaration, Dr. Turban is an expert witness for the plaintiffs in *K.C. et al v Medical Licensing Board of Indiana*. I am an expert witness for the defense in that case, which is currently in progress.

297. Dr. Turban's employment in programs and centers for gender care represents a significant conflict of interest: The income he derives from his medical treatment of these children would be directly affected by the outcome of this case. Individuals who stand to lose income on the basis of research findings cannot be objective in their assessment of those findings. (See Section I.B. *Clinical vs. Scientific Expertise* and Section I.C. *Professional Standard on Conflict of Interest.*)

298. Dr. Turban summarized his opinions in his ¶ 11 with three points. All three deploy vague and ambiguous language that suggest the research literature contains evidence which it does not. Dr. Turban's language repeatedly asserted that medical interventions are causing improvements, in violation of basic scientific principles. (Section IV.B. *Correlation does not imply causation.*) Examples include:

- "interventions improve mental health outcomes" (¶ 11)
- "statistically significant improvements" (¶ 16)

- "shown improvements in mental health" (¶ 17)
- "well-documented benefits of gender-affirming medical care" (¶ 22)

Correlational research studies do not—indeed cannot—support such claims. In all these situations, the group differences are best explained, not as a result of medicalized transition, but as the better functioning youth being the ones who were permitted to transition in the first place (and other factors).

299. Dr. Turban's declaration repeatedly employed language that insinuate causal relationships where only correlation relationships were found, easily misleading readers. Examples include his repeated use of "linked to" (e.g., Turban ¶¶ 12, 18, 19) and "associated with" (Turban ¶ 15). As detailed herein, multiple situations can produce correlational associations and links, only one of which is that X causes Y. Dr. Turban conveys one of these possibilities and withholds from readers the other, even the more logical and parsimonious explanations.

300. Dr. Turban asserted "the claims made by the legislature . . . are not supported by data" (Turban ¶ 12). That assertion is the very opposite of the conclusion of every systematic review conducted of the safety and effectiveness research. Dr. Turban provides no comment or even mention of any of these reviews.

301. Dr. Turban asserted the legislature's claims "are counter to the widely accepted views of the mainstream medical community" (Turban ¶ 12). That assertion is the very opposite of the conclusion of every systematic review of the safety and effectiveness research.

Dr. Turban provides no comment or even mention of any of these reviews.

302. Dr. Turban denied the status of medicalized transition as "experimental." (Turban ¶ 14.) Every institution conducing systematic reviews of the safety and efficacy of those procedure came to the opposite conclusion. (See Section XII. *Experimental.*) Dr. Turban did not mention, never mind challenge, any of them.

303. Dr. Turban claimed "pubertal suppression is associated with a range of improved mental health outcomes," (Turban ¶ 15) on the basis of one survey study of his own (Turban 2020) and five studies by other authors (Achille 2020, Costa 2015, de Vries 2011, de Vries 2014, van der Miesen 2020). The set of five studies are considered within the international systematic reviews (along with the other relevant research), and were not found to demonstrate the conclusion Dr. Turban asserted. (See Section V. *Systematic Reviews.*) These studies are also individually described herein. (See Section XIII. *Studies of Puberty Blockers and Cross-Sex Hormones.*) Dr. Turban's own study represents a survey, and lacked the scientific quality for inclusion in the systematic reviews.

304. Moreover, as already detailed, Dr. Turban violates the scientific method in describing this survey as evidence of treatment causing benefits. Existing standards emphasize that major mental health issues need to be "reasonably under control" before transition is permitted. It was not the case that people became healthier *because of* transition, but that only the healthier people were permitted to transition: As already detailed, surveys do not represent meaningful evidence of clinical

outcomes. (See Section III.F. *Surveys and Cross-Sectional Studies.*)

305. Dr. Turban claimed "studies have likewise found improved mental health outcomes following gender-affirming hormone treatment" (Turban ¶ 16), on the basis of one survey study of his own (Turban 2022) and five studies by other authors (footnotes 9-12: Achille 2020, Allen 2019, Chen 2023, Green 2022, López de Lara 2020). Already considered within the international systematic reviews and the present report are: Achille 2020, Allen 2012, and Chen 2023. López de Lara 2020 studied 23 volunteers from whom psychiatric comorbidities had already been filtered out, and that study has been rejected from systematic review because of its high risk of bias. (SBU 2022, Appendix 2: *Studies excluded due to high risk of bias.*) Dr. Turban's 2022 study and Green 2022 both represent still more analyses from the same survey as Turban 2020, and both are unable to yield reliable causal evidence for the same reasons.

306. In his ¶¶ 23-26, Dr. Turban warns against conflating gender dysphoria studies of children and adolescents, but then proceeds to misrepresent the literature by doing exactly that. Specifically, he removed the word "onset" from childhood-onset and adolescent-onset cases, misdirecting focus to patients' *current* age instead of the age at which their dysphoria began. As the research demonstrates, there are entirely different features and outcomes among childhood-onset, adolescent-onset (and adult-onset) gender dysphoria. (Section IX. *Distinct Mental Health Phenomena.*) That is, Dr. Turban misrepresents cases of childhood-*onset* who age into adolescence to be the same as cases of adolescent-*onset,* despite their *not* having experienced/expressed

dysphoria in childhood and differing on all the other objective features assessed. (See Section IX.C. *Adolescent-Onset Gender Dysphoria.*) Dr. Turban's section title claims "Adolescents who experience gender dysphoria at the onset of puberty rarely come to identify with the assigned sex at birth." That is not accurate: It is the childhood-*onset* cases who *persist* in experiencing dysphoria into adolescence for whom the dysphoria appears to remain, whereas Dr. Turban's vague language insinuates this would also apply also to cases whose dysphoria only just began at puberty/adolescence. Dr. Turban applies the outcomes of childhood-onset *persisters* to adolescent-*onset* cases, immediately after his warning against doing so. Despite noting that "this distinction is vital in the realm of 'desistence studies'" (Turban ¶ 24), Dr. Turban deploys the same vague and misleading language in his summary of opinions, "adolescents who experience gender dysphoria at the onset of puberty rarely come to identity with their assigned sex at birth" (Turban ¶ 11).

307. Dr. Turban's goes on to reverse entirely the application of how children "identify" in the diagnosis research literature. He claimed that the studies demonstrating majority desistance were wrong, because the prior diagnostic category, titled *Gender Identity Disorder in Children* in the DSM-IV[10] "did not require a child to identify as a sex different than their sex assigned at birth" (Turban ¶ 26) and that it is therefore unsurprising that they "did not identify as transgender" later in

[10] There are no differences in the diagnostic criteria between the DSM-IV and DSM-IV-TR or between the DSM-5 and DSM-5-TR. The suffix "-TR" designates "text revision," which indicates changes to the commentary accompanying the diagnostic criteria without changes to the criteria themselves.

life (Turban ¶ 26). In contrast, Dr. Turban asserted the current diagnostic category, titled *Gender Dysphoria in Children* in the DSM-5, requires that "one must identify as a gender different than one's sex assigned at birth" (Turban ¶26). Dr. Turban calls this "a vital distinction" whose implications are true "by definition" (Turban ¶ 26).

308. Despite Dr. Turban's confident wording, his claim is the very reverse of the truth. This is seen simply by putting the criteria for these two versions against each other (italics added). It is the earlier DSM-IV version that *includes* identity and the subsequent DSM-5 version that *excludes* it:

DSM-IV Diagnostic Criteria for Gender Identity Disorder in Children

A. A strong and persistent cross-gender *identification* (not merely a desire for any perceived cultural advantages of being the other sex).

In children, the disturbance is manifested by four (or more) of the following:

(1) repeatedly stated desire to be, or insistence that he or she is, the other sex

(2) in boys, preference for cross-dressing or simulating female attire; in girls, insistence on wearing only stereotypical masculine clothing

(3) strong and persistent preferences for cross-sex roles in make believe play or persistent fantasies of being the other sex

(4) intense desire to participate in the stereotypical games and pastimes of the other sex

(5) strong preference for playmates of the other sex

B. Persistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex.

In children, the disturbance is manifested by any of the following: in boys, assertion that his penis or testes are disgusting or will disappear or assertion that it would be better not to have a penis, or aversion toward tough-and-tumble play and rejection of male stereotypical toys, games, and activities; in girls, rejection or urinating in a sitting position, assertion that she has or will grow a penis, or assertion that she does not want to grow breasts or menstruate, or marked aversion towards normative feminine clothing.

C. The disturbance is not concurrent with a physical intersex condition.

D. The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

DSM-5 Diagnostic Criteria for Gender Dysphoria in Children

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

1. 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).

2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.

3. A strong preference for cross-gender roles in make-believe play or fantasy play.

4. A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender.

5. A strong preference for playmates of the other gender.

6. In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities.

7. A strong dislike of one's sexual anatomy.

8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.

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

309. Dr. Turban's citation of Olson et al. (2022) similarly fails to support his point that only the recent criteria are acceptable. According to Olson et al. (2022):

"This study *did not assess* whether participants met criteria for the Diagnostic and Statistical Manual of Mental Disorders, Fifth edition, diagnosis of gender dysphoria in children." (Olson 2022 at 2, italics added).

310. Dr. Turban's next section, "De-transition and regret among individuals receiving medical treatment for gender dysphoria are uncommon" (¶¶ 27-31) is internally contradictory. He correctly noted in ¶ 28 that "the term 'de-transition' is used inconsistently," yet in ¶ 29 applies the term as if others had used it all with the same one ("the broad heterogeneous category"). Despite having just asserted in the prior section that early diagnoses were "outdated," Dr. Turban in this section now cites as valid research on cases spanning the very same time period (1972-2015) (in Wiepjes 2018). Moreover, the outcomes from the Dutch clinic do not pertain to the current situation: The outcomes from that clinic reflect the strong gate-keeping procedures then applied by that clinic, unlike those being used now.

311. The remaining citation in this section it is again to a survey study of Dr. Turban's (Turban 2021). It represents a survey of people who *are* transgender (and are adults). It is not possible to estimate the number of people who *ceased* to identify as transgender with a survey of people who *currently* identify as transgender (and who participate in the online forums where the survey was advertised). The number reported by Turban 2021 represents the proportion of *re*transitioners, not *de*-transitioners.

312. Although Dr. Turban conceded "While there is undoubtedly a small number of people who start gender-affirming medical interventions . . . " (Turban

¶ 31), there exists no means by which he can know what the correct number is.

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

Executed on May 19, 2023.

/s/ JAMES M. CANTOR
JAMES M. CANTOR, Ph.D.