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 2)

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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 PAUL W. HRUZ, M.D., PH.D

Pursuant to 28 U.S.C. § 1746, I declare:

1. I have been retained by counsel for Defendants as an expert witness in connection with the above-captioned litigation. I have actual knowledge of the matters stated in this report. My professional background, experience, and publications are detailed in my curriculum vitae. A true and accurate copy of my CV is attached as Exhibit A to this report.

2. I am an Associate Professor of Pediatrics in the Division of Pediatric Endocrinology and Diabetes at Washington University School of Medicine. I also have a secondary appointment as Associate Professor of Cellular Biology and Physiology in the Division of Biology and Biological Sciences at Washington University School of Medicine. I served as Chief of the Division of Pediatric Endocrinology and Diabetes at Washington

University from 2012-2017. I served as the Director of the Pediatric Endocrinology Fellowship Program at Washington University from 2008-2016. I am currently serving as Associate Fellowship Program Director at Washington University in St. Louis.

3. Related to the litigation of issues of sex and gender, I have been designated as an expert witness in *Carcaño v. Cooper* (United States District Court for the Middle District of North Carolina, Case No. 1:16-cv-236); *Doe v. Board of Education of the Highland School District* (United States District Court for the Southern District of Ohio, Eastern Division, Case No. 2:16-CV-524); *Whitaker v. Kenosha Unified School District* (United States District Court for the Eastern District of Wisconsin, Case No. 2:16-cv-00943), *Bruce v. South Dakota* (United States District Court for the District of South Dakota, Western Division, Case No. 17-5080); *Kadel v. Falwell* (United States District Court for the Middle District of North Carolina, Case No. 1:19-cv-272-LCB-LPA); *Brandt v. Rutledge* (United States District Court for the Eastern District of Arkansas, Central Division, Case No. 4:21-CV-00450-JM); *D.H. v. Snyder* (United States District Court for the District of Arizona, Case No. 4:20-cv-00335-SHR), Cause DF-15-09887-SD of the 255th Judicial Circuit of Dallas County, TX regarding the dispute between J.A. D.Y. and J.U. D.Y., Children; *Dekker v. Weida* (United States District Court for the Northern District of Florida, Tallahassee Division, Case No. 4:22-cv-00325-RH-MAF); *Boe v. Marshall* (United States District Court for the Middle District of Alabama Northern Division, Civil Action No. 2:22-cv-184-LCB); and *K.C. v. The Medical Licensing Board of* Indiana (United States District Court for the Southern District Of Indiana Indianapolis Division, No.

1:23-cv-00595-JPH-KMB). I have also served as a science consultant or submitted written testimony for court cases in Canada (B.C. Supreme Court File No. E190334) and Great Britain (*Bell v. Tavistock*).

4. I am being compensated at an hourly rate for actual time devoted, at the rate of $400 per hour including report drafting, travel, testimony, and consultation. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

5. My opinions as detailed in this report are based upon my:

a. knowledge, training, and clinical experience in caring for thousands of patients over many years;

b. detailed methodological reviews of hundreds of relevant peer-reviewed science publications;

c. consults, discussions, and team analyses with colleagues and other experts in the field, including attendance and participation in various professional conferences;

d. publications in peer-reviewed scientific journals;

e. editorial work for peer-reviewed scientific journals; and

f. peer-reviewed research grant receipt and review work.

The materials that I have relied upon are the same types of materials that other experts in my field of clin-

ical practice rely upon when forming opinions on the subject, including hundreds of published, peer-reviewed scientific research (and professional) articles.

6. My opinions and hypotheses in this matter are—as all expert reports—subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, and the limitations of social, biological, and medical science. I have not met with, or personally interviewed, anyone in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. In my opinion, a key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information.

BACKGROUND

7. I received my Doctor of Philosophy degree from the Medical College of Wisconsin in 1993. I received my Medical Degree from the Medical College of Wisconsin in 1994.

8. I am board certified in Pediatrics and Pediatric Endocrinology. I have been licensed to practice medicine in Missouri since 2000. My professional memberships include the American Diabetes Association, the Pediatric Endocrine Society, and the Endocrine Society.

9. I have published 62 scholarly articles over my academic career spanning over two decades. This in-

cludes peer-reviewed publications in the leading journals in the fields of metabolism, cardiology, HIV, and ethics. Those journals include Gastroenterology, Circulation, Diabetes, Science Signaling, the Journal of Biological Chemistry, and FASEB Journal. See Exhibit A.

10. I have served as a Reviewer for a number of leading science journals in relevant fields including the Journal of Clinical Endocrinology and Metabolism, the Journal of Biological Chemistry, Diabetes, Scientific Reports, and PLOS ONE, assessing the quality of evidence that is put forward for publication. I have also been involved in the evaluation of clinical trials with colleagues. I have received over $4.6 million in governmental and non-governmental funding for scientific research, including grants from the National Institutes of Health, the American Diabetes Association, The American Heart Association, the March of Dimes, and the Harrington Discovery Institute. I am a member of the Alpha Omega Alpha Medical Honor Society and have received the Armond J. Quick Award for Excellence in Biochemistry, the Eli Lilly Award for Outstanding Contribution to Drug Discovery, and the Julio V. Santiago Distinguished Scholar in Pediatrics Award.

11. During the more than 22 years that I have been in clinical practice, I have participated in the care of hundreds of infants and children, including adolescents, with disorders of sexual development. I was a founding member of the multidisciplinary Disorders of Sexual Development (DSD) program at Washington University. I continue to contribute to the discussion of complex cases and the advancement of research priorities in this field. In the care of these patients, I have acquired expertise in the understanding and management of associated difficulties in gender identification and

gender transitioning treatment issues. I have trained and/or supervised hundreds of medical students, residents, and clinical fellows in the practice of medicine.

12. In my role as a scientist and as the Director of the Division of Pediatric Endocrinology at Washington University, I extensively studied the existing scientific research literature related to the incidence, potential etiology, and treatment of gender dysphoria as efforts were made to develop a Transgender Medicine Clinic at Saint Louis Children's Hospital. I have participated in local, national, and international meetings where the endocrine care of children with gender dysphoria has been discussed in detail and debated in depth. I have met individually and consulted with several pediatric endocrinologists (including Dr. Norman Spack) and other professionals specializing in sexual health (including Eli Coleman) who have developed and led transgender programs in the United States. I have also consulted with, met with, and had detailed discussions with dozens of parents of children with gender dysphoria to understand the unique difficulties experienced by this patient population. I continue to evaluate the ongoing experimental investigation of this condition. I am frequently consulted by other medical professionals to help them understand the complex medical and ethical issues related to this emerging field of medicine.

13. In my clinical practice, I have cared for children from birth to the completion of college in their early twenties who have a variety of hormone-related diseases. This includes disorders of growth, puberty (both precocious and delayed), glucose homeostasis (both hypoglycemia and diabetes mellitus), adrenal function (both adrenal insufficiency and steroid excess), thyroid function, skeletal abnormalities, gonadal dysfunction

(including polycystic ovarian syndrome and ovarian failure), hypopituitarism, and disorders of sexual development. Pediatric patients referred to our practice for the evaluation and treatment of gender dysphoria are cared for by an interdisciplinary team of providers that includes a psychologist and pediatric endocrinologist who have been specifically chosen for this role based upon a special interest in this patient population.

BACKGROUND ON SEX AND GENDER

14. Sex is an objective biological trait intrinsically oriented toward specific roles in the conception and development of new members of a species. Both males and females contribute genetic information in distinct yet complementary ways. Males have the role of delivering sperm produced by testes and the unique paternal DNA contained therein to a female. Females have the role of receiving this male genetic information to join with the maternal genetic information contained in ova produced by ovaries. Sex is not "assigned at birth"; it is permanently determined by biology at conception. This remains the standard definition that has been accepted by the relevant scientific community and used worldwide by scientists, medical personnel, and society in general for decades.[1]

15. The scientific and clinical measurement of sex is done with highly reliable and valid objective methodologies. Visual medical examination of the appearance of the external genitalia is the primary methodology used by clinicians to recognize sex. In cases where genital

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[1] See Miller LR, et al. Considering sex as a biological variable in preclinical research. FASEB J. 2017 Jan;31(1):29-34; Clayton JA. Studying both sexes: a guiding principle for biomedicine. FASEB J. 2016 Feb;30(2):519-24.

ambiguity is present, additional testing modalities including chromosomal analysis, measurement of hormone levels, radiographic imaging of internal sexual anatomy and biological response to provocative testing are utilized. The measurement and assessment of biological sex has been documented by valid and reliable research published in credible journals, and is accepted by the relevant scientific community. Medical recognition of an individual as male or female is correctly made at birth in nearly 99.98% of cases according to external phenotypic expression of primary sexual traits (i.e., the presence of a penis for males and presence of labia and vagina for females).[2]

16. For members of the human species (and virtually all mammals), sex is normatively aligned in a binary fashion (i.e., either male or female) in relation to biologic purpose. The presence of individuals with disorders of sexual development (along the range of the established Prader scale) does not alter this fundamental reality.

17. Due to genetic and hormonal variation in the developing fetus, normative development of the external genitalia in any individual differs with respect to size and appearance while maintaining an ability to function with respect to biologic purpose (i.e., reproduction). Internal structures (e.g., gonad, uterus, vas deferens) normatively align in more than 99.9%+ of mammals with external genitalia, including humans.

18. Due to the complexity of the biological processes that are involved in normal sexual development, it is not

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[2] See L. Sax, How common is Intersex? A response to Anne Fausto-Sterling, 39 J. Sex Rsch. 174 (2002).

surprising that a very small number of individuals are born with defects in this process (1 in 5,000 births).[3] Defects can occur through either inherited or *de novo* mutations in genes that are involved in sexual determination or through environmental insults during critical states of sexual development. Persons who are born with such abnormalities are considered to have a disorder of sexual development (DSD). Most often, this is first detected as ambiguity in the appearance of the external genitalia. Such detection measurements are reliable and valid and accepted by the relevant scientific community.

19. The medical care of persons with DSDs is primarily directed toward identification of the etiology of the defect and treatment of any associated complications. Similar to the diagnosis of other diseases, objective diagnostic tools such as the Prader scale are used to assess, measure, and assign a "stage" to the severity of the deviation from normal. In children with DSDs, characterization based upon phenotype alone does not reliably predict the sex chromosomes present, nor does it necessarily correlate with potential for biological sexual function. The need for making a tentative sex assignment is unique to children with a DSD and does not apply to individuals with normally formed and functional genitalia at birth. Decisions on initial sex assignment in these very rare DSD cases require detailed assessment of objective, reliable medical evidence by a team of expert medical providers. In previous years, the general practice was to make a definitive sex assignment shortly after birth, the belief being that this would allow patients with a disorder of sexual development to

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[3] *Id.*

best conform to the assigned sex and parents-caregivers to help socialize the child to the assigned sex. Current practice is to defer sex assignment until the etiology of the disorder is determined and, if possible, a reliable prediction can be made on likely biologic and psychologic outcomes. When this cannot be done with confidence, a presumptive sex assignment is made. Factors used in making such decisions include karyotype (46XX, 46XY, or other), phenotypic appearance of the external genitalia, and parental desires. The availability of new information can, in rare circumstances, lead to a change in sex determination. Decisions on whether to surgically alter the external genitalia to align with sex are generally deferred until the patient is able to provide consent.[4] The tentative assignment of sex is unique to individuals with a DSD.

20. "Gender," a term that had traditionally been reserved for grammatical purposes, is currently used to describe the psychological and cultural characteristics of a person in relation to biological sex. Gender in such new definitions therefore exists only in reference to subjective personal perceptions and feelings and societal expectations, not biology. The reliability and validity of various usages of the term "gender" is currently controversial. The dangers of incorrectly using the term "gender" in place of "sex" have been acknowledged by the Endocrine Society.[5]

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[4] See P. A. Lee et al., Global Disorders of Sex Development Update since 2006: Perceptions, Approach and Care, 85 Horm. Rsch. Paediatr. 158 (2016).

[5] See A. Bhargava et al., Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Scientific Statement, 42 Endocrine Revs. 219 (2021).

21. "Gender identity" refers to a person's individual experience and perception and unverified verbal patient reports of how they experience being male or female or a combination of these or other categories. The term "gender identity" is controversial. There is no current worldwide definition of "gender identity" accepted by the relevant clinical communities. The measurement error rate for "gender identity" is unknown.

22. People who identify as "transgender" transiently or persistently experience a sex-discordant gender identity.[6]

PUBERTY

23. Puberty is "the morphological and physiological changes that occur in the growing boy or girl as the gonads change from the infantile to the adult state. These changes involve nearly all the organs and structures of the body but they do not begin at the same age nor take the same length of time to reach completion in all individuals. Puberty is not complete until the individual has the physical capacity to conceive and successfully rear children."[7]

24. The principal manifestations of puberty are:

- The adolescent growth spurt; i.e., an acceleration followed by a deceleration of growth in most skeletal dimensions and in many internal organs.

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[6] American Psychological Association, The Diagnostic and Statistical Manual of Mental Disorders, (DSM-5), 451 (2013).

[7] W. A. Marshall et al., Puberty, in F. Falkner et al. eds., 2 Human Growth: A Comprehensive Treatise, 2nd ed., (New York: Springer, 1986), 171.

- The development of the gonads.
- The development of the secondary reproductive organs and the secondary sex characters.
- Changes in body composition, i.e., in the quantity and distribution of fat in association with growth of the skeleton and musculature.
- Development of the circulatory and respiratory systems leading, particularly in boys, to an increase in strength and endurance.[8]

25. The ability to physically conceive children is made possible by the maturation of the primary sex characteristics, the organs and structures that are involved directly in reproduction. In boys, these organs and structures include the scrotum, testes, and penis while in girls they include the ovaries, uterus, and vagina. In addition to these primary sex characteristics, secondary sex characteristics also develop during puberty—the distinctive physical features of the two sexes that are not directly involved in reproduction. Secondary sex characteristics that develop in girls include "the growth of breasts and the widening of the pelvis," while in boys they include "the appearance of facial hair and the broadening of shoulders." Other patterns of body hair and changes in voice and skin occur during puberty in both girls and boys.[9]

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[8] *Id.* at 171-72.

[9] R. V. Kail et al., Human Development: A Life-Span View 276 (7th ed. 2016).

26. Physicians characterize the progress of puberty by marking the onset of different developmental milestones. The earliest visible event, the initial growth of pubic hair, is known as "pubarche;" it occurs between roughly ages 8 and 13 in girls, and between ages 9.5 and 13.5 in boys.[10] In girls, the onset of breast development, known as "thelarche," occurs around the same time as pubarche.[11] "Menarche" is another manifestation of sexual maturation in females, referring to the onset of menstruation, which typically occurs at around 13 years of age and is generally a sign of the ability to conceive.[12] Roughly corresponding to menarche in girls is "spermarche" in boys; this refers to the initial presence of viable sperm in semen, which also typically occurs around 13.[13] (The "-arche" in the terms for these milestones comes from the Greek for beginning or origin). Pubarche and thelarche correspond to the transition from Tanner Stage 1 to Tanner Stage 2 of sexual development. Spermarche and menarche generally occur at Tanner Stage 4 to Tanner Stage 5.

27. Scientists distinguish three main biological processes involved in puberty: adrenal maturation, gonadal maturation, and somatic growth acceleration. "Adrenarche"—the beginning of adrenal maturation—begins between ages 6 and 9 in girls, and ages 7 and 10 in boys. The hormones produced by the adrenal glands

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[10] J. Stang et al., Adolescent Growth and Development 1, 2-3 in J. Stang et al. eds., Guidelines for Adolescent Nutrition Services, (2005), available at http://demoiselle2femme.org/wp-content/uploads/Adolescent-Growth-and-Development.pdf (last visited Apr. 29, 2023).

[11] *Id.* at 2.

[12] Marshall et al., Puberty, at 191-92.

[13] *Id.* at 185.

during adrenarche are relatively weak forms of androgens (masculinizing hormones) known as dehydroepiandrosterone and dehydroepiandrosterone sulfate. These hormones are responsible for signs of puberty shared by both sexes: oily skin, acne, body odor, and the growth of axillary (underarm) and pubic hair.[14]

28. "Gonadarche"—the beginning of the process of gonadal maturation—normally occurs in girls between ages 8 and 13 and in boys between ages 9 and 14.[15] The process begins in the brain, where specialized neurons in the hypothalamus secrete gonadotropin-releasing hormone (GnRH).[16] This hormone is secreted in a cyclical or "pulsatile" manner—the hypothalamus releases bursts of GnRH, and when the pituitary gland is exposed to these bursts, it responds by secreting two other hormones.[17] These are luteinizing hormone (LH) and follicle-stimulating hormone (FSH), which stimulate the growth of the gonads (ovaries in females and testes in males).[18] (The "follicles" that the latter hormone stimulates are not hair follicles but ovarian follicles, the structures in the ovaries that contain immature egg cells.) In addition to regulating the maturation of the gonads and the production of sex hormones, these

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[14] S. E. Oberfield et al., Approach to the Girl with Early Onset of Pubic Hair, 96 J. Clin. Endocrinol. & Metabol. 1610 (2011).

[15] S. F. Witchel et al., Puberty: Gonadarche and Adrenarche, in J. F. Strauss III et al. eds., Yen and Jaffe's Reproductive Endocrinology, 6th ed., 395, 395-446.e16 (2009).

[16] A. E. Herbison, Control of Puberty Onset and Fertility by Gonadotropin-Releasing Hormone Neurons, 12 Nature Revs. Endocrinol. 452 (2016).

[17] *Id.* at 453

[18] *Id.* at 454

two hormones also play an important role in regulating aspects of human fertility.[19]

29. As the gonadal cells mature under the influence of LH and FSH, they begin to secrete androgens (masculinizing sex hormones like testosterone) and estrogens (feminizing sex hormones).[20] These hormones contribute to the further development of the primary sex characteristics (the uterus in girls and the penis and scrotum in boys) and to the development of secondary sex characteristics (including breasts and wider hips in girls, and wider shoulders, breaking voices, and increased muscle mass in boys). The ovaries and testes both secrete androgens as well as estrogens, however the testes secrete more androgens and the ovaries more estrogens.[21]

30. The gonads and the adrenal glands are involved in two separate but interrelated pathways (or "axes") of hormone signaling. These are the hypothalamic-pituitary-gonadal (HPG) axis and the hypothalamic-pituitary-adrenal (HPA) axis.[22] Though both play essential roles in puberty, it is, as just noted, the HPG axis that results in the development of the basic reproduc-

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[19] *Id.* at 452.

[20] M. A. Preece, Prepubertal and Pubertal Endocrinology, in F. Falkner et al. eds., 2 Human Growth: A Comprehensive Treatise, 211, 212 (1986).

[21] R. A. Hess, Estrogen in the adult male reproductive tract: A review, 1 Reproductive Biol. and Endocrinol. 1, (2003); H. G. Burger, Androgen Production in Women, 77 (Suppl.) Fertility and Sterility, S3-5 (2002).

[22] R. D. Romeo, Neuroendocrine and Behavioral Development during Puberty: A Tale of Two Axes, 71 Vitamins and Hormones 1, 1-25 (2005).

tive capacity and the external sex characteristics that distinguish the sexes.[23]

31. The third significant process that occurs with puberty, the somatic growth spurt, is mediated by increased production and secretion of human growth hormone, which is influenced by sex hormones secreted by the gonads (both testosterone and estrogen). Similar to the way that the secretion of GnRH by the hypothalamus induces the pituitary gland to secrete FSH and LH, in this case short pulses of a hormone released by the hypothalamus cause the pituitary gland to release human growth hormone.[24] This process is augmented by testosterone and estrogen. Growth hormone acts directly to stimulate growth in certain tissues, and also stimulates the liver to produce a substance called "insulin-like growth factor 1," which has growth-stimulating effects on muscle.[25]

32. The neurological and psychological changes occurring in puberty are less well understood than are the physiological changes. Men and women have distinct neurological features that may account for some of the psychological differences between the sexes, though the extent to which neurological differences account for psychological differences, and the extent to which neurological differences are caused by biological factors like hormones and genes (as opposed to environmental

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[23] M. E. Wierman et al., Neuroendocrine Control of the Onset of Puberty, 2 Human Growth 225 (1986).

[24] M. A. Preece, Prepubertal and Pubertal Endocrinology, at 218-19.

[25] U. J. Meinhardt et al., Modulation of growth hormone action by sex steroids, 65 Clin. Endocrinol. 413, 414 (2006).

factors like social conditioning), are all matters of debate.

33. Scientists distinguish between two types of effects hormones can have on the brain: organizational effects and activational effects. Organizational effects are the ways in which hormones cause highly stable changes in the basic architecture of different brain regions. Activational effects are the more immediate and temporary effects of hormones on the brain's activity. During puberty, androgens and estrogens primarily have activating effects, but long before then they have organizational effects in the brains of developing infants and fetuses.[26]

34. In sum: Puberty involves a myriad of complex, related, and overlapping physical processes, occurring at various points and lasting for various durations. During this period of life, adrenarche and changes in the secretion of growth hormone contribute to the child's growth and development. With gonadarche, the maturation of sex organs begins and with normal maturation will lead to the emergence of reproductive capacity, as well as the development of the other biological characteristics that distinguish males and females.

PEDIATRIC ENDOCRINE DISORDERS AND TREATMENTS

35. The field of endocrinology is directed toward the care of hormone-related diseases. Pediatric endocrine diseases include disorders of glucose regulation (hypo-

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[26] M. M. Herting et al., Puberty and structural brain development in humans, 44 Frontiers in Neuroendocrinol. 122 (2017); J. Hornung et al., Sex hormones and human brain function, 195 Handb. Clin. Neurol. 175 (2020).

glycemia and diabetes mellitus), disorders of thyroid function (hyper and hypothyroidism), disorders of growth (e.g., short stature, acromegaly, obesity, and poor weight gain), disorders of sexual development and function (e.g., genital ambiguity, precocious and delayed puberty, hypogonadism, polycystic ovarian syndrome), disorders of adrenal function (e.g., adrenal insufficiency and Cushing's syndrome), disorders of pituitary function, lipid disorders, and disorders of bone and mineral metabolism. For all of these conditions, there are objective physical and biochemical criteria for diagnosis and treatment with well-established normal reference ranges for hormones and metabolites.

I. Using GnRH Analogues—"Puberty Blockers"—to Treat Precocious Puberty and Other Conditions

36. Hormone interventions to suppress puberty were not developed for the purpose of treating children with gender dysphoria. Rather, they were first used as a way to normalize puberty for children who undergo puberty too early, a condition known as "precocious puberty."

37. For females, precocious puberty is defined by the onset of puberty before age 8, while for males it is defined as the onset of puberty before age 9.[27] Premature thelarche (the appearance of breast development) is usually the first clinical sign of precocious puberty in girls. For males, precocious puberty is marked by

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[27] K. O. Klein, Precocious Puberty: Who Has It? Who Should Be Treated?, 84 J. Clin. Endocrinol. & Metabol. 411 (1999). See also F. M. Biro et al., Onset of Breast Development in a Longitudinal Cohort, 132 Pediatrics 1019 (2013); C.-J. Partsch et al., Pathogenesis and epidemiology of precocious puberty. Effects of exogenous oestrogens, 7 Human Reproduction Update 292, 293 (2001).

premature testicular enlargement.[28] In addition to the psychological and social consequences that a child might be expected to suffer, precocious puberty can also lead to reduced adult height, since the early onset of puberty interferes with later bone growth.[29]

38. Precocious puberty is divided into two types, central precocious puberty (sometimes labeled "true precocious puberty") and peripheral precocious puberty (sometimes labeled "precocious pseudopuberty").[30] Central precocious puberty is caused by the early activation of the gonadal hormone pathway by GnRH, and is amenable to treatment by physicians. Peripheral precocious puberty, which is caused by secretion of sex hormones by the gonads or adrenal glands independent of signals from the pituitary gland, is less amenable to treatment. Effects of androgen or estrogen hypersecretion can be reduced by administration of drugs that block the activity of the sex hormone receptors. If a tumor is causing the disorder, surgical removal may be necessary.

39. Precocious puberty is rare, especially in boys. A recent Spanish study of central precocious puberty estimated the overall prevalence to be 19 in 100,000 (37 in

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[28] A. Parent et al., The Timing of Normal Puberty and the Age Limits of Sexual Precocity: Variations around the World, Secular Trends, and Changes after Migration, 24 Endocrine Revs. 675 (2011).

[29] J.-C. Carel et al., Precocious puberty and statural growth, 10 Human Reproduction Update 135 (2004).

[30] C.-J. Partsch et al., Pathogenesis and epidemiology of precocious puberty. Effects of exogenous oestrogens, at 294-95.

100,000 girls affected, and 0.46 in 100,000 boys).[31] A Danish study of precocious puberty (not limited to central precocious puberty) found the prevalence to be between 20 to 23 per 10,000 in girls and less than 5 in 10,000 in boys.[32]

40. To diagnose central precocious puberty, hormones from the pituitary gland, LH and FSH, are objectively measured. This can sometimes be done by measurement of baseline levels[33] but often requires assessment after transient stimulation with GnRH. As discussed, these are two hormones that are made in the pituitary gland that signal to the gonads. In males, they lead to production of testosterone. In females, they lead to the production of estrogen. LH and FSH signaling are essential for normal sperm production and ovarian maturation in males and females, respectively.

41. Also subject to objective measurement when diagnosing and treating central precocious puberty are sex steroid hormones, either testosterone or estrogen, and bone growth.

42. Treatment for precocious puberty is somewhat counterintuitive. Rather than stopping the production

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[31] L. Soriano-Guillén et al., Central Precocious Puberty in Children Living in Spain: Incidence, Prevalence, and Influence of Adoption and Immigration, 95 J. Clin. Endocrinol. & Metabol., 4305, 4307 (2011). In some cases, peripheral precocious puberty is caused by an underlying condition, such as a tumor, that can be treated.

[32] G. Teilmann et al., Prevalence and Incidence of Precocious Pubertal Development in Denmark: An Epidemiologic Study Based on National Registries, 116 Pedriatics 1323 (2005).

[33] S. Heo et al., Basal Serum Luteinizing Hormone Value as the Screening Biomarker in Female Central Precocious Puberty, 24 Annals of Pediatr. Endocrinol. & Metabol., 164, 164-71 (2019).

of GnRH, physicians actually provide patients more constant levels of synthetic GnRH (called GnRH analogues or GnRH agonists).[34] As discussed above, when produced endogenously (that is, by the body naturally), GnRH stimulates the pituitary gland to release gonad-stimulating hormones (gonadotropins, LH and FSH). When added exogenously, the additional GnRH "desensitizes" the pituitary, leading to a decrease in the secretion of gonadotropins, which in turn leads to the decreased maturation of and secretion of sex hormones by the gonads (ovaries and testes). The intent and effect of giving puberty blockers is identical when it is given to a male as when it is given to a female in this context: suppressing the secretion of gonadotropin hormones. Even the dosing is the same for males and females, and depends on the person's weight.

43. The first publication describing the use of GnRH analogues in children for precocious puberty appeared in 1981.[35] In the time since GnRH analogues were first proposed, they have become fairly well accepted as a treatment of precocious puberty, with one prominent GnRH analogue, Lupron, approved for that use by the FDA in 1993.[36] However, there remain some questions concerning the effectiveness of treatment with GnRH analogues. A 2009 consensus statement of pediatric en-

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[34] W. F. Crowley, Jr. et al., Therapeutic use of pituitary desensitization with a long-acting LHRH agonist: a potential new treatment for idiopathic precocious puberty, 52 J. Clin. Endocrinol. & Metabol., 370, 370-72 (1981) (LHRH refers to "luteinizing hormone releasing hormone," another term for GnRH.).

[35] *Id.*

[36] "Full Prescribing Information" for Lupron Depot-Ped, FDA.gov (undated), https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020263s036lbl.pdf (last visited April 6, 2023).

docrinologists concluded that GnRH analogues are an effective way to improve the height of girls with onset of puberty at less than 6 years of age, and also recommended the treatment be considered for boys with onset of precocious puberty who have compromised height potential.[37] Regarding the negative psychological and social outcomes associated with precocious puberty, the authors found that the available data were unconvincing, and that additional studies are needed.[38] Puberty blockers have recently been recognized to carry a risk of increased brain pressure that can adversely affect vision and cause severe headaches.[39]

44. When used to treat precocious puberty, the process of desensitization of the pituitary gland by synthetic GnRH is not permanent. After a patient stops taking the GnRH analogues, the pituitary will resume its normal response to the pulsatile secretion of GnRH by the hypothalamus, as evidenced by the fact that children treated for precocious puberty using GnRH analogues will resume normal pubertal development, usually about a year after they withdraw from treatment.[40]

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[37] J.-C. Carel et al., Consensus Statement on the Use of Gonadotropin-Releasing Hormone Analogs in Children, 123 Pediatrics e752, e753 (2009).

[38] *Id.*

[39] Risk of pseudotumor cerebri added to labeling for gonadotropin-releasing hormone agonists, AAP News, July 1, 2022, https://publications.aap.org/aapnews/news/20636/Risk-of-pseudotumor-cerebri-added-to-labeling-for?autologincheck=redirected (last visited April 7, 2023).

[40] M. M. Fisher et al., Resumption of Puberty in Girls and Boys Following Removal of the Histrelin Implant, 164 J. Pediatrics 912, 912-16 (2014).

45. The goal of treating precocious puberty is to allow the child to have pubertal development enter the normal quiescence that is present at that age. This treatment helps to preserve their final adult height, by slowing the rate of bone age advancement. The goal is *not* to delay puberty beyond other children, as delaying too long can lead to adverse effects, including reduced bone marrow density, as discussed below.

46. In addition to being prescribed for children with precocious puberty, GnRH analogues have also been used in adults for a variety of indications, including hormone-sensitive tumors.[41] GnRH analogues have also been given to post-pubertal adolescents undergoing chemotherapy with drugs that can have toxic effects on the gonads.[42]

II. Using Sex Steroids Such as Testosterone and Estrogen to Treat Disorders of Normal Gonadal Function

47. Sex steroids such as testosterone and estrogen are frequently used in the treatment of disorders of normal gonadal function. This includes hypogonadotropic hypogonadism, primary gonadal failure, and delayed puberty.[43] In each of these conditions, there are objec-

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[41] See P. Kumar et al., Gonadotropin-releasing hormone analogs: Understanding advantages and limitations, 7 J. Human Reproductive Scis. 170 (2014).

[42] M. Meli et al., Triptorelin for Fertility Preservation in Adolescents Treated With Chemotherapy for Cancer, 40 J. Pediatr. Hematol./Oncol. 269 (2018).

[43] P. Kumar et al., Male hypogonadism: Symptoms and treatment, 1 J. Advanced Pharmaceutical Technology & Research 297 (2010); K. Voutsadaki et al., Hypogonadism in adolescent girls:

tive laboratory tests that are used to diagnose these conditions and monitor response to treatment. Deficiency of sex steroids has bodily effects that extend beyond sexual function.[44] This includes significant effect on bone density, lean body mass, metabolism, immunity, and neural function.

48. There are major and highly significant differences between male and female responses to sex hormones.[45] Giving estrogen to a biological male is not equivalent to giving the same hormone to a biological female. Likewise, giving testosterone to a biological female is not equivalent to giving the same hormone to a biological male.[46] Differences are not limited to pharmacokinetic effect (i.e., how drugs are absorbed, distributed throughout the body, and metabolized) but are present even at the cellular level.[47] Sex steroids act by altering the expression of the genetic information present in all nucleated cells of the body. Epigenetic differences (i.e., chemical changes to DNA structure) re-

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treatment and long-term effects, 93 Acta Biomedica Atenei Parmensis e2022317 *1 (2022).

[44] M. Alemany, The Roles of Androgens in Humans: Biology, Metabolic Regulation and Health. 23 Int'l. J. Molecular Scis. 11952 (2022); S. Patel et al., Estrogen: The necessary evil for human health, and ways to tame it, 102 Biomed. & Pharmacother. 403 (2018).

[45] See C. Madla et al., Let's talk about sex: Differences in drug therapy in males and females, 175 Advanced Drug Delivery Revs. 113804 (2021).

[46] See O. P. Soldin et al., Sex Differences in Pharmacokinetics and Pharmacodynamics, 48 Clin. Pharmacokinetics 143 (2009); S. Pogun et al., Sex Differences in Drug Effects, in Encyclopedia of Psychopharmacology, 1210, 1210-16 (I. P. Stolerman, ed., 2010).

[47] See, e.g., C. J. Walker et al., Matters of the heart: Cellular sex differences, 160 J. Molecular and Cellular Cardiol. 42 (2021).

sult in sex-differential expression of over 6,500 genes in the body.[48] Consequences of a failure to recognize these differences can result in drug overdose, lack of treatment response, or serious side effects.

49. Several conditions in male minors may indicate a need for endocrinologic treatment with testosterone. For instance, primary hypogonadism from gonadal failure is caused by damage or impaired function of the male testes. Secondary hypogonadism is caused by abnormalities in pituitary structure or function. Hypogonadism can be objectively diagnosed by measurement of testosterone (or its derivatives) and gonadotropin (LH and FSH) levels. When used for the treatment of affected males with hypogonadism, testosterone is administered to achieve levels that are normal for males of the patient's age. For young adult Tanner Stage 5 males, normal testosterone levels range from 300-900 ng/dL.[49] Achievement of appropriate testosterone levels requires careful monitoring, as excess levels can have serious adverse effects, including elevations of red blood cell counts, changes in blood pressure, and brain changes.[50]

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[48] M. Gershoni et al., The landscape of sex-differential transcriptome and its consequent selection in human adults, 15 BMC Biol. 7 (2017).

[49] T. G. Travison et al., Harmonized Reference Ranges for Circulating Testosterone Levels in Men of Four Cohort Studies in the United States and Europe, 102 J. Clin. Endocrinol. & Metabol., 1161 (2017).

[50] S. J. Ohlander et al., Erythrocytosis Following Testosterone Therapy, 6 Sexual Medicine Revs. 77 (2018); T. Kienitz et al., Testosterone and Blood Pressure Regulation, 31 Kidney and Blood Press. Rsch. 71 (2008); M. Scarth et al., Androgen abuse and the brain, 28 Curr. Op. in Endocrinol., Diabetes & Obes. 604 (2021).

50. Testosterone may also be used in males to treat delayed puberty. To treat the condition of constitutional delay (where the person has means to progress through puberty, but onset was delayed), the male would normally be given low doses of testosterone for 3-4 months to "prime the pump" for normal puberty. Assessment of this condition includes measuring levels of LH, FSH, and testosterone, as well as observation of testicular size. Once puberty has been initiated and is progressing, there is no need to administer ongoing testosterone therapy. Normal gonadotropin (LH and FSH) signaling from the pituitary gland will allow continued maturation of the testes, leading to reproductive capacity.

51. Continuing to give external testosterone to a male in normal puberty would suppress the normal function of the testes and can lead to infertility—a result contrary to the goal of endocrinology, which is to restore health. Thus, for instance, a male adolescent undergoing normal puberty who simply desired increased lean body mass (i.e., higher muscle mass) should not normally be given testosterone for that purpose, both because it is considered medically unnecessary and because of the adverse effects of extra testosterone. Among other reasons, these effects explain why testosterone is a controlled substance.

52. Outside the context of gender dysphoria, testosterone is not an indicated treatment for a female child or adolescent. Testosterone, or any androgen, would lead to virilization, which can come with serious adverse effects. This includes impaired fertility, alopecia (hair

loss), disfiguring acne, and metabolic changes that increase risk of heart disease and diabetes.[51]

53. Estrogen can be given to young females to treat the same conditions testosterone treats in young males: constitutional delay and hypogonadism, either primary or secondary. Primary hypogonadism is caused by a defect in the presence or function of the ovaries. Secondary hypogonadism is caused by a defect in the structure or function of the pituitary gland. A female can experience premature ovarian insufficiency where the ovaries become inactive over time, both genetically and through environmental incidents. To diagnose these conditions, hormone levels can be objectively measured. This includes LH, FSH, estradiol, and other levels. (Estradiol is a form of estrogen, and generally the main hormone followed and measured in female endocrinologic practice.) Female estrogen levels will vary throughout the menstrual cycle but are normally 30-400 pg/mL.[52] The physical response to the intervention can also be measured.

54. Estrogen treatments carry risks, including stroke, elevated blood pressure, and changes to bone development. Males are not generally prescribed estrogen (again, outside the context of gender dysphoria), and there is concern that the risks of estrogen are even higher in males.

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[51] R. Yang et al., Effects of hyperandrogenism on metabolic abnormalities in patients with polycystic ovary syndrome: a meta-analysis, 14 Reproductive Biol. and Endocrinol. 67 (2016).

[52] S. Verdonk et al., Estradiol reference intervals in women during the menstrual cycle, postmenopausal women and men using an LC-MS/MS method, 495 Clinica Chimica Acta 198, 198-204 (2019).

GENDER DYSPHORIA AND TREATMENTS

I. Diagnosis

55. In contrast to the conditions discussed above, gender dysphoria is not an endocrine disorder. Instead, it is a diagnostic term for "the distress that may accompany the incongruence between one's experienced or expressed gender and one's" biological sex.[53] Gender dysphoria is associated with high rates of comorbidity, including suicidal ideation, depression, anxiety, poverty, homelessness, eating disorders, and HIV infection.[54] Gender dysphoria as a psychiatric disorder should be distinguished from identifying as transgender or transsexual. As noted, people who identify as transgender "transiently or persistently identify with a gender different from their natal gender." In this definition, "natal gender" refers to sex. Transsexual has an even more specific meaning; it "denotes an individual who seeks, or has undergone, a social transition from male to female or female to male, which in many, but not all, cases also involves a somatic transition by cross-sex hormone treatment and genital surgery."[55]

56. The clinical assessment methodology in sex discordant gender medicine is currently limited to self-reported information from patients without objective scientific markers or medical tests. There are no reliable radiological, genetic, physical, hormonal, or biomarker

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[53] DSM-5, at 451.

[54] M. D. Connolly et al., The Mental Health of Transgender Youth: Advances in Understanding, 59 J. Adolesc. Health 489 (2016); F. Pinna et al., Mental health in transgender individuals: a systematic review, 34 Int'l Rev. of Psychiatry 292 (2022).

[55] DSM-5, at 451.

tests that can establish gender identity or reliably predict treatment outcomes.

57. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions. While the contributors to sex-discordant gender identity remain to be fully identified and characterized, differences both in kind and degree within individuals and across varied populations create challenges in establishing specific approaches to alleviate associated suffering. For example, data from adults cannot be assumed to apply equally to children. Nor can data from children who present with sex-discordant gender pre-pubertally be presumed to apply to the growing number of post-pubertal adolescent females presenting with this condition.

58. Although gender perceptions, feelings, and "identity" usually align with biological sex, some individuals report experiencing discordance in these distinct traits. Specifically, for example, biological females may report experiencing that they identify as men and biological males may report experiencing that they identify as women. As gender by definition is distinct from biological sex, one's gender identity does not change a person's biological sex. There is currently no known reliable and valid methodology for assessing the accuracy or nature of unverified, verbal reports of discordant "identity," nor whether that discordant identity will persist or resolve over time. There is thus no known "error rate" for relying upon such reports to engage in hormonal and surgical treatments.

II. Treatments

59. Moving from diagnosis to treatment, two broad approaches are generally used to treat children with gender dysphoria.[56]

A. Watchful Waiting and Exploratory Therapy

60. The first approach, sometimes called "watchful waiting," motivated by an understanding of the natural history of transgender identification in children, is to neither encourage nor discourage transgender identification, recognizing that existing evidence (discussed next) shows that the vast majority of affected children are likely to eventually realign their reports of gender identification with their sex. This realignment of expressed gender identity to be concordant with sex is sometimes called "desistance."

61. The "watchful waiting" approach does not advocate doing nothing. Rather, it focuses on affirming the inherent dignity of affected people and supporting them in other aspects of their lives, including the diagnosis and treatment of any comorbidities, as individuals proceed through the various stages of physical and psychological development. For instance, the approach may include the use of scientifically validated treatments (e.g., cognitive behavioral therapy) to treat the patient's anxiety, depression, social skills deficits, or other issues.[57] It may also use exploratory therapy to explore

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[56] See K. J. Zucker, On the "Natural History" of Gender Identity Disorder in Children, 47 J. Am. Acad. Child & Adolesc. Psychiatry 1361 (2008).

[57] See J. S. van Bentum et al., Cognitive therapy and interpersonal psychotherapy reduce suicidal ideation independent from their effect on depression, 38 Depression and Anxiety 940 (2021).

potential causes of the dysphoria, which may be linked to trauma, developmental issues, or psychological comorbidities.

62. Despite differences in country, culture, decade, follow-up length, and method, multiple studies have come to a remarkably similar conclusion: Very few gender dysphoric children still want to transition by the time they reach adulthood. Many turn out to have been struggling with sexual orientation issues rather than gender discordant "transgender" identity. The exact number of children who experience realignment of gender identity with biological sex by early adult life varies by study. Estimates within the peer-reviewed published literature range from 50-98%, with most reporting desistance in approximately 85% of children before the widespread adoption of the "affirming" model discussed below.[58] In 2018, for instance, studies found that 67% of children meeting the diagnostic criteria for gender dysphoria no longer had the diagnosis as adults, with an even higher rate (93%) of natural resolution of gender-related distress for the less significantly impacted cases.[59] A March 2021 study, with one of the

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[58] T. D. Steensma et al., Factors Associated With Desistence and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study, 52 J. Am. Acad. of Child & Adolesc. Psychiatry 582 (2013); K. D. Drummond et al., A Follow-up Study of Girls with Gender Identity Disorder, 44 Dev. Psychol. 34 (2008); M. S. Wallien et al., Psychosexual Outcome of Gender-Dysphoric Children, 47 J. Am. Acad. Child & Adolesc. Psychiatry 1413 (2008); Bradley SJ, Zucker KJ. Gender Identity Disorder and Psychosexual Problems in Children and Adolescents. The Canadian Journal of Psychiatry. 1990;35(6):477-486

[59] See, e.g., K. J. Zucker, The myth of persistence: Response to "A critical commentary on follow-up studies and 'desistance' theo-

largest samples in the relevant literature, suggests that most young gender dysphoric children grow out of the condition without medical interventions.[60] Thus, desistance (i.e., the child accepting their natal, biological sex identity and declining "transitioning" treatments) is the outcome for the vast majority of affected children who are not actively encouraged to proceed with sex-discordant gender affirmation.

63. Decades of peer-reviewed, published scientific research have supported the efficacy of the psychological approaches for the majority of patients experiencing gender dysphoria.[61] Cognitive therapy and interpersonal psychotherapy have been found to reduce suicidal ideation independent of their effect on depression.[62] Within the "watchful waiting" model, these data support the investigative use of modern psychotherapeutic approaches to address suicidal ideation in children with gender dysphoria (as well as to treat other psychological ailments).

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ries about transgender and gender non-conforming children" by T. Newhook et al. (2018), 19 Int'l. J. Transgenderism 231 (2018).

[60] See D. Singh et al., A Follow-Up Study of Boys With Gender Identity Disorder, 12 Frontiers in Psychiatry 632784 (2021).

[61] See K. J. Zucker (2008), On the "Natural History," 47 J. Am. Acad. Child & Adolesc. Psychiatry, at 1361, 1361-63; S. J. Bradley et al., Gender Identity Disorder: A Review of the Past 10 Years, 36 J. Am. Acad. Child & Adolesc. Psychiatry 872-80 (1997).

[62] J. S. van Bentum et al. (2021), Cognitive therapy and interpersonal psychotherapy, 38 Depression and Anxiety at 940 (2021); M. W. Gallagher et al., Trajectories of change in well-being during cognitive behavioral therapies for anxiety disorders: Quantifying the impact and covariation with improvements in anxiety, 57 Psychotherapy 379 (2020).

B. Gender Affirming

64. The second, so-called "gender affirming," approach is to affirm the child's present gender identity. This affirmation may have social, medical, legal, and behavioral dimensions. Typically, the "affirming" approach encourages children to embrace transgender identity with social transitioning followed by puberty blockade and hormonal therapy (cross-sex hormones), and potential surgical interventions.[63] This approach is considered below.

65. The first stage of this approach is social affirmation. Included interventions include allowance of name change, use of preferred pronouns, wearing of sex-stereotyped clothing, and access to sex-segregated facilities (bathrooms and locker rooms) corresponding to the child's gender identification. While often presented as a neutral intervention, there is concern that social affirmation will alter the rate of spontaneous desistance. As noted by Steensma et al., "one may wonder whether a childhood transition has an effect by itself and influences the cognitive gender identity representation of the child and/or their future development"; this "hypothesized link between social transitioning and the cognitive representation of the self [may] influence the future rates of persistence."[64] For this reason, in the

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[63] See A. Walch et al., Proper Care of Transgender and Gender Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective, 106 J. Clin. Endocrinol. & Metabol. 305 (2021).

[64] T. D. Steensma et al., Factors Associated with Desistence and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-up Study, Chapter 6 in T. D. Steensma, From Gender Variance to Gender Dysphoria: Psychosexual development of gender atypical children and adolescents, 97, 115 (Ph.D. thesis, Vrije Univer-

original Dutch protocol social transition of prepubertal children was discouraged. The Dutch protocol authors reference the prior work of Wallien and Cohen-Kettenis[65] in asserting that "because most gender dysphoric children will not remain gender dysphoric through adolescence, we recommend that young children not yet make a complete social transition (different clothing, a different given name, referring to a boy as 'her' instead of 'him') before the very early stages of puberty."[66] In the initial 2009 Endocrine Society guidelines, it was stated that "given the high rate of remission of GID [gender identity disorder] after the onset of puberty, we recommend against a complete social role change and hormone treatment in prepubertal children with GID."[67] Current data validate this concern. In the 2022 study by Olson et al., 94% of children who were socially affirmed persisted with sex-discordant gender identity.[68] This is in sharp contrast to the low rates of persistence prior to adoption of social affirmation in

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siteit Amsterdam, 2013), available at https://research.vu.nl/ws/files/42117780/hoofdstuk%2006.pdf (last visited May 1, 2023).

[65] M. S. C. Wallien et al. (2008), Psychosexual Outcome of Gender-Dysphoric Children, 47 J. Am. Acad. Child & Adolesc. Psychiatry, at 1413 (2008).

[66] A. L. C. de Vries et al., Clinical management of gender dysphoria in children and adolescents: the Dutch approach, 59 J. Homosex. 301 (2012).

[67] W. C. Hembree et al., Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline, 94 J. Clin. Endocrinol. & Metabol. 3132, 3132-33 (2009).

[68] K. R. Olson et al., Gender Identity 5 Years After Social Transition, 150 Pediatrics e2021056082. (2022).

pre-pubertal children with sex-discordant gender identity.[69]

66. Before analyzing gender affirmative medical interventions, it is important to understand that underlying biology is not changed by altering bodily features to appear as the opposite sex, and such alterations do not change disease vulnerabilities and drug responses associated with genetically defined sex.[70] Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by genetic makeup, normatively by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally-defined sex.[71] For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. It is possible for some adolescents and

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[69] M. S. C. Wallien et al. (2008), Psychosexual Outcome of Gender-Dysphoric Children, 47 J. Am. Acad. Child & Adolesc. Psychiatry, at 1413-23. The rate of persistence in this study was 27%. *Id.* at 1413, 1416, 1420.

[70] See Klein SL, Flanagan KL. Sex differences in immune responses. Nat Rev Immunol. 2016 Oct;16(10):626-38 and Karlsson Lind L, et al. Sex differences in drugs: the development of a comprehensive knowledge base to improve gender awareness prescribing. Biol Sex Differ. 2017 Oct 24;8(1):32.

[71] See Exploring the biological contributions to human health: does sex matter?, (Institute of Medicine (U.S.), T. M. Wizemann, & M. L. Pardue eds., 2001) (hardcover edition); Exploring the Biological Contributions to Human Health: Does Sex Matter?, (2001), http://www.nap.edu/catalog/10028 (last visited Apr 8, 2023) (electronic editions).

adults to pass unnoticed as the opposite gender that they aspire to be—but with limitations, costs, and risks.[72] And their underlying biology does not change.

1. Puberty Blockers

67. Only in the 1990s did GnRH analogues begin being used to suppress puberty in children who identify as the opposite sex. In 1998, Peggy Cohen-Kettenis and Stephanie van Goozen, psychologists at a Dutch gender clinic, described the case of a 13-year-old female gender-dysphoria patient, on whom a GnRH analogue was used to suppress puberty before the patient received a definitive diagnosis of gender identity disorder at age 16. At age 18, the patient underwent sex-reassignment surgery.[73]

68. The clinic's scientists developed an influential protocol, often referred to as the "Dutch protocol," which involved puberty suppression followed by cross-sex hormones and potential surgical interventions.[74] In many clinics that adhere to the gender affirmation model, the ages for initiating sex-discordant, gender-affirming, sex-steroid hormones has deviated substantially from

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[72] See S. B. Levine, Informed Consent for Transgendered Patients, 45 J. Sex & Marital Therapy, 218 at *6 (2018) ("Informed Consent"); S. B. Levine, Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, 44 J. Am. Acad. Psychiatry & L. 236, 238 (2016) ("Reflections on Legal Battles").

[73] P. T. Cohen-Kettenis et al., Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent, 7 Eur. Child & Adolesc. Psychiatry 246 (1998). See also P, T. Cohen-Kettenis et al., Treatment of Adolescents With Gender Dysphoria in the Netherlands, 20 Child and Adolesc. Psychiatric Clinics of N. Am. 689 (2011).

[74] M. Biggs, The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence, J. Sex & Marital Therapy, 1 (Sept.19, 2022).

the original Dutch protocol. In current protocols puberty blockers (GnRH analogs) are initiated as soon as puberty begins (Tanner Stage 2), which can occur as early as 8 years in females and 9 years in males. While in the Dutch protocol, cross-sex hormones started at 16 years, the Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (SOC-8), the latest guidelines published by the World Professional Association for Transgender Health (WPATH), made no recommendations on specific ages for initiation of gender-affirming medical interventions, stating that decisions need to be made on an individual basis with the possibility of there being compelling reasons to start interventions earlier.[75] Gender-affirming surgery in the Dutch model was reserved to patients 18 years or older. Again, WPATH discusses surgery for minors, noting that "[c]hest masculinization surgery can be considered in minors when clinically and developmentally appropriate," and suggesting that "there may be a benefit for some adolescents to having [vaginoplasties] performed before the age of 18."[76] GnRH analogs are discontinued after gonadectomy is performed as this medication is no longer needed to suppress gonads that are no longer present. Due to the suppressive effect of exogenous sex-steroids on gonadal function, GnRH analogs are often stopped after gender-affirming hormone administration has been titrated to maximal doses re-

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[75] E. Coleman et al., Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, 23 Int'l. J. Transgender Health, 51-5258, 556-66, S1, S65-66 (Sept. 6, 2022) ("SOC-8").

[76] *Id.* at 566.

quired to achieve the desired change in secondary sex characteristics.

69. This gender "affirming" model, with its reliance on hormones and surgical interventions, would make gender dysphoria unique among psychiatric conditions: sex reassignment surgery "for Gender Dysphoria is symptom based. It does not correct a biological abnormality.[77] The same is true for hormone-based interventions.

70. These scientists, along with others, have claimed that puberty suppression is "fully reversible."[78] On this view, puberty suppression "give[s] adolescents, together with the attending health professional, more time to explore their gender identity, without the distress of the developing secondary sex characteristics. The precision of the diagnosis, it is claimed, may thus be improved."[79]

71. This assertion appears to presume that natural sex characteristics interfere with the "exploration" of gender identity, when one would expect that the development of natural sex characteristics might contribute to the natural consolidation of one's gender identity. It is based upon an untested scientific premise that interfering with the development of natural sex characteristics can allow for a more accurate diagnosis of the gen-

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[77] S. B. Levine (2016), Reflections on Legal Battles, 44 J. Am. Acad. Psychiatry & L., at 240.

[78] H. A. Delemarre-van de Waal et al., Clinical management of gender identity disorder in adolescents: a protocol on psychological and paediatric endocrinology aspects, 155 Eur. J. of Endocrinol., S131, S133 (Nov. 1, 2006).

[79] P. T. Cohen-Kettenis et al., The Treatment of Adolescent Transsexuals: Changing Insights, 5 J. Sexual Med. 1892, 1894 (2008).

der identity of the child. Given that nearly all gender dysphoric adolescents who begin puberty blockers proceed to cross-sex hormones,[80] it seems more plausible that the interference with normal pubertal development will influence the gender identity of the child by reducing the prospects for developing a gender identity corresponding to his or her biological sex.

72. Given their potential importance in the lives of the affected children, claims about reversibility require careful examination. In developmental biology, it makes little sense to describe anything as "reversible." If a child does not develop certain characteristics at age 12 because of a medical intervention, then his or her developing those characteristics at age 18 is not a "reversal," since the sequence of development has already been disrupted. This is especially important since there is a complex relationship between physiological and psychosocial development during adolescence. Gender identity is shaped during puberty and adolescence as young people's bodies become more sexually differentiated and mature. Given how little we understand about gender identity and how it is formed and consolidated, we should be cautious about interfering with the normal process of sexual maturation.

73. A more relevant question is whether the physiological and psychosocial development that occurs during puberty can resume in something resembling a normal way after puberty-suppressing treatments are withdrawn. In children with precocious puberty, this

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[80] M. A. T. C. van der Loos et al., Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence: a cohort study in the Netherlands, 6 Lancet Child & Adolesc. Health 869 (2022).

does appear to be the case. Puberty-suppressing hormones are typically withdrawn around the average age for the normal onset of gonadarche, at about age 12, and normal hormone levels and pubertal development gradually resume. For one common method of treating precocious puberty, girls reached menarche approximately a year after their hormone treatments ended, at an average age of approximately 13, essentially the same average age as the general population.[81] The evidence for the safety and efficacy of puberty suppression in boys is less robust, chiefly since precocious puberty is much rarer in boys. Although the risks are speculative and based on limited evidence, boys who undergo puberty suppression may be at greater risk for the development of testicular microcalcifications, which may be associated with an increased risk of testicular cancer, and puberty suppression in boys may also be associated with obesity.[82]

74. Unlike children affected by precocious puberty, adolescents with gender dysphoria do not have any physiological disorders of puberty that are being corrected by the puberty-suppressing drugs. The fact that children with suppressed precocious puberty between ages 8 and 12 resume puberty at age 13 does not mean that adolescents suffering from gender dysphoria whose puberty is suppressed beginning at age 12 will simply resume normal pubertal development later if they choose to withdraw from the puberty-suppressing

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[81] M. M. Fisher et al., Resumption of Puberty in Girls and Boys Following Removal of the Histrelin Implant, 164 J. Pediatrics 912, 912-16 (2014).

[82] S. Bertelloni, Treatment of central precocious puberty by GnRH analogs: long-term outcome in men, 10 Asian J. Androl. 525, 531 (2008).

treatment and choose not to undergo other sex-reassignment procedures. Interrupting puberty in this manner may have significant effects on final stature and bone density.[83]

75. After an extended period of pubertal suppression one cannot "turn back the clock" and reverse changes in the normal coordinated pattern of adolescent psychological development and puberty.[84] Once puberty is blocked, even if eventually unblocked (and assuming signaling from the pituitary gland resumes), the person cannot "buy back" the time when the physical process of puberty has been disrupted at the time when it would normally occur with complementary psychological processes in that stage in the person's life.

76. A possible effect of blocking normally timed puberty is alteration of normal adolescent brain maturation.[85]

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[83] T. Joseph et al., The effect of GnRH analogue treatment on bone mineral density in young adolescents with gender dysphoria: findings from a large national cohort, 32 J. Pediatric Endocrinol. and Metabol. 1077, 1077-81 (2019); D, Klink et al., Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria, 100 J. Clin. Endocrinol. & Metabol., E270-E275 (2015).

[84] See P. W. Hruz et al., Growing Pains, 52 The New Atlantis: A Journal of Technology and Society, 3 (Spring 2017). See also N. Vijayakumar et al., Puberty and the human brain: Insights into adolescent development, 92 Neurosci. & Biobehav. Revs 417 (2018); S. Choudhury, Culturing the adolescent brain: what can neuroscience learn from anthropology?, 5 Social Cognitive and Affective Neurosci. 159 (2010).

[85] See M. Arain et al., Maturation of the adolescent brain, 9 Neuropsychiatric Disease and Treatment, 449 (2013).

77. Another troubling question that has been largely uninvestigated is what psychological consequences there might be for children with gender dysphoria whose puberty has been suppressed and who later come to identify as their biological sex.

78. In addition to the reasons to suspect that puberty suppression may have side effects on physiological, psychological, and brain development, the evidence that something like normal puberty will resume for these patients after puberty-suppressing drugs are removed is very weak. Data obtained from the treatment of precocious puberty cannot be assumed to apply equally to the disruption of puberty that begins after 8 years of age in females and after 9 years of age in males.

79. In addressing the concern of puberty blockers on bone density, it is important to recognize that bone density is normally increasing during the teenage years. Observing an increase in bone density measurement does not indicate lack of adverse effect.[86] The relevant parameter is the bone density in relation to mean bone density in age and size matched controls. This is generally assessed as a "z-score." In the study by Klink,[87] it was observed that with blockade of normally timed puberty, there was a failure to regain pre-treatment z-scores for bone density even after introduction of cross-sex hormones. This supports the concern that in-

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[86] L. K. Bachrach, Acquisition of optimal bone mass in childhood and adolescence, 12 Trends in Endocrinol. & Metabol. 22 (2001).

[87] Klink et al., Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria, 100 J. Clin. Endocrinol. & Metabol., E270-E275 (2015)

terruption of normally timed puberty adversely affects bone density.

2. Cross-Sex Hormones

80. Rather than resuming biologically normal puberty, adolescents treated on the "affirming" model overwhelmingly go from suppressed puberty to medically conditioned cross-sex puberty, when they are administered cross-sex hormones.[88] Specifically, exogenous estrogen is administered to biological men to induce gynecomastia (i.e., the enlargement of breast tissues), and testosterone is administered to biological women to induce virilization (i.e., the development of facial hair and other desired male features) and to interfere with normal ovarian function.

81. Along with (and often before) estrogen is administered to biological males in this treatment, spironolactone may be used as an androgen blocker. Spironolactone is primarily used for the treatment of blood pressure and heart failure. It is a mineralocorticoid antagonist, meaning that it blocks the function of proteins in the kidney that regulate salt retention. But it also has effects in blocking the action of androgens. As discussed, androgens are masculinizing hormones that lead to virilization. Testosterone is a prime androgen, but other androgens are also made in the gonads and adrenal gland. Spironolactone is sometimes used in the treatment of polycystic ovarian syndrome, in which females will undergo virilization due to excess androgen production in the ovaries. This syndrome can have ad-

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[88] M. A. T. C. van der Loos et al. (2022), Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence, 6 Lancet Child & Adolesc. Health, at 869-75.

verse effects on fertility, metabolic health, and cardiovascular health.[89] The diagnosis of polycystic ovarian syndrome is a clinical diagnosis based upon the physical evidence of virilization or androgen effects, insulin resistance, and irregular periods. There are objective biological measures to assess those androgen levels, most notably elevated free testosterone levels. And there are objective measures of dysregulation of relevant signals from the pituitary gland, the LH and the FSH, to complement the clinical diagnosis by looking at the degree of virilization that is present in the patient.

82. Spironolactone would not be prescribed to male patients for an endocrinologic purpose related to androgen production. Once again, this reflects a fundamental biological difference between males and females. Though spironolactone can be used to regulate the levels of potassium and sodium in the body, such treatment would be based on objective markers of those levels.

83. Likewise, the administration of the sex steroid hormones differ by the sex of the individual. It is not identical to give testosterone to a male as it is to give it to a female, nor is it the same treatment to give estrogen to a male versus female. This difference has an established scientific basis. The differences between males and females occurs in every nucleated cell of the body, for males and females have different genetic programming. This is a process known as epigenetics, meaning that there are modifications of the DNA itself that alter the expression of genes when exposed to the same stimulus. As noted above, there are over 6,000 sex-differentially expressed genes. So, if one gives testosterone to a male,

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[89] M. H. Hunter et al., Polycystic Ovary Syndrome: It's Not Just Infertility, 62 Am. Fam. Physician 1079, 1079-88 (2000).

the physiologic effects of that treatment, even in the measurement at which genes are turned on and turned off, will be different than if one gives testosterone to a female.[90]

84. In congenital or acquired conditions where there is a defect in the ability to produce endogenous sex-steroid hormones, the goal of administering testosterone or estrogen is to restore the body to its natural state had the defect not been present. For example, females with Turner syndrome have premature ovarian failure and are therefore given estrogen to preserve bone health and allow normal pubertal maturation. Males with Klinefelter syndrome have primary hypogonadism and are therefore given testosterone to achieve normal lean body mass, bone density, hematocrit, and other androgen mediated bodily changes. Importantly, sex-steroid hormone doses are adjusted to maintain levels within the normal range for the sex of that individual.

85. While the normal range for testosterone levels in a male adolescent who has completed puberty is 300-900 ng/dL, testosterone levels for a female adolescent are 15-70 ng/dL. Testosterone levels can be elevated in females with pathologic conditions such as polycystic ovarian syndrome, but levels generally are less than 150 ng/dL. Levels above 200 ng/dL would generally necessitate evaluation for an adrenal or ovarian tumor.

86. When a patient with gender dysphoria is placed on cross-sex hormones, per the Dutch protocol, puberty-suppressing GnRH analogues continue to be

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[90] M. Gershoni et al., The landscape of sex-differential transcriptome and its consequent selection in human adults, 15 BMC Biol. 7 (2017)

administered until exogenous administration of cross-sex hormones (i.e., sex hormones normally produced by the gonads of the opposite sex) leads to sufficient suppression of endogenous sex hormone production, or the gonads are surgically removed. With pubertal blockade, sex hormones that are normally secreted by the maturing gonads are not produced. This means that adolescents undergoing cross-sex hormone treatment circumvent the most fundamental form of sexual maturation — the maturation of their reproductive organs.

87. For males who are being medically transitioned, exogenously administered estrogen will suppress testosterone production through feedback inhibition of pituitary LH and FSH secretion. Without pubertal blockade, this reduction of endogenous testosterone production is usually not sufficient to fully prevent virilization, and it is therefore necessary to add anti-androgenic medications such as spironolactone. For females being medically transitioned, exogenously administered testosterone will usually result in the cessation of menses and lead to the expected effect of virilization.

88. Patients undergoing gender affirming surgery discontinue GnRH treatment after having their gonads removed, since the secretion of sex hormones that the treatment is ultimately intended to prevent will no longer be possible. These patients are then sterile, as loss or alteration of primary sexual organs leads directly to impairment of reproductive potential.

89. Although the long-term effect of exposing immature gonads to cross-sex hormones is currently unknown, it is generally accepted, even by advocates of transgender hormone therapy, that hormonal treat-

ment impairs fertility, which may be irreversible.[91] Specifically, estrogen administration to males who identify as women results in impaired spermatogenesis and an absence of Leydig cells in the testis.[92] Exogenous testosterone administration to females who identify as men causes ovarian stromal hyperplasia and follicular atresia.[93] Recognition of these consequences is the basis for the development of new areas of medical practice where there is an attempt to restore fertility that has been intentionally destroyed.[94]

90. Gametes (sperm and ova) require natural puberty to mature to the point that they are viable for reproduction.[95] While it is expected that the exposure of immature gonads to cross-sex hormones will lead to infertility, whether affected individuals have permanent sterility has not been established. Much of the uncertainty arises from the novelty of this intervention and

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[91] See L. Nahata et al., Low Fertility Preservation Utilization Among Transgender Youth, 61 J. Adolesc. Health 40 (2017).

[92] C. Schulze, Response of the human testis to long-term estrogen treatment: Morphology of Sertoli cells, Leydig cells and spermatogonial stem cells, 251 Cell and Tissue Rsch. 31 (1988).

[93] T. D. Pache et al., Ovarian morphology in long-term androgen-treated female to male transsexuals. A human model for the study of polycystic ovarian syndrome?, 19 Histopathol. 445 (1991); K. Ikeda et al., Excessive androgen exposure in female-to-male transsexual persons of reproductive age induces hyperplasia of the ovarian cortex and stroma but not polycystic ovary morphology 28 Human Reproduction 453 (2013).

[94] See, e.g., A. J. Ainsworth et al., Fertility Preservation for Transgender Individuals: A Review, 95 Mayo Clinic Proceedings 784, 784-92 (2020).

[95] H. E. Kuhn et al., The Onset of Sperm Production in Pubertal Boys: Relationship to Gonadotropin Excretion, 143 Am. J. Diseases in Children 190 (1989).

the lack of long term follow up. There are limited reports of successful pregnancies after cross-sex hormones, but all of the subjects started gender-affirming hormones as adults after completing puberty.[96] I am not aware of any reports that show this for children who were exposed to puberty blockers before completing puberty followed by cross-sex hormones.

91. There are many other known risks to puberty suppression followed by cross-sex hormones beyond fertility concerns. As noted, emerging data show that treated patients have lower bone density, which may lead to increased fracture risk later in life.[97] Other potential adverse effects include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease.[98] In addition, non-physiological levels of estrogen in males has been shown to increase

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[96] I. de Nie et al., Successful restoration of spermatogenesis following gender-affirming hormone therapy in transgender women, 4 Cell Reports Med. 100858 (2023).

[97] See D. Klink et al. (2015), Bone Mass in Young Adulthood, 100 J. Clin. Endocrinol. & Metabol., at E270-E275.

[98] See L. J. Seal, A review of the physical and metabolic effects of cross-sex hormonal therapy in the treatment of gender dysphoria, 53 Annals Clin. Biochem. 10 (2016); K. Banks et al., Blood Pressure Effects of Gender-Affirming Hormone Therapy in Transgender and Gender-Diverse Adults, 77 Hypertension 2066, 2066-74 (2021); D. Getahun et al., Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study, 169 Annals of Internal Med. 205 (2018); S. Maraka et al., Sex Steroids and Cardiovascular Outcomes in Transgender Individuals: A Systematic Review and Meta-Analysis, 102 J. Clin. Endocrinol. & Metabol., 3914, 3914-23 (2017).

the risk of thromboembolic stroke above the incidence observed in females.[99]

92. Advocates of the gender affirmation approach to gender dysphoria often make misleading or erroneous statements about the potential or known adverse effects of interrupting normally timed puberty with GnRH analogues and the administration of "gender-affirming" sex-steroid hormones. This includes appeal to data on the safety of using these drugs in treating precocious puberty, where the effect of the intervention is to restore the patient to the normal phase of quiescence of the pituitary-gonadal axis. Further assertions that such treatments are the same as those used to treat conditions that are associated with infertility, such as Turner syndrome and Klinefelter syndrome, ignore the striking differences in both physiological attributes and goal of intervention. Some potential adverse effects can only be ascertained with directed testing that goes beyond what is normally performed as screening tests done in medical clinics. Cancer and cardiovascular and metabolic risks often take decades to manifest. The failure to observe patients with myocardial infarction (heart attack), thromboembolic events (stroke), or cancer in adolescent patients exposed to testosterone or estrogen at levels at or exceeding those observed in known disease states (e.g., polycystic ovarian syndrome or hormone-secreting tumors) does not mitigate concerns with these interventions in youth who experience sex-discordant gender identity.

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[99] See, e.g. D. Getahun et al. (2018), Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons, 169 Annals of Internal Med., at 205, *6-*8.

ENDOCRINE SOCIETY AND WPATH GUIDELINES

93. A reasonable understanding of relative risk versus benefit for medical products or procedures is a fundamental obligation in providing appropriate clinical care. This is the bedrock standard of "evidence-based medical practice." When considering clinical practice guidelines, it is essential that physicians recognize the relative risks and benefits of such documents. If done properly, they can distill large data sets into actionable clinical recommendations. However, there is a long history of clinical practice guidelines that have later been found to be deficient, resulting in wasted medical resources, failure to achieve desired benefits, and, at times, substantial harm to patients.[100]

94. As detailed throughout this report, this foundational standard of "evidence-based medical practice" has never been met as to so-called gender affirming care. The field of "affirming care" is characterized by a poor quality of evidence regarding safety and efficacy, as well as attempts to silence standard scientific discussion and consideration of alternative hypotheses; failures to acknowledge existing data showing persistence of suicidality after intervening; the intentional impairment and destruction of normally formed and functioning male and female sexual organs to address psychological-psychiatric distress; the manipulation of language from standard medical definitions; and widespread failures to properly report research data related to gender transitioning.

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[100] See S. H. Woolf et al., Clinical guidelines: potential benefits, limitations, and harms of clinical guidelines, 318 BMJ 527 (1999).

95. Despite the dangers of confirmation bias, existing guidelines base recommendations for "affirming" medical interventions on uncorroborated patient self-reports, assessed by mental health professionals with no methodology for discerning accurate patient reports, no alternative treatments offered, and no alternative explanations (e.g., social contagion) explored. There is no biological test to verify the diagnosis.

I. Endocrine Society

96. In 2009, the Endocrine Society published clinical guidelines for the treatment of patients with persistent gender dysphoria.[101] The recommendations include temporary suppression of pubertal development of children with GnRH agonists followed by hormonal treatments to induce the development of secondary sexual traits consistent with one's gender identity. In developing these guidelines, the authors assessed the quality of evidence supporting the recommendations made with use of the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) system for rating clinical guidelines. As stated in the Endocrine Society publication, "the strength of recommendations and the quality of evidence was low or very low."[102] According to the GRADE system, low recommendations indicate that "[f]urther research is very likely to have an important impact on our confidence in the estimate

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[101] See W. C. Hembree et al. (2009), Endocrine Treatment of Transsexual Persons, 94 J. Clin. Endocrinol. & Metabol. at 3132, 3132-54.

[102] *Id.* at 3132.

of effect and is likely to change the estimate."[103] Very low recommendations mean that "any estimate of effect is very uncertain."[104]

97. The Endocrine Society published an updated set of guidelines in September 2017.[105] Those guidelines show that all recommendations as to "affirming" treatment of adolescents are supported by low or very low-quality evidence.[106] Despite this low-quality evidence in this document, strong recommendations are frequently made on the basis of the "values and preferences" of either the Endocrine Society or the patient.[107] For instance, the Endocrine Society's recommendations ex-

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[103] G. H. Guyatt et al., GRADE: an emerging consensus on rating quality of evidence and strength of recommendations, 336 BMJ 924, 926 (2008).

[104] *Id.*

[105] See W. C. Hembree et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, 102 J. Clin. Endocrinol. & Metabol., 3869, 3869-3903 (2017). See also Corrigendum for "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," 103 J. Clin. Endocrinol. & Metabol. 2758 (July 2018) ("Endocrine Society Clinical Practice Guideline"); Corrigendum for "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," 103 J. Clin. Endocrinol. & Metabol. 699 (Feb. 2018).

[106] J. Block, Gender dysphoria in young people is rising—and so is professional disagreement, 380 BMJ 382, at *2 (2023). See also W. C. Hembree et al. (2017), Endocrine Society Clinical Practice Guideline, 102 J. Clin. Endocrinol. & Metab. at 3869-3903.

[107] See, e.g., W. C. Hembree et al. (2017), Endocrine Society Clinical Practice Guideline, 102 J. Clin. Endocrinol. & Metab., at 3872-73, 3881, 3894.

pressly place "a lower value on avoiding potential harm from early pubertal suppression."[108]

98. Dr. Guyatt, a co-developer of the GRADE system, "found 'serious problems' with the Endocrine Society guidelines, noting that the systematic reviews didn't look at the effect of the interventions on gender dysphoria itself, arguably 'the most important outcome.'" [109] He also criticized the Endocrine Society guidelines for pairing strong recommendations with weak evidence, explaining that such practice is discouraged "except under very specific circumstances."[110] He states that except under very specific circumstances, such practice is discouraged.[111]

99. The Endocrine Society guidelines state that "[w]eak recommendations require more careful consideration of the person's circumstances, values, and preferences to determine the best course of action." [112] These values and preferences include the desire of the individual seeking gender-affirming medical interventions, who may be operating under an *a priori* presumption (encouraged by the Endocrine Society's "strong recommendations") that these will lead to improved mental health. As detailed throughout this declaration, the existing data do not support this presumption. In-

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[108] *Id.* at 3881.

[109] J. Block (2023), Gender dysphoria in young people is rising, 380 BMJ 382, at *2-*3.

[110] *Id.* at *3.

[111] *Id.*

[112] W. C. Hembree et al. (2017), Endocrine Society Clinical Practice Guideline, 102 J. Clin. Endocrinol. & Metab., at 3872-73, 3885.

stead, the existing data substantiate Dr. Guyatt's concerns as summarized by J. Block:

> For Guyatt, claims of certainty represent both the success and failure of the evidence-based medicine movement. "Everybody now has to claim to be evidence based" in order to be taken seriously, he says —that's the success. But people "don't particularly adhere to the standard of what is evidence based medicine—that's the failure." When there's been a rigorous systematic review of the evidence and the bottom line is that "we don't know,'" he says, then "anybody who then claims they do know is not being evidence based."[113]

100. It is highly misleading to imply that the current Endocrine Society guidelines[114] represent the opinions of the Society's 18,000 members. The committee that drafted these guidelines was composed of *less than a dozen* members. The guidelines were never submitted to the entire Endocrine Society membership for comment and approval prior to publication. They also did not undergo external review. Such methodologies are common in association "statements" and "endorsement;" they are not scientific or generally reliable.

101. The panel that drafted the Endocrine Society guidelines was heavily composed of individuals who have significant associations with WPATH. Specifically, all but one of the committee members were leaders in WPATH. Two of the authors served as WPATH's pres-

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[113] J. Block (2023), Gender dysphoria in young people is rising, 380 BMJ 382, at *4.

[114] W. C. Hembree et al. (2017), Endocrine Society Clinical Practice Guideline, 102 J. Clin. Endocrinol. & Metab., at 3872.

ident (Walter J. Meyer and Vin Tangpricha);[115] at least five have served, or are serving, on WPATH's Board of Directors (Peggy Cohen-Kettenis, Louis Gooren, Stephen Rosenthal, Joshua Safer, Guy T'Sjoen);[116] and at least four (Stephen Rosenthal, Joshua Safer, Vin Tangpricha, and Guy T'Sjoen) were authors of WPATH SOC-8[117]. Three (Peggy Cohen-Kettenis, Walter Meyer, and Vin Tangpricha) were authors of WPATH SOC-7.[118]

II. WPATH

102. The World Professional Association for Transgender Health (WPATH) has also issued several iterations of guidelines. The first set of clinical practice guidelines was published in 1979. WPATH published its latest version of their "Standards of Care for the Health

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[115] A. Devor, History, WPATH World Professional Association for Transgender Health, https://www.wpath.org/about/history (last visited Apr 12, 2023) (Walter Meyer III, M.D. (President, 2003-2005)); Profile, Vin Tangpricha MD/PHD, Emory School of Medicine, https://med.emory.edu/departments/medicine/divisions/endocrinology/profile/?u=VTANGPR (last visited Apr 12, 2023).

[116] A. Devor, History, WPATH (Peggy Cohen-Kettenis (Board of Directors, 2003-2005), Louis J. G. Gooren, MD (Board of Directors, 1999-2003)); WPATH, Executive Committee and Board of Director, WPATH World Professional Association for Transgender Health, https://www.wpath.org/about/EC-BOD (last visited Apr 12, 2023) (Stephen Rosenthal, MD (Board of Directors, Member-at-Large, 2020-2024), Joshua Safer, MD (Board of Directors, Member-at-Large, 2022-2026), Guy G. R. T'Sjoen, MD, PhD (EPATH Representative—Term Determined by Board of Directors)).

[117] E. Coleman et al. (2022), SOC-8, 23 Int'l. J. Transgender Health, at 51-5258.

[118] E. Coleman et al., Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7, 13 Int'l. J. Transgenderism 165 (2012) ("SOC-7").

of Transgender and Gender Diverse People" (SOC-8) in September 2022.[119] While this document has been presented as "authoritative" and "evidence-based," numerous concerns have been raised about the updated recommendations. Changes in SOC-8 include removal of age limits for initiation of cross-sex hormones and gender-affirming surgery,[120] recommendations with language sufficiently flexible to encourage the exclusion of parents from the decision-making process if they question or challenge medical interventions,[121] elimination of safeguards for addressing underlying mental health illness before the start of gender-affirming medical interventions,[122] and the addition of a section on "eunuch-identified" people.[123] Many of the recommenda-

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[119] E. Coleman et al. (2022), SOC-8, 23 Int'l. J. Transgender Health, at 51-5258, S1-259.

[120] See, e.g., J. Block (2023), Gender dysphoria in young people is rising, 380 BMJ 382, at *1.

[121] See, e.g., E. Coleman et al. (2022), SOC-8, 23 Int'l. J. Transgender Health, at 5548 and Recommendation 6.11 ("We recommend when gender-affirming medical or surgical treatments are indicated for adolescents, health care professionals working with transgender and gender diverse adolescents involve parent(s)/guardian(s) in the assessment and treatment process, unless their involvement is determined to be harmful to the adolescent *or not feasible*." (emphasis added)).

[122] P. Toro, 7 takeaways for HR from the new transgender guidelines, HR Executive (2022), https://hrexecutive.com/7-takeaways-for-hr-from-the-new-transgender-guidelines/ (last visited Apr 29, 2023) ("Operationally, this means that TGD individuals do not require a mental health evaluation in order to obtain medical or surgical services. This is quite different from the prior guideline, which required mental health sign-off from one or two mental health providers in order to obtain gender-affirming surgery.").

[123] E. Coleman et al. (2022), SOC-8, 23 Int'l. J. Transgender Health, at 51-5258, S1-259.

tions made reflect WPATH's acknowledged agenda as an advocacy group. In SOC-8, WPATH specifically states, "Health is promoted through public policies and legal reforms that advance tolerance and equity for gender diversity and that eliminate prejudice, discrimination, and stigma. WPATH is committed to advocacy for these policy and legal changes."[124] Despite the claim that the SOC-8 guidelines are based upon solid scientific evidence, such recommendations represent ideological positions devoid of rigorous scientific evidence.[125] Scientific data on long-term outcomes in adolescents who are exposed to the U.S. affirmation model simply do not exist.

103. In sum, clinical guidelines or standards of care should provide practitioners with evidence-based standards by which they may reliably inform the patient of projected outcomes, and do so with a known error rate. Such data is the starting point for obtaining informed consent. This information is not provided by either WPATH or Endocrine Society's guidelines.

INFORMED CONSENT

104. The fundamental purpose of the practice of medicine is to treat disease and alleviate suffering. An essential tenet of medical practice is to avoid doing harm in the process. As discussed above, relying on clear, valid, reliable, and definitive evidence on how to best accomplish treatment goals is the essential ethical, professional, scientific, and clinical goals of physicians. Using "affirming" treatments on minors violates this

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[124] *Id.* at 55.

[125] See, e.g., J. Block (2023), Gender dysphoria in young people is rising, 380 BMJ 382, at *1-*3.

essential principle by using experimental treatments on vulnerable populations without properly informing them of the actual risks and limitations of the treatments.[126]

105. It is now universally agreed that medical and psychotherapy patients have a right to proper informed consent. Professional ethics codes, licensing rules and regulations, hospital rules and regulations, state and federal laws, and biomedical conventions and declarations all protect patients' right to informed consent discussions of the risks and benefits of proposed treatments and alternative treatments including no treatment.[127]

106. Essential requirements for informed consent include the ability of the patient or study subject to understand the proposed procedure, full disclosure of known and potential risks and benefits, discussion of alternative treatments, and freedom to act voluntarily. This information is presented verbally and in written form with allowance of sufficient time for the patient to ask questions and for the provider to assess adequate comprehension by the patient. It is well recognized that the signing of a formal consent form does not guarantee that informed consent has been obtained.

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[126] See A. R. Jonsen et al., Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine (4th ed. 1998).

[127] See *id.* ("Informed consent is defined as the willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the nature of the intervention, its risks, and benefits, as well as of alternatives with their risks and benefits."). See also A. L. Katz et al., Informed Consent in Decision-Making in Pediatric Practice, 138 Pediatrics e20161485 (2016) (reaffirmed in AAP Publications Reaffirmed, 151 Pediatrics e2023061452 (2023)).

107. Several aspects of the care of individuals with gender dysphoria may substantially interfere with proper application of these foundational principles.[128] For adolescent children seeking medical gender affirmation, well-established limitations in decision-making ability raise serious concerns about their ability to consent to hormonal and surgical interventions. Adolescents have a known tendency to engage in risky behaviors, exercise poor impulse control, and show frequent failure to appreciate long-term consequences of current choices.[129]

108. For example, the ability of a child to understand implications for future fertility while still developmentally immature can pose a significant barrier to meeting the criterion of appreciating decision consequence. Children are often unlikely to be capable of giving truly informed consent, particularly when it comes to hormonal or surgical treatments that can result in lifelong sterility.[130] Adolescents' inability to adequately weigh potential short-term benefits against long-term risks seems supported by the observation that few adolescents express concern over loss of fertility even when

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[128] P. S. Appelbaum et al., Assessing Patients' Capacities to Consent to Treatment, 319 N. Engl. J. Med. 1635 (1988) (correction issued in Correction, 320 N. Engl. J. Med. 748 (1989)).

[129] Neuroscientists have found that the adolescent brain is too immature to make reliably rational decisions. S-J. Blakemore et al., Decision-Making in the Adolescent Brain, 15 Nature Neurosci. 1184 (2012); B. J. Casey et al., The Adolescent Brain 1124 Annals N.Y. Acad. Scis. 111 (2008).

[130] See C. F. Geier, Adolescent cognitive control and reward processing: Implications for risk taking and substance use, 64 Hormones and Behavior 333 (2013).

directly told of the potential sterilizing effect of medical intervention.[131]

109. Similarly, individuals with transgender identity who also have clinical depression or other serious psychiatric comorbidity may have limited capacity to objectively weigh proposed clinical interventions with potentially irreversible consequences and would therefore fail to meet psychological abilities criteria.[132]

110. In addition, a study subject's underlying belief that he or she was born in the wrong body is the primary reason for seeking medical intervention. Thus, any challenge to this underlying premise is seen as a threat to the affected individual. Under such conditions, an individual will find it difficult, if not impossible, to give truly informed consent.

111. A model relying on parental consent with child assenting to affirmative medical interventions does not remove concerns about the difficulty in obtaining truly informed consent. Since many of the long-term outcomes of gender-affirming interventions are unknown, prospective patients are being asked to consent without sufficient knowledge of inherent risk versus benefit. Without understanding that nearly all adolescents who are put on puberty blockers will proceed to cross-sex hormones, with many subsequently opting for gender-affirming surgeries, focus on gaining consent for this first stage of the affirmative model is difficult if not impossible.

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[131] L. Nahata et al. (2017), Low Fertility Preservation Utilization, 61 J. Adolesc. Health, at 40.

[132] H. Helmchen, Ethics of Clinical Research with Mentally Ill Persons, 262 Eur. Archs. Psychiatry and Clin. Neurosci. 441 (2012).

112. Parents are often told by gender affirmation activists or providers that the failure to allow a gender dysphoric child to medically transition will result in suicide. These "threats" ignore data that challenge this biased assumption.[133]

113. While any cases of suicide are of utmost concern, suicide rates in children with sex-discordant gender identity must be put in context of overall suicidality in the pediatric population independent of gender dysphoria. When considered in this context, the rates of suicidal ideation and attempt in transgender adolescents are similar to those found in adolescents without gender dysphoria who present for psychological care.[134] Furthermore, it is necessary to critically assess, with rigorous scientific data, whether gender affirming medical interventions succeed in preventing suicides. While long-term data are not available for pediatric patients, the adult literature consistently reports continued elevated suicidality after undergoing gender affirming medical interventions.[135] In considering the population-based study in Sweden by Dhejne and colleagues,[136] it is not possible to draw conclusions on the effect of gender affirming interventions on suicide outcome since it was

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[133] See D'Angelo et al., One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria, 50 Archs. Sex. Behav. 7 (2021).

[134] M. Aitken et al., Self-Harm and Suicidality in Children Referred for Gender Dysphoria, 55 J. Am. Acad. Child & Adolesc. Psychiatry, 513 (2016).

[135] N. Adams et al., Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature, 2 Transgender Health 60 (2017).

[136] C. Dhejne et al., Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden, 6 PLOS ONE e16885 (2011).

not a controlled study. Nevertheless, the observation that completed suicide rates following such interventions were 19-fold above the background population clearly demonstrates that gender affirming medical care did not fix the problem of suicide.

114. Researchers have noted that in the "affirming" context, "the informed consent process rarely adequately discloses" either "the uncertain permanence of a child's or an adolescent's gender identity" or "the uncertain long-term physical and psychological health outcomes of gender transition."[137] Levine et al. recently noted the following major deficiencies in the informed consent process under existing "affirming" guidelines and approaches:

- "High rate of desistance/natural resolution of gender dysphoria in children is not disclosed";
- "Implications of very low-quality evidence that underlies the practice of pediatric gender transition are not explained"; and
- "The question of suicide is inappropriately handled."[138]

As discussed above, the informed consent process for "affirming" treatments is further "limited by" "erroneous professional assumptions" and "poor quality of the initial evaluations."[139]

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[137] S. B. Levine et al., Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults, 48 J. Sex & Marital Therapy 706 (2022).

[138] *Id.* at 711, 712, 713.

[139] *Id.* at 706 (Abstract).

115. Given the low quality of scientific evidence available regarding the effects of puberty blockers and cross-sex hormones on children with sex-discordant gender identity as discussed below in this report, the relevant scientific community recognizes that medical gender affirmation of adolescent children remains experimental.[140] Using experimental procedures on uninformed, vulnerable patients is unethical and improper. Some of the most tragic chapters in the history of medicine include violations of informed consent and improper experimentation on patients using methods and procedures that have not been tested and validated by methodologically sound science—such is the case with the gender transition industry. The infamous Tuskegee studies, Nazi and Imperial Japanese wartime experiments, lobotomies (e.g., Dr. Egas Moniz received the 1949 Nobel Prize in Medicine for inventing lobotomies as a "treatment" for schizophrenia[141]), recovered memory therapy, multiple personality disorders, rebirthing

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[140] Ludvigsson JF et al. A systematic review of hormone treatment for children with gender dysphoria and recommendations for research. Acta Paediatr. 2023 Apr 17. Epub ahead of print; "Recommendation of the Council for Choices in Health Care in Finland (PALKO/COHERE Finland): Medical Treatment Methods for Dysphoria Related to Gender Variance In Minors," PALVELUVALIKOIMA, p. 8.

[141] See Bengt Jansson, Egas Moniz: Controversial Psychosurgery Resulted in a Nobel Prize, NobelPrize. org (Oct. 29, 1998), https://www.nobelprize.org/prizes/medicine/1949/moniz/article/ (last visited Apr 11, 2023).

therapy,[142] coercive holding therapy,[143] and other tragic examples should serve as a stark warning to medical providers to properly protect the rights of patients and their families to a proper informed consent process and to not be subjected to experimental, unproven interventions.

EXISTING LITERATURE AND ITS LIMITATIONS

116. Before turning to the existing literature on gender dysphoria and its treatments, it is important to understand the varying types of studies conducted in this and other medical fields, as well as the general approach to scientific testing. Appropriate testing of medical and other scientific hypothesis requires proper study design. First, the researcher formulates a hypothesis as to whether there is a difference—a cause and effect relationship—from the studied intervention. The study starts by assuming the "null hypothesis"—there is no difference—and then one looks for evidence sufficient to disprove the null hypothesis. When conducting the study, statistical significance is of central importance, for it states the likelihood that the observation would exist if the null hypothesis were true. Only if there is a very small likelihood that the null hypothesis is true is it generally appropriate to treat a study as providing evidence that the null hypothesis is, in fact,

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[142] See, e.g., M. Janofsky, Girl's Death Brings Ban on a Kind of Therapy, The New York Times, Apr. 18, 2001, https://www.nytimes.com/2001/04/18/us/girl-s-death-brings-ban-on-a-kind-of-therapy.html (last visited Apr 11, 2023); see also P. Lowe, Rebirthing team convicted: Two therapists face mandatory terms of 16 to 48 years in jail, Rocky Mountain News, Apr. 21, 2001.

[143] See J. Hyde, Holding therapy appears finished, Deseret News (Feb. 23, 2005), https://www.deseret.com/2005/2/13/19877054/holding-therapy-appears-finished (last visited Apr 11, 2023).

false. Accordingly, if a study finding does not reach statistical significance, it would be improper to use the finding as a rejection of the null hypothesis.

117. Case reports or experts' opinions are recognized as the lowest level of evidence. Those are based upon general experiences, not scientific testing. They can be useful for generating novel hypotheses, which can then be tested through experimental testing to establish if there are cause/effect relationships. Next up on the pyramid of quality of evidence would be, for example, cross-sectional studies that are done where one looks at a condition at one point in time. One can merely infer associations from these types of studies. Randomized longitudinal studies can permit, to some extent, the elimination of unrecognized variables that may distort the results. The highest part of the evidence-based pyramid (for individual studies) is randomized controlled trials, in which the investigator attempts to control all aspects of the study with the exception of the independent variable that is being tested. When done properly, this type of study can provide strong evidence of causation. The following illustrates this pyramid:[144]

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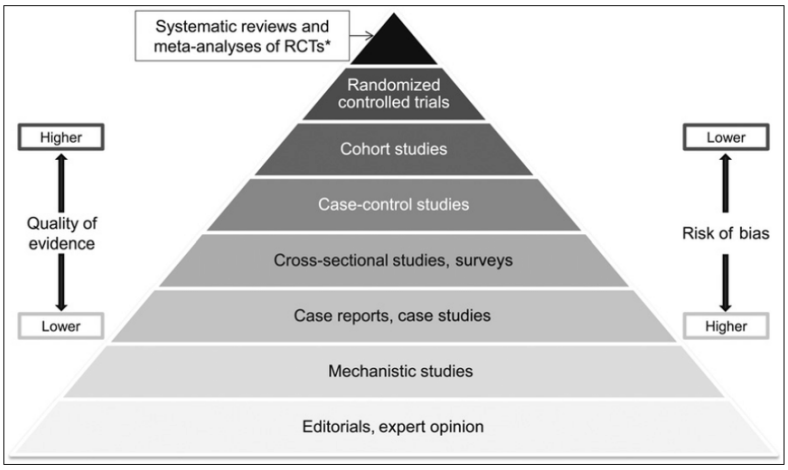
[144] Image available at https://www.researchgate.net/figure/Hierarchy-of-evidence-pyramid-Thepyramidal-shape-qualitatively-integrates-the-amount-of_fig1_311504831. For original source, see E. A Yetley et al., Options for basing Dietary Reference Intakes (DRIs) on chronic disease endpoints: report from a joint US-/Canadian-sponsored working group, 105 Am. J. Clin. Nutrition 249S, 259S (2017).



118. Since the "affirming" model of treating transgender children—as summarized by the WPATH and Endocrine Society guidelines discussed above—are relatively new, long-term outcomes are unknown. Evidence presented as support for short-term reductions in psychological distress following social transition in a "gender-affirming" environment remains inconclusive. Multiple potential confounders are evident. The most notable deficiencies of existing research are the absence of proper control subjects and lack of randomization in study design.[145] No randomized control trials have been performed, and the existing longitudinal studies have serious limitations—most significantly, that they follow cohorts of patients in a non-controlled, unrandomized manner. This design severely limits any conclusions that can be drawn.

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[145] See P. W. Hruz, Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria, 87 Linacre Quarterly 34 (2020).

119. Moreover, many studies find no improvement —or negative effects—from "affirming" care. For instance, a 2020 British study (Carmichael et al.[146]) found "no evidence of change in psychological function with GnRHa treatment as indicated by parent report (CBCL) or self-report (YSR) of overall problems, internalising or externalising problems or self-harm."[147] Puberty blockers used to treat children aged 12 to 15 who had severe and persistent gender dysphoria had no significant effect on their psychological function, thoughts of self-harm, or body image.[148] However, as expected, the children experienced reduced growth in height and bone strength by the time they finished their treatment at age 16.[149]

120. The widely respected Cochrane Review examined hormonal treatment outcomes for male-to-female transitioners over 16 years.[150] They found "insufficient

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[146] P. Carmichael 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, 16 PLOS ONE e0243894, *1, *19 (2021). The acronyms CBCL and YSR refer to Child Behavior CheckList and Youth Self-Report, respectively. *Id.* at Abstract. See also H. Cass, The Cass Review, Independent review of gender identity services for children and young people: Interim report, Feb. 2022, at 31 and n.27, https://cass.independent-review.uk/wp-content/uploads/2022/03/Cass-Review-Interim-Report-Final-Web-Accessible.pdf.

[147] P. Carmichael et al. (2020), Short-term outcomes of pubertal suppression, 16 PLOSONE e0243894, at *19.

[148] *Id.* at *18, *19.

[149] *Id.*

[150] See C. Haupt et al., Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 2020 Cochrane Database of Systematic Revs., Issue 11, Art. No. CD013138 (2020).

evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition."[151] Thus, decades after the first transitioned male-to-female patient, quality evidence for the benefit of transitioning remains lacking.

121. Although appropriate caution is warranted in extrapolating the outcomes observed from prior studies with current treatments, adults who have undergone social transition with or without surgical modification of external genitalia continue to have rates of depression, anxiety, substance abuse, and suicide far above the background population.[152]

122. Given the low quality of scientific evidence currently available regarding the relative risk versus benefit of gender-affirming medical interventions, existing evidence that suicidality remains markedly elevated after engaging in this therapeutic approach, and a general failure to directly test the benefits of psychological intervention to alleviate suffering in people who experience sex-discordant gender identity, before offering gender affirming care as a standard treatment there is an ethical imperative to conduct clinical trials to assess the validity of alternate hypotheses for effective treatment. Dismissal of randomized controlled trials rests upon an erroneous portrayal of clinical trial design. While it may be true that prospective research subjects would reject enrollment in a trial comparing affirmative

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[151] *Id.* at 2.

[152] See N. Adams et al., Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature, 2 Transgender Health 60, 60-75 (2017). See also C. Dhejne et al. (2011), Long-Term Follow-Up of Transsexual Persons, 6 PLOS ONE e16885.

care with no care, proper discussion of the inherent risk of gender affirming interventions, the lack of data showing long term resolution of suicidal ideation, and the goal of alleviating dysphoria through alternate means can provide reasonable expectation of enrolling a sufficient number of study subjects.

123. The 2015 study by Costa et al.[153] provides preliminary evidence that psychotherapy alone is associated with improved mental health. It is important to note that in this study comparing subjects that received psychological support alone versus those who received psychological support together with pubertal blockade, both study groups had significantly improved psychosocial function (CGAS) from baseline. Importantly, there was no statistical difference in CGAS scores between the two study groups throughout the study.[154] A lack of significant difference means that one cannot reject the null hypothesis because any observed differences could be due to random chance. Both groups had final CGAS scores in the 61-70 range, which reflects "some difficulty in a single area but generally functioning well."[155] The magnitude of difference between the CGAS scores at the end of the study was 5 points on a 100-point

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[153] R. Costa et al., Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria, 12 J. Sexual Med. 2206 (2015) (using the Utrecht Gender Dysphoria Scale (UGDS) and the Children's Global Assessment Scale (CGAS) as main outcome measures).

[154] *Id.* at 2206.

[155] D. Shaffer, A Children's Global Assessment Scale (CGAS), 40 Archs. Gen. Psychiatry 1228 (1983).

scale.[156] Of high interest would be an attempt to replicate this study in a randomized manner to better ascertain a causal relationship between psychotherapy and mental health.

I. Change in Patient Population

124. One important (and contentious) issue requiring more study is the recent trend of adolescent female to male gender discordant patients. In the United Kingdom, where centralized medical care provides data to track health care phenomenon, the number of adolescent girls seeking sex transitioning exploded over 4,000% in the last decade. Similarly, in the United States, where we lack the same kinds of centralized health care data, it has been reported that, in 2018, 2% of high school students identified on surveys as "transgender"—this is 200 times greater response, a 20,000% increase—over reports during past decades which showed a rate of only .01%.[157]

125. Along with this increase in transgender patients and identifiers has come a radical and recent transformation of the patient population from early onset males to rapid onset adolescent girls. Currently the majority of new patients with sex-gender discordance are not males with a long, stable history of gender dysphoria since early childhood—as they were for decades,

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[156] R. Costa et al. (2015), Psychological Support, Puberty Suppression, and Psychological Functioning, 12 J. Sexual Med. at 2212 (Table 2).

[157] See M. M. Johns et al., Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students—19 States and Large Urban School Districts, 2017, 68 MMWR Morb. Mortal. Wkly. Rep. 67 (2019).

and under the Dutch protocols—but instead adolescent females with no documented long-term history of gender dysphoria. One might say, as Dr. Lisa Littman has theorized,[158] that these females experienced "rapid onset" transgender identification.

126. This recent change in the typical patient raises questions about our understanding of the origins of transgender identity. For instance, a genetics or "immutable" theory of transgender identity cannot explain the rapid expansion of new gender dysphoria cases (a 4,000% to 20,000% increase), given that our genome is simply not changing that fast. Nor can that theory explain the explosion of adolescent females presenting with gender dysphoria. A "brain structures" theory has only weak medical evidence, and it also cannot explain the rapid expansion of new gender dysphoria cases. As for the theory that increased social acceptance is leading many people who were transgender all along to identify as such to their medical providers, this theory fails to explain why the rate of increase in males and older women transitioning has not kept pace with that for adolescent females. It also does not explain why many adolescent females are found transitioning along with their "social peer group clusters."

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[158] See L. Littman, Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria, 13 PLOS ONE e0202330 (2018); Erratum in L. Littman, Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria, 14 PLOS ONE e0214157 (2019).

II. Methodological Problems with "Affirming" Literature

127. The published literature relied on to advocate for the use of puberty blockers, cross-sex hormones, and gender-affirming surgeries in minors consists almost entirely of studies with major methodological limitations.[159] As detailed next, these include:

- Significant recruitment biases, including internet-based convenience sampling;
- Relatively small sample sizes for addressing a condition that is likely to be multifactorial;
- Short-term follow-up;
- Lack of randomization to different treatment arms;
- Failure to consider alternate hypotheses;
- Failure to include proper control groups;
- Reliance on cross sectional sampling that may identify associations, but cannot establish causal relationships between intervention and outcome;
- A high rate of patients lost to follow up in longitudinal analyses, which is relevant to questions of regret, desistance, and completed suicide;
- Biased interpretation of study findings with a goal of validating *a priori* conclusions rather

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[159] See generally P. W. Hruz (2020), Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria, 87 Linacre Quarterly, at 34.

than seeking evidence to disprove the null hypothesis; and

- Ignoring starkly contradictory research documenting the lack of effectiveness of "transitioning" procedures, the low quality of research in this area, and the ongoing contentions and disagreements over this highly controversial, experimental medical field.

128. Some or all of these methodological and statistical flaws are present in the following studies, which are commonly relied on by advocates of "affirming" treatments. This list is not exhaustive but is rather presented to demonstrate the serious scientific deficiencies in the published literature related to the care of individuals who experience sex-discordant gender identity.

The Bränström Long-Term Treatment Outcome Study: The historic Bränström study[160] is a long-term treatment outcome research investigation testing the effects of hormonal and surgical "transitioning" treatments on patients. Ultimately, but only after the authors' initial findings had come under public scrutiny,[161]

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[160] R. Bränström et al., Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study, 177 Am. J. Psychiatry 727 (2020). See also Correction to Bränström and Pachankis, 177 Am. J. Psychiatry 734 (2020).

[161] N. H. Kalin, Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process, 177 Am. J. Psychiatry 764 (2020) (writing on behalf of the Journal to announce a correction and an addendum published as a result of additional research requested and undertaken in response to the criticism of the Bränström study). See, e.g., A. Van Mol et al., Gender-Affirmation Surgery Conclusion Lacks Evidence, 177 Am. J. Psychia-

this study found no reliable benefits from these treatments.[162] In addition, the study suggested *increased* suicide attempts and anxiety disorders following the "gender transitioning" treatments.[163]

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try 765 (2020) (Letter to the Editor); A. Van Mol et al., Correction: Transgender Surgery Provides No Mental Health Benefit, Public Discourse, Sept. 13, 2020, https://www.thepublicdiscourse.com/2020/09/71296/ (last visited Apr 11, 2023). See also S. B. Levine, Reflections on the Clinician's Role with Individuals Who Self-identify as Transgender, 50 Archs. Sex Behav. 3527, 3530 (2021).

[162] See A. van Mol et al. (2020), Gender-Affirmation Surgery Conclusion Lacks Evidence, 177 Am. J. Psychiatry at 765 (Letter to the Editor). See also N. H. Kalin (2020), Reassessing: A Comment by the Editor on the Process, 177 Am. J. Psychiatry at 764; SEGM, Correction of a Key Study: No Evidence of "Gender-Affirming" Surgeries Improving Mental Health, https://segm.org/ajp_correction_2020 (Aug. 30, 2020).

[163] See, e.g., H. Anckarsäter et al., Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery, 177 Am. J. Psychiatry 764 (2020) (Letter to the Editor); A. van Mol et al., Gender-Affirmation Surgery Conclusion Lacks Evidence, 177 Am. J. Psychiatry 765 (2020) (Letter to the Editor); W. J. Malone et al., Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological Distress, 177 Am. J. Psychiatry 766 (2020) (Letter to the Editor); M. Landén, The Effect of Gender-Affirming Treatment on Psychiatric Morbidity Is Still Undecided, 177 Am. J. Psychiatry 767, 767-68 (2020) (Letter to the Editor); A. Wold, Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article, 177 Am. J. Psychiatry 768 (2020) (Letter to the Editor) (noting that "among the individuals examined in the study, the risk of being hospitalized for a suicide attempt was 2.4 times higher if they had undergone gender-corrective surgery than if they had not.").

Of note, significant research errors suggested that the authors had initially attempted to manipulate and misreport the findings of the study.[164] After publication of the original article in October 2019, "letters containing questions on the statistical methodology employed in the study led the [American Journal of Psychiatry] to seek statistical consultations."[165] According to the Journal, "[t]he results of these consultations were presented to the study authors," who on request "reanalyzed the data."[166] That reanalysis led the authors to recant their initial misreporting, as "the results demonstrated no advantage of surgery in relation to subsequent mood or anxiety disorder-related health care visits or prescriptions or hospitalizations following suicide attempts."[167] And the Bränström study at no point showed any advantages from hormonal treatments in improving mental health outcomes.[168]

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[164] See, e.g., H. Anckarsäter et al. (2020) Methodological Shortcomings, 177 Am. J. Psychiatry at 764-65); D. Curtis, Study of Transgender Patients: Conclusions Are Not Supported by Findings, 177 Am. J. Psychiatry 766 (2020); A. van Mol et al. (2020), Gender-Affirmation Surgery Conclusion Lacks Evidence, 177 Am. J. Psychiatry at 765-66. See also A. Ring et al., Confounding Effects on Mental Health Observations After Sex Reassignment Surgery, 177 Am. J. Psychiatry 768, 768-69 (2020) (Letter to the Editor) (noting that "the same data [used in the Bränström study] may be modeled in a way that leads to the opposite conclusion" of that reached by Bränström study.).

[165] Correction to Bränström and Pachankis, 177 Am. J. Psychiatry 734 (2020).

[166] *Id.*

[167] *Id.*

[168] R. Bränström et al. (2020), Reduction in Mental Health Treatment Utilization, 177 Am. J. Psychiatry at 727. See also D. Curtis, Study of Transgender Patients: Conclusions Are Not Supported

Thus, the Bränström study is devoid of any solid indication that medical interventions would objectively improve medical or mental health outcomes for transgender persons. Furthermore, because neither the original study nor the subsequent correction provide any statistically significant support for hormone treatment, the Bränström study has done nothing to close any of what the Cass Review, a formal independent review of gender identity services in the United Kingdom, has described as existing "gaps in the evidence base for hormone treatment" of minors.[169] Meanwhile, as discussed later in this report, several factors, including increased caution among some care providers, are resulting in a profound collapse of support for these experimental procedures across Europe, most notably in clinics providing treatment for minors.[170]

A 2011 Dutch study by De Vries et al.[171] is often cited to support longitudinal evidence of benefit from pubertal blockade. Although the study found slight improvements in mood and the risk of behavioral disorders with pubertal blockade over baseline, the study included no control group, and all 70 participants received ongoing psychological support. Thus, the authors were unable to determine the basis of the limited observed improvement. The authors acknowledge that psychological sup-

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by Findings, 177 Am. J. Psychiatry 766 (2020) (Letter to the Editor) (stating that the Bränström study "does not demonstrate that either hormonal treatment or surgery has any effect on this morbidity.").

[169] H. Cass (2022), The Cass Review—Interim Report, at 23.

[170] See, e.g., infra International Responses, ¶¶ 134 et seq.

[171] A. L. C. de Vries et al., Puberty Suppression in Adolescents With Gender Identity Disorder: A Prospective Follow-Up Study, 8 J. Sexual Med. 2276 (2011).

port or other reasons may have contributed to (or wholly caused) this observation. By the very nature of the trial, at best the study can provide a rationale for doing further studies that could show whether "affirming" interventions provide a benefit. The study does not (and cannot) answer the central question: whether the administration of puberty blockers is the solution to the problem and whether alternative approaches that do not carry the same risks relative to purported benefits (e.g., psychological interventions) may have the same or superior benefits.

Moreover, there remain questions about the extent to which the protocol used in these early Dutch studies may be relevant to the patient population presenting today. For decades transgender patients were mostly older adults or very young boys. As noted, over the last few years, a tsunami of teenaged girls has flipped the demographic ratio of transgender patients—now up to 7:1 for teen girls relative to teen boys. The newly presenting cases are vastly overrepresented by adolescent females, the majority of whom also have significant mental health problems and neurocognitive comorbidities such as autism-spectrum disorder or ADHD.[172] Furthermore, estimates of gender-dysphoria transgenderism are rocketing upwards from 1 in 10,000 to, in youth, "as high as 9%."[173] This unexplained, radical transformation of patient demographics raises questions about the applicability even of the limited existing literature

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[172] See N. M. de Graaf et al., Reflections on emerging trends in clinical work with gender diverse children and adolescents, 24 Clin. Child Psychol. and Psychiatry 353 (2019).

[173] See K. M. Kidd et al., Prevalence of Gender-Diverse Youth in an Urban School District, 147 Pediatricse2020049823 (2021).

on this issue, particularly as to the Dutch protocol. Dr. Thomas Steensma, a prominent investigator of the Dutch protocol—the original model for transitioning treatments—has recently noted that "[w]e don't know whether studies we have done in the past can still be applied to this time,"[174] specifically because of the unexplained surge in female adolescents reporting gender dysphoria. "Many more children are registering, but also of a different type . . . Suddenly there are many more girls applying who feel like a boy."[175] He concluded with the warning that "[w]e conduct structural research in the Netherlands. But the rest of the world is blindly adopting our research."[176]

A 2014 follow-up study by De Vries et al.[177] encompassed 55 of the original 70 patients; 15 were lost to follow-up or not included. It has the same limitations that were present in assessing the original 2011 study, including a carefully selected patient population that is

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[174] See B. Tetelepta, More research is urgently needed into transgender care for young people: "Where does the large increase of children come from?," Voorzij, Feb. 26, 2021, available at https://www.voorzij.nl/more-research-is-urgently-needed-into-transgender-care-for-young-people-where-does-the-large-increase-of-children-come-from/ (last visited Apr 11, 2023) (translation from B. Tetelepta, Dringend meer onderzoek nodig naar transgenderzorg aan jongeren: 'Waar komt de grote stroom kinderen vandaan?,' Algemeen Dagblad, Feb. 27, 2021, available at https://www.ad.nl/nijmegen/dringend-meer-onderzoek-nodig-naar-transgenderzorg-aan-jongeren-waar-komt-de-grote-stroom-kinderen-vandaan~aec79d00/ (last visited Apr 11, 2023)).

[175] *Id.*

[176] *Id.*

[177] A. L. C. de Vries et al., Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment, 134 Pediatrics 696 (2014).

not representative of the broader population, especially now. Having a longer study does not obviate the limitations of the study design in making a conclusion that can be applied to the gender clinics that are operating in the United States.

In addition to the concerns of the Dutch studies already exposed, "[t]he linchpin result of the Dutch studies is the reported *resolution of gender dysphoria*, as measured by the Utrecht Gender Dysphoria Scale (UGDS)."[178] The UGDS is a tool developed in the mid-1990s to assess the degree of gender dysphoria experienced by research subjects with separate surveys for male and female subjects.[179] Yet, as several researchers (E. Abbruzzese et al.) recently explained, the observed "drop was an artifact of switching the scale from 'female' to 'male' versions (and vice versa) before and after treatment, prompting a problematic reversal in the scoring."[180] "The *same* gender dysphoric individual, effectively answering the *same* question (albeit linguistically inverted)"—e.g., "Every time someone treats me like a girl [or boy] I feel hurt"—"results in either the maximum or the minimum 'gender dysphoria' score—depending on which sexed version of the scale was used."[181] Thus, because researchers used different scales of the UGDS before and after treatment, "it is

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[178] E. Abbruzzese et al., The Myth of "Reliable Research" in Pediatric Gender Medicine: A critical evaluation of the Dutch Studies —and research that has followed, J. Sex & Marital Therapy, Jan. 2, 2023, at 1, 7-8.

[179] Cohen-Kettenis PT, van Goozen SH. Sex reassignment of adolescent transsexuals: a followup study. J Am Acad Child Adolesc Psychiatry. 36(2):263-71 (1997); .

[180] *Id.* at 1, 8.

[181] *Id.* at 8.

impossible to determine if [the result shows] a real difference in gender dysphoria between groups or if this is an artifact of measurement error."[182] Indeed, if anything, "[t]he fact that after gender reassignment, the UGDS scores were low on the opposite-sex scale indicates that the subjects would have scored high on the natal sex scale, which corresponds to a *persistence in transgender identity*."[183] This, of course, is the opposite result purportedly reached by the 2014 De Vries study.

The 2018 paper by Wiepjes et al.[184] is a retrospective review of records from all patients of the Center of Expertise on Gender Dysphoria gender clinic in Amsterdam from 1972-2015. While the study appears to report on the regret rates among a large cohort of adolescents (812) and children (548),[185] regret is only reported for children and adolescents who had undergone gonadectomy once over 18 years of age.[186] Of the adolescents, 41% started puberty suppression. Of those who started GnRH agonists, only 2% stopped this intervention (meaning that 98% of those who started puberty suppression progressed to cross-sex hormone therapy).[187] An additional 32%, having already completed puberty, started cross-sex hormone therapy without use of a

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[182] *Id.* at 9 (internal quotation and citation omitted).

[183] *Id.* at 10 (emphasis in original).

[184] C. M. Wiepjes et al., The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets, 15 J. Sexual Med. 582 (2018).

[185] *Id.* at 584 (Table 1).

[186] *Id.* at 585, 587. See also *id.* at 582 (Abstract).

[187] *Id.* at 585 ("Of adolescents, 41.0% started PS, whereas only 1.9% of these adolescents stopped PS and did not start HT (Table 1).").

GnRH agonist.[188] Classification of regret was very stringent, requiring physician documentation of patient verbalized regret after gonadectomy and start of sex-concordant hormones to treat the iatrogenic hypogonadism.[189] This means there are significant limitations to the conclusions that can be drawn from this paper. There is no discussion in the paper regarding adolescent regret of use of puberty blockers, cross-sex hormones, or mastectomies. Importantly, 36% of patients were lost to follow up.[190] This is notable given that gonadectomy iatrogenically induces the pathologic state of primary hypogonadism. Affected patients have a lifelong dependency for exogenously administered sex-steroid hormones, and thus an acute need for ongoing follow-up. Their failure to return to the physicians who provided gender-affirming interventions raises serious questions about their outcome. It is reasonable to hypothesize that some may have experienced regret or completed suicide. Yet due to missing data, their fate remains unknown. It is also significant that the average time to regret was 130 months.[191] The authors themselves acknowledge that it may be too early to predict regret in patients who started hormone therapy in the past 10 years.[192]

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[188] *Id.*

[189] *Id.* at 583-84, 587 (with columns in Table 4 indicating the type of detransitions for each patient listed and the specific reversal treatments undertaken for each patient listed).

[190] *Id.* at 589.

[191] *Id.* at 589.

[192] *Id.* at 589.

The 2022 Tang et al. paper[193] is a retrospective chart review that aims to assess surgical outcomes in adolescents aged 12-17 years who underwent bilateral mastectomy for gender dysphoria from 2013-2020 within the Kaiser Permanente Health Care System in Northern California. The authors identified 209 subjects who had undergone this procedure. Of this group, only 137 had follow-up data more than 1 year after surgery. Complications were found in 7.3% with two of the subjects expressing regret within this interval. Despite claims to the contrary, this study documents that surgeries are being performed on adolescents with gender dysphoria as early as 12 years of age. There are several serious limitations of this study. This includes a retrospective study design, which as noted above cannot establish a causal relationship between intervention and outcome. There is also lack of outcome data on 82 of the 209 subjects (39%) with potential for bias in the outcome of missing subjects. Furthermore, the follow-up was very short (mean of 2.1 years). As noted above for the Wiepjes study,[194] this timeframe is insufficient to ascertain regret.

The 2018 Olson-Kennedy et al. paper[195] presents the results of a survey of biologically female patients with male gender identity at the lead author's institution us-

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[193] Tang A, Hojilla JC, Jackson JE, Rothenberg KA, Gologorsky RC, Stram DA, Mooney CM, Hernandez SL, Yokoo KM. Gender-Affirming Mastectomy Trends and Surgical Outcomes in Adolescents. Ann Plast Surg. 2022 May;88(4 Suppl):S325-S331.

[194] Wiepjes et al., at 589.

[195] J. Olson-Kennedy et al., Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts, 172 JAMA Pediatrics 431 (2018).

ing a novel rating system for "chest dysphoria" created by the study authors.[196] There were an equal number (68) of nonsurgical and post-surgical subjects surveyed.[197] Those who had undergone bilateral mastectomies were reported to have less chest dysphoria than those who did not receive this intervention.[198] Limitations of this study include convenience sampling of nonsurgical study subjects with high potential for selection bias. As in the above studies, cross-sectional design precludes establishment of a causal relationship between intervention and outcome measures. The primary outcome measure was not assessed by a validated assessment tool. Test validation is particularly relevant in assessing adolescent questionnaires due to a variety of cognitive and situational factors in this population.[199] Rigorous validation methods have been previously used in several other established questionnaires addressing adolescent self-perception.[200] Furthermore, as noted in the above studies, the short follow-up time (about 2 years) is insufficient to assess an outcome (regret) that has been shown to occur a decade after the intervention.[201]

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[196] *Id.* at 432.

[197] *Id.* at 431.

[198] *Id.* at 431 (Abstract).

[199] See N. D. Brener et al., Assessment of factors affecting the validity of self-reported health-risk behavior among adolescents: evidence from the scientific literature, 33 J. Adolesc. Health 436 (2003).

[200] See N. Palenzuela-Luis et al., Questionnaires Assessing Adolescents' Self-Concept, Self-Perception, Physical Activity and Lifestyle: A Systematic Review, 9 Children 91 (2022).

[201] Wiepjes et al., at 589

A 2019 study by Allen et al.[202] considered suicidality after cross-sex hormones. It was limited by a very small patient population (47), had no control group, had a short follow-up period (mean < 1 year), and again ignored that patients receiving the interventions also received psychological support.

A 2019-2020 study by Turban et al. in JAMA Psychiatry[203] aimed to consider "recalled exposure to gender identity conversion efforts [GICE] (ie, psychological interventions that attempt to change one's gender identity from transgender to cisgender) associated with adverse mental health outcomes in adulthood."[204] However, this paper has been repeatedly and pointedly criticized for a number of improper extrapolations and serious methodological defects,[205] several of which stem

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[202] L. R. Allen et al., Well-being and suicidality among transgender youth after gender-affirming hormones, 7 Clin. Practice in Pediatric Psychol. 302 (2019).

[203] J. L. Turban et al., Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults, 77 JAMA Psychiatry 68 (2020) (originally posted online on September 11, 2019).

[204] *Id.* at 68.

[205] See, e.g., D'Angelo et al. (2021), One Size Does Not Fit All, 50 Archs. Sex. Behav., at 7; R. Byng et al., Misinterpretation of the findings of this study may limit safe, ethical treatment options for gender-questioning and gender-diverse people, Comment on J. L. Turban et al., Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults, 77 JAMA Psychiatry 68 (2020), Comment posted on Oct. 8, 2019, available at https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2749479; H. Horvath, A deeply flawed analysis, Comment on J. L. Turban et al., Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults, 77 JAMA Psychiatry 68

from its reliance on flawed data from the 2015 U.S. Transgender Survey (USTS).[206]

The USTS was an anonymous online survey conducted in the summer of 2015[207] and "is the largest survey examining the experiences of transgender people in the United States, with 27,715 respondents."[208] Anonymous surveys are not rigorous sources of evidence, and the data from this survey are compromised by numerous biases and irregularities. The 2015 USTS Report and Executive Summary were published by the National Coalition for Transgender Equality (NCTE).[209]

(2020), Comment posted on Oct. 6, 2019, available at https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2749479; J. Mason, Not all therapy is conversion therapy, Comment on J. L. Turban et al., Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults, 77 JAMA Psychiatry 68 (2020), Comment posted on Sept. 27, 2019, available at https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2749479. These three Comments on Turban's article at JAMA Psychiatry, the comments by Byng et al., H. Horvath, and J. Mason, shall collectively be referred to as "Three Comments on J. L. Turban, Associations (2019-2020), at 77 JAMA Psychiatry 68."

[206] 2015 U.S. Transgender Survey Report, 2022 U.S. Trans Survey, https://www.ustranssurvey.org/reports (last visited Apr 25, 2023).

[207] S. E. James et al., The Report of the 2015 U.S. Transgender Survey, 4, Washington, DC: National Center for Transgender Equality (2016), available at https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf (last visited Apr. 25, 2023) ("USTS 2015 Report").

[208] *Id.*

[209] S. E. James et al., USTS 2015 Report; S. E. James et al., Executive Summary of the Report of the 2015 U.S. Transgender Survey, 16, Washington, DC: National Center for Transgender Equality (2016), available at https://transequality.org/sites/default/files/

Several authors of the USTS Report have been actively involved in policy work and legal advocacy at both the state and federal level, and in legislatures and courts.[210] More broadly, the USTS is currently supported by a coalition including several trans advocacy groups that, like the NCTE, are active in the realm of public policy.[211] In 2022, the USTS conducted another survey in partnership with several other trans advocacy organizations, and results are expected to be released later in 2023.[212] The current homepage for the USTS describes the 2022 survey as "the largest survey of trans people, by trans people, in the United States."[213]

The Turban et al. 2019-2020 JAMA Psychiatry study relying on the USTS survey tool has been criticized on account of several limitations and weaknesses of that survey tool—and resulting data—such as convenience sampling[214] and recruitment of patients through transgender advocacy organizations.[215] Furthermore, the

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docs/usts/USTS-Executive-Summary-Dec17.pdf (last visited Apr. 25, 2023).

[210] S.E. James et al. (2015), USTS 2015 Report, at 241-42.

[211] See 2022 U.S. Trans Survey, USTS Homepage (featuring logos from and hyperlinks to BTAC, the Black Trans Advocacy Coalition; the TransLatin@ Coalition; and NQAPIA, the National Queer Asian Pacific Islander Alliance).

[212] 2022 U.S. Trans Survey, 2022 U.S. Trans Survey, https://www.ustranssurvey.org (last visited Apr 25, 2023) (USTS Homepage); FAQ's, 2022 U.S. Trans Survey, https://www.ustranssurvey.org/faq (last visited Apr 28, 2023) (Who Conducts the USTS?).

[213] *Id.*

[214] See, e.g., Three Comments on J. L. Turban, Associations (2019-2020), at 77 JAMA Psychiatry 68.

[215] Three Comments on J. L. Turban, Associations (2019-2020), at 77 JAMA Psychiatry 68.

USTS "sampling method's inadequacy"[216] renders it highly unlikely that the survey tool (and thus the Turban 2019-2020 study data) captures or adequately accounts for populations integral to this study and its conclusions, such as "the population whose earlier gender dysphoria was alleviated through cognitive behavioral therapy or other standard approaches,"[217] or "individuals exposed to GICE who subsequently adopted a gender identity concordant with their biological sex."[218] Another crucial defect is the failure of Turban et al. to "control for comorbid psychiatric illness, the greatest single predictor of suicidality."[219]

In their comment, Byng et al. concluded:

> [T]he authors underplay the serious methodological weaknesses, particularly the likely confounding effects of co-existing mental health problems. They then take this association and in the abstract and conclusion seek to imply causation. Hence, the find-

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[216] H. Horvath, A deeply flawed analysis, Comment on J. L. Turban et al. (2019-2020), 77 JAMA Psychiatry 68.

[217] *Id.*

[218] R. Byng et al., Misinterpretation of the findings, Comment on J.T. Turban et al. (2019-2020), 77 JAMA Psychiatry at 68.

[219] R. Byng et al., Misinterpretation of the findings, Comment on J.T. Turban et al. (2019-2020), 77 JAMA Psychiatry at 68. See also J. Mason, Not all therapy is conversion therapy, Comment on J. L. Turban et al. (2019-2020), 77 JAMA Psychiatry 68 ("Turban et al allowed a number of study limitations—including convenience sampling and failure to control for mental illness, a key predictor of suicidality—which should make any savvy reader wary of accepting the study conclusions about the harms of therapy aimed at alleviating GD.").

ings could mislead frontline clinicians and public policymakers alike.[220]

D'Angelo et al.,[221] in their response to the Turban et al. 2019-2020 JAMA Psychiatry study, highlighted further limitations of the USTS survey tool.[222] These include demand bias (i.e., the good subject effect[223]), a high number of respondents who reported having not transitioned medically or socially (and reported no desire to do so in the future), and several data irregularities.[224] One notable data irregularity was that a high number of USTS respondents reported that their age was exactly 18 years.[225] Another was that "information about treatments received does not appear to be accurate, as a number of [USTS] respondents reported the initiation of puberty blockers after the age of 18 years, which is highly improbable."[226] These irregularities

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[220] R. Byng et al., Misinterpretation of the findings, Comment on J.T. Turban et al. (2019-2020), 77 JAMA Psychiatry at 68. See also H. Horvath, A deeply flawed analysis, Comment on J.T. Turban et al. (2019-2020), 77 JAMA Psychiatry at 68 ("It is surprising that so eminent a scholar as Dr. Turban did not perceive the methodological errors to which he was evidently susceptible in preparing his recent analysis of suicidality in transgender persons.").

[221] *Id.*

[222] *Id.* at 7. See J. L. Turban et al., Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults, 77 JAMA Psychiatry 68 (2020).

[223] A. L. Nichols et al., The Good-Subject Effect: Investigating Participant Demand Characteristics, 135 J. Gen. Psychol. 151 (2008).

[224] D'Angelo et al. (2021), One Size Does Not Fit All, 50 Archs. Sex. Behav., at 8.

[225] *Id.*

[226] *Id.* at 8 (internal citation omitted).

raise serious questions about the reliability of the USTS data and therefore the reliability of conclusions based on that data.[227] Because the 2019-2020 Turban study in JAMA Psychiatry is founded on a data set from an anonymous survey replete with flaws such as bias and convenience sampling, and because the study fails to control for multiple population gaps in the survey data and multiple key variables (such as co-morbid psychological illness), its conclusions are unreliable and potentially misleading.

Additional flaws and limitations of the USTS 2015 Survey data are set forth below in this report's summaries of the Turban et al. 2020 Pediatrics study, the Almazan et al. 2021 study, and the 2022 Turban et al. study, all papers which relied substantially on the USTS data.[228]

Another 2020 study by Turban et al. in Pediatrics[229] is often cited as proof that pubertal blockade prevents su-

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[227] See generally *id.* at 7-16.

[228] See infra discussion of the 2022 Turban et al. study. Also, further caution is warranted in evaluating the literature as the flawed data from the 2015 USTS may appear in other studies, including studies that have yet to be published. Upon request, the USTS makes the raw data from the 2015 survey available to researchers through the Inter-University Consortium for Political and Social Research (ICPSR). See Data Requests, 2022 U.S. Trans Survey, https://www.ustranssurvey.org/data-requests (last visited Apr 25, 2023). See also ICPSR, 2015 U.S. Transgender Survey (USTS) (ICPSR 37229), Version Date: May 22, 2019, https://www.icpsr.umich.edu/web/RCMD/studies/37229 (last visited Apr. 29, 2023).

[229] J. L. Turban et al., Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145 Pediatrics e20191725 (2020). See also Erratum for TURBAN 2019-1725, 147 Pediatrics e2020049767 (2021).

icide in transgender youth. But this study also used the same unreliable, biased sampling methodology, the 2015 USTS.[230] As stated in the paper, the authors considered "a cross-sectional online survey of 20,619 transgender adults aged 18 to 36 years" from the 2015 U.S. Transgender Survey.[231] In addition to the defects in the 2015 USTS anonymous online survey discussed above, there is no evidence of study subject identities, no way to assess for potential false subjects, and no medical diagnosis for entry into the survey. Also, the patient sample was compromised by ascertainment bias.[232] It is impossible for deceased persons, including those who have succumbed to suicide, to respond to an online survey necessary for their inclusion into the data set. No causation can be determined from this retrospective, cross-sectional design. Furthermore, the study apparently failed to even assess individuals who may have desisted or regretted transitions.[233] Thus, the study "does not include outcomes for people who may have initiated pubertal suppression and subsequently no longer identify as transgender."[234]

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[230] *Id.* at *2-*3 and n.6.

[231] *Id.* at *1, *2-*3.

[232] P. W. Hruz, Suicidality in Gender Dysphoric Youth Offered Pubertal Blockade Remains Alarmingly High, Comment on Comment on J. L. Turban, Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145 Pediatrics e20191725, Comment published on Jan. 26, 2020, available at https://publications.aap.org/pediatrics/article/145/2/e20191725/68259/Pubertal-Suppression-for-Transgender-Youth-and?autologincheck=redirected (last visited April 24, 2023).

[233] J. L. Turban et al. (2020), Pubertal Suppression, 145 Pediatrics e20191725, at *1-*8.

[234] *Id.* at *7.

Turban's misleading claim of lower suicidal ideation for treated patients is based upon "lifetime suicidality."[235] It fails to recognize or acknowledge that the decision to provide puberty blockers was likely influenced by the mental health of the subjects at the time of presentation.[236] Specifically, the most seriously mentally ill patients would have been denied puberty blockers.[237] The study can only be understood in light of these limitations and confounding issues.

According to the study, those who received treatment with pubertal suppression, when compared with those who wanted pubertal suppression but did not receive it, had lower odds of lifetime suicidal ideation (adjusted odds ratio = 0.3; 95% confidence interval = 0.2-0.6).[238] In Table 3 of the paper, under "Suicidality (past 12 months)" reductions for suppressed group versus non-suppressed were seen for ideation (50.6% v 64.8%) and "ideation with plan" (55.6% v 58.2%).[239] However, it is important to note that differences in suicidal "ideation with plan and suicide attempt" and "attempt resulting for inpatient care" did not reach statistical signifi-

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[235] *Id.* at *4.

[236] M. Biggs, Comment on J. L. Turban, Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145 Pediatrics e20191725, Comment published on Jan. 30, 2020, available at https://publications.aap.org/pediatrics/article/145/2/e20191725/68259/Pubertal-Suppression-for-Transgender-Youth-and?autologincheck=redirected (last visited April 24, 2023).

[237] *Id.*

[238] J. L. Turban et al. (2020), Pubertal Suppression, 145 Pediatrics e20191725, at *1.

[239] *Id.* at *5.

cance.[240] When discussing the results of their study, the authors fail to mention this lack of statistical significance in two of the most serious measures and, instead, reference only suicidal ideation. It would be reasonable to be concerned from an observation of over 40% attempted suicide in the treated group that the intervention was unsuccessful in improving health.[241]

Thus, much like the previously discussed Turban et al. 2019-2020 JAMA Psychiatry study, this Turban et al. 2020 Pediatrics study is severely compromised by unsound methodology, flawed and biased data from the 2015 USTS, and improper or weak extrapolations.

A 2020 study by Van der Miesen et al.[242] was a cross-sectional Dutch study that measured some patients who received puberty blockers and some who did not. The study had three populations of subjects: One was pa-

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[240] *Id.* at *5 and Table 2 (indicated by lack of an asterisks next to the P column for the Univariate Analyses). See also use of the asterisks in Table 1, at *4.

[241] See generally M. Biggs, Comment on J. L. Turban, Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145 Pediatrics e20191725, Comment published on Jan. 30, 2020, available at https://publications.aap.org/pediatrics/article/145/2/e20191725/68259/Pubertal-Suppression-for-Transgender-Youth-and?autologincheck=redirected (last visited April 24, 2023), and the multiple Letters to the Editor that criticized the multiple methodological errors in this study, https://pediatrics.aappublications.org/content/145/2/e20191725/tab-e-letters#re-pubertal-suppression-for-transgender-youth-and-risk-of-suicidal-ideation. See also M. Biggs, Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria, 49 Archs. Sex. Behav. 2227 (2020).

[242] A. I. R. van der Miesen et al., Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared With Cisgender General Population Peers, 66 J. Adolesc. Health 699 (2020).

tients presenting to the gender clinic who had not received any intervention, the second was patients who had received puberty blocker, and the third was adolescents from the general population.[243] Because of this study's cross-sectional nature, it cannot establish a causal relationship between intervention and effect. It also represents a non-probability sample with potential for significant biases in subject recruitment. In addition, the subjects assessed before and after treatment are different populations. Among the differences between these groups is patient age (mean of 14.5 and 16.8 years before and after treatment, respectively).[244] This two-year age difference is important as developmental progress during adolescence is known to influence psychological well-being.[245] There was also the same limitation noted in the 2011 de Vries study, that the treated population also received psychological support.[246]

A 2021 study by Bustos et al.[247] attempts to provide a systematic review of 27 observational or interventional

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[243] *Id.* at 700.

[244] *Id.*

[245] J. He et al., Meta-analysis of gender differences in body appreciation, 33 Body Image 90 (2020).

[246] A. I. R. van der Miesen et al. (2020), Psychological Functioning, 66 J. Adolesc. Health, at 703.

[247] V. P. Bustos et al., Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence, 9 Plastic and Reconstructive Surg.—Global Open e3477 (2021); Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence—Erratum, 10 Plastic and Reconstructive Surg.—Global Open e4340 (2022) ("The systematic review was reconducted, and the meta-analysis was re-run with the updated numbers with no significant or major changes. The updated tables and figures are included below.").0

studies that report on regret or detransition following gender-transition surgeries. A total of 7,928 subjects were included in their meta-analysis.[248] The authors concluded that only 1% or less of those who had gender-transition surgeries expressed regret.[249] It is important to understand the serious methodological limitations and high risk of bias contained within this study's analysis.[250] This includes failure to include major relevant studies addressing this question,[251] inaccurate analysis within one of the studies considered,[252] and the general lack of controlled studies, incomplete and generally short-term follow-up, large numbers of lost subjects, and lack of valid assessment measures in the published literature addressing this question.[253] As noted by Expósito-Campos and D'Angelo (2021), moderate to high risk of bias was present in 23 of the 27 studies included in the analysis.[254] Furthermore, 97% of subjects

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[248] V. P. Bustos et al. (2021), Regret after Gender-affirmation Surgery, 9 Plastic and Reconstructive Surg.—Global Open e3477, at *1.

[249] *Id.*

[250] See P. Expósito-Campos et al., Letter to the Editor: Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence, 9 Plastic and Reconstructive Surg.—Global Open e3951 (2021).

[251] *Id.* See, e.g., C. Dhejne et al., An Analysis of All Applications for Sex Reassignment Surgery in Sweden, 1960-2010: Prevalence, Incidence, and Regrets, 43 Archs. Sex. Behav. 1535 (2014).

[252] C. M. Wiepjes et al., The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets, 15 J. Sexual Med. 582 (2018).

[253] P. Expósito-Campos et al. (2021), Letter to the Editor regarding Bustos et al., Regret after Gender-affirmation Surgery, (2021), 9 Plastic and Reconstructive Surg., at *1.

[254] *Id.*

analyzed were found within studies deemed to be of fair to poor scientific quality.[255] Thus, this study cannot be used as strong support for the contention that regret is rare.

The 2021 study by Narayan et al.[256] examines anonymous survey results from 154 surgeons affiliated with WPATH. The response rate for this survey was 30%.[257] Of the respondents, 57% had encountered patients with surgical regret.[258] It is important to recognize that this study was specifically directed toward patients who had undergone surgical transition. Acknowledged biases of this study include selection bias, recall bias, and response bias.[259] This type of study cannot accurately identify the prevalence in the transgender population as a whole, and is particularly limited in the ability to assess potential for regret in the pediatric population.

The 2021 Almazan et al. study is "a secondary analysis of data from the 2015 US Transgender Survey" (USTS).[260] As a secondary analysis that is entirely reliant on the highly flawed and bias 2015 USTS data set, this study is subject to the resulting deficiencies already discussed above in the summaries of the 2019-2020 Turban et al.

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[255] *Id.*

[256] S. K. Narayan et al., Guiding the conversation—types of regret after gender-affirming surgery and their associated etiologies, 9 Annals of Translational Med. 605 (2021).

[257] *Id.*

[258] *Id.*

[259] *Id.* at 9.

[260] A. N. Almazan et al., Association Between Gender-Affirming Surgeries and Mental Health Outcomes, 156 JAMA Surg. 611 (2021).

JAMA Psychiatry study and the 2020 Turban et al. Pediatrics study.

In addition, the Almazan study itself has come under even more direct critique. In a Comment in response to the study, D. Curtis noted that the two groups the study compared are too dissimilar to one another to draw meaningful conclusions and that the authors failed to adequately highlight the magnitude of several differences.[261] Curtis lists a number of these differences—including significant differences in age, education (degree-status), employment status, gender identification, household income, and sexual orientation.—and then concludes:

> The two groups are so radically different that we really cannot assume that the multivariate analyses carried out allow us to conclude that differences in psychopathology are likely the result of surgical intervention. . . . We cannot agree that the results provide strong evidence that gender-affirming surgery is causally associated with improved mental health outcomes.[262]

In short, the Almazan study is discredited by both unreliable data and improper comparisons.

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[261] D. Curtis, Unrecognized confounding may explain differences in mental health outcomes, Comment on A. N. Almazan et al., Association Between Gender-Affirming Surgeries and Mental Health Outcomes, 156 JAMA Surg. 611 (2021), available at https://jamanetwork.com/journals/jamasurgery/fullarticle/2779429.

[262] *Id.*

The 2022 Van der Loos study[263] is a Dutch cohort study that investigates the continuation rate of gender affirming interventions in people who began puberty blockers and gender affirming hormones during adolescence. The authors claim that the study provides evidence against desistance after receiving gender-affirming hormones. While the paper gives the impression that subjects represent a period of study extending from 1972 to 2018, the majority of subjects recently started hormone interventions. The length of time for follow-up (mean of 3.5 years for males and 2.3 years for females) and the average age at follow-up (20.2 years for males and 19.3 years for females) are inadequate to support the authors' claim. Notably, research from these same investigators has suggested that the average time to detransition is over 10 years.[264] Thus, it would be necessary for the study to assess patients at least a decade after starting gender-affirming hormones to make any meaningful conclusions on desistance. Furthermore, as a retrospective cohort study without a control group, the study design cannot determine the effect of gender affirming therapy on whether the intervention influences the rate of desistance that would have occurred without the provision of gender-affirming hormones.

The 2022 Nos et al. study[265] is a retrospective cohort study that reports on the likelihood of starting on

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[263] M. A. T. C. van der Loos et al. (2022), Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence, 6 Lancet Child & Adolesc. Health at 869-75.

[264] C. M. Wiepjes et al. (2018), The Amsterdam Cohort of Gender Dysphoria Study (1972-2015), 15 J. Sexual Med., at 582-90.

[265] A. L. Nos et al., Association of Gonadotropin-Releasing Hormone Analogue Use With Subsequent Use of Gender-Affirming Hor-

gender-affirming hormones (GAH) based upon whether or not subjects were treated with puberty blockers. While the title and abstract give the impression that puberty blocker use is not linked to subsequent GAH, the data fail to support this conclusion. Since nearly all of the patients in this study who did not receive GnRHa were given GAH, it is not possible to determine whether GnRHa could increase this outcome. The comparison groups differed by age at time of initial presentation (age 10-13 years versus 14-17 years). GnRHa use was higher among the younger patients owing to the fact that they had not completed puberty at the time of first visit. A lag in progression to GAH use in this group is heavily influenced by the difference in age at time of initial presentation. The older group was eligible to start GAH at the time of study entry while those in the younger group were not. When adjusted for age, the rates of progression to GAH use is nearly identical. Importantly, among the patients who received GnRHa, 94% (64 out of 70) went on to take gender affirming hormones. Thus, the study further confirms that, rather than serving as a "pause button" for gender dysphoric adolescents, GnRHa use is an intervention that will lead to progression to gender affirming hormones.

The 2022 Green at al. study[266] purported to measure suicide attempts and access to cross-sex hormones. Though this study had a large cohort of patients,[267] it

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mones Among Transgender Adolescents, 5 JAMA Netw. Open e2239758 (2022).

[266] A. E. Green et al., Association of Gender-Affirming Hormone Therapy With Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth, 70 J. Adolesc. Health 643 (2022).

[267] *Id.* at 644.

suffered many biases in patient recruitment—which was done over the Internet[268] and provided a cross-sectional analysis[269] which can, at best, demonstrate correlation but not causation. Similar to other studies, it did not assess the effect of psychiatric medications or psychotherapy on outcomes. It also failed to include variables to assess at what age youth began puberty blockers or the duration which they had received gender-affirming hormones.

The 2022 Turban et al. study[270] is a retrospective cross-sectional investigation to assess whether there is an association between adolescent access to gender-affirming hormones and mental health. By nature of its retrospective cross-sectional design, the study is not able to make any conclusions regarding a causal relationship between GAH access and mental health. Like the Almazan et al. study and the two prior studies from Turban discussed above, this 2022 Turban study rests entirely on data from the USTS[271] and therefore suffers from similar defects.[272] Caution is warranted in evaluating any and all studies that either use or conduct further analysis of the USTS data because those studies would naturally be subject to any limitations, flaws, biases, irregularities, or anomalies in this source data.

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[268] *Id.*

[269] *Id.* at 647.

[270] J. L. Turban et al., Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults, 17 PLOS ONE e0261039 (2022).

[271] *Id.* at *3.

[272] See supra discussion of Alamazan et al., USTS, D'Angelo et al, and D. Curtis comment on Almazan et al.

The authors of the Turban 2022 study claim that there is an association between getting gender-affirming hormones and favorable mental health outcomes compared to those who desired but did not receive this intervention.[273] However, since the methodology used is similar to the author's 2020 study on the effects of access to puberty blockers on lifetime suicidality, already discussed above, and used the same 2015 U.S. Transgender Survey (USTS), it is subject to all of the associated limitations and biases.[274] Participants in the USTS were recruited through transgender advocacy organizations and subjects were asked to "pledge" to promote the survey among friends and family.[275] Thus, there are serious concerns of selection bias.[276] It also suffers from recall bias[277] and an inability to verify the veracity of the claims of treatments given to the study respondents.

Review of the data contained within the paper leads to conclusions that are far different than those stated by the study authors regarding mental health of the study participants. While the odds ratio for past-year suicidal ideation was statistically different between those who did and those who did not get GAH, there was no difference in those who had a suicide plan, actually attempted suicide, or were hospitalized for a suicide at-

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[273] J. L. Turban et al. (2022), Access to gender-affirming hormones, 17 PLOS ONE e0261039, at *1, *1.

[274] D'Angelo et al. (2021), One Size Does Not Fit All, 50 Archs. Sex. Behav. at 7-16.

[275] *Id.* at 8.

[276] S. Tyrer et al., Sampling in epidemiological research: issues, hazards and pitfalls, 40 BJPsych Bull. 57 (2016).

[277] See generally S. S. Coughlin, Recall bias in epidemiologic studies, 43 J. Clin. Epidemiol. 87 (1990).

tempt.[278] This is important since the rationale for accepting the attendant risks of gender-affirming hormones is to prevent suicide. As pointed out by Michael Biggs in a commentary on this article,[279] the data presented in this study negate the purported significance of effects of puberty blocker access on mental health as reported in Turban's 2020 Pediatrics article. As with many of the other studies considered in this report, the Turban et al. 2022 study is also discredited both by deficient data-sampling techniques and by flawed reasoning and unsound methodology overall.

The 2022 Tordoff study[280] is a prospective observational cohort study that assessed the mental health of patients presenting to the Seattle Children's gender clinic over a one-year period of follow-up. The authors claimed that access to gender-affirming care had signif-

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[278] J. L. Turban et al. (2022), Access to gender-affirming hormones, 17 PLOS ONE e0261039, at *5-*8 ("We detected no difference for other mental health variables measured.").

[279] M. Biggs, Estrogen is associated with greater suicidality among transgender males, and puberty suppression is not associated with better mental health outcomes for either sex, Comment on J. L. Turban et al., Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults, 17 PLOS ONE e0261039 (2022), Comment posted on Jan. 19, 2022, available at https://journals.plos.org/plosone/article/comment?id=10.1371/annotation/dcc6a58e-592a-49d4-9b65-ff65df2aa8f6 ("Conversely, a previous article by Turban et al. claimed to find a positive association between puberty suppression (using a Gonadotropin-Releasing Hormone agonist) and mental health—but this did not control for cross-sex hormones." (citing J. L. Turban et al. 2020, Pubertal suppression, 145 Pediatrics e20191725)).

[280] D. M. Tordoff et al., Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care, 5 JAMA Netw. Open e220978 (2022). For errata, see Data Errors in eTables 2 and 3, 5 JAMA Netw. Open e2229031 (2022).

icantly improved mental health with lower odds ratios of depression and suicidality. This purported finding was widely publicized by the University of Washington and was featured on several news media sites.[281] A detailed critique of the paper's data and flawed conclusions has been posted online.[282] Contrary to the authors' claims, data contained in the paper did not show improvement in mental health over the one-year study period. At entry into the study, 57% of the subjects who reported receiving treatment with puberty blockers or gender-affirming hormones (PB/GAH) had moderate to severe depression.[283] At the end of the study, 56% of the subjects who reported receiving PB/GAH had moderate to severe depression.[284] Rates for moderate to severe anxiety were 57% and 51% at baseline and 12 months,

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[281] See, e.g., Teens who received gender-affirming care had 60% lower odds of depression, UW study finds, king5.com, Published Mar. 12, 2022, Updated Sept. 7, 2022, https://www.king5.com/article/news/health/gender-affirming-care-reduces-depression-university-of-washington-study-transgender-nonbinary/281-bcfece1b-a7cb-4c95-80d0-3f02c597d783 (last visited Apr 30, 2023); Medical treatments cut risks for depression, suicide among transgenderyouth, UPI, https://www.upi.com/Health_News/2022/03/01/medical-treatments-transgenderyouth/3211646078081/ (last visited Apr 30, 2023).

[282] See J. Singal, Researchers Found Puberty Blockers And Hormones Didn't Improve Trans Kids' Mental Health At Their Clinic. Then They Published A Study Claiming The Opposite. (Updated), Singal-Minded (Apr. 6, 2022), https://jessesingal.substack.com/p/researchers-found-puberty-blockers (last visited Apr 13, 2023). See also Jesse Singal, Authors, Macmillan, https://us.macmillan.com/author/jessesingal (last visited Apr 30, 2023).

[283] D. M. Tordoff et al. (2022), Mental Health Outcomes, 5 JAMA Netw. Open e220978, at Online Supplementary Materials (Tordoff Supplement) and eTable 3 (at *4).

[284] *Id.*

respectively, for subjects who reported receiving PB/GAH.[285] Self-harm or suicidal thoughts were 43% and 37% at baseline and 12 months, respectively for subjects who reported receiving PB/GAH.[286] These are alarmingly high numbers for an intervention that is touted to be lifesaving. J. Singal notes that "[a]mong the kids who went on hormones, there isn't genuine statistical improvement here from baseline to the final wave of data collection.[287] Singal contacted one of the authors to ask about the data in eTable 3 and to confirm that there was, in fact, no improvement within the group of participants that had received puberty-blocking or hormonal interventions. Singal writes:

> [The authors] reference "improvements" twice . . . but offer no statistical demonstration anywhere in the paper or the supplemental material. I wanted to doublecheck this to be sure, so I reached out to one of the study authors. They wanted to stay on background, but they confirmed to me that there was no improvement over time among the kids who went on hormones or blockers.[288]

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[285] *Id.*

[286] *Id.*

[287] Singal (2022), Research Found Puberty Blockers And Hormones Didn't Improve Trans Kids' Mental Health, https://jessesingal.substack.com/p/researchers-found-puberty-blockers (last visited Apr 30, 2023).

[288] J. Singal (2022), Research Found Puberty Blockers And Hormones Didn't Improve Trans Kids' Mental Health, https://jessesingal.substack.com/p/researchers-found-puberty-blockers (last visited Apr 30, 2023) (linking at the phrase "on background" to J. Bender et al., Levels of Attribution, in J. Bender et al., Writing & Reporting for the Media, 11th ed., Oxford University Press (2016), available at https://global.oup.com/us/companion.websites/978019020

The reported statistical difference in odds ratios were comparisons between those who started on puberty blockers and cross-sex hormones and those who did not receive hormones. Importantly, there was a marked difference in the number of dropout subjects in the treated and non-treated groups (17.4% versus 80%, respectively).[289] It is reasonable to speculate that the small number of subjects who remained in the study but did not receive hormones had significant co-morbidities that prevented them from accessing this intervention. In any event, the actual data from this study demonstrates that access to puberty blockers and gender affirming hormones did not improve mental health over the first year of treatment. This is drastically different from what the authors and the media claimed.

The 2023 Chen et al. study[290] is a longitudinal observational study of patients receiving care at four gender centers in the United States. The primary conclusion made by the authors is that "GAH improved appearance congruence and psychosocial functioning."[291] However, there are major limitations and weaknesses in the data that limit the conclusions that can be made. The most glaring problem is that the study was observational and

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0886/student/chapter10/gline/level/#:~:text=%E2%80%9COn%20background%2C%E2%80%9D%20which%20is,the%20source%20by%20her%20position. (last visited May 1, 2023)).

[289] D. M. Tordoff et al. (2022), Mental Health Outcomes, 5 JAMA Netw. Open e220978, at 1, and Tordoff Supplement at eTable2 (*4), eTable3 (*4). See also J. Singal (2022), Research Found Puberty Blockers And Hormones Didn't Improve Trans Kids' Mental Health, at nn.3-4.

[290] D. Chen et al., Psychosocial Functioning in Transgender Youth after 2 Years of Hormones, 388 N. Engl. J. Med. 240 (2023).

[291] *Id.* at 240.

did not include a control group. Thus, there is no ability to draw causal conclusions. At best, the authors can find associations. A revealing critique of the paper by De Vries and Hannema that was published alongside this article exposes some of these concerns.[292] Akin to many of the other papers in this field, there is no way to determine whether any of the changes were contributed by or due solely to psychiatric interventions.[293] It is also notable that even though the study was designed to recruit only subjects with good mental health at baseline, 48 of the 307[294] study subjects (15.6%) were described as having severe or moderate depression at this time point.[295] At the end of the two-year follow-up, 30 of the 219 remaining subjects (13.7%) were reported to have major depression. Furthermore, two patients committed suicide during the two-year observation period, "one after 6 months of follow-up and the other after 12 months of follow-up."[296] This is an outcome that in most other situations would lead to a halt in study and detailed inquiry by an institutional review board.[297] The

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[292] A. L. C. De Vries et al., Growing Evidence and Remaining Questions in Adolescent Transgender Care, 388 N. Engl. J. Med. 275, (2023).

[293] *Id.* at 276.

[294] While 315 participants enrolled in the Chen study, only 307 participants remained at the conclusion of the study. D. Chen et al. (2023), Psychosocial Functioning, 388 N. Engl. J. Med. at 243.

[295] *Id.* at 243.

[296] *Id.* at 243.

[297] NIH Guide: Guidance on Reporting Adverse Events to Institutional Review Boards for NIHSupported Multicenter Clinical Trials, NOT-99-107, June 11, 1999, available at https://grants.nih.gov/grants/guide/notice-files/NOT99-107.html (last visited Apr 13, 2023) (also accessible through NIH Funding Opportunities and Notices for The Week Ending 06-11-99, available at https://grants.

paper claims to present two-year follow-up data in this cohort. However, only about half of the study participants were assessed at all five of the study time points,[298] and 30% did not have 24-month data collected.[299] Even if one accepted the follow-up period, this is likely not long enough to make firm conclusions about long-term efficacy. Several key outcomes that according to the original study protocol were to be measured (gender dysphoria, trauma symptoms, self-injury, suicidality, body esteem, and quality of life) are not reported in this paper.[300] The reason for these omissions is not apparent in the published manuscript. The study authors failed to report on robust measures of psychological well-being such as the number on antidepressants and other psychotropic medications.[301] The study effects for many of the measures reported was very modest at best and, even when statistically significant, do not have any meaningful clinical significance. For example, the depression scores showed little change over two years in

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nih.gov/grants/guide/WeeklyIndex.cfm?WeekEnding=06-11-99 (last visited Apr 13, 2023)). See also NIH Grant Policy Statement, § 4.1.15.6 Data and Safety Monitoring (U.S. Department of Health and Human Services, National Institutes of Health, December 2022) available at https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf (last visited April 13, 2022) (setting planning standards for reporting of adverse events to institutional review boards in NIH grant-funded clinical trials).

[298] D. Chen et al. (2023), Psychosocial Functioning, 388 N. Engl. J. Med. at 240.

[299] D. Chen et al. (2023), Psychosocial Functioning, 388 N. Engl. J. Med. at 240, Supplementary Appendix at 8 (Table S2. Coverage for Key Variables).

[300] D. Chen et al. (2023), Psychosocial Functioning, 388 N. Engl. J. Med. at 240-50.

[301] *Id.*

the highest severity group.[302] There is also significant heterogeneity in responses with some subjects showing improvement, some no change, and others worsening.[303] Consequently, these data do not alleviate the serious concerns raised regarding the safety and efficacy of gender-affirming medical interventions.

129. Many conclusions in the above studies are drawn or characterized in fundamentally unscientific ways without apparent regard to the scientific process of disproving a null hypothesis. Instead, these studies —along with the comments, responses, and professional criticism they have received—suggest that the authors began with a conclusion and then looked for data to support that conclusion. That is a vastly unsound way of doing science, and patients will not be aware of these methodological limitations and distortions when informed of these purported conclusions.

130. There remains a significant and unmet need to improve our understanding of the biological, psychological, and environmental basis for the manifestation of patient reports of discordance of gender identity and biological sex in affected individuals, as well as the long-term effects of "affirming" interventions.[304] In particular, there is a concerning lack of randomized controlled

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[302] D. Chen et al. (2023), Psychosocial Functioning, 388 N. Engl. J. Med. at 240, Supplementary Appendix at 13 (Table S6. Proportions of Youth Scoring in the Clinical Range for Depression and Anxiety at Each Timepoint).

[303] D. Chen et al. (2023), Psychosocial Functioning, 388 N. Engl. J. Med. at 240-50.

[304] J. Olson-Kennedy et al., Research priorities for gender nonconforming/transgender youth: gender identity development and biopsychosocial outcomes, 23 Current Op. in Endocrinol., Diabetes & Obesity 172, 172-79 (2016).

trials or adequately controlled longitudinal studies comparing outcomes of youth with gender dysphoria who received psychological support, were encouraged to socially transition, or were put on medical interventions, and how these differential treatments affect the usual and natural progression to resolution of gender dysphoria and other variables. Such studies can be ethically designed and executed with provisions for other dignity-affirming measures to all treatment groups.[305] But they have not been performed in the existing literature, leaving that literature in a state insufficient to enable sound conclusions about the efficacy of "affirming" treatments.

INTERNATIONAL RESPONSES

131. Recognizing the paucity of evidence supporting "affirming" treatments, along with the proven risks of those treatments, other countries are increasingly limiting use of those treatments.

132. **Finland**: The National Science Review in Finland carefully examined all relevant science and suspended transition treatments for minors under age 16.[306] The review determined that "[t]he first-line treatment for gender dysphoria is psychosocial support and,

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[305] See generally J. Sugarman, Ethics in the Design and Conduct of Clinical Trials, 24 Epidemiologic Reviews 54, 54-58 (2002).

[306] See 2020 Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland) Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors, Palveluvalikoima, Nov. 6, 2020, available at https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf. See also Recommendations—Choices in health care, Palveluvalikoimaneuvosto, https://palveluvalikoima.fi/en/recommendations (last visited Apr 13, 2023).

as necessary, psychotherapy and treatment of possible comorbid psychiatric disorders."[307] According to the review, "[c]ross-sex identification in childhood, even in extreme cases, generally disappears during puberty."[308] The review also found: "Potential risks of GnRH therapy include disruption in bone mineralization and the as yet unknown effects on the central nervous system";[309] "there are no medical treatment[s] [for transitioning] that can be considered evidence-based";[310] and, "[t]he reliability of the existing studies with no control groups is highly uncertain."[311] Thus, "because of this uncertainty, no decisions should be made that can permanently alter a still-maturing minor's mental and physical development,"[312] and "[n]o gender confirmation surgeries are performed on minors."[313] "Since reduction of psychiatric symptoms cannot be achieved with hormonal and surgical interventions, it is not a valid justification for gender reassignment. A young person's identity and personality development must be stable so that they can genuinely face and discuss their gender dysphoria, the significance of their own feelings, and the need for various treatment options. For children and adolescents, these factors are key reasons for postponing any interventions until adulthood. . . . In light of

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[307] PALKO / COHERE Finland, Recommendation, Nov. 6, 2020 (unofficial translation), at 5.

[308] *Id.*

[309] *Id.* at 6.

[310] *Id.*

[311] *Id.* at 7.

[312] *Id.*

[313] *Id.*

available evidence, gender reassignment of minors is an experimental practice."[314]

133. **Sweden**: The world-renowned Karolinska Hospital reviewed the current research and suspended pediatric gender transitions for patients under 16 outside of experimental, monitored clinical trials settings as of May 2021.[315] Treatment will focus on psychotherapy and assessment.[316] The "Dutch protocol" for treating gender-

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[314] *Id.* at 7-8.

[315] Karolinska Universitetssjukhuset—Astrid Lindgrens Barnsjukhus, English, unofficial translation, Guideline Regarding Hormonal Treatment of Minors with Gender Dysphoria at Tema Barn —Astrid Lindgren Children's Hospital (ALB), K2021-4144, Apr. 2021, at 2, available at https://segm.org/sites/default/files/Karolinska%20Guideline%20K2021-4144%20April%202021%20%28English%2C%20unofficial%20translation%29.pdf; KarolinskaUniversitetssjukhuset—Astrid Lindgrens Barnsjukhus, English, unofficial translation, Policy Change Regarding Hormonal Treatment of Minors with Gender Dysphoria at Tema Barn—Astrid Lindgren Children's Hospital, K2021-3343, Mar. 2021, at 1-2, available at https://segm.org/sites/default/files/Karolinska%20Policy%20Change%20K2021-3343%20March%202021%20%28English%2C%20unofficial%20translation%29.pdf. See also Karolinska Universitetssjukhuset—Astrid Lindgrens Barnsjukhus, Riktlinje gällande hormonell behandling till minderariga patienter med könsdysfori inom Tema Barn, K2021-4144, Apr. 2021, available at https://segm.org/sites/default/files/Karolinska%20Riktlinje%20K2021-4144%20April%202021%20%28Swedish%29.pdf (Swedish-language document); Karolinska Universitetssjukhuset—Astrid Lindgrens Barnsjukhus, Policyförändring gällande hormonell behandling till minderariga patienter med könsdysfori inom Tema Barn—Astrid Lindgrens Barnsjukhus, K2021-3343, Mar. 2021, available at https://segm.org/sites/default/files/Karolinska%20Policyförändring%20K2021-3343%20March%202021%20%28Swedish%29.pdf (Swedish-language document)

[316] See Society for Evidence-Based Medicine, Sweden's Karolinska Ends All Use of Puberty Blockers and Cross-Sex Hormones

dysphoric minors has been discontinued over concerns of medical harm and uncertain benefits.[317]

Moreover, in a national policy review, a report commissioned by the Swedish government concluded that:

- We have not found any scientific studies which explains the increase in incidence in children and adolescents who seek the heath care because of gender dysphoria.
- We have not found any studies on changes in prevalence of gender dysphoria over calendar time, nor any studies on factors that can affect the societal acceptance of seeking for gender dysphoria.
- There are few studies on gender affirming surgery in general in children and adolescents and only single studies on gender affirming genital surgery.
- Studies on long-term effects of gender affirming treatment in children and adolescents are few, especially for the groups that have appeared during the recent decennium. . . .

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for Minors Outside of Clinical Studies, SEGM.org, May 5, 2021, https://segm.org/Sweden_ends_use_of_Dutch_protocol ((featuring links to PDF copies of the Karolinska Policy and Guidelines documents, along with unofficial English translations, at the bottom of the page).

[317] *Id.*

- . . . No relevant randomized controlled trials in children and adolescents were found.[318]

From these findings, the Swedish National Board of Heath in December of 2022 issued updated guidelines for the care of adolescents and children with gender dysphoria.[319] This medical board concluded that "the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatments."[320] Noting that there is uncertainty about the cause for the rapid rise in number of people

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[318] See Sweden Policy Review, Gender dysphoria in children and adolescents: an inventory of the literature, SBU Policy Support no 307, 2019, https://www.sbu.se/307e.

[319] Socialstyrelsen—The National Board of Health and Welfare, Vård av barn och ungdomar med könsdysfori Nationellt kunskapsstöd med rekommendationer till profession och beslutsfattare (2022), https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-12-8302.pdf (full report in Swedish, PDF format). See also Uppdaterat kunskapsstöd för vård vid könsdysfori hos unga, Socialstyrelsen (2022), https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/uppdaterat-kunskapsstod-for-vard-vid-konsdysforihos-unga/ (last visited Apr 14, 2023) (announcing and publishing the full Swedish report); Socialstyrelsen—The National Board of Health and Welfare, Care of children and adolescents withgender dysphoria Summary of national guidelines, December 2022, https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf (Englishlanguage Summary from Socialstyrelsen).

[320] Socialstyrelsen—The National Board of Health and Welfare, Care of children and adolescents with gender dysphoria Summary of national guidelines, December 2022, at 3, https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf (English-language Summary from Socialstyrelsen). See also J. Block (2023), Gender dysphoria in young people is rising-and so is professional disagreement, 380 BMJ 382, at *2, *3.

being diagnosed with gender dysphoria, documented evidence of detransitioning young adults with uncertainty regarding the prevalence of this outcome, and lack of uniformity in experience-based knowledge among providers, GnRH analogues, gender-affirming hormones and mastectomy should be provided only in exceptional cases and ideally as part of an experimental trial.[321]

The results of the Swedish systematic review of the current published literature related to hormone treatment of gender dysphoric youth that served as the basis for this policy change were published on April 17, 2023 in the peer reviewed journal Acta Paediatrica.[322] The authors of this systematic review identified 9,934 abstracts related to hormone administration to children with gender dysphoria among the English language literature as of November 9, 2022. From these abstracts, 36 studies met their rigorous inclusion criteria for in-depth analysis. Twelve studies were assessed to have a high risk of bias and were therefore excluded from analysis. The remaining 24 studies were assessed for findings relevant to the inclusion criteria. This included 21 studies in which adolescents were given GnRH analogues (a.k.a. puberty blockers) and 3 studies where cross-sex hormones were administered without prior GnRHa treatment. Among the studies, the authors did not find any randomized controlled trials addressing the psychosocial effects, bone health, body composition

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[321] *Id.* at 3-4.

[322] Ludvigsson JF, Adolfsson J, Höistad M, Rydelius PA, Kriström B, Landén M. A systematic review of hormone treatment for children with gender dysphoria and recommendations for research. Acta Paediatr. 2023 Apr 17. doi: 10.1111/apa.16791. Epub ahead of print. PMID: 37069492.

and metabolism or persistence in children with gender dysphoria undergoing treatment with GnRHa medications. The authors of this study found serious methodological weaknesses in each of the three longitudinal observational studies assessed. This included small sample size, and high attrition rates. This prevented any verifiable conclusions regarding the long-term effects of hormone therapy on psychological health to be drawn. GnRHa therapy was found to delay bone maturation and bone mineral density gain that was only partially recovered by cross-sex hormone administration when studied at age 22 years. Among the key finding of this published peer reviewed study were that the long long-term effects of hormone therapy on psychosocial health are unknown, GnRHa treatment delays bone maturation and gain in bone mineral density and that GnRHa treatment in children with gender dysphoria should be considered experimental treatment of individual cases rather than standard procedure.

134. **United Kingdom**: The British official medical review office, National Institute of Health and Care Excellence (NICE), published reports on the use of both puberty blockers and hormones for transitioning purposes.[323] The assessment of the evidence into the drugs was commissioned by the National Health Service England (NHS). The review found that the evidence for using puberty-blocking drugs to treat young people struggling with their gender identity is "very low certainty."[324] The review on GnRH analogues found only

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[323] Nice Evidence Reviews—Cass Review, https://cass.independentreview.uk/nice-evidence-reviews/ (last visited Apr. 29, 2023).

[324] NICE, Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria,

"small, uncontrolled observational studies, which are subject to bias and confounding, and all the results are of very low certainty using modified GRADE. They all reported physical and mental health comorbidities and concomitant treatments very poorly."[325]

NICE also reviewed the evidence base for cross-sex hormones.[326] This review found the evidence of clinical effectiveness and safety of cross-sex hormones was also of "very low" quality.[327] The review concluded: "Any potential benefits of gender-affirming hormones must be weighed against the largely unknown long-term safety profile of these treatments in children and adolescents with gender dysphoria."[328]

A recent independent review of gender identity services in the United Kingdom, by Dr. Hilary Cass, concluded that "Evidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and internationally."[329] In summarizing a few of the key points and context from the Interim Report, the Cass Review stated, "There is lack of consensus and open discussion

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(Oct. 2020), https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_GnRH-analogues_For-upload_Final.pdf.

[325] *Id.* at 11-12.

[326] NICE, Evidence review: Gender-affirming hormones for children and adolescents with gender dysphoria, (Oct. 2020), https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_Gender-affirming-hormones_For-upload_Final.pdf.

[327] See, e.g., *id.* at 7, 47.

[328] *Id.* at 14.

[329] H. Cass (2022), The Cass Review—Interim Report, at 18.

about the nature of gender dysphoria and therefore about the appropriate clinical response."[330]

Following the Cass Review, the NHS ordered the closure of the Tavistock clinic, the UK's only dedicated gender identity clinic for children and young people.[331] As the BBC summarized, the Cass Review found that "the current model of care was leaving young people 'at considerable risk' of poor mental health and distress, and having one clinic was not 'a safe or viable long-term option.'"[332] The Tavistock will be replaced by a new regional hospital-based service where related services for mental health and autism can be provided by clinicians who have expertise in safeguarding and supporting children.[333] Thus, gender-related distress will be addressed "within a broader child and adolescent health context."[334]

This new model is in sharp contrast to recommendations made by WPATH in SOC-8. (Indeed, WPATH

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[330] The Cass Review, Interim report—Cass Review, Publications, https://cass.independent-review.uk/publications/interim-report/ (last visited Apr 14, 2023) (announcing the submission of the Interim Report to NHS and summarizing some key findings).

[331] J. Andersson et al., NHS to close Tavistock child gender identity clinic, BBC News, Jul. 28, 2022, https://www.bbc.com/news/uk-62335665.

[332] *Id.*

[333] Letter from Dr. Hilary Cass, Chair, Independent Review of Gender Identity Services for Children and Young People, to John Stewart, National Director Specialised Commissioning, NHS England, (Jul. 19, 2022), at 2, https://cass.independent-review.uk/wp-content/uploads/2022/07/Cass-Review-Letter-to-NHSE_19-July-2022.pdf.

[334] *Id.*

criticizes the UK's recent approach.[335]) Differences in approach include the prioritization of parent versus child expectations for care, recommendations against social affirmation of pre-pubertal youth, the provision of puberty blockers within the experimental setting, initial focus on exploration and treatment of mental health problems, and use of psychological support as a primary intervention.[336]

135. **Norway:** Adding to the growing list of European countries acknowledging the lack of reliable scientific evidence supporting the gender affirmation model, the Norwegian Healthcare Investigation Board (Ukom) issued in March of 2023 a new report on the treatment of people with gender incongruence and gender dysphoria.[337]

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[335] WPATH, WPATH, ASIAPATH, EPATH, PATHA, and USPATH Response to NHS England in the United Kingdom (UK) Statement regarding the Interim Service Specification for the Specialist Service for Children and Young People with Gender Dysphoria (Phase 1 Providers) by NHS England, (2022), https://www.wpath.org/media/cms/Documents/Public%20Policies/2022/25.11.22%20AUSPATH%20Statement%20reworked%20for%20WPATH%20Final%20ASIAPATH.EPATH.PATHA.USPATH.pdf?_t=1669428978#:~:text=the%20specialist%20service.-,WPATH%2C%20ASIAPATH%2C%20EPATH%2C%20PATHA%2C%20and%20USPATH%20believe%20that,to%20puberty%20suppression%20and%20gender%2D.

[336] See generally, E. Coleman et al. (2022), SOC-8, 23 Int'l. J. Transgender Health, at 51-5258; H. Cass (2022), The Cass Review—Interim Report.

[337] Ukom. Pasientsikkerhet for barn ogunge med kjønnsinkongruens. https://ukom.no/rapporter/pasientsikkerhet-for-barn-og-unge-med-kjonnsinkongruens/sammendrag March 2023

As reported by Jennifer Block in the BMJ,[338] this report is highly critical of the guidelines published by Norway's Healthcare directory in 2020. The report expressed concerns that the 2020 guidelines were not based upon systematic review of the scientific literature on the treatment of gender dysphoria. According to Stine Marit Moen, Ukom's medical director, "The report found that there is insufficient evidence for the use of puberty blockers and cross sex hormone treatments in young people, especially for teenagers who are increasingly seeking health services and being referred to specialist healthcare. Ukom defines such treatments as utprøvende behandling, or 'treatments under trial.'"[339]

CONCLUSIONS

136. There are no long-term, peer-reviewed, published, reliable, and valid research studies documenting the reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

137. There are no long-term, peer-reviewed, published, reliable, and valid research studies documenting any valid and reliable biological, medical, surgical, radiological, psychological, or other objective assessment of gender identity or gender dysphoria.

138. A large percentage of children (over 80% in some studies) who questioned their gender identity will, if not affirmed in a sex-discordant gender identity, develop an acceptance of their natal (biological) sex.

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[338] Block J. Norway's guidance on paediatric gender treatment is unsafe, says review. BMJ. 2023 Mar 23;380:697

[339] *Id.*

139. A currently unknown percentage and number of patients reporting gender dysphoria suffer from mental illness(es) that complicate and may distort their judgments and perceptions of gender identity.

140. There are no long-term, peer-reviewed, published, reliable, and valid research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are helped by such procedures.

141. There are no long-term, peer-reviewed, published, reliable, and valid research studies documenting the number or percentage of patients receiving gender-affirming medical interventions who are injured or harmed by such procedures.

142. "Affirming" treatments have no known, peer-reviewed, and published error rates.

143. The gender-affirming approach has limited, very weak scientific support for short-term alleviation of dysphoria and no long-term outcomes data demonstrating superiority over the other approaches.

144. Because of the major methodological limitations and weaknesses of the extant published literature in the field of gender dysphoria, one cannot make a conclusion that "affirming" treatments are justified as a safe and effective long-term solution to gender dysphoria in consideration of the significant risks and unsubstantiated long-term benefits.

145. With the limited and poor-quality data currently available about the purported efficacy of blocking normally timed puberty, administering cross-sex hormones, and gender-affirming surgeries in alleviating psychological morbidity for youth who experience sex-

discordant gender identity and the serious medical risks associated with these interventions, it cannot be concluded that this approach is "medically necessary." Use of such medical interventions remains a largely experimental approach.

146. Experimentation on gender-discordant youths is especially likely to cause harm to patients from historically marginalized communities. That is because children in such communities are disproportionally affected by gender discordance. These include:

- children with a history of psychiatric illness;[340]
- children of color;[341]
- children with mental developmental disabilities;[342]
- children on the autistic spectrum;[343] and

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[340] See, e.g., R. Kaltiala-Heino et al., Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development, 9 Child Adolesc. Psychiatry Mental Health 9 (2015).

[341] See, e.g., G. N. Rider et al., Health and Care Utilization of Transgender and Gender Nonconforming Youth: A Population-Based Study, 141 Pediatrics e20171683 (2018).

[342] See, e.g., C. Bedard et al., Gender Identity and Sexual Orientation in People with Developmental Disabilities, 28 Sexuality and Disability 165 (2010).

[343] See, e.g., A. L. C. De Vries et al., Autism Spectrum Disorders in Gender Dysphoric Children and Adolescents, 40 J. Autism Dev. Disord. 930 (2010).

- children residing in foster care homes and adopted children.[344]

147. Patients suffering from gender dysphoria or related issues have a right to be protected from experimental, potentially harmful treatments lacking reliable, valid, peer-reviewed, published, long-term scientific evidence of safety and effectiveness.

148. The treatment protocols and recommendations of politically influenced, non-science associations like WPATH and the American Academy of Pediatrics that engage in consensus-seeking methodologies by vote rather than science are not based on competent, credible, methodologically sound science, and have no known or published error rate.

149. The committee that developed the Endocrine Society gender-dysphoria guidelines relied on low-quality scientific evidence in making strong treatment recommendations and failed to adequately review the scientific evidence pertaining to long-term risk of medical interventions to affirm sex-discordant gender identity

150. Administering hormones to a child whose gender dysphoria is highly likely to resolve is risky, unscientific, and unethical. Iatrogenic damages from these interventions, including sterility, stunted growth, metabolic changes that increase risk of heart disease and diabetes, and many more, are often irreversible.

151. Because of these concerns about the safety, efficacy, and scientific validity of controversial, unproven, and experimental treatment paradigms, I have not per-

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[344] See, e.g., D. E. Shumer et al., Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic, 2 Transgender Health 76 (2017).

sonally engaged in the delivery of gender-affirming medical interventions to children with gender dysphoria. Given the unproven long-term benefits and the well-documented risks and harms of "transitioning" children, I decline to participate in such experimental treatments until the science has proven that the relative risks and benefits of this approach warrant such procedures.

152. My decision is strengthened by the knowledge that the vast majority of children who report gender dysphoria will, if not affirmed in their sex-discordant gender identity grow out of the problem—a natural coping-developmental process—and willingly accept their biological sex. Since there are no reliable assessment methods for identifying the small percentage of children with persisting sex-gender identity discordance from the vast majority who will accept their biological sex, and since puberty blocking treatments, hormone transition treatments, and surgical transition treatments are all known to have potentially life-long devastating, negative effects on patients, I and many colleagues view it as unethical to treat children with an unknown future by using experimental, aggressive, and intrusive gender affirming medical interventions.

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

Executed on May 19, 2023.

/s/ PAUL W. HRUZ
PAUL W. HRUZ, M.D., Ph.D.

EXHIBIT 5

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

Case No. 3:23-cv-00376

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

v.

JONATHAN SKRMETTI, ET AL., DEFENDANTS

EXPERT DECLARATION OF
STEPHEN B. LEVINE, M.D.

TABLE OF CONTENTS

I. CREDENTIALS

1. I am Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine and maintain an active private clinical practice. I received my M.D. from Case Western Reserve University in 1967 and completed a psychiatric residency at the University Hospitals of Cleveland in 1973. I became an Assistant Professor of Psychiatry at Case Western in 1973, became a Full Professor in 1985, and in 2021 was honored to be inducted into the Department of Psychiatry's "Hall of Fame."

2. Since July 1973, my specialties have included psychological problems and conditions relating to individuals' sexuality and sexual relations, therapies for sexual problems, and the relationship between love, intimate relationships, and wider mental health. In 2005, I received the Masters' and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research. I am a Distinguished Life Fellow of the American Psychiatric Association.

3. I have served as a book and manuscript reviewer for numerous professional publications. I have been the Senior Editor of the first (2003), second (2010), and third (2016) editions of the *Handbook of Clinical Sexuality for Mental Health Professionals*. In addition to five previously solo-authored books for professionals, I have published *Psychotherapeutic Approaches to Sexual Problems* (2020). The book has a chapter titled "The Gender Revolution."

4. In total I have authored or co-authored over 180 journal articles and book chapters, 27 of which deal with the issue of gender dysphoria. I was an invited member of a Cochrane Collaboration subcommittee that sought

to publish a review of the scientific literature on the effectiveness of puberty blocking hormones and of cross-sex hormones for gender dysphoria for adolescents. Cochrane Reviews are a well-respected cornerstone of evidence-based practice, comprising a systematic review that aims to identify, appraise, and synthesize all the empirical evidence that meets pre-specified eligibility criteria in response to a particular research question.

5. I first encountered a patient suffering what we would now call gender dysphoria in July 1973. In 1974, I founded the Case Western Reserve University Gender Identity Clinic and have served as Co-Director of that clinic since that time. Across the years, our Clinic treated hundreds of patients who were experiencing a transgender identity. An occasional child was seen during this era. I was the primary psychiatric caregiver for several dozen of our patients and supervisor of the work of other therapists. I was an early member of the Harry Benjamin International Gender Dysphoria Association (later known as WPATH) and served as the Chairman of the committee that developed the 5th version of its Standards of Care. In 1993 the Gender Identity Clinic was renamed, moved to a new location, and became independent of Case Western Reserve University. I continue to serve as Co-Director.

6. In the course of my five decades of practice treating patients who suffered from gender dysphoria, I have at one time or another recommended or supported social transition, cross-sex hormones, and surgery for particular patients, but only after extensive diagnostic and psychotherapeutic work.

7. In 2006, Judge Mark Wolf of the Eastern District of Massachusetts asked me to serve as an independent, court-appointed expert in a litigation involving the treatment of a transgender inmate within the Massachusetts prison system. In that litigation, the U.S. Court of Appeals for the First Circuit in a 2014 (En Banc) opinion cited and relied on my expert testimony. I have been retained by the Massachusetts Department of Corrections as a consultant on the treatment of transgender inmates since 2007.

8. In 2019, I was qualified as an expert and testified concerning the diagnosis, understanding, developmental paths and outcomes, and therapeutic treatment of transgenderism and gender dysphoria, particularly as it relates to children, in the matter of *In the Interest of J.A.D.Y. and J.U.D.Y.*, Case No. DF-15-09887-S, 255th Judicial District, Dallas County, TX (the "*Younger* litigation").

9. In 2019, I provided written expert testimony in the landmark case in the United Kingdom in the case of *Bell v. The Tavistock and Portman NHS Foundation Trust*. I have provided expert testimony in other litigation as listed in my curriculum vitae, which is attached as Exhibit "A".

10. I am regularly requested to speak on the topic of gender dysphoria and have given countless presentations to academic conferences and Departments of Psychiatry around the country. In May 2022, I organized and co-presented a symposium on the management of adolescent-onset transgender identity at American Psychiatric Association's Annual Meeting.

11. A fuller review of my professional experience, publications, and awards is provided in my curriculum vitae, a copy of which is attached hereto as Exhibit "A".

12. The bases for my opinions expressed in this report are my professional experience as a psychiatrist, my knowledge of the pertinent scientific literature, and my review of the complaints filed by the plaintiffs and the United States and the expert declarations of Armand H. Matheny Antommaria, M.D., Ph.D, FAAP, HEC-C, Jack Turban, M.D., Aron Janssen, M.D., and Deanna Adkins, M.D.

13. I am being compensated for my time spent in connection with this case at a rate of $400.00 per hour. My compensation is not dependent upon the outcome of this litigation or the substance of my opinions.

II. SUMMARY

14. A summary of the key points that I explain in this report is as follows:

a. Sex as defined by biology and reproductive function is clear, binary, and cannot be changed. While hormonal and surgical procedures may enable some individuals to "pass" as the opposite gender during some or all of their lives, such procedures carry with them physical, psychological, and social risks, and no procedures can enable an individual to perform the reproductive role of the opposite sex. (Section III.A.)

b. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions, with widely differing pathways and characteristics depending on age of onset, biological sex, mental health, intelligence, motivations for gender transition, socioeco-

nomic status, country of origin, etc. Data from one population (e.g., adults) cannot be assumed to be applicable to others (e.g., children). (Section III.B.)

c. Among practitioners in the field, there are currently widely varying views concerning both the causes of and appropriate therapeutic response to gender dysphoria in children and adolescents. There are no generally accepted "standards of care," and existing studies do not provide a basis for a scientific conclusion as to which therapeutic response results in the best long-term outcomes for affected individuals. The scientific basis for affirmative care is uncertain. (Section III.)

d. Transgender identity is not biologically based; it is not determined prenatally. Rather, gender dysphoria is a psychiatric condition that cannot be identified by any biological test or measurement. (Sections V.A, IV.B.)

e. Disorders of sexual development ("DSDs") are biologically-based phenomena. It is an error to conflate and/or scientifically link DSDs with incidents of gender dysphoria. (Sections V.C, V.D.)

f. The large majority of children who are diagnosed with gender dysphoria "desist"—that is, their gender dysphoria does not persist—by puberty or adulthood. Desistance is also increasingly observed among teens and young adults who have experienced "rapid onset gender dysphoria"—first manifesting gender dysphoria during or shortly after adolescence. (Section VI.A., VI.B.)

g. "Social transition"—the active affirmation of transgender identity—in young children is a power-

ful social intervention that will substantially reduce the number of children "desisting" from transgender identity. Therefore, the profound implications of "affirmative" treatment—which include taking puberty blockers and cross-sex hormones—must be taken into account where social transition is being considered. (Section VII.A,, VII.B.)

h. Administration of puberty blockers is not a benign "pause" of puberty, but rather a powerful medical and psychotherapeutic intervention that almost invariably leads to persistence in a transgender identity and, ultimately, to the administration of cross-sex hormones. (Section VII.C.)

i. The knowledge base concerning the "affirmative" treatment of gender dysphoria available today has very low scientific quality with many relevant long-term implications remaining unknown. (Section VIII.A.)

j. There are no studies that show that affirmation of transgender identity in young children reduces suicide or suicidal ideation, or improves long-term outcomes, as compared to other therapeutic approaches. Meanwhile, multiple studies show that adult individuals living transgender lives suffer much higher rates of suicidal ideation, completed suicide, and negative physical and mental health conditions than does the general population. This is true before and after transition, hormones, and surgery. (Section VIII.B., VIII.C.)

k. In light of what is known and not known about the impact of affirmation on the incidence of suicide, suicidal ideation, and other indicators of mental and physical health, it is scientifically baseless, and

therefore unethical, to assert that a child or adolescent who express an interest in a transgender identity will kill him- or herself unless adults and peers affirm that child in a transgender identity. (Section IX.)

l. Hormonal interventions to treat gender dysphoria are experimental in nature and have not been shown to be safe, but rather put an individual at risk of a wide range of long-term and even life-long harms including: physical health risks; sterilization and the associated emotional response; impaired sexual response; surgical complications and lifelong aftercare; alienation of family and romantic relationships; elevated mental health risks of depression, anxiety, and substance abuse. (Section X.)

III. BACKGROUND ON THE FIELD

A. The biological baseline of the binary sexes

15. Biological sex is very well defined in all biological sciences including medicine. It is pervasively important in human development throughout the lifecycle.

16. Sex is not "assigned at birth" by humans visualizing the genitals of a newborn; it is not imprecise. Rather, it is clear, binary, and determined at conception. The sex of a human individual at its core structures the individual's biological reproductive capabilities—to produce ova and bear children as a mother, or to produce semen and beget children as a father. As physicians know, sex determination occurs at the instant of conception, depending on whether a sperm's X or Y chromosome fertilizes the egg. A publication of the federal government's National Institute of Health accurately summarizes the scientific facts:

> "Sex is a biological classification, encoded in our DNA. Males have XY chromosomes, and females have XX chromosomes. Sex makes us male or female. Every cell in your body has a sex—making up tissues and organs, like your skin, brain, heart, and stomach. Each cell is either male or female depending on whether you are a man or a woman." (NIH, How Sex and Gender Influence Health and Disease, 2022.)

17. The binary of biological sex is so fundamental and wide-ranging in its effects on human (and mammal) development and physiology that since 2014, the NIH has required all funded research on humans or vertebrate animals to include "sex as a biological variable" and give "adequate consideration of both sexes in experiments." (NIH 2015.) In 2021, the Endocrine Society issued a position paper elaborating on the application of the NIH requirement. The Endocrine Society correctly stated that "Sex is a biological concept . . . all mammals have 2 distinct sexes;" that "biological sex is . . . a fundamental source of intraspecific variation in anatomy and physiology;" and that "In mammals, numerous sexual traits (gonads, genitalia, etc.) that typically differ in males and females are tightly linked to each other because one characteristic leads to sex differences in other traits." (Bhargava et al. 2021 at 221, 229.)

18. The Endocrine Society emphasized that "The terms sex and gender should not be used interchangeably," and noted that even in the case of those "rare" individuals who suffer from some defect such that they "possess a combination of male- and female-typical characteristics, those clusters of traits are sufficient to classify most individuals as either biologically male or

female." They concluded, "Sex is an essential part of vertebrate biology, but gender is a human phenomenon. Sex often influences gender, but gender cannot influence sex." (Bhargava et al. 2021 at 220-221, 228.)

19. As these statements and the NIH requirement suggest, biological sex pervasively influences human anatomy, its development and physiology. This includes, of course, the development of the human brain, in which many sexually dimorphic characteristics have now been identified. In particular, the Endocrine Society and countless other researchers have determined that human brains undergo particular sex-specific developmental stages during puberty. This predictable developmental process is a genetically controlled coordinated endocrine response that begins with pituitary influences leading to increases in circulating sex hormones. (Bhargava et al. 2021 at 225, 229; Blakemore et al. 2010 at 926-927, 929; NIH 2001.)

20. Humans have viewed themselves in terms of binary sexes since the earliest historical records. Recognizing a concept of "gender identity" as something distinct from sex is a rather recent innovation whose earliest manifestations likely began in the late 1940s. Its usage became common in medicine in the 1980s and subsequently in the larger culture. Definitions of gender have been evolving and remain individual-centric and subjective. In a statement on "Gender and Health," the World Health Organization defines "gender" as "the characteristics of women, men, girls and boys that are socially constructed" and that "var[y] from society to society and can change over time," and "gender identity" as referring to "a person's deeply felt, internal and individual experience of gender." (WHO Gender and Health.) As these definitions indicate, a person's "felt"

"experience of gender" is inextricably bound up with and affected by societal gender roles and stereotypes—or, more precisely, by the affected individual's *perception* of societal gender roles and stereotypes and their personal idiosyncratic meanings. Typically, gendered persons also have subtly different, often idiosyncratic, reactions to societal gender roles and stereotypes without preoccupation with changing their anatomy.

21. Thus, the self-perceived gender of a child begins to develop along with the early stages of identity formation generally, influenced in part from how others label the infant: "I love you, son (daughter)." This designation occurs thousands of times in the first two years of life when a child begins to show awareness of the two possibilities. As acceptance of the designated gender corresponding to the child's sex is the outcome in >99% of children everywhere, anomalous gender identity formation begs for understanding. Is it biologically shaped? Is it biologically determined? Is it the product of how the child was privately regarded and treated? Is it a product of the quality of early life caregiver attachments? Does it stem from trauma-based rejection of maleness or femaleness, and if so, flowing from what trauma? Does it derive from a tense, chaotic interpersonal parental relationship without physical or sexual abuse? Is it a symptom of another, as of yet, unrevealed, emotional disturbance or neuropsychiatric condition (autism)? The answers to these relevant questions are not scientifically known but are not likely to be the same for every trans-identified child, adolescent, or adult.

22. Under the influence of hormones secreted by the testes or ovaries, numerous additional sex-specific differences between male and female bodies continuously

develop postnatally, culminating in the dramatic maturation of the primary and secondary sex characteristics with puberty. These include differences in hormone levels, height, weight, bone mass, shape, musculature, internal organ size, body fat levels and distribution, and hair patterns, as well as physiological differences such as menstruation and ejaculation. These are genetically programmed biological consequences of sex—the actual meaning of sex over time. Among the consequences of sex is the evolution and consolidation of gender identity during childhood, adolescence, and adulthood.

23. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally defined sex. For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the trans individual to become "a complete man" or "a complete woman," this is not biologically attainable. (Levine 2018 at 6; Levine 2016 at 238.) It is possible for some adolescents and adults to pass unnoticed—that is, to be perceived by most individuals as a member of the gender that they aspire to be—but with limitations, costs, and risks, as I detail later.

B. Definition and diagnosis of gender dysphoria

24. Specialists have used a variety of terms over time, with somewhat shifting definitions, to identify and speak about a distressing incongruence between an individual's genetically determined sex and the gender with which they identify or to which they aspire. The American Psychiatric Association first used the term "gender identity disorder" in its *Diagnostic and Statistical Manual of Mental Disorders* in 1980 (DSM-III). The term "gender dysphoria" was introduced in the 2013 version of the DSM (DSM-5). Today's version of the DSM ("DSM-5-TR") defines gender dysphoria with separate sets of criteria for adolescents and adults on the one hand, and children on the other.

25. There are at least five distinct pathways to gender dysphoria: early childhood onset; onset near or after puberty with no prior cross gender patterns; onset after defining oneself as gay for several or more years and participating in a homosexual lifestyle; adult onset after years of heterosexual transvestism; and onset in later adulthood with few or no prior indications of crossgender tendencies or identity. (Levine 2021.)

26. Gender dysphoria has very different characteristics depending on age and sex at onset. Young children who are living a transgender identity commonly suffer materially fewer symptoms of concurrent mental distress than do older patients. (Zucker 2018 at 10.) The developmental and mental health patterns for each of these groups are sufficiently different that data developed in connection with one of these populations cannot be assumed to be applicable to another.

27. The criteria used in DSM-5-TR to identify Gender Dysphoria include a number of signs of discomfort

with one's natal sex and vary somewhat depending on the age of the patient, but in all cases require "clinically significant distress or impairment in . . . important areas of functioning" such as social, school, or occupational settings. The symptoms must persist for at least six months.

28. Children who conclude that they are transgender are often unaware of a vast array of adaptive possibilities for how to live life as a man or a woman—possibilities that become increasingly apparent over time to both males and females. A boy or a girl who claims or expresses interest in pursuing a transgender identity often does so based on stereotypical notions of femaleness and maleness that reflect constrictive notions of what men and women can be. (Levine 2017 at 7.) A young child's—or even an adolescent's—understanding of this topic is quite limited. Nor can they grasp what it may mean for their future to be sterile. (Levine et al, 2022.) These children and adolescents consider themselves to be relatively unique; they do not realize that discomfort with the body and perceived social role is neither rare nor new to civilization. What is new is that such discomfort is thought to indicate that they must be a trans person.

C. Impact of gender dysphoria on minority and vulnerable groups

29. Given that, as I discuss later, a diagnosis of gender dysphoria is now frequently putting even young children on a pathway that leads to irreversible physical changes and sterilization by young adulthood, it should be of serious concern to all practitioners that minority and vulnerable groups are receiving this diagnosis at disproportionately high rates. These include: children

of color (Rider et al. 2018), children with mental developmental disabilities (Reisner et al. 2015), children on the autistic spectrum (at a rate more than 7x the general population) (Shumer et al. 2016; van der Miesen et al. 2018), children with ADHD (Becerra-Culqui et al. 2018), children residing in foster care homes, adopted children (at a rate more than 3x the general population) (Shumer et al. 2017), victims of childhood sexual or physical abuse or other "adverse childhood events" (Thoma 2021 et al.; Newcomb et al. 2020; Kozlowska et al.,2021), children with a prior history of psychiatric illness (Edwards-Leeper et al. 2017; Kaltiala- Heino et al. 2015; Littman 2018), and more recently adolescent girls (in a large recent study, at a rate more than 2x that of boys) (Rider et al. 2018 at 4).

D. Three competing conceptual models of gender dysphoria and transgender identity

30. Discussions about appropriate responses by mental health professionals ("MHPs") to actual or subthreshold gender dysphoria are complicated by the fact that various speakers and advocates (or a single speaker at different times) view transgenderism through at least three very different paradigms, often without being aware of, or at least without acknowledging, the distinctions.

31. Gender dysphoria is **conceptualized and described by some professionals and laypersons as though it were a serious, physical medical illness that causes suffering**, comparable to diseases that are curable before it spreads, such as melanoma or sepsis. Within this paradigm, whatever is causing distress associated with gender dysphoria—whether secondary sex characteristics such as facial hair, nose and jaw shape, presence or ab-

sence of breasts, or the primary anatomical sex organs of testes, ovaries, penis, or vagina—should be removed to alleviate the illness. The promise of these interventions is the cure of the gender dysphoria.

32. Gender dysphoria is a psychiatric, not a medical, diagnosis. Since its inception in DSM-III in 1980, it has always been specified in the psychiatric DSM manuals and has not been specified in medical diagnostic manuals. Notably, gender dysphoria is the only psychiatric condition to be treated by surgery, even though no endocrine or surgical intervention package corrects any identified biological abnormality. (Levine 2016 at 240.)

33. Gender dysphoria is alternatively **conceptualized in developmental terms**, as an adaptation to a psychological problem that may have been first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans lives are not exceptions to this axiom. (Levine 2016 at 238.) MHPs who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply uncomfortable self or a sense of self impaired by later adversity or abuse. The purpose is to ameliorate suffering when the underlying problem cannot be solved. MHPs first work with the patient and (ideally) family to learn about the events and processes that may have led to the trans person repudiating the gender associated with his sex. The developmental paradigm is mindful of temperamental, parental bonding, psychological, sexual, and physical trauma influences, and the fact that young children work out their psychological issues through fantasy and play and adolescents work out

their issues by adopting various interests and identity labels.

34. There is evidence among adolescents that peer social influences through "friend groups" (Littman 2018) or through the internet can increase the incidence of gender dysphoria or claims of transgender identity. Responsible MHPs will want to probe these potential influences to better understand what is truly deeply tied to the psychology of the patient, and what may instead be being "tried on" by the youth as part of the adolescent process of self-exploration and self-definition. The dramatic recent increase in adolescents who do not identify as heterosexual is evidence of social influences in today's cultural environment.

35. In addition, the developmental paradigm recognizes that, with the important exception of genetic sex, essentially all aspects of an individual's identity evolve —often markedly—across the individual's lifetime. This includes gender. Some advocates assert that a transgender identity is biologically caused, fixed from early life, and eternally present in an unchanging manner. As I review later, however, this assertion is not supported by science.[1]

36. The third paradigm through which gender dysphoria is alternatively conceptualized is from **a sexual minority rights perspective**. Under this paradigm, any response other than medical and societal affirmation and implementation of a patient's claim to "be" the opposite gender is a violation of the individual's civil right

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[1] Even the advocacy organization The Human Rights Campaign asserts that a person can have "a fluid or unfixed gender identity." https://www.hrc.org/resources/glossary-of-terms.

to self-expression. Any effort to ask "why" questions about the patient's condition, or to address underlying causes, is viewed as a violation of autonomy and civil rights. In the last few years, this paradigm has been successful in influencing public policy and the education of pediatricians, endocrinologists, and many mental health professionals. Obviously, however, this is not a medical or psychiatric perspective. Unfortunately, it appears to be the most powerful perspective that exists in the public, non-scientific debate.

E. Four competing models of therapy

37. Few would disagree that the human psyche is complex. Few would disagree that children's and adolescents' developmental pathways typically have surprising twists and turns. The complexity and unpredictability of childhood and adolescent development equally applies to trans-identifying youth. Because of past difficulties of running placebo-controlled clinical trials in the transgender treatment arena, substantial disagreements among professionals about the causes of trans identities and their ideal treatments exist. These current disagreements might have been minimized if trans treated persons were carefully followed up to determine long term outcomes. They have not been. When we add this to the very different current paradigms for understanding transgender phenomena, it is not scientifically surprising that disagreements are sharply drawn. It is with this in mind that I summarize below the leading approaches, and offer certain observations and opinions concerning them.

(1) The "watchful waiting" therapy model

38. In Section V.A below I review the uniform finding of eleven follow-up studies that the large majority

of children who present with gender dysphoria will desist from desiring a transgender identity by adulthood if left untreated by social transition approaches.

39. When a pre-adolescent child presents with gender dysphoria, a "watchful waiting" approach seeks to allow for the fluid nature of gender identity in children to naturally evolve—that is, take its course from forces within and surrounding the child. Watchful waiting has two versions:

a. Treating any other psychological co-morbidities —that is, other mental illnesses as defined by DSM-5-TR (separation anxiety disorder, attention deficit hyperactivity disorder, autism spectrum disorder, obsessive compulsive disorder, etc), or subthreshold for diagnosis but behavioral problems that the child may exhibit (school avoidance, bedwetting, inability to make friends, aggression/defiance) without a focus on gender (**model #1**); and

b. No treatment at all for anything but a regular follow-up appointment. This might be labeled a "hands off" approach **(model #2)**.

(2) The psychotherapy model: Alleviate distress by identifying and addressing causes (model #3)

40. One of the foundational principles of psychotherapy has long been to work with a patient to identify the causes of observed psychological distress and then to address those causes as a means of alleviating the distress. The National Institute of Mental Health has promulgated the idea that 75% of adult psychopathology has its origins in childhood experience.

41. Many experienced practitioners in the field of gender dysphoria, including myself, have believed that

it makes sense to employ these long-standing tools of psychotherapy for patients suffering gender dysphoria, asking the question as to what factors in the patient's life are the determinants of the patient's repudiation of his or her natal sex. (Levine 2017 at 8; Spiliatis 2019; Levine 2021.Levine et al, 2022) I and others have reported success in alleviating distress in this way for at least some patients, whether the patient's sense of discomfort or incongruence with his or her natal sex entirely disappeared or not. Relieving accompanying psychological co-morbidities leaves the patient freer to consider the pros and cons of transition as he or she matures.

42. Among other things, the psychotherapist who is applying traditional methods of psychotherapy may help—for example—the male patient to appreciate the wide range of masculine emotional and behavioral patterns as he grows older. He may discuss with his patient, for example, that one does not have to become a "woman" to be kind, compassionate, caring, noncompetitive, to love the arts, and to be devoted to others' feelings and needs. (Levine 2017 at 7.) Many biologically male trans individuals, from childhood to older ages, speak of their perceptions of femaleness as enabling them to discuss their feelings openly, whereas they perceive boys and men to be constrained from emotional expression within the family and larger culture, and to be aggressive. Men, of course, can be emotionally expressive, just as they can wear pink. Converse examples can be given for girls and women. These types of ideas regularly arise during psychotherapies.

43. As I note above, many gender-nonconforming children and adolescents in recent years derive from minority and vulnerable groups who have reasons to feel

isolated and have an uncomfortable sense of self. A trans identity may be a hopeful attempt to redefine the self in a manner that increases their comfort and decreases their anxiety. The clinician who uses traditional methods of psychotherapy may not focus on their gender identity, but instead work to help them to address the actual sources of their discomfort. They may enable the patient to understand the commonality of discomfort with the body's physiology, the growth process, and the struggle to accept oneself during the pubertal developmental process. Patients need to understand that this discomfort with one's body, per se, and one's attractiveness relative to others, typically lasts for several or more years. Success in this effort may remove or reduce the desire for a redefined identity. This often involves a focus on disruptions in their attachment to parents in vulnerable children, for instance, those in the foster care system.

44. Because "watchful waiting" can include treatment of accompanying psychological co-morbidities, and the psychotherapist who hopes to relieve gender dysphoria may focus on potentially causal sources of psychological distress rather than on the gender dysphoria itself, there is no sharp line between "watchful waiting" and the psychotherapy model in the case of prepubescent children.

45. To my knowledge, there is no evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents, and women. On the other hand, anecdotal evidence of such outcomes does exist; I and other clinicians have witnessed reinvestment in the patient's biological sex in some individ-

ual patients who are undergoing psychotherapy. The Internet contains many such reports, and I have published a paper on a patient who sought my therapeutic assistance to reclaim his male gender identity after 30 years living as a woman and is in fact living as a man today. (Levine 2019.) I have seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist. There are now a series of articles and at least one major book on the psychological treatment of adolescents. (D'Angelo et al. 2021 at 7-16; Evans & Evans 2021.) Among detransitioners, a large percentage express regret that their affirmative therapists did not recommend psychotherapy before encouraging hormonal treatment (*Littman, (2021). Individuals treated for gender dysphoria with medical and/or surgical transition who subsequently detransitioned: A survey of 100 detransitioners. Archives of Sexual Behavior, 50(8)3353-3369). Exposito-Campos pointed out the large amount reports on detransition and the far greater traffic on various nonprofessional websites (Exposito-Campos, 2021).*

(3) The affirmation therapy model (model #4)

46. While it is widely agreed that the therapist should not directly challenge a claimed transgender identity in a child, some advocates and practitioners go much further, and promote and recommend that any expression of transgender identity should be immediately accepted as decisive, and thoroughly affirmed by means of consistent use of clothing, toys, pronouns, etc., associated with transgender identity. They argue that the child should be comprehensively resocialized in grade school or junior or senior high school in their aspired-to gender. As I understand it, this is asserted as a reason

why male students who assert a female gender identity must be permitted to compete in girls' or women's athletic events. These advocates treat any question about the causes of the child's transgender identification as inappropriate. They may not recognize the child's ambivalence. They assume that observed psychological comorbidities in the children or their families are unrelated or will get better with transition, and need not be addressed by the MHP who is providing supportive guidance concerning the child's gender identity.

47. Some advocates, indeed, assert that unquestioning affirmation of any claim of transgender identity in children is essential, and that the child will otherwise face a high risk of suicide or severe psychological damage. This claim is simply not supported by the clinical data we have available to us. Indeed, available long-term data contradicts this claim. I address physical and mental health outcomes in Section VII below, and suicide in Section VIII below.

48. The commonly referenced scientific basis for affirmative care of both early life onset and adolescent onset gender dysphoria are two reports from deVries et al (2011, 2014) that seemingly demonstrated the resolution of gender dysphoria after a sequence of puberty blocking hormones, cross-sex hormones, and breast removal or vaginoplasty. However, recently three articles describing the distinct limitations of the "Dutch Protocol" have been widely circulating throughout the world. (Levine et al, 2022; Biggs, 2022, Abbruzzese et al, 2023). It is now apparent that the basis for such affirmative care is not scientifically solid. Rapid diffusion of the innovative Dutch Protocol occurred without the scientifically required confirmatory more rigorous studies. The one attempt to repeat their protocol in the UK failed to

demonstrate psychological benefits claimed by the Dutch studies. (Carmichael et al 2021).

49. I do not know what proportion of practitioners are using which model. However, in my opinion, in the case of young children, prompt and thorough affirmation of a transgender identity disregards the principles of child development and family dynamics and is not supported by science. Instead of science, this approach is currently being reinforced by an echo-chamber of approval from other like-minded child-oriented professionals who do not sufficiently consider the known negative medical and psychiatric outcomes of trans adults. Rather than recommend social transition in grade school, the MHP must focus attention on the child's underlying internal and familial issues. Ongoing relationships between the MHP and the parents, and the MHP and the child, are vital to help the parents, child, other family members, and the MHP to understand over time the issues that need to be dealt with by each of them.

50. Likewise, since the child's sense of gender develops in interaction with his parents and their own gender roles and relationships, the responsible MHP will almost certainly need to delve into family and marital dynamics. This, however, requires time and effort and for many parents, a challenge to find a therapist to do such work with them.

IV. THERE IS NO CONSENSUS OR AGREED "STANDARD OF CARE" CONCERNING THERAPEUTIC APPROACHES TO CHILD OR ADOLESCENT GENDER DYSPHORIA.

51. There is far too little firm clinical evidence in this field to permit any evidence-based standard of care. Given the lack of scientific evidence, it is neither sur-

prising nor improper that—as I detailed in Section II—there is a diversity of views among practitioners as to the best therapeutic response for the child, adolescent, or young adult who suffers from gender dysphoria.

52. Reviewing the state of opinion and practice in 2021, the Royal Australian and New Zealand College of Psychiatrists observed that "There are polarised views and mixed evidence regarding treatment options for people presenting with gender identity concerns, especially children and young people." (RANZCP, 2021.) Similarly, a few years earlier prominent Dutch researchers noted: "[T]here is currently no general consensus about the best approach to dealing with the (uncertain) future development of children with GD, and making decisions that may influence the function and/or development of the child—such as social transition." (Ristori & Steensma 2016 at 18.)[2] In this Section, I comment on some of the more important areas of disagreement within the field.

A. Experts and organizations disagree as to whether "distress" is a necessary element for diagnoses that justifies treatment for gender identity issues.

53. As outlined in Section II.B above, "clinically significant distress" is one of the criteria used in DSM-5 to identify gender dysphoria. This indicates a heightened level of distress that rises beyond a threshold level of social awkwardness or discomfort with the changing body. It is known that many trans-identified youth with incongruence between their sexed bodies and their gen-

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[2] *See also* Zucker 2020 which questions the merit of social transition as a first-line treatment.

der identity choose not to take hormones; their incongruence is quite tolerable as they further clarify their three elements of sexual identity—gender identity, orientation, and intention (what the person wants to do with a partners body during sex and what that person wants to do to their own body to be aroused). This population raises the questions of what distress is being measured when DSM-5-TR criteria are met and what else might be done about it. However, there is no "clinically significant distress" requirement in World Health Organization's International Classification of Diseases (ICD-11) criteria for gender incongruence, which rather indicates "a marked and persistent incongruence between an individual's experienced gender and the assigned sex." (World Health Organization 2019.)

54. Therefore, even between these two committee-based authorities, there is a significant disagreement as to what constitutes a gender condition justifying life-changing interventions. To my knowledge, some American gender clinics and practitioners are essentially operating under the ICD-11 criteria rather than the DSM-5-TR criteria, prescribing transition for children, hormonal interventions for slightly older children, and different hormones for adolescents who assert a desire for a transgender identity whether or not they are exhibiting "clinically significant distress." Others adhere to the DSM-5 diagnostic standard.

55. It is ironic that affirmative care is said by advocates to be life enhancing and often to be lifesaving because of the risk of suicide. Based on the DSM-5-TR criterion, distress is required for the diagnosis and its subsequent hormonal and surgical treatments. Gender incongruence is often referred to as a unique form of suffering. Yet, ICD-11 the criteria for the diagnosis of

Gender Inco7ngruence do not require distress, just the wish to have the characteristics of the other sex and to change their own sex demarcating features. It seems that as the field moves on in time, the emphasis is on desire rather than distress, pain, or suffering. The intense suffering required for the diagnosis of this former "medical disorder" has now become "this is not a disorder at all, and people should be given what they desire, whether or not they are distressed or whether their functioning is impaired."

56. I will add that even from within one "school of thought," it is not responsible to make a single, categorical statement about the proper treatment of children or adolescents presenting with gender dysphoria or other gender-related issues. There is no single pathway to the development of a trans identity and no reasonably uniform short- or long-term outcome of medically treating it. As individuals grow physically, mature psychologically, and experience or fail to experience satisfying romantic relationships, their life course depends on their differing psychological, social, familial, and life experiences. There should be no trust in assertions that trans identified youth must be treated in a particular manner to avoid harm for two reasons. First, there is no systematic data on the nature of, and the rate of harms of either affirmative treatment, no treatment, or psychological only treatment. Second, as in other youthful psychiatric and other challenges, outcomes vary. There is no psychiatric condition—depression, anxiety, schizophrenia—where one size fits all.

B. Opinions and practices vary widely about the utilization of social transition for children and adolescents.

57. The World Professional Association for Transgender Health (WPATH) has published a guidance document under the title "Standards of Care." Below, I will provide some explanation of WPATH and its "Standards of Care," which are not the product of a strictly scientific organization, and they are by no means accepted by all or even most practitioners as setting out best practices.

58. Here, however, I will note that WPATH does not take a position concerning whether or when social transition may be appropriate for pre-pubertal children. Instead, the WPATH "Standards of Care version 7" states that the question of social transition for children is a "controversial issue" and calls for mental health professionals to support families in what it describes as "difficult decisions" concerning social transition. Its version 8, however, no longer uses the word "controversial" even though it extensively discusses the dangers of harms versus the possibility of benefits of early transition (Coleman et al, 2022.)

59. Dr. Erica Anderson is a prominent practitioner in this area who identifies as a transgender woman, who was the first transgender president of USPATH, and who is a former board member of WPATH. Dr. Anderson recently resigned from those organizations and has condemned automatic approval of transition upon the request of a child or adolescent, noting that "adolescents . . . are notoriously susceptible to peer influence," that transition "doesn't cure depression, doesn't cure anxiety disorders, doesn't cure autism-spectrum

disorder, doesn't cure ADHD," and instead that "a comprehensive biopsychosocial evaluation" should proceed allowing a child to transition. (Davis 2022.) And as I have explained previously, my own view based on 50 years of experience in this area favors strong caution before approving life-altering interventions such as social transition, puberty blockers, or cross-sex hormones.

C. The WPATH "Standards of Care" is not an impartial or evidence-based document.

60. Because WPATH is frequently cited by advocates of social, hormonal, and surgical transition, I provide some context concerning that private organization and its "Standards of Care." WPATH insists its guidance is evidence-based. But its reviews of the evidence strikingly omit evidence to the contrary. This renders it unbalanced or biased and not in keeping with the traditions of respected clinical science.

61. I was a member of the Harry Benjamin International Gender Dysphoria Association from 1974 until 2001. From 1997 through 1998, I served as the Chairman of the eight-person International Standards of Care Committee that issued the fifth version of the Standards of Care. I resigned my membership in 2002 due to my regretful conclusion that the organization and its recommendations had become dominated by politics and ideology, rather than by scientific process, as it was years earlier. In approximately 2007, the Harry Benjamin International Gender Dysphoria Association changed its name to the World Professional Association for Transgender Health (WPATH).

62. WPATH is a voluntary membership organization. Since at least 2002, attendance at its biennial

meetings has been open to trans individuals who are not licensed professionals. While this ensures taking patients' needs into consideration, it limits the ability for honest and scientific debate, and means that WPATH can no longer be considered a purely professional organization. Its associate members are not health care professionals. The later have various medical specialties, various mental health degrees, and varying experience and approaches to caring for these patients.

63. WPATH takes a decided view on issues as to which there is a wide range of opinion among professionals. WPATH explicitly views itself as not merely a scientific organization, but also as an advocacy organization. (Levine 2016 at 240.) WPATH is supportive to those who want sex reassignment surgery ("SRS"). Skepticism as to the benefits of SRS to patients, and strong alternate views, are not well tolerated in discussions within the organization or their educational outreach programs. Such views have been known to be shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings. Two groups of individuals that I regularly work with have attended recent and separate WPATH continuing education sessions. There, questions about alternative approaches were quickly dismissed with "There are none. This is how it is done." Such a response does not accurately reflect what is known, what is unknown, and the diversity of clinical approaches in this complex field.

64. The reviews of WPATH's 7th edition of standards of care published in 2021 by Dahlen et al and Sapir in 2022 have clarified the low quality, low reliability, and bias inherent in its recommendations. (Dahlen et al 2022.) Its 8th edition, which is three times the length of

the 7th, has not gained additional confidence in its scientific merit. The Standards of Care ("SOC") document is the product of an effort to be balanced, but it is not politically neutral. WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. It articulates policy. These aspirations sometimes conflict. The limitations of the Standards of Care, however, are not primarily political. They are caused by the lack of rigorous research in the field, which allows room for passionate convictions on how to care for the transgendered. And, of course, once individuals have socially, medically, and surgically transitioned, WPATH members and the trans people themselves at the meetings are committed to supporting others in their transitions. Not only have some trans participants been distrustful or hostile to those who question the wisdom of these interventions, their presence makes it difficult for professionals to raise their concerns. Vocal trans rights advocates have a worrisome track record of attacking those who have alternative views. (Dreger 2015; McNamarra, et al 2022.)

65. In recent years, WPATH has fully adopted some mix of the medical and civil rights paradigms. It has downgraded the role of counseling or psychotherapy as a requirement for these life-changing processes. WPATH no longer considers preoperative psychotherapy to be a requirement. It is important to WPATH that the person has gender dysphoria; but the pathway to the development of this state is not. (Levine 2016 at 240.) The trans person is assumed to have thoughtfully considered his or her options before seeking hormones, for instance. In actual practice, that thoughtful person may be as young as age 11!

66. Most psychiatrists and psychologists who treat patients suffering sufficiently severe distress from gender dysphoria to seek inpatient psychiatric care are not members of WPATH. Many psychiatrists, psychologists, and pediatricians who treat some patients suffering gender dysphoria on an outpatient basis are not members of WPATH. WPATH represents a self-selected subset of the profession along with its many non-professional members; it does not capture the clinical experiences of others. WPATH claims to speak for the medical profession; however, it does not welcome skepticism and therefore, deviates from the philosophical core of medical science. There are pediatricians, psychiatrists, endocrinologists, and surgeons who object strongly, on professional grounds, to transitioning children and providing affirmation in a transgender identity as the first treatment option. WPATH does not speak for all of the medical profession.

67. In 2010 the WPATH Board of Directors issued a statement advocating that incongruence between sex and felt gender identity should cease to be identified in the DSM as a pathology.[3] This position was debated but not adopted by the (much larger) American Psychiatric Association, which maintained the definitions and diagnoses of gender dysphoria as a pathology in the DSM-5 manual issued in 2013.

68. In my experience some current members of WPATH have little ongoing experience with the mentally ill, and many trans care facilities are staffed by MHPs who are not deeply experienced with recognizing and treating frequently associated psychiatric comor-

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[3] WPATH *De-Psychopathologisation Statement* (May 26, 2010), available at wpath.org/policies (last accessed January 21, 2020).

bidities. Further, being a mental health professional, per se, does not guarantee experience and skill in recognizing and effectively intervening in serious or subtle patterns. Because the 7th version of the WPATH SOC deleted the requirement for therapy, trans care facilities that consider these Standards sufficient are permitting patients to be counseled to transition by means of social presentation, hormones, and surgery by individuals with masters rather than medical degrees. The 8th version of the SOC continues this tradition. When this document recommends a comprehensive psychiatric evaluation, it fails to elaborate its duration, the topics to be covered, and necessary treatment results of the commonly found previous and co-current psychiatric conditions. It emphasizes the test the evaluation; it does not emphasize what to do with the identified problems, other than to state that they must be under reasonable control. Policy statements are one thing, but how those policies are implemented is another.

D. Opinions and practices differ widely with respect to the proper role of psychological counseling before, as part of, or after a diagnosis of gender dysphoria.

69. In Version 7 of its Standards of Care, released in 2012, WPATH downgraded the role of counseling or psychotherapy, and the organization no longer sees psychotherapy without transition and hormonal interventions as a potential path to eliminate gender dysphoria by enabling a patient to return to or achieve comfort with the gender identity aligned with his or her biology. Around the world, many prominent voices and practitioners disagree. For example, renowned gender therapists Dr. Laura Edwards-Leeper and Dr. Erica Anderson (who, as mentioned above, identifies as a

transgender woman) have recently spoken out arguing that children and adolescents are being subjected to puberty blockers and hormonal intervention far too quickly, when careful and extended psychotherapy and investigation for potential causes of feelings of dysphoria (such as prior sexual abuse) should be the first port of call and might resolve the dysphoria. (Edwards-Leeper & Anderson 2021; Davis 2022.)

70. In a recently published position statement on gender dysphoria, the Royal Australian and New Zealand College of Psychiatrists emphasized the critical nature of mental health treatment for gender dysphoric minors, stressing "the importance of the psychiatrist's role to undertake thorough assessment and evidence-based treatment ideally as part of a multidisciplinary team, especially highlighting co-existing issues which may need addressing and treating." The Royal College also emphasized the importance of assessing the "psychological state and context in which Gender Dysphoria has arisen," before any treatment decisions are made. (RANZCP, 2021.)

71. Dr. Paul Hruz of the University of Washington St. Louis Medical School has noted, "The WPATH has rejected psychological counseling as a viable means to address sex–gender discordance with the claim that this approach has been proven to be unsuccessful and is harmful. (Coleman et al. 2012.) Yet the evidence cited to support this assertion, mostly from case reports published over forty years ago, includes data showing patients who benefited from this approach (Cohen-Kettenis and Kuiper 1984)." (Hruz 2020.)

72. In several recent publications, my colleagues and I have demonstrated that both the Endocrine Society's

and WPATH's citations for the scientific basis of affirmative care of adolescents reference the same two Dutch studies. We have demonstrated in considerable detail the limitations of these studies, their lack of applicability to today's transgendered youth, and the dangers of following therapeutic fashion rather than evidence-based medicine. (Levine et al, 2022; Abbruzzese et al, 2023.)

E. Opinions and practices vary widely with respect to the administration of puberty blockers and cross-sex hormones.

73. There is likewise no broadly accepted standard of care with respect to use of puberty blockers. The WPATH Standards of Care explicitly recognize the lack of any consensus on this important point, stating: "Among adolescents who are referred to gender identity clinics, the number considered eligible for early medical treatment—starting with GnRH analogues to suppress puberty in the first Tanner stages—differs among countries and centers. Not all clinics offer puberty suppression . . . The percentages of treated adolescents are likely influenced by the organization of health care, insurance aspects, cultural differences, opinions of health professionals, and diagnostic procedures offered in different settings."

74. The use of puberty blockers as a therapeutic intervention for gender dysphoria is often justified by reference to the seminal work of a respected Dutch research team that developed a protocol that administered puberty blockers to children no younger than age 14. However, it is well known that many clinics in North America now administer puberty blockers to children at much younger ages than the "Dutch Protocol" allows.

(Zucker 2019.) The Dutch protocol only treated children with these characteristics: a stable cross gender identity from early childhood; dysphoria that worsened with the onset of puberty; were otherwise psychologically healthy; had healthy families; the patient and family agreed to individual and family counselling throughout the protocol. But the experience and results of the Dutch model is being used as a justification for giving puberty blockers to children who differ considerably from these criteria. Its authors have also recently noted this fact (de Vries 2020).

75. However, Zucker notes that "it is well known" that clinicians are administering cross-sex hormones, and approving surgery, at ages lower than the minimum age thresholds set by that "Dutch Protocol." (Zucker 2019 at 5.)

76. Similarly, at least one prominent clinic—that of Dr. Safer at Columbia's Mt. Sinai Medical Center—is quite openly admitting patients even for *surgical* transition who are not eligible under the criteria set out in WPATH's Standards of Care. A recent study published by Dr. Safer and colleagues revealed that of a sample of 139 individuals, 45% were eligible for surgery "immediately" under the center's own criteria, while only 15% were eligible under WPATH's criteria. That is, *three times* as many patients immediately qualified for surgery under the center's loose standards than would have qualified under WPATH criteria. (Lichenstein et al. 2020.)

77. Internationally, there has been a recent marked trend *against* use of puberty blockers, as a result of extensive evidence reviews by national medical bodies, which I discuss later. The main gender clinic in Sweden

has declared that it will no longer authorize use of puberty blockers for minors below the age of 16. Finland has similarly reversed its course, issuing new guidelines that allow puberty blockers only on a case-by-case basis after an extensive psychiatric assessment. A landmark legal challenge against the UK's National Health Service in 2020 by "detransitioner" Keira Bell led to the suspension of the use of puberty blockers and new procedures to ensure better psychological care, as well as prompting a thorough evidence review by the National Institute for Health and Care Excellence (NICE 2021a; NICE 2021b).[4] That review in 2022 reorganized trans adolescent care throughout the UK and emphasized the need to focus on the patients' psychological state rather than treat first the gender incongruence. Puberty blockers are not to be initially employed.

78. In this country, some voices in the field are now publicly arguing that *no* comprehensive mental health assessment at all should be required before putting teens on puberty blockers or cross-sex hormones (Ghorayshi 2022), while Dr. Anderson and Dr. Edwards-Leeper argue that U.S. practitioners are already moving too quickly to hormonal interventions. (Edwards-Leeper & Anderson 2021; Davis 2022.) It is evident that opinions and practices are all over the map.

79. In 2018, committee of the American Academy of Pediatricians issued a policy statement supporting administration of puberty blockers to children diagnosed with gender dysphoria. No other American medical as-

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[4] The decision requiring court approval for administration of hormones to any person younger than age 16 was later reversed on procedural grounds by the Court of Appeal and is currently under consideration by the UK Supreme Court.

sociation has endorsed the use of puberty blockers. Pediatricians are neither endocrinologists nor psychiatrists. Many pediatricians were horrified by the recommendation. Dr. James Cantor published a peer-reviewed paper detailing that the Academy's statement was not evidence-based and misdescribed the few scientific sources it did reference. (Cantor 2019.) It has been well noted in the field that the AAP has declined invitations to publish any rebuttal to Dr. Cantor's analysis. But this is all part of ongoing debate, simply highlighting the absence of any generally agreed standard of care. In 2022, the same committee of the AAP modified their recommendation supporting alternative treatments but still held out that affirmative care is still a viable option. Evidence after all is required for policy decisions and the 2018 evidence base is now widely appreciated as insubstantial. Nonetheless, the 2018 policy, now softened considerably, is what is quoted as "social transition is supported by the American Academy of Pediatrics." No mention is made of the many pediatricians who find this policy to be dangerous.

80. The 2017 Endocrine Society Guidelines themselves expressly state that they are *not* "standards of care." The document states: "The guidelines cannot guarantee any specific outcome, *nor do they establish a standard of care*. The guidelines are not intended to dictate the treatment of a particular patient." (Hembree et al. 2017 at 3895 (emphasis added).) Nor do the Guidelines claim to be the result of a rigorous scientific process. Rather, they expressly advise that their recommendations concerning use of puberty blockers are based only on "low quality" evidence.

81. The 2017 Guidelines assert that patients with gender dysphoria often must be treated with "a safe and

effective hormone regimen . . . " Notably, however, the Guidelines do not make any firm statement that use of puberty blockers for this purpose *is* safe, and the Guidelines go no further than "suggest[ing]" use of puberty blockers—language the Guidelines warn represents only a "weak recommendation." (Hembree 2017 at 3872.) Several authors have pointed out that not only were the Endocrine Society suggestions regarding use of puberty blockers reached on the basis of "low quality" evidence, but its not-quite claims of 'safety' and 'efficacy' are starkly contradicted by several in-depth evidence reviews. (Laidlaw et al., 2019; Malone et al. 2021.) The most recent systematic independent reviews of hormonal treatment of adolescents reaffirmed the poor quality of evidence making their use questionable (Brignardello-Peterson, & Wiercioch 2022; Ludviggsson et al, 2023). I detail these contradictory findings in more detail in Section VII below.

82. While there is too little meaningful clinical data and no consensus concerning best practices or a "standard of care" in this area, there are long-standing ethical principles that do or should bind all medical and mental health professionals as they work with, counsel, and prescribe for these individuals.

83. One of the oldest and most fundamental principles guiding medical and psychological care—part of the Hippocratic Oath—is that the physician must "do no harm." This states an ethical responsibility that cannot be delegated to the patient. Physicians themselves must weigh the risks of treatment against the harm of not treating. If the risks of treatment outweigh the benefits, principles of medical ethics prohibit the treatment.

V. TRANSGENDER IDENTITY IS NOT BIOLOGICALLY BASED.

84. There is no medical consensus that transgender identity has any biological basis. Furthermore, there is considerable well-documented evidence that is inconsistent with the hypothesis of a biological basis for gender identity—at least in the large majority of currently-presenting patients.

A. No theory of biological basis has been scientifically validated.

85. At the outset, the attempt to identify a single, biological cause for psychiatric conditions (including gender dysphoria) has been strongly criticized as "out of step with the rest of medicine" and as a lingering "ghost" of an understanding of the nature of psychiatric conditions that is now broadly disproven. (Kendler 2019 at 1088-1089.) Gender dysphoria is defined and diagnosed only as a psychiatric, not a medical, condition. Courts need to have clarified that just because some physicians use medication and surgery to treat gender dysphoria does not make it a "medical condition" or that the psychological identity has been determined by a biological mechanism.

86. While some have pointed to very small brain scan studies as evidence of a biological basis, no studies of brain structure of individuals identifying as transgender have found any statistically significant correlation between any distinct structure or pattern and transgender identification, after controlling for sexual orientation and exposure to exogenous hormones. (Sarawat et al. 2015 at 202; Frigerio et al. 2021.)

87. Indeed, the Endocrine Society 2017 Guidelines recognizes: "With current knowledge, we cannot predict the psychosexual outcome for any specific child," and "there are currently no criteria to identify the GD/gender-incongruent children to whom this applies. At the present time, clinical experience suggests that persistence of GD/gender incongruence can only be reliably assessed after the first signs of puberty." (Hembree et al. 2017 at 3876.)

88. In short, no biological test or measurement has been identified that provides any ability to predict which children will exhibit, and which children will persist in, gender dysphoria or a transgender identification. Unless and until such a test is identified, the theory of a biological basis is a hypothesis still searching for support. A hypothesis is not a fact, and responsible scientists will not confuse the two. It should be noted that employing the belief in biological determinism of gender dysphoria eases a doctor's ethical qualms about changing the body to fit the current state of a patient's mind. These doctors may consider themselves fixing a mistake of nature as they would when repairing a cleft palate or providing cortisone to a child whose adrenal glands' function is insufficient.

B. Large changes across time and geography in the epidemiology of transgender identification are inconsistent with the hypothesis of a biological basis for transgender identity.

89. In fact, there is substantial evidence that the "biological basis" theory is incorrect, at least with respect to the large majority of patients presenting with gender dysphoria today.

90. **Vast changes in incidence:** Historically, there were very low reported rates of gender dysphoria or transgender identification. In 2013, the DSM-5 estimated the incidence of gender dysphoria in adults to be at 2-14 per 100,000, or between 0.002% and 0.014%. (APA 2013 at 454.) Recently however, these numbers have increased dramatically, particularly in adolescent populations. Recent surveys estimate that between 2-9% of high school students self- identify as transgender or "gender non-conforming." with a significantly large increase in adolescents claiming "nonbinary" gender identity as well. (Johns et al. 2019; Kidd et al. 2021.) Consistent with these surveys, gender clinics around the world have seen numbers of referrals increase rapidly in the last decade, with the Tavistock clinic in London seeing a 30-fold increase in the last decade (GIDS 2019), and similar increases being observed in Finland (Kaltiala-Heino et al. 2018), the Netherlands (de Vries 2020), and Canada (Zucker 2019). The rapid change in the number of individuals experiencing gender dysphoria points to social and cultural, not biological, causes.

91. **Large change in sex ratio:** In recent years there has been a marked shift in the sex ratio of patients presenting with gender dysphoria or transgender identification. The Tavistock clinic in London saw a ratio of 4 biological females(F):5 biological males(M) shift to essentially 11F:4M in a decade. (GIDS 2019.) One researcher summarizing multiple sources documented a swing of 1F:2M or 1F:1.4M through 2005 to 2F:1M generally (but as high as 7F:1M) in more recent samples. (Zucker 2019 at 2.) This phenomenon has been noted by Dr. Erica Anderson, who said: "The data are very clear that adolescent girls are coming to gender clinics in greater proportion than adolescent boys. And this is a

change in the last couple of years. And it's an open question: What do we make of that? We don't really know what's going on. And we should be concerned about it." (Davis 2022.) Again, this large and rapid change in who is experiencing gender dysphoria points to social, not biological, causes.

92. **Clustering:** Dr. Littman's recent study documented "clustering" of new presentations of gender dysphoria among natal females in specific schools and among specific friend groups. This again points strongly to social causes for gender dysphoria at least among the adolescent female population. (Littman 2018.)

93. **Desistance:** As I discuss later, there are very high levels of desistance among children diagnosed with gender dysphoria, as well as increasing (or at least increasingly vocal) numbers of individuals who first asserted a transgender identity during or after adolescence, underwent substantial medical interventions to "affirm" that trans-identity, and then "desisted" and reverted to a gender identity congruent with their sex. (See Section V.B below.) These narratives, too, point to a social and/or psychological cause, rather than a biological one.

94. **"Fluid" gender identification:** Advocates and some practitioners assert that gender identity is not binary but can span an almost endless range of gender identity self-labels, which a given individual may try on, inhabit, and often discard. (A recent article identifies 72.[5]) I have not heard any theory offered for how there

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[5] Allarakha, *What Are the 72 Other Genders?*, MedicineNet, available at: https://www.medicinenet.com/what_are_the_72_other_genders/article.html.

is or could be a biological basis for gender identity as now expansively defined.

95. I frequently read attempts to explain away the points in this Section V. They include: these problems always existed, but children are now learning that there are effective treatments for their dilemma and are simply seeking them. And children have hidden their transidentity throughout childhood and now that trans people are recognized and accepted, they are presenting themselves. And now pediatricians realize that girls can have gender dysphoria and are referring them to gender clinics. But these are all mere hypotheses unsupported by concrete evidence. One set of unproven hypotheses cannot provide support for the unproven hypothesis of biological basis. And none of these hypotheses could even potentially explain the failure of science thus far to identify any predictive biological marker of transgender identification. There is much sociological evidence that in the last decade, increasing numbers of adolescents are identifying as something other than heterosexual. Biological phenomena do not evolve suddenly.

96. **Therapies affect gender identity outcomes:** Finally, the evidence shows that therapeutic choices can have a powerful effect on whether and how gender identity does change, or gender dysphoria desists. Social transition of juveniles, for instance, strongly influences gender identity outcomes to such an extent that it has been described a "unique predictor of persistence." (See Section VI.B below.) Again, this observation cuts against the hypothesis of biological origin.

C. Disorders of sexual development (or DSDs) and gender identity are very different phenomena, and it is an error to conflate the two.

97. Some have pointed to individuals who suffer from disorders of sexual development (DSDs) as evidence that sex is not binary or clearly defined, or as somehow supporting the idea that transgender identification has a biological basis. I have extensively detailed that sex is clear, binary, and determined at conception. (Section III.) Here I explain that gender dysphoria is an entirely different phenomenon than DSDs—which unlike transgender identity are indeed biological phenomena. It is an error to conflate the two distinct concepts.

98. Every DSD reflects a genetic enzymatic defect with negative anatomic and physiological consequences. As the Endocrine Society recognized in a 2021 statement: "Given the complexities of the biology of sexual determination and differentiation, it is not surprising that there are dozens of examples of variations or errors in these pathways associated with genetic mutations that are now well known to endocrinologists and geneticists; in medicine, these situations are generally termed *disorders of sexual development* (DSD) or *differences in sexual development*." Gender Identity on the other hand is uniformly defined as a subjective "sense" of being, a feeling or state of mind. (Section II.C.)

99. The vast majority of those who experience gender dysphoria, or a transgender identity, do not suffer from any DSD, nor from any genetic enzymatic disorder at all. Conversely, many who suffer from a DSD do not experience a gender identity different from their chromosomal sex (although some may). In short, those who suffer from gender dysphoria are not a subset of those

who suffer from a DSD, nor are those who suffer from a DSD a subset of those who suffer from gender dysphoria. The two are simply different phenomena, one physical with psychological effects, the other mental with physical effects only if treated medically or surgically. The issue here is not whether biological forces play a role in personality development; it is whether there is strong evidence that it is determinative. Science has come too far to revert to single explanations for gender dysphoria or any psychiatric diagnosis.

100. The importance of this distinction is evident from the scientific literature. For example, in a recent study of clinical outcomes for gender dysphoric patients, Tavistock Clinic researchers *excluded* from their analysis any patients who did not have "normal endocrine function and karyotype consistent with birth registered sex." (Carmichael et al. 2021 at 4.) In other words, the researchers specifically *excluded* from their study anyone who suffered from genetic-based DSD, or a DSD comprising any serious defect in hormonal use pathways, to ensure the study was focused only on individuals experiencing the psychological effects of what we might call "ordinary" gender dysphoria.

D. Studies of individuals born with DSDs suggest that there may be a biological predisposition towards *typical* gender identifications, but they provide no support for a biological basis for *trans*gender identification.

101. Studies of individuals born with serious DSDs have been pointed to as evidence of a biological basis for transgender identification. They provide no such support.

102. One well-known study by Meyer-Bahlburg reviewed the case histories of a number of XY (i.e. biologically male) individuals born with severe DSDs who were surgically "feminized" in infancy and raised as girls. (Meyer-Bahlburg 2005.) The majority of these individuals nevertheless later adopted male gender identity—suggesting a strong biological predisposition towards identification aligned with genetic sex, even in the face of feminized genitalia from earliest childhood, and parental "affirmation" in a transgender identity. But at the same time, the fact that some of these genetically male individuals did *not* later adopt male gender identity serves as evidence that medical and social influences can indeed encourage and sustain transgender identification.

103. Importantly, the Meyer-Bahlburg study did *not* include any individuals who were assigned a gender identity congruent with their genetic sex who subsequently adopted a *trans*gender identity. Therefore, the study can provide no evidence of any kind that supports the hypothesis of a biological basis for *trans*gender identity. A second study in this area (Reiner & Gearhart 2004) likewise considered exclusively XY subjects, and similarly provides evidence only for a biological bias towards a gender identity congruent with one's genetic sex, even in the face of medical and social "transition" interventions. None of this provides any evidence at all of a biological basis for transgender identity.

VI. GENDER IDENTITY IS EMPIRICALLY NOT FIXED FOR MANY INDIVIDUALS.

104. There is extensive evidence that gender identity changes over time for many individuals.[6] That evidence is summarized below.

A. Most children who experience gender dysphoria ultimately "desist" and resolve to cisgender identification.

105. A distinctive and critical characteristic of juvenile gender dysphoria is that multiple studies from separate groups and at different times have reported that in the large majority of patients, absent a substantial intervention such as social transition or puberty blocking hormone therapy, it does *not* persist through puberty.

106. A recent article reviewed all existing follow-up studies that the author could identify of children diagnosed with gender dysphoria (11 studies) and reported that "every follow-up study of GD children, without exception, found the same thing: By puberty, the majority of GD children ceased to want to transition." (Cantor 2019 at 1.) Another author reviewed the existing studies and reported that in "prepubertal boys with gender discordance . . . the cross gender wishes usually fade over time and do not persist into adulthood, with only 2.2% to 11.9% continuing to experience gender discordance." (Adelson et al. 2012 at 963; see also Cohen-Kettenis 2008 at 1895.) The Endocrine Society recognized this important baseline fact in its 2017 Guidelines. (Hembree 2017 at 3879.) It should be noted that the reason that the Dutch Protocol waited until age 14 to

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[6] See n1 *supra*.

initiate puberty blockers was that it was well known that many children would desist if left free of hormonal intervention until that age.

107. Findings of high levels of desistance among children who experience gender dysphoria or incongruence have been reaffirmed in the face of critiques through thorough reanalysis of the underlying data. (Zucker 2018.)

108. As I explained in detail in Section V above, it is not yet known how to distinguish those children who will desist from that small minority whose trans identity will persist.

109. It does appear that prevailing circumstances during particularly formative years can have a significant impact on the outcome of a juvenile's gender dysphoria. A 2016 study reviewing the follow-up literature noted that "the period between 10 and 13 years" was "crucial" in that "both persisters and desisters stated that the changes in their social environment, the anticipated and actual feminization or masculinization of their bodies, and the first experiences of falling in love and sexual attraction in this period, contributed to an increase (in the persisters) or decrease (in the desisters) of their gender related interests, behaviors, and feelings of gender discomfort." (Ristori & Steensma 2016 at 16.) In 2022, Olson et al. published data about the very low rates of desistence five years after social transition of children between ages of 3 and 12 (Olsen et al, 2022.) As I discuss again in Section VII below, there is considerable evidence that early transition and affirmation causes far more children to persist in a transgender identity.

B. Desistance is increasingly observed among teens and young adults who first manifest GD during or after adolescence.

110. Desistance within a relatively short period may also be a common outcome for post-pubertal youths who exhibit recently described "rapid onset gender disorder." I have observed an increasingly vocal online community of young women who have reclaimed a female identity after claiming a male gender identity at some point during their teen years, and young "detransitioners" (individuals in the process of reidentifying with their birth sex after having undergone a gender transition) are now receiving increasing attention in both clinical literature and social media channels.

111. Almost all scientific articles on this topic have appeared within the last few years. Perhaps this historic lack of coverage is not entirely surprising – one academic who undertook an extensive review of the available scientific literature in 2021 noted that the phenomenon was "socially controversial" in that it "poses significant professional and bioethical challenges for those clinicians working in the field of gender dysphoria." (Expósito Campos 2021 at 270.) This review reported on the multiple reasons for why individuals were motivated to detransition, which included coming to "understand[ ] how past trauma, internalized sexism, and other psychological difficulties influenced the experience of GD."

112. In 2021, Lisa Littman of Brown University conducted a ground-breaking study of 100 teenage and young adults who had transitioned and lived in a transgender identity for a number of years, and then "detransitioned" or changed back to a gender identity

matching their sex. Littman noted that the "visibility of individuals who have detransitioned is new and may be rapidly growing." (Littman 2021 at 1.) Of the 100 detransitioners included in Littman's study, 60% reported that their decision to detransition was motivated (at least in part) by the fact that they had become more comfortable identifying as their natal sex, and 38% had concluded that their gender dysphoria was caused by something specific such as trauma, abuse, or a mental health condition. (Littman 2021 at 9.)

113. A significant majority (76%) did not inform their clinicians of their detransition. (Littman 2021 at 11.)

114. A similar study that recruited a sample of 237 detransitioners (the large majority of whom had initially transitioned in their teens or early twenties) similarly reported that a common reason for detransitioning was the subject's conclusion that his or her gender dysphoria was related to other issues (70% of the sample). (Vandenbussche 2021.)

115. The existence of increasing numbers of youth or young adult detransitioners has also been recently noted by Dr. Edwards-Leeper and Dr. Anderson. (Edwards-Leeper & Anderson 2021.) Edwards-Leeper and Anderson noted "the rising number of detransitioners that clinicians report seeing (they are forming support groups online)" which are "typically youth who experienced gender dysphoria and other complex mental health issues, rushed to medicalize their bodies and regretted it." Other clinicians working with detransitioners have also noted the recent phenomenon. (Marchiano 2020.)

116. A growing body of evidence suggests that for many teens and young adults, a post-pubertal onset of transgender identification can be a transient phase of identity exploration, rather than a permanent identity, as evidenced by a growing number of young detransitioners (Entwistle 2020; Littman 2021; Vandenbussche 2021). Previously, the rate of detransition and regret was reported to be very low, although these estimates suffered from significant limitations and were likely undercounting true regret (D'Angelo 2018). As gender-affirmative care has become popularized, the rate of detransition appears to be accelerating.

117. A recent study from a UK adult gender clinic observed that 6.9% of those treated with gender-affirmative interventions detransitioned within 16 months, and another 3.4% had a pattern of care suggestive of detransition, yielding a rate of probable detransition in excess of 10%. Another 21.7%, however, disengaged from the clinic without completing their treatment plan. While some of these individuals later re-engaged with the gender service, the authors concluded, "detransitioning might be more frequent than previously reported." (Hall et al. 2021.)

118. Another study from a UK primary care practice found that 12.2% of those who had started hormonal treatments either detransitioned or documented regret, while the total of 20% stopped the treatments for a wider range of reasons. The mean age of their presentation with gender dysphoria was 20, and the patients had been taking gender-affirming hormones for an average 5 years (17 months-10 years) prior to discontinuing. Comparing these much higher rates of treatment discontinuation and detransition to the significantly lower rates reported by the older studies, the research-

ers noted: "Thus, the detransition rate found in this population is novel and questions may be raised about the phenomenon of overdiagnosis, overtreatment, or iatrogenic harm as found in other medical fields" (Boyd et al. 2022 at 15.) Indeed, given that regret may take up to 8-11 years to materialize (Dhejne et al., 2014; Wiepjes et al., 2018), many more detransitioners are likely to emerge in the coming years. Detransitioner research is still in its infancy, but the Littman and Vandenbussche studies in 2021 both report that detransitioners from the recently transitioning cohorts feel they were rushed into medical gender-affirmative interventions with irreversible effects, often without the benefit of appropriate, or in some instances any, psychologic exploration.

VII. TRANSITION AND AFFIRMATION ARE IMPORTANT PSYCHOLOGICAL AND MEDICAL INTERVENTIONS THAT CHANGE GENDER IDENTITY OUTCOMES.

A. If both a typical gender or a transgender long-term gender identity outcome are possible for a particular patient, the alternatives are not medically neutral.

119. Where a juvenile experiences gender dysphoria, the gender identity that is stabilized will have a significant impact on the course of their life. Living in a transgender identity for a time will make desistance, if it is ever considered, more difficult to accomplish.

120. If the juvenile desists from the gender dysphoria and becomes reasonably comfortable with a gender identity congruent with their sex—the most likely outcome from a statistical perspective absent affirming intervention—the child will not require ongoing phar-

maceutical maintenance and will not have their fertility destroyed post-puberty.

121. However, if the juvenile persists in a transgender identity, under current practices, the child is most likely to require regular administration of hormones for the rest of their lives, exposing them to significant physical, mental health, and relational risks (which I detail in Section IX below), as well as being irreversibly sterilized chemically and/or surgically. The child is therefore rendered a "patient for life" with complex medical implications to further a scientifically unproven course of treatment.

B. Social transition of young children is a powerful psychotherapeutic intervention that radically changes outcomes, almost eliminating desistance.

122. Social transition has a critical effect on the persistence of gender dysphoria. It is evident from the scientific literature that engaging in therapy that encourages social transition before or during puberty—which would include participation on athletic teams designated for the opposite sex—is a psychotherapeutic intervention that dramatically changes outcomes. A prominent group of authors has written that "The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood." (Guss et al. 2015 at 421.) Similarly, a comparison of recent and older studies suggests that when an "affirming" methodology is used with children, a substantial proportion of children who would otherwise have desisted by adolescence—that is, achieved comfort identifying with their natal sex—instead persist in a transgender identity. (Zucker 2018 at 7.) Olson's publication

not only affirmed Zucker's observation but provided very low rates of retransition or desistence among those socialized before or after grade school years. (Olson et al, 2022.)

123. Indeed, a review of multiple studies of children treated for gender dysphoria across the last three decades found that early social transition to living as the opposite sex severely reduces the likelihood that the child will revert to identifying with the child's natal sex, at least in the case of boys. That is, while, as I review above, studies conducted before the widespread use of social transition for young children reported desistance rates in the range of 80-98%, a more recent study reported that fewer than 20% of boys who engaged in a partial or complete social transition before puberty had desisted when surveyed at age 15 or older. (Zucker 2018 at 7[7]; Steensma et al. 2013.[8]) Another researcher observed that a partial or complete gender social transition prior to puberty "proved to be a unique predictor of persistence." (Singh et al. 2021 at 14.)

124. Some vocal practitioners of prompt affirmation and social transition even proudly claim that essentially *no* children who come to their clinics exhibiting gender dysphoria or cross-gender identification desist in that identification and return to a gender identity consistent

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[7] Zucker found social transition by the child to be strongly correlated with persistence for natal boys, but not for girls. (Zucker 2018 at 5.)

[8] Only 2 (3.6%) of 56 of the male desisters observed by Steensma et al. had made a complete or partial transition prior to puberty, and of the twelve males who made a complete or partial transition prior to puberty, only two had desisted when surveyed at age 15 or older. Steensma 2013 at 584.

with their biological sex.[9] This is a very large change as compared to the desistance rates documented apart from social transition.

125. Even voices generally supportive of prompt affirmation and social transition are acknowledging a causal connection between social transition and this change in outcomes. As the Endocrine Society recognized in its 2017 Guidelines: "If children have completely socially transitioned, they may have great difficulty in returning to the original gender role upon entering puberty . . . [S]ocial transition (in addition to GD/gender incongruence) has been found to contribute to the likelihood of persistence." (Hembree et al. 2017 at 3879.) The fact is that these unproven interventions with the lives of kids and their families have systematically documented outcomes. Given this observed phenomenon, I agree with Dr. Ken Zucker who has written that social transition in children must be considered "a form of psychosocial treatment." (Zucker 2020 at 1.)

126. Moreover, as I review below, social transition cannot be considered or decided alone. Studies show that engaging in social transition starts a juvenile on a "conveyor belt" path that almost inevitably leads to the administration of puberty blockers, which in turn almost inevitably leads to the administration of cross-sex hormones. The emergence of this well-documented path means that the implications of taking puberty blockers *and* cross-sex hormones must be taken into ac-

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[9] *See, e.g.,* Ehrensaft 2015 at 34: "In my own clinical practice . . . of those children who are carefully assessed as transgender and who are allowed to transition to their affirmed gender, we have no documentation of a child who has 'desisted' and asked to return to his or her assigned gender."

count even where "only" social transition is being considered or requested by the child or family. As a result, there are a number of important "known risks" associated with social transition.

C. Administration of puberty blockers is a powerful medical and psychotherapeutic intervention that radically changes outcomes, almost eliminating desistance on the historically observed timeline.

127. It should be understood that puberty blockers are usually administered to early-stage adolescents as part of a path that includes social transition. Yet medicine does not know what the long-term health effects on bone, brain, and other organs are of a "pause" between ages 11-16. Medicine also does not know if the long-term effects of these compounds are different in boys than in girls. The mental health professional establishment likewise does not know the long-term effects on coping skills, interpersonal comfort, and intimate relationships of this "pause" while one's peers are undergoing their maturational gains in these vital arenas of future mental health. I address medical, social, and mental health risks associated with the use of puberty blockers in Section X. Here, I note that the data strongly suggests that the administration of puberty blockers, too, must be considered to be a component of a "psychosocial treatment" with complex implications, rather than simply a "pause."

128. Multiple studies show that the large majority of children who begin puberty blockers go on to receive cross-sex hormones. (de Vries 2020 at 2.) A recent study by the Tavistock and Portman NHS Gender Identity Development Service (UK)—the world's largest gender clinic—found that 98% of adolescents who un-

derwent puberty suppression continued on to cross-sex hormones. (Carmichael et al 2021 at 12.)[10]

129. These studies demonstrate that going on puberty blockers virtually eliminates the possibility of desistance in juveniles. Rather than a "pause," puberty blockers appear to act as a psychosocial "switch," decisively shifting many children to a persistent transgender identity. Therefore, as a practical and ethical matter, the decision to put a child on puberty blockers must be considered as the equivalent of a decision to put that child on cross-sex hormones, with all the considerations and informed consent obligations implicit in that decision.

VIII. TRANSITION AND AFFIRMATION ARE EXPERIMENTAL THERAPIES THAT HAVE NOT BEEN SHOWN TO IMPROVE MENTAL OR PHYSICAL HEALTH OUTCOMES BY YOUNG ADULTHOOD.

130. It is undisputed that children and adolescents who present with gender dysphoria exhibit a very high level of mental health comorbidities. (Section III.C.) Whether the gender dysphoria is cause or effect of other diagnosed or undiagnosed mental health conditions, or whether these are merely coincident comorbidities, is hotly disputed, but the basic fact is not.

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[10] *See also* Brik 2020 where Dutch researchers found nearly 97% of adolescents who received puberty blockers proceeded to cross-sex hormones.

A. The knowledge base concerning therapies for gender dysphoria is "very low quality."

131. It is important for all sides to admit that the knowledge base concerning the causes and treatment of gender dysphoria has low scientific quality. In evaluating claims of scientific or medical knowledge, it is axiomatic in science that no knowledge is absolute, and to recognize the widely accepted hierarchy of reliability when it comes to "knowledge" about medical or psychiatric phenomena and treatments. Unfortunately, in this field opinion is too often confused with knowledge, rather than clearly locating what exactly is scientifically known. In order of increasing confidence, such "knowledge" may be based upon data comprising:

a. Expert opinion—it is perhaps surprising to educated laypersons that expert opinion standing alone is the lowest form of knowledge, the least likely to be proven correct in the future. Reliance on well-known or well-credentialled "experts," or the head of a gender clinic, is sometimes referred to as eminence-based medicine. Their opinions do not garner as much respect from professionals as what follows;

b. A single case or series of cases (what could be called anecdotal evidence) (Levine 2016 at 239.);

c. A series of cases with a control group;

d. A cohort study;

e. A randomized double-blind clinical trial;

f. A review of multiple trials;

g. A meta-analysis of multiple trials that maximizes the number of patients treated despite their

methodological differences to detect trends from larger data sets.

132. Prominent voices in the field have emphasized the severe lack of scientific knowledge in this field. The American Academy of Child and Adolescent Psychiatry has recognized that "Different clinical approaches have been advocated for childhood gender discordance. . . . There have been no randomized controlled trials of any treatment. [T]he proposed benefits of treatment to eliminate gender discordance . . . must be carefully weighed against . . . possible deleterious effects." (Adelson et al. at 968-69.) Similarly, the American Psychological Association has stated, "because no approach to working with [transgender and gender nonconforming] children has been adequately, empirically validated, consensus does not exist regarding best practice with pre-pubertal children." (APA 2015 at 842.)

133. Critically, "there are no randomized control trials with regard to treatment of children with gender dysphoria." (Zucker 2018 at 8.) On numerous critical questions relating to cause, developmental path if untreated, and the effect of alternative treatments, the knowledge base remains primarily at the level of the practitioner's exposure to individual cases, or multiple individual cases. As a result, claims to certainty are not justifiable. (Levine 2016 at 239.)

134. Within the last two years, at least five formal, independent, systematic evidence reviews concerning hormonal interventions for gender dysphoria have been conducted. All five found all of the available clinical evidence to be very low quality.

135. The British National Health Service (NHS) commissioned formal "evidence reviews" of all clinical

papers concerning the efficacy and safety of puberty blockers and cross-sex hormones as treatments for gender dysphoria. These evidence reviews were performed by the U.K. National Institute for Health and Care Excellence (NICE), applying the respected "GRADE" criteria for evaluating the strength of clinical evidence.

136. Both the review of evidence concerning puberty blockers and the review of evidence concerning cross-sex hormones were published in 2020, and both found that *all* available evidence as to both efficacy and safety was "very low quality" according to the GRADE criteria. (NICE 2021a; NICE 2021b.) This work is sometimes referred to as the Cass Report.[11] "Very low quality" according to GRADE means there is a high likelihood that the patient *will not experience* the hypothesized benefits of the treatment. (Balshem et al. 2011.)

137. Similarly, the highly respected Cochrane Library—the leading source of independent systematic evidence reviews in health care—commissioned an evidence review concerning the efficacy and safety of hormonal treatments now commonly administered to "transitioning transgender women" (i.e., testosterone suppression and estrogen administration to biological males). That review, also published in 2020, concluded that "We found insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition." (Haupt et al. 2020 at 2.) It must be understood that both the NICE and the Cochrane reviews considered *all* published scientific studies concerning these treatments. Similarly, McMasters University's skillful methodological unit recently

[11] https://cass.independent-review.uk/publications/interim-report/

reached the same conclusion (Brignardello-Peterson, & Wiercioch, 2022).

138. As to social transition, as I have noted above, considerable evidence suggests that socially transitioning a pre-pubertal child puts him or her on a path from which very few children escape—a path which includes puberty blockers and cross-sex hormones before age 18. And for some, surgery before the age of majority. A decision about social transition for a child must be made in light of what is known and what is unknown about the effects of those expected future interventions. Social transition, therefore, is not merely reversible behavioral change. It is the beginning of a medically dependent future and should be explained as such.

139. I discuss safety considerations in Section IX below. Here, I detail what is known about the effectiveness of social and hormonal transition and affirmation to improve the mental health of individuals diagnosed with gender dysphoria.

B. Youth who adopt a transgender identity show no durable improvement in mental health after social, hormonal, or surgical transition and affirmation.

140. As I noted above, the evidence reviews for the efficacy and safety of hormonal interventions published in 2020 concluded that the supporting evidence is so poor that there is "a high likelihood that the patient will not experience the hypothesized benefits of the treatment." There is now some concrete evidence that, on average, they do not experience those benefits.

141. An important paper published in 2021 by Tavistock clinic clinicians provided the results of the first lon-

gitudinal study that measured widely used metrics of general psychological function and suicidality before commencement of puberty blockers, and then at least annually after commencing puberty blockers. After up to three years, they "found no evidence of change in psychological function with GnRHa treatment as indicated by parent report (CBCL) or self-report (YSR) of overall problems, internalizing or externalizing problems or self-harm" as compared to the pre-puberty-blocker baseline evaluations. "Outcomes that were not formally tested also showed little change." (Carmichael at al. 2021, at 18-19.) Similarly, a study by Bränström and Pachankis of the case histories of a set of individuals diagnosed with GD in Sweden found no positive effect on mental health from hormonal treatment. (Landen 2020.)

142. A cohort study by authors from Harvard and Boston Children's Hospital found that youth and young adults (ages 12-29) who self-identified as transgender had an elevated risk of depression (50.6% vs. 20.6%) and anxiety (26.7% vs. 10.0%); a higher risk of suicidal ideation (31.1% vs. 11.1%), suicide attempts (17.2% vs. 6.1%), and self-harm without lethal intent (16.7% vs. 4.4%) relative to the matched controls; and a significantly greater proportion of transgender youth accessed inpatient mental health care (22.8% vs. 11.1%) and outpatient mental health care (45.6% vs. 16.1%) services. (Reisner et al. 2015 at 6.) Similarly, a recent longitudinal study of transgender and gender diverse youth and young adults in Chicago found rates of alcohol and substance abuse "substantially higher than those reported by large population-based studies of youth and adults." (Newcomb et al. 2020 at 14.) Members of the clinical and research team at the prominent

Dutch VU University gender dysphoria center recently compared mental health metrics of two groups of subjects before (mean age 14.5) and after (mean age 16.8) puberty blockers. But they acknowledged that the structure of their study meant that it "can . . . not provide evidence about . . . long-term mental health outcomes," and that based on what continues to be extremely limited scientific data, "Conclusions about the long-term benefits of puberty suppression should . . . be made with extreme caution." In other words, we just don't know. (van der Miesen et al. 2020, at 703.)

143. Kiera Bell, who was diagnosed with gender dysphoria at the Tavistock Clinic, given cross-sex hormones, and treated by mastectomy, before desisting and reclaiming her female gender identity, and a Swedish teen girl who appeared in a recent documentary after walking that same path, have both stated that they feel that they were treated "like guinea pigs," experimental subjects. They are not wrong.

144. A recent two-year prospective uncontrolled multisite NIMH study of 315 adolescents found that at the average age of 18 the primary benefit of hormones was happiness with their aesthetic appearance. The effects on depression and anxiety were very small and highly variable. There were two suicides in the study population. (Chen et al 2023.) This work did not address the relevant long term mental health outcomes of such treatment before their two-year finding. However, in May 2022 a group from Sweden performed a systematic review of the mental health effects of hormonal transition because they asserted that the literature did not provide sufficient evidence to inform clinical decision making. They concluded that candidates for hormones had a high percentage of mental health prob-

lems, and the methodological quality of the 32 papers studied (representing between 3,000 and 4,000 patients) did not allow for a firm answer as to whether mental health was improved by hormonal treatment. (Thompson et al 2022).

C. Long-term mental health outcomes for individuals who persist in a transgender identity are poor.

145. The responsible MHP cannot focus narrowly on the short-term happiness of the young patient but must instead consider the happiness and health of the patient from a "life course" perspective. When we look at the available studies of individuals who continue to inhabit a transgender identity across adult years, the results are strongly negative.

146. In the United States, the death rates of trans veterans are comparable to those with schizophrenia and bipolar diagnoses—20 years earlier than expected. These crude death rates include significantly elevated rates of substance abuse as well as suicide. (Levine 2017, at 10.) Similarly, researchers in Sweden and Denmark have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period. (Dhejne et al. 2011; Simonsen et al. 2016.) The Swedish follow-up study similarly found a suicide rate in the post-SRS population 19.1 times greater than that of the controls; both studies demonstrated elevated mortality rates from medical and psychiatric conditions. (Levine 2017, at 10.)

147. A study in the American Journal of Psychiatry reported high mental health utilization patterns of adults for ten years after surgery for approximately 35% of patients. (Bränström & Pachankis, 2020.) Indeed, earlier Swedish researchers in a long-term study of all patients

provided with SRS over a 30-year period (median time since SRS of > 10 years) concluded that individuals who have SRS exhibit such poor mental health that they should be provided very long-term psychiatric care as the "final" transition step of SRS. (Dhejne et al. 2011, at 6-7.) Unfortunately, across the succeeding decade, in Sweden and elsewhere their suggestion has been ignored.

148. The most recent all-cause mortality study from the UK found a significant excess of deaths among trans individuals compared to age matched controls of both sexes. External causes of death (suicide, homicide, accidental poisoning) were particularly higher than control groups (Jackson et al 2023). The risk of death was 34% greater among trans identified individuals than the general population. The mean age of the trans group was 36 years.

149. I will note that these studies do not tell us whether the subjects first experienced gender dysphoria as children, adolescents, or adults, so we cannot be certain how their findings apply to each of these subpopulations which represent quite different pathways. But in the absence of knowledge, we should be cautious.

150. Meanwhile, no studies show that affirmation of pre-pubescent children or adolescents leads to more positive outcomes (mental, physical, social, or romantic) by, e.g., age 25 or older than does "watchful waiting" or ordinary therapy.

151. The many studies that I have cited here warn us that as we look ahead to the patient's life as a young adult and adult, the prognosis for the physical health, mental health, and social wellbeing of the child or adolescent who transitions to live in a transgender identity

is not good. Gender dysphoria is not "easily managed" when one understands the marginalized, vulnerable physical, social, and psychological status of adult trans populations and their premature death patterns.

IX. TRANSITION AND AFFIRMATION DO NOT DECREASE, AND MAY INCREASE, THE RISK OF SUICIDE.

A. The risk of suicide among transgender youth is confused and exaggerated in the public mind.

152. While suicide is closely linked to mental health, I comment on it separately because rhetoric relating to suicide figures so prominently in debates about responses to gender dysphoria.

153. At the outset, I will note that any discussion of suicide when considering younger children involves very long-range and very uncertain prediction. Suicide in pre-pubescent children is extremely rare, and the existing studies of gender identity issues in pre-pubescent children do not report significant incidents of suicide. Any suggestion otherwise is misinformed. Our focus for this topic, then, is on adolescents and adults.

154. Some authors have reported rates of suicidal thoughts and behaviors among trans-identifying teens or adults ranging from 25% to as high as 52%, generally through non-longitudinal self-reports obtained from non-representative survey samples. (Toomey et al. 2018.) Some advocates of affirmative care assert that the only treatment to avoid this serious harm is to affirm gender identity. Contrary to these assertions, no studies show that affirmation of children (or anyone else) reduces suicide, prevents suicidal ideation, or improves long-term outcomes, as compared to either a

"watchful waiting" or a psychotherapeutic model of response, as I have described above. Rhetorical references to figures such as 40%—and some published studies—confuse suicidal thoughts and actions that represent a cry for help, manipulation, or expression of rage with serious attempts to end life. Such statements or studies ignore a crucial and long-recognized distinction.

155. I have included suicidality in my discussion of mental health above. Here, I focus on actual suicide. Too often, in public comment suicidal thoughts are blurred with suicide. Yet the available data tells us that suicide among children and youth suffering from gender dysphoria is extremely rare.

156. An important analysis of data covering patients as well as those on the waiting list (and thus untreated) at the UK Tavistock gender clinic—the world's largest gender clinic—found a total of only four completed suicides across 11 years' worth of patient data, reflecting an estimated cumulative 30,000 patient-years spent by patients under the clinic's care or on its waiting list. This corresponded to an annual suicide rate of 0.013%. The proportion of individual patients who died by suicide was 0.03%, which is orders of magnitude smaller than trans adolescents who self-report suicidal behavior or thoughts on surveys. (Biggs 2022b.)

157. Thus, only a minute fraction of trans-identifying adolescents who report thoughts or conduct considered to represent "suicidality" commit suicide. I agree with Dr. Zucker that the assertion by, for example, Karasic and Ehrensaft (2015) that completed suicides among transgender youth are "alarmingly high" "has no formal and systematic empirical basis." (Zucker 2019 at 3.)

158. Professor Biggs of Oxford, author of the study of incidence of suicide among Tavistock clinic patients, rightly cautions that it is "irresponsible to exaggerate the prevalence of suicide." (Biggs 2022b at 4.) It is my opinion that telling parents—or even allowing them to believe from their internet reading—that they face a choice between "a live son or a dead daughter" is both factually wrong and unethical. Informed consent requires clinicians to tell the truth and ensure that their patients understand the truth. To be kind, the clinicians who believe such figures represent high risk of ultimate suicide in adolescence simply do not know the truth; they are ill-informed.

B. Transition of any sort has not been shown to reduce levels of suicide.

159. Every suicide is a tragedy, and steps that reduce suicide should be adopted. I have noted above that suicidality (that is, suicidal thoughts or behaviors, rather than suicide) is common among transgender adolescents and young adults before, during, and after social and medical transition. If a medical or mental health professional believes that an individual he or she is diagnosing or treating for gender dysphoria presents a suicide risk, in my view it is unethical for that professional merely to proceed with treatment for gender dysphoria and hope that "solves the problem." Rather, that professional has an obligation to provide or refer the patient for evidence-based therapies for addressing depression and suicidal thoughts that are well-known to the profession. (Levine 2016, at 242.)

160. This is all the more true because there is in fact no evidence that social and/or medical transition reduces the risk or incidence of actual suicide. As there

are no long-term comparative studies of gender dysphoric adolescents with suicidal ideation, per se, let alone a comparative study of those who were given hormones and those who did not take hormones, there is no scientific basis for declaring affirmative care as reducing suicidal risk. In his analysis of those who were patients of or on the waiting list of the Tavistock clinic, Professor Biggs found that the suicide rate was not higher among those on the clinic's waiting list (and thus as-yet untreated), than for those who were patients under care. (Biggs 2022b.) And as corrected, Bränström and Pachankis similarly acknowledge that their review of records of GD patients "demonstrated no advantage of surgery in relation to . . . hospitalizations following suicide attempts." (I assume for this purpose that attempts that result in hospitalization are judged to be so serious as to predict a high rate of future suicide if not successfully addressed.")[12] Long-term life in a transgender identity, however, correlates with very high rates of completed suicide.

161. As with mental health generally, the patient, parent, or clinician fearing the risk of suicide must consider not just the next month or year, but a life course perspective.

162. There are now four long-term studies that analyze completed suicide among those living in transgender identities into adulthood. The results vary significantly but are uniformly highly negative. Dhejne re-

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[12] Turban et al. (2020) has been described in press reports as demonstrating that administration of puberty suppressing hormones to transgender adolescents reduces suicide or suicidal ideation. The paper itself does not make that claim, nor permit that conclusion.

ported a long-term follow-up study of subjects after sex reassignment surgery. Across the thirty-year study, subjects who had undergone SRS committed suicide at 19.1 times the expected rate compared to general population controls matched by age and both sexes. MtF subjects committed suicide at 13.9 times the expected rate, and FtM subjects committed suicide at 40.0 times the expected rate. (Dhejne et al. 2011 Supplemental Table S1.)

163. Asscheman, also writing in 2011, reported results of a long-term follow-up of all transsexual subjects of the Netherlands' leading gender medicine clinic who started cross-sex hormones before July 1, 1997, a total of 1331 patients. Due to the Dutch system of medical and death records, extensive follow-up was achieved. Median follow-up period was 18.5 years. The mortality rate among MtF patients was 51% higher than among the age-matched general population; the rate of completed suicide among MtF patients was six times that of the age-matched general population. (Asscheman et al. 2011.)

164. Importantly, Asscheman et al. found that "No suicides occurred within the first 2 years of hormone treatment, while there were six suicides after 2-5 years, seven after 5-10 years, and four after more than 10 years of CSH treatment at a mean age of 41.5 years." (Asscheman et al. 2011 at 637-638.) This suggests that studies that follow patients for only a year or two after treatment are insufficient. Asscheman et al.'s data suggest that such short-term follow-up is engaging only with an initial period of optimism, and it will simply miss the feelings of disillusion and the increase in completed suicide that follows in later years.

165. A retrospective, long-term study published in 2020 of a very large cohort (8263) of patients referred to the Amsterdam University gender clinic between 1972 and 2017 found that the annual rate of completed suicides among the transgender subjects was "three to four times higher than the general Dutch population." "[T]he incidence of observed suicide deaths was almost equally distributed over the different stages of treatment." The authors concluded that "vulnerability for suicide occurs similarly in the different stages of transition." (Wiepjes et al. 2020.) In other words, neither social nor medical transition reduced the rate of suicide.

166. As with Asscheman et al., Wiepjes et al. found that the median time between start of hormones and suicide (when suicide occurred) was 6.1 years for natal males, and 6.9 years for natal females. Again, short- or even medium-term studies will miss this suicide phenomenon.

167. A 2021 study analyzed the case histories of a cohort of 175 gender dysphoria patients treated at one of the seven UK adult gender clinics who were "discharged" (discontinued as patients) within a selected one-year period. The authors reported the rather shocking result that 7.7% (3/39) of natal males who were diagnosed and admitted for treatment, and who were between 17 and 24 years old, were "discharged" because they committed suicide *during* treatment. (Hall et al. 2021, Table 2.)

168. None of these studies demonstrates that the hormonal or surgical intervention *caused* suicide. That is possible, but as we have seen, the population that identifies as transgender suffers from a high incidence of comorbidities that correlate with suicide. What these

studies demonstrate—at the least—is that this remains a troubled population in need of extensive and careful psychological care that they generally do not receive, and that neither hormonal nor surgical transition and "affirmation" resolve their underlying problems and put them on the path to a stable and healthy life.

169. In sum, claims that affirmation will reduce the risk of suicide for children and adolescents are not based on science. Instead, transition of any sort must be justified, if at all, as a life-enhancing measure, not a life-saving measure. (Levine 2016, at 242.) In my opinion, this is an important fact that patients, parents, and even many MHPs fail to understand.

X. HORMONAL INTERVENTIONS ARE EXPERIMENTAL PROCEDURES THAT HAVE NOT BEEN PROVEN SAFE.

170. A number of voices in the field assert that puberty blockers act merely as a "pause" in the process of puberty-driven maturation, suggesting that this hormonal intervention has been proven to be fully reversible. This is also an unproven belief.

171. On the contrary, no studies have been done that meaningfully demonstrate that either puberty blockers or cross-sex hormones, as prescribed for gender dysphoria, are safe in other than the short run. No studies have attempted to determine whether the effects of puberty blockers, as currently being prescribed for gender dysphoria, are fully reversible. There are only pronouncements. In fact, there are substantial reasons for concern that these hormonal interventions are not safe. Multiple researchers have expressed concern that the full range of possible harms have not even been correctly conceptualized.

172. Because, as I have explained in Section VI, recent evidence demonstrates that prepubertal social transition almost always leads to progression on to puberty blockers which in turn almost always leads to the use of cross-sex hormones, physicians bear the ethical responsibility for a thorough informed consent process for parents and patients that includes this fact and its full implications. Informed consent does not mean sharing with the parents and patients what the doctor believes: it means sharing what is known and what is not known about the intervention. So much of what doctors believe is based on mere trust in what they have been taught. Neither they themselves nor their teachers may be aware of the scientific foundation and scientific limitations of what they are recommending.

A. Use of puberty blockers has not been shown to be safe or reversible for gender dysphoria.

173. As I noted above, the recent very thorough literature review performed for the British NHS concluded that *all* available clinical evidence relating to "safety outcomes" from administration of puberty blockers for gender dysphoria is of "very low certainty." (NHS 2020, at 6.)

174. In its 2017 Guidelines, the Endocrine Society cautioned that "in the future we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols" including "careful assessment of . . . the effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain (including effects on cognitive, emotional, social, and sexual development)." (Hembree et al. 2017, at 3874.) No such "careful" or "rigorous" evaluation of these very serious safety questions has yet been done.

175. Some advocates assume that puberty blockers are "safe" because they have been approved by the Food and Drug Administration (FDA) for use to treat precocious puberty—a rare condition in which the puberty process may start at eight or younger. No such conclusion can be drawn. As the "label" for Lupron (one of the most widely prescribed puberty blockers) explains, the FDA approved the drug only *until* the "age was appropriate for entry into puberty." The study provides no information at all as to the safety or reversibility of instead *blocking* healthy, normally-timed puberty's beginning, and *throughout* the years that bodywide continuing changes normally occur. Given the physical, social, and psychological dangers to the child with precocious puberty, drugs like Lupron are effective in returning the child to a puerile state like their peers without a high incidence of significant side effects—that is, they are "safe" to reverse the condition. But use of drugs to suppress normal puberty has multiple organ system effects whose long-term consequences have not been investigated.

176. Systematic data reviews are scientifically more reliable than individual reports with definable methodologic limitations. Without quoting extensively from the reviews done by Sweden, Finland, UK, and McMasters University, suffice it to say that their conclusions agree that the risks of puberty suppression and cross-sex hormones outweigh the possible benefits. They also point to the great unexplained increase in incidence of gender dysphoria, the increased incidence of detransi-

tion and regret, and the lack of evidence of efficacy.[13] (Swedish National Board of Health and Welfare, 2022).

177. **Fertility:** The Endocrine Society Guidelines rightly say that research is needed into the effect of puberty blockade on "gonadal function" and "sexual development." The core purpose and function of puberty blockers is to prevent the maturation of the ovaries or testes, the sources of female hormones and male hormones when stimulated by the pituitary gland. From this predictable process fertility is accomplished within a few years. Despite widespread assertions that puberty blockers are "fully reversible," there has been no study published on the critical question of whether patients ever develop normal levels of fertility if puberty blockers are terminated after a "prolonged delay of puberty." The 2017 Endocrine Society Guidelines are correct that are no data on achievement of fertility "following prolonged gonadotropin suppression" (that is, puberty blockade). (Hembree et al. 2017, at 3880.)

178. **Bone strength:** Multiple studies have documented adverse effects from puberty blockers on bone density. (Klink et al. 2015; Vlot et al. 2016; Joseph et al. 2019.) The most recent found that after two years on puberty blockers, the bone density measurements for a significant minority of the children had declined to clinically concerning levels. Density in the spines of some subjects fell to a level found in only 0.13% of the population. (Biggs 2021.) Some other studies have found less-concerning effects on bone density. While the

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[13] https:/www.sociialstyrelsen.se/globalassets/sharepointdokument/artikelkatalog/kunskapsstod/2022-7799.pdf

available evidence remains limited and conflicting, it is not possible to conclude that the treatment is "safe."

179. **Brain development:** Important neurological growth and development in the brain occurs across puberty. The anatomic and functional effect on brain development of blocking the natural puberty process has not been well studied. A prominent Australian clinical team recently expressed concern that "no data were (or are) available on whether delaying the exposure of the brain to a sex steroid affects psychosexual, cognitive, emotional, or other neuropsychological maturation." (Kozlowska et al. 2021, at 89.) In my opinion, given the observed correlation between puberty and brain development, the default hypothesis must be that there *would* be a negative impact. For the purpose of protecting patients all over the world, the burden of proof should be on advocates to first demonstrate to a reasonable degree of certainty that brain structure and its measurable cognitive and affect processing are not negatively affected. This recalls the ethical principle: Above All Do No Harm.

180. The Endocrine Society Guidelines acknowledge as much, stating that side effects of pubertal suppression "may include . . . unknown effects on brain development," that "we need more rigorous evaluations of . . . the effects of prolonged delay of puberty in adolescents on . . . the brain (including effects on cognitive, emotional, social, and sexual development)," and stating that "animal data suggests there may be an effect of GnRH analogs [puberty blockers] on cognitive function." (Hembree et al. 2017, at 3874, 3882, 3883.) Given this concern, one can only wonder why this relevant question has not been scientifically investigated in a large group of natal males and females.

181. There has been a longitudinal study of one natal male child, assessed before, and again 20 months after, puberty suppression was commenced. It reported a reduction in the patient's "global IQ," measured an anomalous absence of certain structural brain development expected during normal male puberty, and hypothesized that "a plausible explanation for the G[lobal] IQ decrease should consider a disruption of the synchronic [i.e., appropriately timed] development of brain areas by pubertal suppression." (Schneider et al. 2017, at 7.) This should cause parents and practitioners serious concern.

182. Whether any impairment of brain development is "reversed" upon later termination of puberty blockade has, to my knowledge, not been studied at all. As a result, assertions by medical or mental health professionals that puberty blockade is "fully reversible" are unjustified and based on hope rather than science.

183. Without a number of additional case studies—or preferably statistically significant clinical studies—two questions remain unanswered: Are there brain anatomic or functional impairment from puberty blockers? And are the documented changes reversed over time when puberty blockers are stopped? With these questions unanswered, it is impossible to assert with certainty that the effects of this class of medications are "fully reversible." Such an assertion is another example of ideas based on beliefs rather than on documentation, on hope not science.

184. **Psycho-social harm:** Puberty is a time of stress, anxiety, bodily discomfort during physical development, and identity formation for *all* humans. No careful study has been done of the long-term impact on the

young person's coping skills, interpersonal comfort, and intimate relationships from remaining puerile for, e.g., two to five years while one's peers are undergoing pubertal transformations, and of then undergoing an artificial puberty at an older age. However, pediatricians and mental health professionals hear of distress, concern, and social awkwardness in those who naturally have a delayed onset of puberty. In my opinion, individuals in whom puberty is delayed multiple years are likely to suffer at least subtle negative psychosocial and self-confidence effects as they stand on the sidelines witnessing their peers developing the social relationships (and attendant painful social learning experiences) that come with adolescence. (Levine 2018 at 9.) Social anxiety and social avoidance are common findings in the evaluation of trans-identified children and teens. Are we expected to believe that creating years of being further different than their peers has no lasting internal consequences? Do we ignore Adolescent Psychiatry's knowledge of the importance of peer groups among adolescents?

185. We simply do not know what all the psychological impacts of NOT grappling with puberty at the ordinary time may be, because it has not been studied. And we have no information as to whether that impact is "fully reversible." We should at least consider that the normal pubertal ushering of an adolescent into the world of sexual attraction, romantic preoccupations, sexual desires, and forays into interpersonal intimate relationships can be a positive experience for an untreated trans identified child. In contrast, puberty is presented solely as a negative process to be avoided by puberty blockers. In psychiatry we have the concept that conflict is inevitable, and its resolution strengthens

a person's capacities to deal with the future. This applies to individuals of any age.

186. In addition, since the overwhelming proportion of children who begin puberty blockers continue on to cross-sex hormones, it appears that there is an important element of "psychological irreversibility" in play. The question of to what extent the physical and developmental impacts of puberty blockers might be reversible is an academic one, if psycho-social realities mean that very few patients well ever be able to make that choice once they have started down the road of social transition and puberty blockers.

B. Use of cross-sex hormones in adolescents for gender dysphoria has not been shown to be medically safe except in the short term.

187. As with puberty blockers, all evidence concerning the safety of extended use of cross-sex hormones is of "very low quality." The U.K. NICE evidence review cautioned that "the safety profiles" of cross-sex hormone treatments are "largely unknown," and that several of the limited studies that do exist reported high numbers of subjects "lost to follow-up," without explanation—a worrying indicator. (NICE 2020b.)

188. The 2020 Cochrane Review reported that: "We found insufficient evidence to determine the . . . safety of hormonal treatment approaches for transgender women in transition." (Haupt et al. 2020 at 4.) Even the Endocrine Society tagged all its recommendations for the administration of cross-sex hormones as based on "low quality evidence." (Hembree et al. 2017 at 3889.)

189. **Sterilization:** It is undisputed, however, that harm to the gonads is an expected effect, to the extent

that it must be assumed that cross-sex hormones will sterilize the patient. Thus, the Endocrine Society 2017 Guidelines caution that "[p]rolonged exposure of the testes to estrogen has been associated with testicular damage," that "[r]estoration of spermatogenesis after prolonged estrogen treatment has not been studied," and that "[i]n biological females, the effect of prolonged treatment with exogenous testosterone upon ovarian function is uncertain." (Hembree et al. 2017, at 3880.)[14]

190. The Guidelines go on to recommend that the practitioner counsel the patient about the (problematic and uncertain) options available to collect and preserve fertile sperm or ova before beginning cross-sex hormones. The life-long negative emotional impact of infertility on both men and women has been well studied. While this impact has not been studied specifically within the transgender population, the opportunity to be a parent is likely a human, emotional need, and so should be considered an important risk factor when considering gender transition for any patient. What has been documented is the low rate of acceptance of banking sperm or ova in this population, which is an expensive ongoing process.

191. **Sexual response:** Puberty blockers prevent maturation of the sexual organs and response. Some, and perhaps many, transgender individuals who did not go through puberty consistent with their sex and are then put on cross-sex hormones face significantly di-

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[14] *See also* Guss et al. 2015 at 4 ("a side effect [of cross-sex hormones] may be infertility") and at 5 ("cross-sex hormones . . . may have irreversible effects"); Tishelman et al. 2015 at 8 (Cross-sex hormones are "irreversible interventions" with "significant ramifications for fertility").

minished sexual response as they enter adulthood and are unable ever to experience orgasm. In the case of males, the cross-sex administration of estrogen limits penile genital growth and function. In the case of females, prolonged exposure to exogenous testosterone impairs vaginal function. Much has been written about the negative psychological and relational consequences of anorgasmia among non-transgender individuals that is ultimately applicable to the transgendered. (Levine 2018, at 6.) At the same time, prolonged exposure of females to exogenous testosterone often increases sexual drive to a distracting degree. It is likely that parents and physicians are uncomfortable discussing any aspects of genital sexual activity with patients. And these young often interpersonally sexually inexperienced patients are both too embarrassed to talk about the subject and too young to seriously consider the topic.

192. **Cardiovascular harm:** Several researchers have reported that cross-sex hormones increase the occurrence of various types of cardiovascular disease, including strokes, blood clots, and other acute cardiovascular events. (Getahun et al. 2018; Guss et al. 2015; Asscheman et al. 2011.) With that said, I agree with the conclusion of the Endocrine Society committee (like that of the NICE Evidence Review) that: "A systematic review of the literature found that data were insufficient (due to very low-quality evidence) to allow a meaningful assessment of patient-important outcomes, such as death, stroke, myocardial infarction, or venous thromboembolism in transgender males. Future research is needed to ascertain the potential harm of hormonal therapies." (Hembree et al. 2017 at 3891.) Future research questions concerning long-term harms

need to be far more precisely defined. The question of whether cross-sex hormones are safe for adolescents and young adults cannot be answered by analogies to hormone replacement therapy in menopausal women (which is not a cross-sex usage). Medicine has answered safety questions for menopausal women in terms of cancer and cardiovascular safety: at what dose, for what duration, and at what age range. The science of endocrine treatment of gender dysphoric youth is being bypassed by short-term clinical impressions of safety even though physicians know that cardiovascular and cancer processes often develop over many years.

193. Further, in contrast to administration for menopausal women, hormones begun in adolescence are likely to be administered for four to six decades. The published evidence of adverse impact, coupled with the lack of data sufficient to reach a firm conclusion, make it irresponsible to assert that cross-sex hormones "are safe." We must not forget the diverse sources of evidence of premature death among the trans communities.

194. **Harm to family and friendship relationships:** As a psychiatrist, I recognize that mental health is a critical part of health generally, and that relationships cannot be separated from and profoundly impact mental health. Gender transition routinely leads to isolation from at least a significant portion of one's family in adulthood. In the case of a juvenile transition, this will be less dramatic while the child is young, but commonly increases over time as siblings who marry and have children of their own do not wish the transgender individual to be in contact with those children. By adulthood, the friendships of transgender individuals tend to be confined to other transgender individuals (often "virtual"

friends known only online) and the generally limited set of others who are comfortable interacting with transgender individuals. (Levine 2017, at 5.) My concerns about this are based on decades of observations in my professional work with patients and their families. It is important to recognize that the tradition throughout medicine is the focus on the patient. This is true in adolescent medicine as well and seems natural and self-evident. However, when a trans identity occurs in a family, every member—parents, siblings, grandparents, etc.—is affected. I am used to watching parents become depressed, siblings take sides, and family dysfunction increase. It is rare to find a medical or mental health professional whose work reflects that each of these family members are deeply connected and share in the uncertainties that are embedded in any trans identity. There may be too much focus on the trans person as a patient and not enough as a trans person developing in an interpersonal, ever-changing matrix called a family.

195. **Sexual-romantic harms associated with transition:** After adolescence, transgender individuals find the pool of individuals willing to develop a romantic and intimate relationship with them to be greatly diminished. When a trans person who passes well reveals his or her natal sex, many potential mates lose interest. When a trans person does not pass well, options are likely further diminished. But regardless of a person's appearance, these adults soon learn that many of their dates are looking for exotic sexual experiences rather than genuinely loving relationships. (Levine 2017, at 5, 13; Levine 2013, at 40.)

C. The timing of harms.

196. The multi-year delay between start of hormones and the spike in completed suicide observed by Professor Biggs in the Tavistock data (as discussed in Section VIII above) warns us that the safety and beneficence of these treatments cannot be judged based on short-term studies, or studies that do not continue into adulthood. Similarly, several of the harms that I discuss above would not be expected to manifest until the patients reaches at least middle-age. For example, stroke or other serious cardiovascular event is a complication that is unlikely to manifest during teen years even if its likelihood over the patient's lifetime has been materially increased via obesity, lipid abnormalities, and smoking. Regret over sterilization or over an inability to form a stable romantic relationship may occur sooner. Psychological challenges of being a trans adult may become manifest after the medical profession is only doing routine follow up care—or, in many cases, has lost contact with the patient altogether. Because few, if any, clinics in this country are conducting systematic long-term follow-up with their child and adolescent patients, the doctors who counsel, prescribe, or perform hormonal and surgical therapies are unlikely ever to become aware of the later negative life impacts, however severe. These concerns are compounded by the findings in the recent "detransitioner" research that 76% did not inform their clinicians of their detransition. (Littman 2021.)

197. The possibility that steps along the transition and affirmation pathway, while lessening the pain of gender dysphoria in the short term, could lead to additional sources of crippling emotional and psychological pain, are too often not considered by advocates of social

transition and not considered at all by the trans child. (Levine 2016, at 243.) Clinicians must distinguish the apparent short-term safety of hormones from likely or possible long-term consequences, and help the patient or parents understand these implications as well. The young patient may feel, "I don't care if I die young, just as long I get to live as a woman." The mature adult may take a different view. Hopefully, so will the child's physician.

198. Individual patients often pin excessive hope in transition, believing that transition will solve what are in fact ordinary social stresses associated with maturation, or mental health comorbidities. In this way, transition can prevent them from mastering personal challenges at the appropriate time or directly addressing conditions that require treatment. When the hoped-for "vanishing" of other mental health or social difficulties does not occur, disappointment, distress, and depression may ensue. It is noteworthy that half of the respondents to the larger "detransitioner" survey reported that their transition had not helped the gender dysphoria, and 70% had concluded that their gender dysphoria was related to other issues. (Vandenbussche 2021.) Without the clinical experience of monitoring the psychosocial outcomes of these young patients as they age into adulthood, many such professionals experience no challenge to their affirmative beliefs. But medical and mental health professionals who deliver trans affirmative care for those with previous and coexisting mental health problems have an ethical obligation to inform themselves, and to inform patients and parents, that these dramatic treatments are not a panacea.

199. Whether we consider physical or mental health, science does not permit us to say that either puberty

blockers or cross-sex hormones are "safe," and the data concerning the mental health of patients before, during, and after such treatments strongly contradict the assertion that gender dysphoria is "easily managed."

XI. REPLY TO THE EXPERT REPORTS OF DRS. ARMAND H. MATHENY ANTOMMARIA, DEANNA ADKINS, JACK TURBAN, AND ARON JANSSEN

A. WPATH & Endocrine Society Guidelines.

200. Section (D) of Dr. Janssen's report emphasizes how WPATH and The Endocrine Society guidelines require that trans youth undergo careful psychiatric assessment prior to starting puberty-delaying or hormonal medications. However, neither these guidelines nor Dr. Janssen provide instruction for how to perform the assessments. Instead, it is left to the individual "qualified" mental health professional—that is, mental health professionals who uncritically accept WPATH's and The Endocrine Society's standards of care. These organizations assured professionals that psychiatric, social, and learning problems did not preclude medical interventions. The frequently observed co-morbidities—autism, ADD, ADHD, learning difficulties, depression, eating disorders, anxiety states, self-harm, suicidality, and substance dependence—just had to be "under reasonable control" for a trans youth to qualify for medical interventions. This guidance, too, is not further defined. (Coleman et al., 2022). Of what value to the patient is a careful psychiatric assessment if it is not followed by a serious attempt to modify or ameliorate the observed co-morbidities? Such assessments may be useful for research purposes if instruments are designed to measure the impact of affirmative care on these co-morbidities, but this is not happening. The at-

tempt to ameliorate the co-morbidities takes time measured in months if not longer. The downgrading of mental health treatment has led to a dramatically short duration between assessment and endocrine treatment. This was the source of the dismay of Edwards-Lepper and Anderson discussed above. (Edwards-Lepper & Anderson, 2021).

201. In 2022, WPATH removed all age requirements for the use of puberty blockers, cross-sex hormones, and mastectomies from its guidelines. In the place of age restrictions, health care providers must assess the capacity of adolescents (even 9 year-olds in the first blushes of puberty are called adolescents) to give informed consent (assent in legal terms). WPATH guidance used to indicate that 13- and 14-years-olds were too young to undergo mastectomies; now, following the removal of age restrictions from the guidelines (Coleman et al., 2012, 2022), the operation seems justifiable for minors in their early-teen years. Patient, family, and detransitioner reports indicate that many affirmative care clinics perform brief psychiatric evaluations and fail to inquire about the influence of past processes and events on the development of a trans identity. (Levine et al., 2022). See paragraph 207 for a more recent reference to rushed care without meeting the requirement for a comprehensive psychiatric evaluation.

B. Informed Consent.

202. Neither Dr. Janssen nor Dr. Adkins question whether adolescents can provide informed consent; even more concerning, Dr. Turban's report does not even include the word "consent." They appear unaware of the longstanding international ethical unease about youthful gender dysphoria because of seven unan-

swered questions. One of these questions is whether these often highly psychiatric symptomatic youth are competent to make decisions about their future bodies. (Vrouenraets et al., 2015). One aspect of our recent widely read article on the subject focused on whether any adolescent has lived long enough to provide an ethical and legal informed consent for puberty blockers, cross-sex hormones, or mastectomies. (Levine et al., 2022). For purposes of affirmative care, adolescence begins at Tanner stage 2 of pubertal development, which can be attained in many children at age 9. Clinicians continue to discuss and study whether a young patient is cognitively and emotionally able to process the meaning of the social, biological, sexual, interpersonal, and psychological consequences of each step in affirmative care. (Levine, 2018; Vrouenraets et al., 2022). Forty therapists, for example, resigned from Tavistock clinic, the world's largest transgender youth clinic, because of what has been done to these children in the name of helping them. (Biggs, 2022). When thinking about this issue, it is useful for all adults concerned to recall being a child or adolescent and to consider their experience with their children's maturity at ages 9 to 18. Judgment improves over time, and in no other arena are children and teens given responsibility to make such life changing decisions.

203. Dr. Adkins acknowledges that the Endocrine Society Guidelines require "informed consent" from patients but fails to mention how informed consent is obtained from minors. (Adkins, p. 10.) Similarly, Dr. Janssen mentions that the WPATH standards of care require clinicians to assess whether a patient has the requisite "capacity for decision-making." (Janssen, p. 12-13.) Both reports brush over the fact that legally in-

formed consent from those under 18 must be provided by parents or guardians. Adolescents may only assent, not consent. Dr. Adkins and Dr. Janssen rely on the Endocrine Society Guidelines, which require the physician to assess the adolescent's decision-making capacity prior to prescribing puberty blockers and hormones, as if the clinician knows how to do this, and as if a 14-year-old can comprehend, let alone make a wise decision about, future sterility, sexual dysfunction, and impaired physical health.

204. Clinicians who perceive that an adolescent can give informed consent ignore an important question: does the co-existence of psychopathology limit the patient's ability to carefully think through the requested treatment? (Vrouenraets et al., 2015.) Experienced mental health professionals wonder whether adolescents' urgency for hormones or surgery—what affirmative doctors may justify as medically necessary—is a sign of the inability to consider all the necessary pros and cons of the treatments. It is imperative that clinicians understand the possible relationships between these young persons' psychopathy and gender dysphoria. Affirmative care advocates expect that their treatment will lessen the intensity of, and possibly even eradicate, the psychopathy because the depression, anxiety, social avoidance, etc. are responses to the gender dysphoria itself. Thus, we read claims of improvements after each element of affirmative care. (Note what the systematic reviews have said about this evidence.) Since the majority of adult psychiatric problems have their origins in childhood, the possibility exists that gender dysphoria is actually created in some young people's minds as a solution to preexisting psychiatric problems. Another explanation is that psychopathology in-

dicates inadequate coping skills for dealing with life circumstances. These poor adaptive capacities will ultimately create ongoing young adult problems despite the treatment for the gender dysphoria. Finally, the poor outcomes of post-surgical patients may be due to long standing difficulties originally unrelated to gender dysphoria. Regardless of which explanation is correct in any patient, a more reasonable approach to caring for trans-identified youth is to address therapeutically the psychiatric symptoms apart from their gender distress. I see no evidence in Dr. Adkins' or Dr. Turban's reports that they have even considered this vital topic. Possibly more concerning is the fact that Dr. Janssen nods to the concept without analyzing its implications for his opinions.

205. Parental consent for medical and surgical care rests upon the clinicians' willingness to share what is known and uncertain about the benefits and harms of treatment over time. Doctors must not mislead these concerned adults into thinking there is no alternative to affirmative care. They should not frighten them into thinking that by delaying such care they are putting their child at risk of suicide. Many affirmative care clinicians, because they don't understand the vital differences between suicidality and suicide, provide unethical coercive guidance commonly summarized as, "Would you rather have a trans daughter than a dead son?"

206. Clinicians can only inform parents and adolescents about what they themselves understand about the science. (Levine et al., 2022). The issue of informed consent often rests upon whether clinicians rely upon the previous treatment patterns—fashion-based medicine—or whether they base their thinking on evidence-based medicine.

207. International interest in the necessary components of informed consent can be seen from the reception that our March 2022 article has had. As of May 13, 2023, the paper has been downloaded across the world 61,138 times. We presume that Drs. Adkins, Turban, and Janssen have read this paper. If they have not, one can only wonder just how aware they are about the scientific dialogue occurring on gender dysphoria. If they have read it, they have chosen to ignore it, even as clinicians all over the world have been recommending it to others at a startling pace.

208. It is my recurrent experience from case reviews, detransitioners' accounts, and communication with distressed parents and my own patients, that many of the hormone providers and surgeons rely heavily on the mental health professional's referral of the patient as the basis for the next affirmative care element. Clinicians are incorrectly assuming that medical and surgical interventions are clinically and ethically justified ("medically necessary") because a mental health professional cleared the patient for the intervention. The clinicians briefly review the possible medical or surgical complications of the intervention—hormones or surgery —they are providing. They typically do not know the mental health professional's degree, years of experience, or processes that led to the referral. The Endocrine Society's and WPATH's psychiatric evaluation policies sound substantial, but the devil is in the details of how they are carried out. (Edwards-Lepper & Anderson, 2021). In guidelines, this is described as requiring an interdisciplinary team of clinicians. Ideally, this team meets to discuss each case in depth so that the endocrinologist, the surgeon, and the MHPs share in person what is known about the patient. On February 9,

2023, such a high throughput process with minimal psychiatric evaluation at a gender clinic in Missouri was called out by a whistle blower in an affidavit, alleging multiple ethical violations. Missouri's attorney general and senator announced separate investigations.[15]

209. For years, affirmative care specialists have been promulgating their conviction that even a young child knows what gender he or she will always have. They have assured themselves that once cross-sex behavior patterns are consonant with a child's expressed interest in being a member of the opposite sex, their current identity is fixed for life. Such ideas are clearly incorrect, but they have pervaded advocates' writings for decades.

210. Beginning on page 15 of his report, Dr. Antommaria discusses informed consent. The counter to Dr. Antommaria's assertions can be found in the paper entitled "Reconsidering Informed Consent for Trans-identified Children, Adolescents and Young Adults." (Levine et al., 2022). As noted above, it has been received with unprecedented readership throughout the world in only one year and is in the top 5% of all scientific articles published since 2012. To date, it has been downloaded approximately a thousand times per week. Our two subsequent publications are following similar patterns.

211. Affirmative Care advocates have always recognized that informed consent was legally and ethically required. The issues are the following: (1) what in-

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[15] Missouri Independent (2023). *Missouri agencies launch investigation into health center for transgender youth*. https://missouri-independent.com/2023/02/09/missouri-agencies-launchinvestigation-into-health-center-for-transgender-youth/.

formed consent consists of, (2) how it is obtained, (3) what information is provided to the patient, (4) whether an ill-informed physician can conduct a legal and ethical consent process, and (5) whether a minor can consent. Contrary to Dr. Antommaria's assertions, it has not been proven that youth are mature enough to provide informed consent. One may wonder how this could be convincingly, scientifically proven. Detransitioners, who are surfacing at a new great rate, now say that they were too young to assent to treatment and could not grasp that their other psychological problems should have been discussed in psychotherapy before they assented to affirmative care. There remains considerable uncertainty among parents, patients, and mental health professionals about the cognitive maturational capacity of youth to assent. One must remember that in some settings, nine, ten, and eleven-year-olds are being treated with puberty blockers. Block has estimated that there are 18,000 children in the U.S. on these drugs. (Block 2023.) The research on the ability to consent was done by those in the forefront of affirmative care and was initiated because clinicians feel ethically uneasy about this care. There is simply no way to prove this is ethical because a passionate 14-year-old knows what will make her happy in the future. (Vrouenraets, et al., 2020, 2021). Doctors may not be capable of leading a proper informed consent process because they do not have sufficient knowledge of the dangers of the medical treatments. If the clinician is unaware of the elevated suicide rates after gender conforming surgeries and hormonal treatment, if they are unaware of the premature mortality of adult trans persons, and if they do not recognize the multidimensional problems described by advocates within the trans communities, then they cannot help parents to consider the immedi-

ate benefits and the long terms risks involved in affirmative care. This problem may be an artifact of being a pediatric-centered professional. The study of adults may not seem that relevant to those who care for these children.

C. The Diagnosis of Gender Dysphoria

212. Dr. Antommaria and Dr. Janssen rely on the DSM-5 and DSM-5-TR (collectively "DSM") to support the assertion that gender dysphoria is a medical diagnosis. (Antommaria, p. 18; Janssen, p. 7). However, DSM contains no diagnosis of migraine headaches, thyrotoxicosis, or any other problem that has been historically labelled as medical and treated with medications and surgery. In fact, DSM contains a list of psychiatric disorders, which are patterns of dysfunction without known anatomic or fundamental physiological disruption. Treatments for these conditions target mood, thinking, or anxiety responses to living one's life with its contradictions, disappointments, and possibilities. These conditions are ideally treated by psychotherapy alone or with a combination of psychotherapy and medication.

213. Gender dysphoria is in the DSM and gender incongruence is in the ICD-11 system of classification. In the ICD-11, both sexual dysfunction and gender incongruence are in a special section called Factors Relating to Sexual Health. In the DSM, gender dysphoria is in its own section. These special sections came about for social and political reasons (Reed et al., 2016)—to aid in these patients' low self-esteem and to decrease societal discrimination. If gender dysphoria and gender incongruence were internationally recognized to be a medical diagnosis, it would not have a presence in the DSM and

would be listed in the ICD-11 section for medical illnesses.

214. In fact, the move to depathologize gender dysphoria and gender incongruence created a paradox that has been somewhat resolved by these special sections. Those who view gender dysphoria as just another aspect of human diversity are faced with the problem that medical treatments to better align the body with the mind require a diagnosis of disease for insurance coverage. Insisting these treatments are not cosmetic, advocates settled on getting insurance coverage and keeping it a psychiatric diagnosis but in a special section. This is a political compromise on the part of the advocates for medical and surgical treatments of gender dysphoria. This was the acknowledged debate when the diagnosis of gender dysphoria was retained in DSM-5.

215. Looking deeply into the vital issue of causation, all sexual behavior and sexual identities are created by an interaction of biological, psychological developmental, interpersonal, and cultural influences. Having a biological influence manifested by a child's temperament is not the same as being caused by biology. Advocates have been looking for a hypothesized biological cause in hormone profiles, brain structure, and genetic profiles. Short of finding convincing evidence, they simply declare it is biologically caused. Obviously, there is an important distinction between influenced and caused. The declaration that gender dysphoria or gender incongruence is a medical diagnosis defies its history in DSM versions since transsexualism first was classified more than a half century ago.

216. The use of puberty blockers (PB) and cross sex hormones (CSH), which of course change normal anat-

omy and physiology, must be ethically justified to privilege respect for patient autonomy over the primary, time-honored principle dating to 2,500 years ago: Above All Do No Harm. Four comforting but false beliefs justify calling gender dysphoria a medical diagnosis: (1) A prenatal process created GD, whenever it is expressed in the lifecycle; (2) Any trans identity is unchangeable, immutable; (3) The incongruity between the sex of the body and one's gender identity will cause lifelong suffering if not addressed with PB, CSH, and surgery; and (4) There are no alternative treatments that can help.

217. Calling gender dysphoria a medical diagnosis is a rhetorical device to lessen the ethical concern of doing harm in the long run. Said more plainly, calling gender dysphoria a medical diagnosis is a rationalization. It makes the doctor feel better about any potential danger, such as causing sterility.

218. While patients' histories of their symptoms is inherent in all medical treatment, the point is that patients self-report their gender dysphoria and its duration, and the physician bases his or her diagnosis on that self-report. The idea that the diagnosis is based on the physician's perceptions—a qualified person making the diagnosis—is a transparent slight-of-hand for the fact that doctors have no way of ascertaining the truthfulness of the self-report. In medicine, patient history is the beginning of a process that is followed by a physical, laboratory, and radiologic examination before a diagnosis is made. With gender dysphoria, the process begins and ends with the patient's history.

D. Strength of Evidence

219. The evaluation of guidelines, such as those published by WPATH, is an esoteric skill set of those with an erudite knowledge. (Dahlen et al., 2021). Gordon Guyatt, Professor in the Department of Health Research Methods at McMasters University, is one such highly qualified evaluator. He invented the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) system. GRADE is a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations. With over 100 adopting organizations worldwide, it is the most widely used tool for grading the quality of evidence. (Guyatt et al., 2008). Guyatt found serious problems with the Endocrine Society's guidelines. He also noted that WPATH did not reveal how many systematic reviews of evidence were undertaken and what their findings were. Scientific reviews require transparency. Another reviewer of WPATH 8th version, Helfand (quoted extensively in Block, 2023), noted that there were several instances in which the strength of evidence presented to justify a recommendation was "at odds with what their own systematic reviewers found." Helfand also noted that WPATH's recommendations did not distinguish when one was based on systematic review of evidence and when it was based on consensus. (Block, 2023). Rafferty, the author of the AAP's 2018 guidance recommending social transition and affirmative care for children, and puberty blockers for older children at Tanner 2, stated that "their process doesn't quite fit the definition of a systemic review." (Block, 2023).

220. In paragraph 64 of his report, Dr. Antommaria indicates that "gender-affirming medical care under

clinical practice guidelines, like the Endocrine Society's, is evidence based." Dr. Janssen makes a similar claim, citing WPATH SOC 8 in paragraph 33 of his report. Of course, the guidelines are "evidence based," but the Endocrine Society itself admits the evidence basis is of low quality—as have multiple other reviews of the evidence. (Cass, COHERE, Brignardello-Peterson & Wiercioch, and SBU). WPATH SOC 7 and 8 have been reviewed in the same low evidence basis. (Dahlen et al., 2021, Block, 2023). Moreover, all nine of the authors of the Endocrine Society's guidelines are professionals who prescribe or recommend hormones or provide surgery for trans youth. (Hembree et al., 2017). That is a far cry from the 70% standard for the GRADE field. The bias is: one finds for the procedures that one performs.

221. In paragraph 22 of his report, Dr. Antommaria states that randomized trials of individuals with gender dysphoria are, at times, "unethical." But the reason he asserts that the randomized trials are unethical is that he and others in the U.S. believe the treatments are superior to no treatment or psychotherapy. He ignores the utter lack of knowledge about the long-term outcomes and the indicators of other adult transgender people's problems. The failure to do rigorous studies following de Vries, whose replication failed (Carmichael, 2020), is part of the problem today.

E. Low Regret Rates

222. In paragraph 56 of this report, Dr. Antommaria, like WPATH, asserts that the regret rate for adult gender-diverse patients who received affirmative care is 1.1%. He does not explain how regret is being defined to obtain this figure. (Hall et al., 2021). Regret,

of course, is a common, if not universal, human experience. Transgender adolescents are not exceptions. Regret and acceptance of affirmative care can co-exist. It is not an either/or phenomenon. Regret does not preclude experiencing benefits from changing one's appearance. (Chen et al., 2023). Aesthetic benefits typically appear first. Regret's complexity can be seen in the observation that some detransitioners say that they do not have regret for having originally transitioned, but once they presented themselves as a trans person, regret eventually led to detransition. (MacKinnon, et al., 2022).

223. Though Dr. Antommaria's and Dr. Turban's reports touch on the topic of regret, they fail to adequately consider (or to consider at all) the interplay between regret and infertility secondary to gender affirming care. Transgender-identifying adolescents are generally not concerned about their future infertility. Regret is likely to appear 10 to 15 years later. Many of these teens are inexperienced with partner sex and say that they are not interested in it anyway. Later, as sexual dysfunction because of hormones, surgery, or anxiety about physical intimacy becomes a recurrent experience, regret appears. Isolation from family over time, the inability to find a stable relationship, the experience of discrimination, their need for ongoing medical care, and their coping with substance use to quell anxiety and depression—matters that they may have been warned about—begin to create waves of regret. Some eventually express regret over not having had a chance to explore their array of concerns in psychotherapy before they transitioned. (Littman, 2021).

224. Regret rates less than 1%, as quoted by Dr. Turban, defy credulity. Typical of other advocates for

affirmative care, rates of regret < 2% are repeatedly quoted without discussion of how regret was defined and what percentage of the original populations were lost to follow up. These figures do not encompass patients of any age outside of medical systems who identify as trans and then return to a sex-gender compatible state. Dr. Turban's influence of external factors seems to think that external influences have no intrapsychic manifestations. This comes about because Dr. Turban does not recognize, or at least acknowledge, that trans adolescents and adults are ambivalent about their trans processes even if they are not perceived to be so by advocates.

225. There must be a hierarchy of intensity of regret related to the situations patients ultimately find themselves in. Suicide and suicide attempts must be considered as a possible manifestation of regret. After having undergone mastectomies or genital reconstruction, detransitioners rank high on the list of regret whether they consult a surgeon to see if their anatomy can be restored or an endocrinologist to administer their gonadal hormones. (Littman, 2021).

226. Lower on this hierarchy are those who recognize they are disappointed with their cross-gender lives for various reasons, whether they take steps to detransition or not. Detransitioners, and those who are resigned to making the best of their circumstances, are often angry at themselves for their naïve adolescent certainty and at their professionals' unconcerned compliance with their requests. (Littman, 2021). Lesser adaptive challenges occur to those who detransition after estrogen or testosterone has created new permanent features. (Boyd et al., 2022). Estrogen-induced larger breasts can be surgically removed, but it is not

clear to what extent the long-term use of estrogen threatens sexual and testicular reproductive function. Testosterone-induced low register voices stay largely in the male range, facial hair does not disappear, and lactation is not possible when mastectomies are repaired with implants.

227. Those who detransition before taking hormones may have the least problematic new adaptations, but this too creates concerns. Years of binding may reshape breasts, for instance. Parents who objected to transition typically rejoice when an offspring detransitions. Parents who supported the transition may go through a period of embarrassment, grief, and guilt. While Dr. Antommaria's figure about regret could not possibly adequately summarize the phenomena, it does make affirmative care advocates comfortable.

XII. THE MOST RECENT SYSTEMATIC REVIEW PUBLISHED IN THE FIELD HIGHLIGHTS MANY OF THE POINTS MADE ABOVE

228. In closing this report, I would like to summarize a recently published article in detail because it highlights many of the points I have been making.

229. On April 17, 2023, a systemic review of the hormonal treatment for children with gender dysphoria was published by an eight-person team of scientists with appointments in various departments: epidemiology, pediatrics, gastroenterology, health technology, clinical science, women's and children's health, psychiatry and neurochemistry, and neuroscience and physiology. (Landen et al, 2023). It is likely that this report was one of the bases for Sweden's new national health policy, which makes psychotherapy (instead of hormonal treatment) the initial treatment approach for

transgender-identified children and adolescents. Sweden now allows hormonal treatment to be only offered in research protocols. The article contains five tables, the last of which describes how future research should be conducted and reported. This table indirectly demonstrates the profound methodological problems with the current studies and gives guidance to the Karolinska Institute in Stockholm, at which future adolescents may be enrolled in protocols.

230. This project assessed psychosocial effects, bone health, body composition and metabolisms, and therapy persistence in children less than age 18 years of age who were treated with puberty blockers. The study initially identified 9,934 English language articles on the topic, but as is usual for such processes, selected 24 studies from 2014 onward for intense scrutiny. The GRADE system, which provides four levels of evidence (very low, low, moderate, high), was used to analyze the 24 studies. Puberty blockers (PB) were typically administered to patients between 11- and 15-years-old, but the actual age range spanned from 9 to 18.6 years.

231. Six studies focused on psychosocial and mental health parameters. Global function was evaluated for 113 patients, but the certainty of the evidence "[could not] be assessed." When suicidal ideation was evaluated for 28 patients, there was no change noted and the certainty of evidence "[could not] be assessed." Similar conclusions about the certainty of evidence were found when assessing gender dysphoria, depression, anxiety, cognition, and quality of life. Each of the six studies were downgraded because of selection bias, lack of precision in measurement, absence of long-term follow-up, and inability to separate effects of the hormone from psychotherapeutic effects. One study of 20 patients on

cognitive effects found no differences between the treated and untreated patients but had no pre- and post-treatment measurements. This missing method could have shown the variable effects from patient to patient—positive, negative, or no change. Mean data obscures this important information. (Landen et al, 2023).

232. The conclusion based on six longitudinal studies on bone density, only one of which was prospective, was graded "low certainty." Three studies found that before the start of PBs, bone density was lower than age mates. Bone mineralization increased less than age mate controls while on PBs, but the absolute density remained unchanged after two to three years. Even after five-plus years of cross sex hormones, the lumbar spine scores were significantly lower than before PBs were started, while other volume and femoral neck scores had normalized. A separate study of female to males on testosterone for 1-2 years failed to regain scores registered at the start of PBs. When bone geometry was studied, those treated at the onset of puberty resembled the values of their **experienced** gender, whereas those who started PBs later in puberty remained consonant with their **biological sex**. (Landen et al, 2023).

233. Puberty blockers arrest the puberty growth spurt and lead to increased fat mass and decreased lean body mass.

234. Obesity at age 22 was more prevalent in the transgender populations.

235. From the abstract review of almost 10,000 studies, no randomized controlled studies were identified. In general, the 24 identified studies lacked control groups and intra-individual analyses, had high attrition

rates (lost to follow-up or missing data), and failed to assess long term outcomes. No data were presented that dealt with those who stopped PB. The authors noted that their conclusions were consistent with the UK systemic review. The Swedish review concluded that the effects on psychosocial and somatic health are "unknown". (Landen et al, 2023).

236. Given these and similar findings from other systemic reviews free from commercial bias, such as the other recent one from McMasters University (Brignardello-Peterson & Wiercioch, 2022), it is my opinion that the terms "experimental," "unproven," or "dangerously uncertain" are justified when considering the absence of long term follow up data and the deficiencies within the current literature.

237. Given the considerable risk of harms, which include premature death (Jackson et al, 2023) and other less obvious problems discussed in this report, the question of whether minors may provide consent for medical and surgical treatments quickly arises. Others have asked, with life experiences being limited, brain development being incomplete, and psychiatric co-morbidities being present, whether any adolescent can legally give informed consent for medicalization. This is why parents are legally required to provide consent and the minor only assents. However, they cannot be expected to understand the limitations of the science pointed out by the Swedish systemic review. My concern is that the American affirmative care clinicians and institutions that support such care also simply do not understand the limitations of science in this politicized arena.

238. When the frequently encountered psychiatric co-morbidities of trans youth are entered into

consideration—autism, depression, social avoidance, anxiety states, eating disorders, suicidality, and self-harming patterns—it seems prudent not to assume that a young person has the capacity to think through the momentousness of the decision. We might expect U.S. physicians, who know the nature of scientific uncertainty, to be concerned with this haunting question of decision-making capacity, as have the Europeans. (Vrouenraets, et al, 2020.)

I declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury that the foregoing is true and correct. Executed this 18th day of May, 2023.

/s/ STEPHEN B. LEVINE, M.D.
STEPHEN B. LEVINE, M.D.

EXHIBIT 6

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

Case No. 3:23-cv-00376

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

v.

JONATHAN SKRMETTI, ET AL., DEFENDANTS

EXPERT DECLARATION OF DR. SVEN ROMÁN

Background And Qualifications

1. I am a Swedish child and adolescent clinical psychiatrist and have been practicing medicine since 2000, with my focus on child and adolescent psychiatry since 2004. As discussed more completely below, I have personally witnessed the rise of a new class of gender dysphoria patients in Sweden, which now dominate the population of these patients in Sweden. I was educated in medicine at Karolinska Institutet (which would be translated to English as Karolinska Institute), which is the most well-known and prestigious international medical training institute in Sweden. Karolinska children's hospital, called Astrid Lindgren's Children's Hospital, has also played a significant role in the ongoing conversation about treatment of minors with gender dysphoria, as it has handled significant numbers of child and adult patients with this condition. I have been treating patients with a variety of psychiatric disorders, both in an inpatient and out-patient setting, since 2004. I meet

with and treat patients suffering from virtually the entire range of disorders identified in the DSM-5. I have participated in approximately 600 to 700 neuropsychiatric investigations and evaluations.

2. In the course of my work, I have met with approximately 30 children who have been identified or self-identified as suffering from gender dysphoria. In some cases, I have met with these children after active medical intervention has begun (puberty blockers and cross-sex hormones). Surgical intervention in minor children in Sweden is extremely rare and there are very few such cases and therefore I have not encountered one. Other patients with gender dysphoria I have met with have presented to me prior to medical intervention. For the reasons I give below, I have not referred patients to gender clinics for medical intervention because (1) I have consistently believed that there was a lack of evidence to support such medical interventions and (2) because in my experience all such patients I have met with have other psychiatric conditions in addition to their professed gender dysphoria. Treatment of these other conditions has been shown to also resolve gender dysphoria in many such cases. Through my involvement with GENID, discussed below, I have learned that parents report that children frequently desist from their gender dysphoria when they receive psychotherapy or other interventions to address psychiatric comorbidities. Teenagers routinely experience mild body dysmorphia (unhappiness with their physical appearance) and sometimes psychotherapy and the maturation process are all a child needs to resolve what the child may call gender dysphoria.

3. I have written on a variety of medical subjects for major Swedish newspapers and have published arti-

cles in the medical press in Sweden. On the subject of gender dysphoria, several of the articles have been translated into English and have been widely disseminated internationally. I have also written or co-authored two articles on this subject in the foreign medical journals The American Journal of Psychiatry and Dagens Medicin in Norway. My list of publications is attached to my CV, which is Exhibit A to this declaration.

4. I have spoken about childhood gender dysphoria in several recognized Swedish podcasts, on Finnish public service radio, in the French daily newspaper Le Figaro, and on 21 May a documentary will be broadcast on French TV channel M6, including footage of my lecture in the Swedish Parliament on 16 September 2021. Since 2019, I have held five lectures and one hearing to members of the Swedish Parliament by invitation, including two lectures in 2019 and 2021 on the subject of gender dysphoria in children.

5. My opinions in this declaration are based on my clinical experience, as well as my review of the literature both in Sweden and the rest of the world, though I will focus on the Swedish experience and the resulting systematic review of the Swedish National Health Service. The systematic review published just last month by Dr. Michael Landén and his colleagues conclusively establishes that there is insufficient evidence to support hormonal interventions in gender dysphoric youth. I am being compensated at my customary consulting rate of 160 euros/hour. My compensation does not depend on the content of my testimony.

The Rise Of Gender Dysphoria In Sweden

6. In Sweden, the Gender Identity Challenge (GENID) association was formed in 2018 by parents of trans children and also trans young adults. The parents and former patients in the association were distressed that children had received irreversible pharmacological and surgical treatment and were unsure whether the benefits outweighed the risks. They approached journalists, authorities and doctors and wrote opinion pieces. It was their hard work that paved the way for a public debate on the subject to start in spring 2019.

7. It was an opinion piece and a TV program that started that public conversation. The article was published on March 13, 2019 in Sweden's second largest morning newspaper, Svenska Dagbladet.[1] It was signed by seven people, including the internationally renowned professor of child and adolescent psychiatry, Christopher Gillberg, and four other professors. Dr. Gillberg is perhaps the most famous Swedish child psychiatrist living today and his opinion carried very much weight with the national health authorities. Dr. Gillberg gave testimony to the UK high court in its judicial inquiry into the Tavistock gender clinic which was heavily relied upon by that body to conclude that hormonal interventions are not appropriate for children.

8. The TV program I mentioned was broadcast on 3 April 2019 in the investigative, and in Sweden very well-known, program Uppdrag Granskning (Mission Re-

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[1] Gillberg, Christopher, et al. (March 13, 2019), The gender change in children is a great experiment. Swedish daily newspaper. https://www.svd.se/konsbytena-pa-barn-ar-ett-stortexperiment

view) and was called "The trans train and teenage girls."

9. For my part, I began my participation in the debate when I was quoted in August 2019 in an editorial in Sweden's largest daily newspaper Dagens Nyheter and within just over a month published two debate articles, one in Dagens Nyheter and one in the medical journal Dagens Medicin.[2,3]

10. The development of gender dysphoria diagnoses in Sweden is astonishing and is what gave rise, in part, to concerns raised by GENID and others. Gender dysphoria was extremely uncommon in the early 2000s. In 2001, a total of 2 children (age group 0-17 years) were diagnosed with gender dysphoria, in 2021 the number was 440, a 220-fold increase.[4] A total of 12 people under 25 were diagnosed with gender dysphoria in 2001, by 2021 the figure was 1,865. It is my understanding that Sweden has the highest rate of gender dysphoria in children (patients per 100,000 population) in the entire world. More recent data from our government shows the trend potentially leveling out for girls after GENID, Dr. Gillberg, and others began raising concerns, though the COVID pandemic and its restrictions may have caused an increase among boys.

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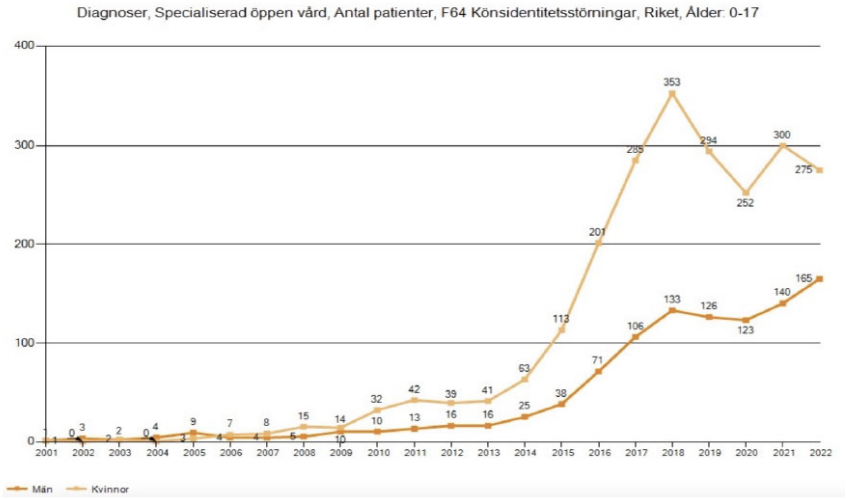
[2] https://www.dn.se/asikt/konsdysfori-sprids-som-en-epidemi-pa-natet/

[3] https://www.dagensmedicin.se/opinion/debatt/stoppa-omedel-bart-all-behandling-av-konsdysfori-for-barn-ochunga-vuxna/

[4] https://sdb.socialstyrelsen.se/if_paro/val.aspx Swedish National Board of Health and Welfare



11. The increase in the diagnosis of childhood gender dysphoria was moderate until 2007, the year the iPhone was introduced (I touch later in this expert opinion on why gender dysphoria, like many psychiatric diagnoses, is often socially contagious), and then the increase accelerated to become very high from 2014 onwards, when social media had become ubiquitous among adolescents.

12. The differences between boys and girls seen above is not unexpected in my experience as a psychiatrist. What is surprising is the significant increase in the number of diagnoses in both sexes.

13. 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 media. For example, Richard Orange, *Teenage transgender row*

splits Sweden as dysphoria diagnoses soar by 1,500%, The Observer 22 Feb 2020, reported on the suicide of a 32-year old trans woman.

14. Due to the accumulating data on remorse and suicide, the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) conducted a systematic inventory of the research. On December 20, 2019, the SBU published the systematic scoping review "Gender dysphoria in children and adolescents: an inventory of the literature."[5] The survey showed that the scientific support for medical treatment of gender dysphoria in children was non-existent or extremely weak. I quote the conclusions below.

- We have not found any scientific studies which explains the increase in incidence in children and adolescents who seek the heath care because of gender dysphoria.
- We have not found any studies on changes in prevalence of gender dysphoria over calendar time, nor any studies on factors that can affect the societal acceptance of seeking for gender dysphoria.
- There are few studies on gender affirming surgery in general in children and adolescents and only single studies on gender affirming genital surgery.
- Studies on long-term effects of gender affirming treatment in children and adolescents are few,

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[5] https://www.sbu.se/en/publications/sbu-bereder/gender-dysphoria-in-children-and-adolescents-an-inventory-of-the-literature/

especially for the groups that have appeared during the recent decade.

- The scientific activity in the field seems high. A large part of the identified studies are published during 2018 and 2019.
- Almost all identified studies are observational, some with controls and some with evaluation before and after gender affirming treatment. No relevant randomized controlled trials in children and adolescents were found.
- We have not found any composed national information from Sweden on:

  – the proportion of those who seek health care for gender dysphoria that get a formal diagnosis

  – the proportion starting endocrine treatment to delay puberty

  – the proportion starting gender affirming hormonal treatment

  – the proportion subjected to different gender affirming surgery

15. From June 2020 to March 2021, four events in Finland, the Netherlands and the UK also influenced attitudes towards the treatment of gender dysphoria in Sweden.

16. In June 2020, the Finnish Ministry of Health, under the leadership of the Nordic region's leading pediatric gender dysphoria researcher, Rittakertu Kaltiala, issued new guidelines: psychological treatment should

be the first line of treatment for everyone with gender dysphoria, both children and adults.[6]

17. Annelou de Vries, who is behind the protocol used by all guidelines, "The Dutch protocol," writes in the September 2020 issue of the American College of Pediatricians' journal *Pediatrics*: the protocol is incorrectly applied to the ROGD group, they should be treated primarily with psychiatric care. "ROGD" is an acronym for Rapid Onset Gender Dysphoria, the new group of children with gender dysphoria characterized by onset in adolescence, the majority are born female and often have one or more psychiatric syndromes.[7]

18. On December 1, 2020, 23-year-old Keira Bell—a detransitioner who was given puberty blockers at age 16, treated with testosterone at 17, and underwent a mastectomy by surgeons when she was 20—won a Supreme Court case against the Tavistock Clinic in London. As a result, no children under 16 would receive gender reassignment treatment at that clinic without judicial approval.[8] Tavistock's gender clinic has subse-

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[6] Kaltiala-Heino, R., Sumia, M., Työläjärvi, M. et al. Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development. Child Adolesc Psychiatry Ment Health 9, 9 (2015). https://doi.org/10.1186/s13034-015-0042-y

[7] de Vries ALC. Challenges in Timing Puberty Suppression for Gender-Nonconforming Adolescents. Pediatrics. 2020 Oct;146(4): e2020010611. doi: 10.1542/peds.2020-010611. Epub 2020 Sep 21. https://pubmed.ncbi.nlm.nih.gov/32958612/

[8] Carl-Michael Edenborg, "Ångrade könstransition—stämde kliniken" (Regretted gender transition—sued the clinic). Svenska Dagbladet, May 28, 2021. https://www.svd.se/fallet-bell-angrade-konstransition--stamde-kliniken

quently been closed as a result of an interim review by Dr. Hilary Cass.

19. The English National Health Service, NHS, published on March 11, 2021 an Evidence review: *Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria.* It concludes that there is a lack of evidence for the medical treatment of minors.[9]

20. A major shift towards a more restrictive approach to the treatment of children with gender dysphoria took place in March 2021, when Karolinska University Hospital, inspired by the international events of the last 10 months, issued a new policy statement.[10] The hospital runs the leading pediatric gender clinic in all of Sweden, Astrid Lindgren's Childrens Hospital. The new policy 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." The Astrid Lindgren's Children's Hospital 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 Children's Hospital announced that "In

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[9] National Institute for Health and Care Excellence (NICE). Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria. NICE Publishers;NHS England; NHS Improvement. 11 March, 2021. https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidencereview_GnRH-analogues_For-upload_Final.pdf

[10] https://segm.org/sites/default/files/Karolinska%20_Policy_Statement_English.pdf

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 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). The Karolinska Hospitals new policy became effective April 1, 2021.

21. An article from August 31, 2021 in the medical journal Läkartidningen shows that 5 of the 6 gender dysphoria clinics in Sweden are following the new policy of Astrid Lindgren's Children's Hospital, Umeå in northern Sweden is the single clinic that continues with prior practice.[11]

22. On November 24, 2021, the investigative TV program Uppdrag Granskning broadcast the third episode in 2.5 years about young transgender people.[12] The report shows that about 440 children have received puberty blockers over the past 5 years and that in Stockholm there have been reports of 13 children who have had severe side effects, one of whom has a skeleton like an 80-90 year old. The underreporting of side effects is potentially high.

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[11] Katrin Trysell, "De flesta har skärpt rutiner för ny hormonbehandling hos minderåriga" (Most have tightened procedures for new hormone therapy for minors). Läkartidningen, August 31, 2021. https://lakartidningen.se/aktuellt/nyheter/2021/08/de-flesta-har-skarpt-rutiner-for-ny-hormonbehandling-hosminderariga/

[12] https://www.svtplay.se/video/33313874/uppdrag-granskning/uppdrag-granskning-transbarnen?info=visa

23. On February 8, 2022, the newspaper Svenska Dagbladet published Professor Mikael Landén's article "Withdraw the proposal on gender identity".[13] Dr. Landén is considered one of the leading psychiatrists on the issue of gender dysphoria and has been treating patients in this area since at least the early 2000s. The Swedish government has proposed a new law that from 2024 makes it possible to choose your own gender without testing your gender identity. For children from the age of 12, it is proposed that parents make the application. Landén's objections: It is impossible to determine this for oneself or as a parent of one's child; the state must keep track of the real gender; a simple search of employers, authorities and private individuals reveals those individuals who at some point in their lives have had a gender identity crisis, which is intrusive; the proposal risks causing irreparable damage to children.

24. A quote from Mikael Landén's article: "I think the government has confused the individual's right to personal identity with the right to control the behavior and thoughts of others. That we have the right to live and express ourselves as we wish does not mean that we have the right to control how others categorize us. If I —as a man—were to exercise my right to change my legal gender to female, the legal gender will be wrong. With the government's proposal, I can still force those around me to incorrectly categorize me as a woman when I apply for a job, end up in prison, compete in wrestling or choose a locker room at Friskis & Svettis (a fitness center). Regulating the behavior and expression of others in this way is an infringement of human rights, not an enhancement of them."

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[13] https://www.svd.se/dra-tillbaka-forslaget-om-konstillhorighet

25. Another quote from the article by Mikael Landén, the conclusion on the right of children to change their gender identity: "The issues become even more problematic when it comes to children. Exploring different identities as a teenager is a natural developmental step towards adulthood. Identity formation options vary with the zeitgeist. While young people in the eighties wondered whether they were a synthesizer or a punk, young people today are asked to consider whether they are male or female. Even though this is not a real choice—gender is natural—some young people will still experiment with gender expression and explore what applies to them, what is known as an identity crisis. Personal identity is formed in several stages and reassessed over time. The search for identity is not a single irreversible event. We don't see many 55-year-old punks on the streets, even though their identification was very strong when they were young." Finally, the last paragraph of Mikael Landén's article: "Changing legal gender during what may be a temporary identity crisis risks putting people on an irreversible path towards medical treatments that can lead to sterility and bodily harm."

The Majority Of Gender Dysphoria Patients Today

26. Our experiences of gender dysphoria in Sweden are similar to those of the rest of the Western world. The new group with gender dysphoria, which began to seriously increase in numbers in 2014, differs significantly from the group of people with gender dysphoria on which the DSM-5 diagnostic manual is based. DSM-5 was published in 2013 and the preceding work took

place the year before that.[14] The criteria are based on mainly men, onset in early childhood or early adulthood and a gender dysphoria based on social roles or behaviour. In the new group, a clear majority are of the female sex, gender dysphoria set on at puberty and is based on gender identity. Since the new group differs so much from the group on which DSM-5 is based, many in the Swedish medical community now strongly question the reliability of the diagnosis.

27. In psychiatry, it is very common for syndromes to be socially transmitted, especially among teenage and young adult females. Those who have similar problems are in contact or socialize and in these subcultures there can be a kind of competition to go the furthest. One example is anorexia, and experience has shown that it is often directly counterproductive to admit these patients to inpatient care, because then these girls and young women are inspired by the other anorexia patients, and a very destructive desire to extremes. Another example of social contagion is self-harm. It emerged as an epidemic in the early 1990s and has since escalated. Even for this group of patients, inpatient care is often counterproductive. It is not uncommon for patients with self-harm to post pictures and videos of self-harm on social media and, while in hospital, to contact like-minded people and ask when they will be admitted to the clinic.

28. My view is that gender dysphoria in children and young adults is largely explained as a social contagion. A slight increase in prevalence started in 2007, when the

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[14] American Psychiatric Association (2013) Diagnostic and Statistical Manual of Mental Disorders. Fifth edition. Arlington, VA. American Psychiatric Publishing.

first smartphone was launched. However, it took a few years before the majority of teenagers had a smartphone, and this coincides quite well with the sharp increase in the diagnosis of gender dysphoria in young people. American journalist Abigail Schrier's book *Irreversible Damage: The Transgender Craze Seducing Our Daughters* (2020) provides a vivid and detailed account of the social contagion of gender dysphoria.[15] In the 1990s and even in the 2000s, teenage girls had greater social contact in the non-virtual world, but since the 2010s, many only have social contact via social media on smartphones/computers.

29. The fact that gender dysphoria is socially contagious is also illustrated by the fact that the gender dysphoria diagnosis among children in Sweden decreased in 2019 and 2020, when the public debate was initiated. But when Sweden from spring 2020 to 2021 had restrictions due to the COVID-19 pandemic, including distance learning in upper secondary schools and universities and less incidence of organized sport, many teenagers and young adults became socially isolated and then the trend reversed and the number of gender dysphoria diagnoses for children increasing again.

30. The high comorbidity must also be considered. There is a possibility that the majority of patients in the new group have autism or autism-like conditions. In their teens, people with autism have even more concerns about their body and identity than other adolescents. Other comorbidity in gender dysphoria is self-harming behavior, eating disorder, mental trauma, depression and emotional instability. All of the above con-

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[15] Schrier, A. Irreversible Damage: The Transgender Craze Seducing Our Daughters. (2020). Regnery Publishing.

ditions are subject to evidence-based treatment. Gender dysphoria completely lacks evidence-based treatment for children, and probably also for adults 18 to 25 years. The Table below, from the Socialstyrelsen report in 2020 shows the high rates of comorbidity in girls ages 13-17.

Table 1. Prevalence of various psychiatric diagnoses (primary diagnosis in the open and inpatient care) among persons diagnosed with gender dysphoria (F64) and the population in 2016–2018, by age and registered sex.

Women (%)		Age (years)				
		13-17	18-24	25-29	30-44	45-64
With Gender Dysphoria	F1 Harmful use / dependence	1.5	4.4	4.3	2.6	2.9
	F2 schizophrenia etc.	0.4	1.0	1.4	1.1	4.3
	F30-31 Bipolar Disease	0.4	2.6	5.2	5.6	2.9
	F32-39 Depression	28.9	25.0	13.4	12.7	11.9
	F4 Anxiety disorders	32.4	28.5	23.3	19.8	13.3
	F60-61 Personality Syndrome	0.0	4.0	6.7	4.4	2.9
	F84 Autism	15.2	14.7	11.1	8.7	4.3
	F9 ADHD etc.	19.4	18.4	14.6	12.8	5.7
	X60-84, Y10-34 Self-harm	7.8	6.6	4.4	2.0	1.9
General Population	F1 Harmful use / dependence	0.7	1.8	1.2	0.9	0.9
	F2 schizophrenia etc.	0.0	0.2	0.3	0.4	0.7
	F30-31 Bipolar Disease	0.1	0.6	0.9	0.9	0.7
	F32-39 Depression	2.8	3.7	2.7	2.3	1.8
	F4 Anxiety disorders	4.2	6.4	4.9	4.4	3.2
	F60-61 Personality Syndrome	0.0	0.7	0.9	0.6	0.3
	F84 Autism	1.3	1.2	0.7	0.4	0.1
	F9 ADHD etc.	4.4	4.0	2.4	1.5	0.7
	X60-84, Y10-34 Self-harm	0.9	1.2	0.8	0.5	0.4

31. Similar patterns are seen in boys.

Men (%)	Age (years)	13-17	18-24	25-29	30-44	45-64
With Gender Dysphoria	F1 Harmful use / dependence	4.4	6.3	6.0	4.1	6.2
	F2 schizophrenia etc.	0.7	1.3	1.6	2.4	4.1
	F30-31 Bipolar Disease	0.0	1.3	2.7	2.8	2.8
	F32-39 Depression	13.8	18.2	19.2	14.9	10.0
	F4 Anxiety disorders	21.0	20.9	21.3	17.1	15.1
	F60-61 Personality Syndrome	1.5	3.6	3.5	3.7	3.9
	F84 Autism	12.3	16.3	12.7	9.4	4.4
	F9 ADHD etc.	13.0	13.5	10.2	8.8	6.2
	X60-84, Y10-34 Self-harm	4.4	4.6	2.3	2.3	1.3
General population	F1 Harmful use / dependence	0.8	2.3	2.1	1.8	1.8
	F2 schizophrenia etc.	0.1	0.4	0.6	0.7	0.8
	F30-31 Bipolar Disease	0.0	0.2	0.4	0.5	0.5
	F32-39 Depression	1.1	2.0	1.9	1.5	1.2
	F4 Anxiety disorders	1.7	3.0	2.9	2.5	1.8
	F60-61 Personality Syndrome	0.0	0.1	0.2	0.2	0.1
	F84 Autism	2.4	1.6	0.9	0.5	0.2
	F9 ADHD etc.	7.7	4.1	2.4	1.6	0.7
	X60-84, Y10-34 Self-harm	0.5	0.9	0.8	0.5	0.4

32. The DSM-5 diagnostic manual states that if a patient has multiple psychiatric conditions, the main problem must be defined. In the case of gender dysphoria, an alternative condition is often the main problem. When adequately treating the main problem, other conditions often disappear, which can thus be regarded as secondary to the main problem.

33. It is my experience and the opinion of many psychiatrists in Sweden that psychosocial treatment of gender dysphoria for children and young adults should always be tried first. As discussed below, after concerns began to be raised in 2018, the Swedish national health service and government initiated a comprehensive review that has resulted in essentially a ban on puberty blockers, cross-sex hormones, and surgeries in chil-

dren. I say "essentially" a ban because there is the possibility of truly exceptional cases and for research. One example would be someone who has already begun on these therapies and needed to be given some time to continue until it was appropriate to stop.

34. The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) published a pre-print on February 22, 2022, *Hormone treatment of children and adolescents with gender dysphoria, a systematic review and evaluation of medical aspects*. It was published as an accepted and reviewed article in *Acta Pædiatrica* on April 17, 2023, I receite the conclusions of the study below.[16]

National Health Response To Concerns About Quality Of Evidence

35. Sweden's national health care policy regarding trans issues has developed quite similarly to that of the UK. Twenty 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. As reported above, 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.)

36. On December 16, 2022, The National Board of Health and Welfare published the updated national

[16] https://onlinelibrary.wiley.com/doi/10.1111/apa.16791

guidelines Care of children and adolescents with gender dysphoria.

37. They concluded: "Caution in the use of hormonal and surgical treatment. At group level (i.e. for the group of adolescents with gender dysphoria, as a whole), the National Board of Health and Welfare currently assesses that the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatments."[17] Like others, the National Board of Health and Welfare says now that hormonal and surgical treatment in minors can only occur in exceptional cases.

38. SBU did its work, Karolinska made its decision, and the government changed its recommendations. Recently, as mentioned, that work was the subject of peer review and published in a premier academic journal. Dr. Michael Landén is the last (most important) author. This comprehensive and now peer-reviewed article accurately addresses the state of scientific research and shows conclusively that there is no demonstrated (as of yet) benefit to these therapies. This study is so important that I quote the entire abstract in the following paragraphs.

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 Eng-

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[17] https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf

lish-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 randomized controlled trials were identified. The few longitudinal observational studies were hampered 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.

39. Adolescence is the most transformative time in a person's life. We now know that the brain undergoes a major change. It matures at different rates , and myelination—the formation of a fatty sheath around the projections of each neuron—occurs from the back to front. The frontal lobe matures last, at 25-30 years of age. This is where overall thinking and judgment are located. A teenager can therefore not understand the consequences of an irreversible sex change treatment. It is my opinion that the irreversible measure of sterilization should not be carried out until the age of 25, and

it is therefore appropriate to have the same age limit for gender reassignment treatment for gender dysphoria.

I swear under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

/s/ SVEN ROMÁN
DR. SVEN ROMÁN
19 May 2023

EXHIBIT 7

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
MICHAEL K. LAIDLAW, M.D.

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EXPERT REPORT OF MICHAEL K. LAIDLAW, M.D.

I, Michael K. Laidlaw, M.D., hereby declare as follows:

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

2. I am a board-certified endocrinologist. I received my medical degree from the University of Southern California in 2001. I completed my residency in internal medicine at Los Angeles County/University of Southern California Medical Center in 2004. I also completed a fellowship in endocrinology, diabetes and metabolism at Los Angeles County/University of Southern California Medical Center in 2006.

3. The information provided regarding my professional background is detailed in my curriculum vitae. A true and correct copy of my curriculum vitae is attached as Exhibit A.

4. In my clinical practice as an endocrinologist, I evaluate and treat patients with hormonal and/or gland disorders. Hormone and gland disorders can cause or be associated with psychiatric symptoms, such as depression, anxiety, and other psychiatric symptoms. Therefore, I frequently assess and treat patients demonstrating psychiatric symptoms and determine whether their psychiatric symptoms are being caused by a hormonal issue, gland issue, or something else.

5. I have been retained by Defendants in the above-captioned lawsuit to provide an expert opinion on the efficacy and safety of sex reassignment treatment.

6. If called to testify in this matter, I would testify truthfully and based on my expert opinion. The opin-

ions and conclusions I express herein are based on a reasonable degree of scientific certainty.

7. I am being compensated at an hourly rate of $450 per hour plus expenses for my time spent preparing this declaration, and to prepare for and provide testimony in this matter. I am being compensated at an hourly rate of $650 for testimony at depositions or trial. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

8. My opinions contained in this report are based on: (1) my clinical experience as an endocrinologist in particular dealing with hormone excess, hormone deficiency, and hormone balance; (2) my clinical experience evaluating individuals who have or have had gender incongruence including a detransitioner; (3) my knowledge of research and studies regarding the treatment of gender dysphoria, including for minors and adults; and (4) my first-hand personal experience in human research as a physician, having been involved in two studies, one involving magnesium and bone density and the other involving ultrasound use for detecting recurrent thyroid cancer.[1] I frequently review medical studies conducted by others and have experience assessing the strengths and weaknesses of such studies.

9. I was provided with and reviewed the following case-specific materials: The complaints of the plaintiffs

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[1] For the latter study I helped to design an Institutional Review Board ("IRB") approved protocol. Furthermore, I received certification in the required course "Understanding the Fundamentals: Responsibilities and Requirements for the Protection of Human Subjects in Research" at the University of Southern California in 2003.

and the United States, the various declarations submitted by the Plaintiffs, the expert declarations submitted by Dr. Adkins, Dr. Janssen, Dr. Turban, and Dr. Antommaria, medical records produced by plaintiffs for L.W., John Doe, and Ryan Roe,[2] and Tennessee Senate Bill 1, codified at Tenn. Code Ann. § 68-33-101, *et seq.*

10. A true and correct copy of my CV is attached to this declaration. In the previous four years, I have provided expert testimony in the following cases: United States District Court for the Northern District of Florida Tallahassee Division, *AUGUST DEKKER, et al., Plaintiffs, v. SIMONE MARSTILLER, et al., Defendants*, Case No. 4:22-cv-00325-RHMAF, 2022-2023; United States District Court for the Western District of Washington, *C. P., by and through his parents, Patricia Pritchard and Nolle Pritchard, and PATRICIA PRITCHARD, Plaintiff, vs. BLUE CROSS BLUE SHIELD OF ILLINOIS*, Defendants, Case No. 3:20-cv-06145-RJB, 2022; District Court of Travis County, Texas, 459th Judicial District, *PFLAG, INC., ET AL., Plaintiffs, v. GREG ABBOTT, ET AL., Defendants*, Case No. D-1-GN-22-002569, 2022; Superior Court of the State of California, County of Tulare, *JULIANA PAOLI v. JOSEPH HUDSON* et al., Case No. 279126, 2021; United States District Court for the District of Arizona, *DH and John Doe, Plaintiffs, vs. Jami Snyder, Director of the Arizona Health Care Cost Containment System, in her official capacity, Defendant*, Case No. 4:20-cv-00335-SHR, 2020; Supreme Court of British Columbia, File No. S2011599, Vancouver Registry. Between *A.M. Plaintiff and Dr. F and Daniel*

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[2] John Doe and Ryan Roe are using pseudonyms for the purpose of this case.

McKee Defendants, 11/23/20 & 11/25/20; and Court of Appeal File No. CA45940, Vancouver Registry, B.C. Canada, Supreme Court File No. E190334, between *A.B. Respondent/Claimant, and C.D. Appellant/Respondent, and E.F. Respondent/Respondent*, 24 Jun 2019.

11. In my professional opinion, treatment interventions on behalf of children and adults diagnosed with gender dysphoria must be held to the same scientific standards as other medical treatments. These interventions must be optimal, efficacious, and safe. Any treatment which alters biological development in children should be used with extreme caution. Except in the case of a fatal injury or disease, the minor will become an adult and present to the adult physician. The adult physician must be able to have a thorough understanding of any condition which alters the biological development of children and, in the case of the endocrinologist, be knowledgeable about the long-term effects of hormones on the human body, particularly when the hormones are being used in ways that alter development.

12. The following expresses my expert opinion regarding minors who present with a disparity between their biological sex and internal feeling about their gender, specifically with regard to the use of social transition, medications which block normal pubertal development, the applications of hormones of the opposite sex, and surgical procedures that alter the genitalia and/or breasts for those individuals.

I. Background

A. Biological Sex in Contrast to Gender Identity

13. A recognition and understanding of biological sex is critical to my practice as an endocrinologist because the endocrine physiology of men and women, boys and girls, differ.

14. Biological sex is the objective physical condition of having organs and body parts which correspond to a binary sex. There are only two physical sexes, male and female. The male is identified as having organs and tissues such as the penis, testicles, and scrotum. The female sex is identified by having organs and tissues such as the labia, vagina, uterus, and ovaries. Biological sex is easily identified by physical observation such that adults and even young children can identify the biological sex of a newborn baby.

15. It is also noteworthy that the physical organs described above as representing biological sex have a physical genetic correlate. In other words, it is a well-established scientific fact that two X chromosomes identify the cells correlating to a female person, and an X and a Y chromosome correlate to a male person.

The Diagnostic and Statistical Manual of Mental Disorders (DSM-5 TR) states "sex and sexual refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and non-ambiguous internal and external genitalia." Note that gender identity is not a component of biological sex as defined by the DSM 5.

16. Gender identity in the DSM 5 is defined separately: "Gender identity is a category of social identity

and refers to an individual's identification as male, female, or, occasionally, some category other than male or female." (DSM 5-TR). So, we can see that gender identity is not a physical entity but is described as a social identity. It is a subjective identification known only once a patient makes it known. It cannot be identified by any physical means, cannot be confirmed by any outside observer, and can change over time.

17. Gender identity is a psychological concept. It has no correlate in the human body. In the letter to the editor I wrote with my colleagues, we wrote in our critique of the Endocrine Society Guidelines that "There are no laboratory, imaging, or other objective tests to diagnose a 'true transgender' child." (Laidlaw et al., 2019).

18. For example, one cannot do imaging of the human brain to find the gender identity. Likewise, there is no other imaging, laboratory tests, biopsy of tissue, autopsy of the brain, genetic testing, or other biological markers that can identify gender identity. There is no known gene that maps to gender identity or to gender dysphoria. In other words, there is no objective physical measure to identify either gender identity or gender dysphoria.

19. This is in contrast to endocrine disorders which have a measurable physical change in either hormone levels or gland structure that can be confirmed by physical testing. Therefore, gender dysphoria is a purely psychological phenomenon and not an endocrine disorder. But as my colleagues and I wrote in our letter to the editor, it becomes an endocrine condition through gender affirmative therapy: "Childhood gender dysphoria (GD) is not an endocrine condition, but it becomes one through iatrogenic puberty blockade (PB)

and high-dose cross-sex (HDCS) hormones. The consequences of this gender-affirmative therapy (GAT) are not trivial and include potential sterility, sexual dysfunction, thromboembolic and cardiovascular disease, and malignancy." (Laidlaw et al. 2019).

20. Importantly, none of the plaintiffs have presented any evidence that a brain scan, blood tests, biopsy or other biological tests or markers were performed to confirm the gender identity.

21. Furthermore, no genetic studies have ever identified a transgender gene or genes. And none of the three minor plaintiffs have presented evidence of genetic testing that was performed to verify the gender identity.

22. Dr. Adkins wrote, "'Biological sex, biological male or female: These terms refer to physical aspects of maleness and femaleness. As these may not be in line with each other (e.g., a person with XY chromosomes may have female-appearing genitalia), the terms biological sex and biological male or female are imprecise and should be avoided.'" (Adkins dec, p. 4 FN 1 citing Hembree et al., 2017). However, sex is clearly identified in 99.98% of cases by chromosomal analysis (Sax, 2002). Sex is also clearly recognized at birth in 99.98% of cases (Id.). Therefore, sex is a clear provable objective reality that can be identified through advanced testing such as karyotyping, or simple genital identification at birth by any layperson. The other 0.02% of cases have some disorder of sexual development (DSD). DSDs do not represent an additional sex or sexes, but simply a disorder on the way to binary sex development (Chan et al., 2021). Importantly, none of the plaintiffs have been diagnosed with a disorder of sexual development.

23. Dr. Janssen states, "The lack of evidence demonstrating that gender identity can be altered, either for transgender or for non-transgender individuals, underscores the innate nature and immutability of gender identity." (Janssen decl, p. 6). But he offers no explanation as to what sort of testing procedures are performed to confirm an immutable gender identity.

B. Human Sexual Development

1. Embryologic development

24. Another confirmation that there are only two biological sexes comes from what is known about embryologic development and fertilization. The biologic development of the human person begins with a gamete from a female termed an ovum or egg and a gamete from a biological male which is termed sperm. The fertilization of the egg by the sperm begins the process of human biological development. The cells of the fertilized ovum then multiply, and the person undergoes the incredible changes of embryologic development.

25. It is noteworthy that the male sperm comes from the biological male and the female egg comes from the biological female. There is no other third or fourth or fifth type of gamete that exists to begin the development of the human person. This is consistent with the binary nature of human sex (Alberts et al., 2002).

26. The sex binary of the human embryo is further developed between roughly weeks 8 to 12 of human development. There are two primitive structures present within the developing embryo called the Wolffian duct and Mullerian ducts (Larsen et al., 2003). The Wolffian ducts develop into substructures of the genitalia including the vas deferens and epididymis which belong exclu-

sively to the male sex. For the female, the Mullerian ducts go on to form the uterus, fallopian tubes, cervix and upper one third of the vagina which belong exclusively to the female sex (Id.)

27. Significantly once the male structures are developed from Wolffian ducts, the Mullerian ducts are obliterated. This means that throughout the rest of embryological development the Mullerian ducts will not form into biological female structures. Likewise, in the female, the Wolffian ducts are destroyed by week 12 and will not form male structures at any point in the future (Id.).

28. Thus, we can see in very early development that the sex binary is imprinted physically not only in the chromosomes, but also on the very organs that the body produces. Additionally, the potential to develop organs of the opposite sex is eliminated. Thus, in the human being there are only two physical tracts that one may progress along, the one being male and the other being female (Wilson and Bruno, 2022).

2. Pubertal Development

29. As mentioned previously, at the time of birth an infant's sex is easily identified through observation of the genitalia. Corresponding internal structures could also be confirmed through imaging if needed.

30. In early childhood, some low level of sex hormones is produced by the sex glands. The male testes produce testosterone. The female ovaries produce primarily the hormone estrogen. These sex glands remain quiescent for the most part, producing low levels of sex hormones until the time of pubertal development.

31. Puberty is an essential part of human development. Its purpose is to achieve full adult sexual function and reproductive capacity.

32. Puberty is a time of development of the sex organs, body, and brain. There are well known changes in physical characteristics of the male such as growth of facial hair, deepening of the voice, and increasing size of the testicles and penis. Importantly the testicles will develop sperm under the influence of testosterone and become capable of ejaculation. Because of these changes, the male will become capable of fertilizing an egg. The inability to produce sperm sufficient to fertilize an egg is termed infertility.

33. For the female, pubertal development includes changes such as breast development, widening of the pelvis, and menstruation. The female will also begin the process of ovulation which is a part of the menstrual cycle and involves the release of an egg or eggs from the ovary. Once the eggs are released in a manner in which they can become fertilized by human sperm then the female is termed fertile. The inability to release ovum that can be fertilized is infertility (Kuohong and Hornstein, 2021).

3. Tanner stages of development

34. From a medical perspective it is important to know the stage of pubertal development of the developing adolescent. This can be determined through a physical examination of the body. The female will have changes in breast characteristics and pubic hair development. Similarly, the male will have changes in testicular size and pubic hair development. These findings can be compared to the Tanner staging system which will allow the stage of puberty to be known.

35. Tanner stages are divided into five. Stage 1 is the pre-pubertal state before pubertal development of the child begins. Stage 5 is full adult sexual maturity. Stages 2 through 4 are various phases of pubertal development (Greenspan and Gardner, 2004).

36. Awareness of the Tanner stage of the developing adolescent is also useful to assess for maturation of sex organ development leading to fertility. For girls, the first menstruation (menarche) occurs about two years after Tanner stage 2 and will typically be at Tanner stage 4 or possibly 3 (Emmanuel and Boker, 2022). The first appearance of sperm (spermarche) will typically be Tanner stages 4 (Id.). If puberty is blocked or disrupted before reaching these critical stages, the sex glands will be locked in a premature state and incapable of fertility.

4. Biological Sex Cannot Be Changed

37. It is not possible for a person to change from one biological sex to the other, and there is no technology that allows a biological male to become a biological female or vice-versa. It is not technologically possible at this time to change sex chromosomes; these will remain in every cell throughout life. It is not technologically possible to transform sex glands from one to the other. In other words, there are no hormones or other means currently known to change an ovary into a testicle or a testicle into an ovary.

38. Furthermore, as noted earlier, several of the sex specific structures (such as the epididymis of the male or uterus of the female) are produced early in embryological development from around weeks 8 to 12. The primitive ducts which lead to these organs of the opposite sex are obliterated. There is no known way to re-

suscitate these ducts and continue development of opposite sex structures.

39. It is also not possible to produce gametes of the opposite sex. In other words, there is not any known way to induce the testicles to produce eggs. Nor is there any known way to induce the ovaries to produce sperm. Therefore, creating conditions for a biological female to create sperm capable of fertilizing another ovum is impossible. The induction of opposite sex fertility is impossible.

40. In fact, as I will discuss, gender affirming therapy actually leads to infertility and potential sterilization.

C. Endocrine Disorders

41. Before discussing gender dysphoria and gender affirmative therapy from the perspective of an endocrinologist, it is helpful to discuss the background of endocrine diseases. This background demonstrates the difference in gender dysphoria, which is a psychological diagnosis, and other conditions treated by endocrinologists, which are physical diagnoses.

42. Endocrinology is the study of glands and hormones. Endocrine disorders can be divided into three main types: those that involve hormone excess, those that involve hormone deficiency, and those that involve structural abnormalities of the glands such as cancers.

43. It is important for the endocrinologist to determine the cause of hormone gland excess or deficiency in order to devise an appropriate treatment plan. The plan will generally be to help bring the hormones back into balance and thus bring the patient back to health.

44. To give an example of hormone excess, hyperthyroidism is a term which means overactivity of the thyroid gland. In this condition excess thyroid hormone is produced by the thyroid gland. This results in various physical and psychological changes for the afflicted patient. Examples of physical changes can include tachycardia or fast heart rate, hand tremors, and weight loss. Examples of psychological symptoms include anxiety, panic attacks, and sometimes even psychosis.

45. An endocrinologist can recognize thyroid hormone excess in part by signs and symptoms but can also confirm the diagnosis with laboratory testing that shows the thyroid hormones to be out of balance. Once this is determined and the degree of excess is known, then treatments can be given to bring these levels back into balance to benefit the patient's health and to prevent other disease effects caused by excess hormone.

46. To give another example, consider a deficiency of insulin. Insulin is a hormone which regulates blood glucose levels. If there is damage to the pancreas such that insulin levels are very low, then blood glucose levels will rise. If the glucose levels rise to a certain abnormally high level, then this is considered diabetes. In the case of type 1 diabetes, insulin levels are abnormally low and therefore blood glucose levels are abnormally high leading to a variety of signs and symptoms. For example, the patient may have extreme thirst, frequent urination, muscle wasting, and weight loss. They may often experience lethargy and weakness.

47. In this case laboratory tests of glucose and insulin levels can confirm the diagnosis. Once diabetes is confirmed, the patient is then treated with insulin to

help restore glucose balance in the body and prevent long-term complications of diabetes.

48. To give an example of a structural abnormality, a patient may have a lump on the thyroid gland in the neck. This may be further examined by an imaging test such as an ultrasound. A needle biopsy can be performed so that the cells can be examined under a microscope. A trained medical professional such as a pathologist can then examine the cells to determine if they are benign or cancerous. In the case of a thyroid cancer, a surgical procedure known as a thyroidectomy may be performed to remove the diseased thyroid gland in order to treat the cancer.

49. Noteworthy in the preceding three examples is that all three disease conditions are diagnosed by physical observations. In other words, a laboratory test of a hormone, an imaging test of an organ, an examination of cells under a microscope, or all three may be employed in the diagnosis of endocrine disease.

D. Gender Dysphoria is a Psychological Diagnosis

50. Gender dysphoria, on the other hand, is not an endocrine diagnosis, it is in fact a psychological diagnosis. It is recognized as a persistent state of distress that stems from the feeling that one's gender identity does not align with their physical sex (DSM-5 TR). It is diagnosed purely by psychological methods of behavioral observation and questioning. The criterion for diagnosis is found in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5 TR).

51. Drs. Adkins, Antommaria, and Janssen advocate for the use of Endocrine Society's Guideline (ESG) on gender dysphoria. The guidelines discuss the impor-

tance of a psychological evaluation by a qualified clinician. The guidelines state "GD/gender incongruence may be accompanied with psychological or psychiatric problems (43-51). It is therefore necessary that clinicians who prescribe hormones and are involved in diagnosis and psychosocial assessment meet the following criteria: (1) are competent in using the DSM and/or the ICD for diagnostic purposes, (2) are able to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) are trained in diagnosing psychiatric conditions, (4) undertake or refer for appropriate treatment, (5) are able to do a psychosocial assessment of the patient's understanding, mental health, and social conditions that can impact gender affirming hormone therapy, and (6) regularly attend relevant professional meetings." (Hembree et al., 2017).

52. Dr. Adkins states that "before any medical treatment is initiated," "mental health evaluations should be conducted" by a clinician trained "in child and adolescent gender development (as well as child and adolescent psychopathology)." (Adkins Decl, p. 11) It is not clear based on the records produced whether a qualified psychologist or psychiatrist has evaluated the three minor plaintiffs and has determined that they have met DSM-5 criteria for the diagnosis of gender dysphoria.

53. As a practicing endocrinologist and scientist, I have made a study of GD and its treatment for two reasons: 1) I want to be sure that my colleagues and I understand the science before we treat any patients with GD; and 2) I am concerned that the medical society that claims to speak for me and other endocrinologists has abandoned scientific principles in endorsing treatments

for GD that have questionable scientific support. The opinions expressed in this report are the result of my own experience, studies, education, and review of the scientific literature related to GD.

II. Gender Affirmative Therapy

54. In the section that follows I discuss four interventions (social transition, blocking normal puberty, opposite sex hormones, and surgery) some clinicians are using to treat gender dysphoria. Each intervention can lead to iatrogenic harms to the patient. The term "iatrogenic" is used in medicine to describe harms or newly created medical conditions that are the result of a treatment. These harms will be described in detail below. I speak of these harms because it is important to understand that once a patient begins gender affirmative therapy (GAT) it is more likely the patient will continue on to surgery (de Vries et al., 2014). Thus, GAT interrupts the natural desistance process and instead places the patient on a lifetime regimen of hormonal and surgical care. A good understanding of these harms is also critical to my practice as an endocrinologist, because if I did not understand these harms, I could not advise patients of the risks associated with GAT.

55. There are three general approaches to treating gender dysphoria in minors (Zucker, 2020). One is psychosocial treatment that helps the young person align their internal sense of gender with their physical sex. Another would be to "watch and wait" and allow time and maturity to help the young person align sex and gender through natural desistance, while providing psychological support and therapy as needed and addressing comorbidities. The third option, which is the focus

of that which follows, is referred to as gender affirmative therapy.

56. Gender affirmative therapy of adults and minors consists of psychosocial, medical, and surgical interventions that attempt to psychologically and medically alter the patient so that they come to believe they may become similar to the physical sex which aligns with their gender identity (but not their biological sex) and thereby reduce gender dysphoria. GAT consists of four main parts: 1) social transition, 2) blocking normal puberty or menstruation, 3) high dose opposite sex hormones, and 4) surgery of the genitalia and breasts.

57. The application of this medical therapy to minors[3] is a fairly new intervention and is associated with a number of harms both known and unknown. GAT suf-

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[3] "[T]he US Department of Health and the Food and Drug Administration reference approximate age ranges for these phases of life, which consist of the following: (1) infancy, between birth and 2 years of age; (2) childhood, from 2 to 12 years of age; and (3) adolescence, from 12 to 21 years of age. Additionally, *Bright Futures* guidelines from the American Academy of Pediatrics identify adolescence as 11 to 21 years of age, dividing the group into early (ages 11-14 years), middle (ages 15-17 years), and late (ages 18-21 years) adolescence. The American Academy of Pediatrics has previously published a statement on the age limit of pediatrics in 1988, which was reaffirmed in 2012 and identified the upper age limit as 21 years with a note that exceptions could be made when the pediatrician and family agree to an older age, particularly in the case of a child with special health care needs. Recent research has begun to shed more light on the progression of mental and emotional development as children progress through the adolescent years into young adulthood. It is increasingly clear that the age of 21 years is an arbitrary demarcation line for adolescence because there is increasing evidence that brain development has not reliably reached adult levels of functioning until well into the third decade of life." (Hardin, 2017) (footnotes omitted).

fers from a lack of a quality evidence-base, poorly performed studies, and ongoing unethical human experimentation. As discussed below, in my professional opinion as an endocrinologist, no child should be given these treatments.

A. Social transition

58. The first stage of gender affirmative therapy is termed social transition. Social transition is a psychological intervention. The child may be encouraged to adopt the type of clothing and mannerisms or behaviors which are stereotypical of the opposite sex within a culture. For example, in the United States a boy might wear his hair long and wear dresses in order to socially transition. A girl may cut her hair short and wear clothes from the boys' section of a department store.

59. Social transition of the child has been noted by expert researcher in the field of child gender dysphoria, Ken Zucker, to itself be a form of iatrogenic harm (Zucker, 2020). This is because the social transition process may solidify the young person's belief that they are in fact the sex opposite of their biological sex. The 2017 Endocrine Society Guidelines state that "[s]ocial transition is associated with the persistence of GD/gender incongruence as a child progresses into adolescence." (Hembree et al., 2017). A recent study also supports the contention that children who undergo social transition are more likely to have their gender dysphoria persist into adolescence. In the 2022 article "Gender Identity 5 Years After Social Transition", which studied 317 socially transitioned youths, the authors found that "most participants were living as binary transgender youth (94.0%)." (Olson et al., 2022).

60. From an endocrine point of view, it is understandable that a child having the outward appearance of the opposite sex, would believe that he or she is destined to go through puberty of the opposite sex as they have only a poor understanding of the internal structures of the body, the function of the sex glands, the role of the sex glands in fertility, and so forth.

61. Therefore, it would be quite frightening for a boy who believes he is a girl to be turning into a man with all of the adult features that accompany manhood. Vice versa, the girl who has become convinced that she is a boy will be frightened by the physical changes brought on by womanhood.

62. In fact, it would appear children and adolescents who have gone through a social transition may be anticipating a sort of disease state in the future by the hormone changes that will occur as a normal and natural part of human development. Until relatively recently in human history, it has not been possible to interfere with puberty through pharmaceutical means.

B. Medications which Block Pubertal Development

1. Background

63. A second stage of gender affirmative therapy may involve blocking normal pubertal development. This may be done with puberty blocking medications (PB) that act directly on the pituitary to cause the endocrine condition known as hypogonadotropic hypogonadism (HH).

64. To understand what is occurring in this process, it is helpful to be aware of normal hormone function during pubertal development. There is a small pea-sized gland in the brain called the pituitary. It is sometimes

referred to as the "master gland" as it controls the function of several other glands. One key function, for our purposes, is the control of the sex glands. There are two specific hormones produced by the pituitary referred to as luteinizing hormone (LH) and follicle stimulating hormone (FSH). These are responsible for sex hormone production and fertility. The LH and FSH act as signals to tell the sex glands to begin or to continue their function.

65. In the adult male, the production of LH will cause adult levels of testosterone to be produced by the testicles. In the adult female, the production of LH will cause adult levels of estrogen to be produced by the ovaries.

66. In early childhood, prior to the beginning of puberty, the pituitary function with respect to the sex glands is quiescent. However, during pubertal development LH will signal the testicle to increase testosterone production and this carries the boy through the stages of pubertal development into manhood. Likewise for the female, the interaction of LH with the ovaries increases estrogen production and carries the girl through the stages of development into womanhood.

67. Hypogonadotropic hypogonadism is a medical condition in which the pituitary does not send the hormonal signals (LH and FSH) to the sex glands. Therefore, the sex glands are unable to make their sex specific hormones of testosterone or estrogen.

68. If this condition occurs during puberty, the effect will be to stop pubertal development. This is a disease state which is diagnosed and treated by the endocrinologist.

69. Medications such as GnRH analogues (sometimes called puberty blockers) act on the pituitary gland to lower the pituitary release of LH and FSH levels dramatically. The result is a blockage of the signaling of the pituitary to the testicles or ovaries and therefore underproduction of the sex hormones. This will stop normal menstrual function for the female and halt further pubertal development. For the male this will halt further pubertal development. If the male had already reached spermarche, then production of new sperm will stop.

2. GnRH Agonist Medication Effects Vary by Use Case

70. There are a variety of uses for GnRH agonists. The use and outcome can be very different for different applications.

71. For example, the medication called Lupron, a GnRH agonist, was developed to treat prostate cancer. The idea being that blocking pituitary hormones will block the adult male's release of testosterone from the testicles. Since testosterone will promote the growth of prostate cancer, the idea is to lower testosterone levels to a very low amount and therefore prevent the growth and spread of prostate cancer. This is a labeled use of the medication. In other words, there is FDA approval for this use.

72. Another labeled use of GnRH agonist medication is for the treatment of central precocious puberty. In the disease state of central precocious puberty, pituitary signaling is activated at an abnormally young age, say age four, to begin pubertal development. A GnRH agonist may be used to halt puberty which has begun at an abnormally early time. Here, the action of the medication on the pituitary will disrupt the signaling to the

sex glands, stop early sex hormone production, and, therefore, stop abnormal pubertal development.

73. Then, at a more normal time of pubertal development, say age 11, the medication is stopped and puberty is allowed to proceed. The end result is to restore normal sex gland function and timing of puberty. This is a labeled use for a GnRH agonist medication.

74. What about the use of GnRH analogue medications such as Lupron in gender affirmative therapy? In these cases, we have physiologically normal children who are just beginning puberty or are somewhere in the process of pubertal development. They have healthy pituitary glands and sex organs. However, a puberty blocking medication is administered to stop normal pubertal development.

75. In this case the condition of hypogonadotropic hypogonadism described above (a medical disease) is induced by medication and is an iatrogenic effect of treating the psychological condition of gender dysphoria. GnRH analogue medications have not been FDA approved for this use. The use of GnRH analogue medication for this purpose in adolescents is experimental as there have been no randomized controlled trials for this specific use case.

76. Dr. Adkins states that "[i]n the case of puberty blocking medication, once stopped, a patient's endogenous puberty resumes." (Adkins decl., p. 13). However, she does not provide any evidence to support her claim.

77. Dr. Adkins asserts there is "over 40 years of data on the impact of pubertal suppression treatment on children who undergo precocious puberty that we can apply to the transgender population." (Adkins dec., p. 15).

But she fails to acknowledge that use of GnRHa for treatment of precocious puberty is very different from the non-FDA approved use case of administering GnRHa to stop appropriately timed puberty in children with gender dysphoria.

78. Dr. Adkins further states, "Pubertal suppression medication is also used in adolescents and adults undergoing chemotherapy to preserve fertility and in patients with hormone sensitive cancers." (Adkins decl, p. 15). The use of GnRHa in conjunction with chemotherapy for a life-threatening cancer treatment is very different than its use in GAT. Such treatment for cancer is based on an objective and verifiable physical examination, typically the biopsy of a cancerous tumor. Again, no such objective validation of an immutable gender identity exists; therefore, the underlying diagnosis is uncertain, and her comparison is faulty.

79. In my opinion, there is not sufficient evidence to conclude that the use of puberty blockers to block natural puberty is safe when administered as part of gender affirming therapy, or that its effects are reversible.

3. Hypogonadotropic Hypogonadism

80. As described above, hypogonadotropic hypogonadism is a condition in which the pituitary fails to send signals to the gonads thereby preventing the testicle of the male from making testosterone or the ovary of the female from making estrogen.

81. As an endocrinologist I frequently evaluate patients to ascertain if they have the condition of hypogonadotropic hypogonadism. This is done by a laboratory evaluation. If the patient has this condition, I then determine the cause and the proper treatment.

82. The primary hormone of the pituitary which is abnormal in this condition is called luteinizing hormone or LH. In order to diagnose the condition, a laboratory test with reference ranges based on the person's sex and age is used to evaluate the blood sample.

83. For example, figure 1 shows the normal laboratory reference range for LH over the course of a month in an adult pre-menopausal female (0.5-76.3 mIU/mL) (Quest LH, 2023). A very low level of LH (red) with low estrogen levels indicates hypogonadotropic hypogonadism[4].

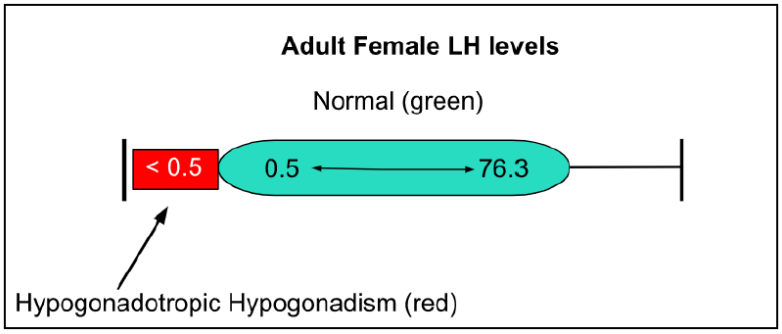

Figure 1.

84. As one can see, in hypogonadotropic hypogonadism the level of LH is below the reference range. In the female, this causes the cessation of estrogen production, and in the male it causes cessation of testosterone production. In adolescents of either sex, this will stop further pubertal development. For females in mid-puberty or beyond, this condition will also stop normal menstrual cycles and ovulation. For the male in mid-pu-

[4] Levels will be similarly low for adolescents, though the normal reference range is different.

berty or beyond, it will cause the cessation of normal sperm production.

85. As an endocrinologist, I would confirm the condition of hypogonadotropic hypogonadism based on laboratory results and then treat this medical condition.

86. What occurs to pituitary hormones and the sex hormones[5] when administering a GnRH analogue medication such as Lupron? The effect is identical to figure 1. Over time, the result of the medication is to cause very low LH levels (red) leading to low sex hormone levels thereby medically inducing the condition of hypogonadotropic hypogonadism.

87. In gender affirmative therapy, the medical condition of hypogonadotropic hypogonadism is being deliberately created by the use of medications called GnRH analogues, one of which is called Lupron.

4. Adverse Health Consequences of Blocking Normal Puberty

a. Infertility

88. There are a number of serious health consequences that occur as the result of blocking normal puberty. The first problem is infertility.

89. Dr. Adkins states, "Pubertal suppression on its own has no impact on fertility." (Adkins decl., p. 19). That statement is incorrect. As I explain below, GnRHa have profound implications for fertility.

90. The Endocrine Society Guidelines recommend beginning puberty blockers as early as Tanner stage 2.

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[5] The primary sex hormones being estrogen for females and testosterone for males.

As discussed earlier, this is the very beginning of puberty. Fertility development happens later generally in Tanner stage 4. One can see that if the developing person is blocked at Tanner stage 2 or 3 as advocated by the guidelines, this is prior to becoming fertile. The gonads will remain in an immature, undeveloped state.

91. If they remain blocked in an early pubertal stage then even the addition of opposite sex hormones will not allow for the development of fertility. In fact, high dose opposite sex hormones may permanently damage the immature sex organs leading to sterilization. Certainly, the removal of the gonads by surgery will ensure sterilization.

92. In a Dutch study by de Vries et al. that included seventy adolescents who took puberty blockers, all seventy decided to go on to hormones of the opposite sex (de Vries, et al. 2011). In a follow-up study by de Vries et al., the overwhelming majority went on to have sex reassignment surgery by either vaginoplasty for males or hysterectomy with ovariectomy for females (de Vries, et al. 2014). These surgeries resulted in sterilization. This is why puberty blockers, rather than being a "pause" to consider aspects of mental health, are instead a pathway towards future sterilizing surgeries and potentially sterilizing hormonal treatments.

93. Dr. Antommaria writes, "The [Endocrine Society] 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." (Antommaria decl, p. 17). However, even though procedures to preserve fertility are available, studies show that less than 5% of adolescents in North America receiving GAT even attempt

fertility preservation (FP) that might be beneficial for those in late pubertal stages (Tanner 4 and 5) (Nahata, 2017). Moreover, for those in early pubertal stages (Tanner 2 and 3), "ovarian tissue cryopreservation is still considered experimental in most centers and testicular tissue cryopreservation remains entirely experimental. These experimental forms of FP would be the only options in children [with puberty] blocked prior to spermarche and menarche and are high in cost and limited to specialized centers. Even with FP there is no guarantee of having a child. (Laidlaw, Cretella, et al., 2019).

94. Dr. Antommaria attempts to suggest that the risks associated with puberty blockers for treatment of gender dysphoria are comparable to the risks associated with using puberty blockers to treat precocious puberty (Antommaria decl., p. 19). But this assertion fails to recognize the very different effects of PB medication in early childhood versus during adolescence.

95. As an example, if a four-year-old child is diagnosed with precocious puberty, the abnormally early puberty may be halted by GnRH analogues (puberty blocking medication). The child will at a later time have the puberty blocker discontinued and at that point normal pubertal development will be allowed to proceed. Therefore, when they are no longer taking the medication, they will gain natural fertility.

96. In contrast, puberty blocking medication given to minors as a part of GAT occurs during natural puberty which is precisely the time that the adolescent person will gain reproductive function. The effects of puberty blocker (PB) on the adolescent are to prevent sperm production in the male and ovulation in the fe-

male which produces the infertile condition. Importantly, so long as the minor continues PB they will remain infertile. Should they continue on to opposite sex hormones as part of GAT, then they will remain infertile. There is the additional possibility that cytotoxic effects of high dose opposite sex hormones will damage the immature gonads leading to permanent sterility.

b. Sexual Dysfunction

97. Another problem I would expect to find in youths who have HH and puberty stopped at an early stage is sexual dysfunction. The child will continue their chronological age progression toward adulthood and yet remain with undeveloped genitalia. This will lead to sexual dysfunction including potential erectile dysfunction and inability to ejaculate and orgasm for the male. For the female with undeveloped genitalia potential sexual dysfunction may include painful intercourse and impairment of orgasm.

98. The impairment of sexual function was evident in the TLC reality show "I am Jazz". In the show, Jazz, who was identified male at birth, had been given puberty blockers at an early pubertal stage. In an episode where Jazz visits a surgeon and has a discussion about sexual function, Jazz states: "I haven't experienced any sexual sensation." Regarding orgasm, Jazz says: "I don't know, I haven't experienced it"[6] (TLC, accessed 2022).

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[6] Jazz's age is somewhere in the mid-teens during this episode.

c. Negative Effects of Hypogonadotropic Hypogonadism on Bone Density

99. Puberty is a time of rapid bone development. This time period is critical in attaining what we call peak bone density or the maximum bone density that one will acquire in their lifetime (Elhakeem, 2019).

100. Any abnormal lowering of sex hormones occurring during this critical time will stop the rapid accumulation of bone and therefore lower ultimate adult bone density. If a person does not achieve peak bone density, they would be expected to be at future risk for osteoporosis and the potential for debilitating spine and hip fractures as adults. Hip fractures for the older patient very significantly increase the risk of major morbidity and death (Bentler, 2009). Allowing a "pause" in puberty for any period of time leads to an inability to attain peak bone density.

101. DEXA scans are used to evaluate changes in bone density and to help evaluate risk for future fractures. In my practice I order and interpret DEXA scans for this purpose.

102. The Z-score of a DEXA scan is used to compare a patient's bone density to the same population based on age and sex. For example, a person who has a bone density similar to the average of the population would be at the 50th percentile. Those who have greater relative bone density would be above the 50th percentile. Those who have lower bone density would have a Z score below the 50th percentile.

103. Puberty blockers used in adolescence to cause HH will inhibit the normal accrual of bone density. This can be evaluated by DEXA scan. In a study in the UK,

44 patients aged 12-15 with gender dysphoria were given puberty blockers and tests of bone density were done at baseline, 12 months, 24 months and 36 months (Carmichael, 2021).

104. Figure 2 shows the Z-scores of the average age matched population percentile which is 50%. It shows the average baseline (before puberty blockers) Z-score percentile for the study participants. It also shows the bone density percentile at 12, 24, and 36 months. One can see that the average baseline z score was about 32% compared to peers of similar age and sex. At 12 months this had decreased to about 15%, and by 24 months it had declined further to about 5% compared to their peers and remained at this low level.

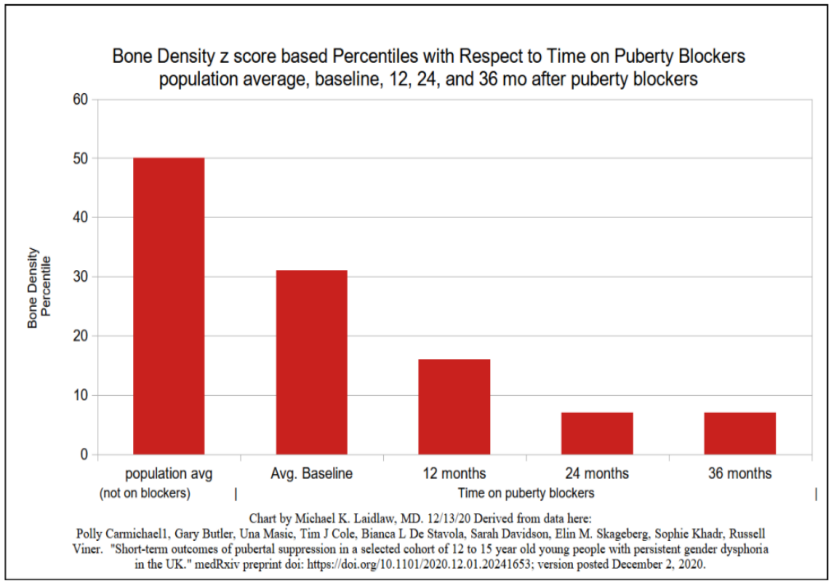

Figure 2

105. This is the same pattern of diminishing bone density compared to their peers that one would see in hypogonadotropic hypogonadism due to a pituitary injury. However, in these cases hypogonadotropic hypogonadism was caused by GnRH analogues (puberty blocking medication) that lead to greatly diminished bone density compared to their peers of the same age.

106. In natal females, hypogonadotropic hypogonadism leads to amenorrhea, meaning the absence of menstrual periods. Amenorrhea is detrimental to bone health: "In addition to this[7] important long-term consequence of amenorrhea, other problems, such as premature bone demineralization or inadequate bone formation, are likely to put amenorrheic women at high risk for osteoporosis and fracture" (Santoro, 2011).

107. Dr. Adkins states, "Pubertal suppression can be initiated up to mid-puberty and works by pausing endogenous puberty at the stage it has reached when the treatment begins. This has the impact of limiting the influence of a person's endogenous hormones on the body." (Adkins decl, p. 9). In actuality, allowing a "pause" in puberty for any period of time leads to an inability to attain peak bone density and puts the patient at future risk for osteoporosis and serious fractures as I have described.

108. Another consideration is the effects of HH in adolescents and late teens on the maturation of the human brain. Much of what happens is unknown. However, "sex hormones including estrogen, progesterone,

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[7] "This" refers to cardiovascular disease: "Diagnosis and treatment of amenorrheic states is of increasing clinical importance because lifetime menstrual irregularities are known to be predictive of subsequent CVD in women."

and testosterone can influence the development and maturation of the adolescent brain." (Arain, 2013). Therefore, there are unknown, but likely negative, consequences to blocking normal puberty with respect to brain development.

d. Psychosocial Development

109. A third major problem with blocking normal puberty involves psychosocial development. Adolescence is a critical time of physical, mental, and emotional changes for the adolescent. It is important that they develop socially in conjunction with their peers.

110. While I am not a psychologist, I am familiar with and rely upon the literature in this area for the rationale of the treatment of precocious puberty[8]. It is generally accepted in endocrinology that there are psychological benefits to adolescents who go through puberty around the same time as their peers, and this is why puberty blockers (GnRH analogues) in central precocious puberty are sometimes used to delay a child's abnormally early pubertal development to a more age-appropriate time.

111. The development of the adolescent along with their peers is also well recognized in the psychological literature: "For decades, scholars have pointed to peer relationships as one of the most important features of adolescence." (Brown, 2009). If one is left behind for several years under the impression that they are awaiting opposite sex puberty, they will miss important opportunities for socialization and psychological develop-

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[8] "The other concern often used as a rationale for treatment is negative psychosocial consequences of precocious puberty, particularly in girls" [emphasis added] (Eugster, 2019).

ment. Psychosocial development will be necessarily stunted as they are not developing with their peers. This is a permanent harm as the time cannot be regained.

112. Aside from the multiple serious problems that are iatrogenically acquired by blocking normal puberty, there appear to be independent risks of the puberty blocking medication themselves. For example, one can read the labeling of a common puberty blocking medication called Lupron Depot-Ped and find under psychiatric disorders: "emotional lability, such as crying, irritability, impatience, anger, and aggression. Depression, including rare reports of suicidal ideation and attempt. Many, but not all, of these patients had a history of psychiatric illness or other comorbidities with an increased risk of depression" (Lupron, 2022). This is particularly concerning given the high rate of psychiatric comorbidity with gender dysphoria (Kaltiala-Heino, 2015).

5. The Effect of Puberty Blockers on Desistance

113. As stated earlier, a very high proportion of minors diagnosed with gender dysphoria will eventually desist or come to accept their physical sex. Puberty blockers have been shown to dramatically alter natural desistance.

114. In a Dutch study that included seventy adolescents who took puberty blockers, all seventy decided to go on to hormones of the opposite sex (de Vries, et al. 2011). In a follow-up study, the overwhelming majority went on to have sex reassignment surgery by either vaginoplasty for males or hysterectomy with ovariectomy for females (de Vries, et al. 2014). These surgeries resulted in sterilization. This is why puberty blockers,

rather than being a "pause" to consider aspects of mental health, are instead a pathway towards future sterilizing surgeries.[9]

C. Opposite Sex Hormones

115. The third stage of gender affirmative therapy involves using hormones of the opposite sex (also called cross sex hormones) at high doses to attempt to create secondary sex characteristics in the person's body.

116. In GAT, what is termed "cross sex hormones" is the use of hormones of the opposite sex to attempt to create secondary sex characteristics. To do so, very high doses of these hormones are administered. When hormone levels climb above normal levels they are termed supraphysiologic.

1. Testosterone

117. Testosterone is an anabolic steroid of high potency. It is classified as a Schedule 3 controlled substance by the DEA: "Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence" (DEA, 2022). A licensed physician with a valid DEA registration is required to prescribe testosterone.

118. I prescribe testosterone to men for testosterone deficiency. The state of testosterone deficiency can cause various problems including problems of mood,

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[9] The surgeries were consequential in another important way. One person who had a vaginoplasty died of post-surgical complications of necrotizing fasciitis, which is a rapidly progressive and very severe infection of the soft tissues beneath the skin and which has a high mortality (Id.).

sexual function, libido, and bone density. Prescription testosterone is given to correct the abnormally low levels and bring them back into balance. The dose of testosterone must be carefully considered and monitored to avoid excess levels in the male as there are a number of serious concerns when prescribing testosterone. The use of high dose testosterone in females is experimental.

119. Let's contrast the FDA approved use of testosterone in males versus its experimental use in females. Testosterone is FDA approved for use in adult men as well as the pediatric male population aged 12 and older (Actavis, 2018). There is no FDA approved usage of testosterone for women or pediatric aged females.[10] The prescribing indications for adult males and pediatric males are identical and are to treat the conditions of low testosterone caused by either primary hypogonadism or secondary hypogonadism (Id.). The intent of testosterone for women and pediatric aged females in GAT is to cause severe hyperandrogenism. In this case the purpose, effects, and ultimate outcome of the FDA approved usage of testosterone for males versus the experimental use for females in GAT are very different. Therefore the low-quality evidence guidelines of the Endocrine Society/WPATH are not an acceptable substitute for proper scientific studies including randomized controlled trials (Malone et al., 2021; Hembree et al., 2017).

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[10] "Testosterone Cypionate Injection, USP is indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone" (Actavis, 2018).

120. Regarding the potential for abuse, the labeling reads "Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication . . . Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions . . . Abuse and misuse of testosterone are seen in male and female adults and adolescents . . . There have been reports of misuse by men taking higher doses of legally obtained testosterone than prescribed and continuing testosterone despite adverse events or against medical advice." (Actavis Pharma, 2018)

121. Adverse events with respect to the nervous system include: "Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia." (Actavis Pharm, 2018)

122. With regard to ultimate height, "[t]he following adverse reactions have been reported in male and female adolescents: premature closure of bony epiphyses with termination of growth" (Actavis Pharma, Inc., 2018). What this means is that testosterone applied to the adolescent will cause premature closure of the growth plates, stopping further gains in height in the growing individual, and ultimately making the person shorter than they otherwise would have been.

123. With respect to the cardiovascular system of men using ordinary doses, "Long-term clinical safety trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy in men" (Actavis Pharma, 2018). No clinical safety trials have been performed for women or adolescent girls to my knowledge.

124. "There have been postmarketing reports of venous thromboembolic events [blood clots], including deep vein thrombosis (DVT) [blood clot of the extremity such as the leg] and pulmonary embolism (PE) [blood clot of the lung which may be deadly], in patients using testosterone products, such as testosterone cypionate" (Actavis Pharma, 2018).

125. A very recently published study of adverse drug reactions (ADRs) as part of gender affirming hormone therapies in France states that "[o]ur data show a previously unreported, nonnegligible proportion of cases indicating cardiovascular ADRs in transgender men younger than 40 years . . . In transgender men taking testosterone enanthate, all reported ADRs were cardiovascular events, with pulmonary embolism in 50% of cases" (Yelehe et al., 2022).

126. There are also serious concerns regarding liver dysfunction: "Prolonged use of high doses of androgens . . . has been associated with development of hepatic adenomas [benign tumors], hepatocellular carcinoma [cancer], and peliosis hepatis [generation of blood-filled cavities in the liver that may rupture]—all potentially life-threatening complications" (Actavis Pharma, 2018).

a. Hyperandrogenism

127. Hyperandrogenism is a medical condition of elevated blood androgens such as testosterone. As an endocrinologist I frequently evaluate patients to determine if they have the condition of hyperandrogenism. Hyperandrogenism in the female or male is harmful and can lead to various maladies.

128. In order to diagnose hyperandrogenism, a laboratory blood test of testosterone is done. In hyper-

androgenism, one will find testosterone levels elevated above the reference range.

129. For example for females aged 18 or older, the normal reference range is 2-45 ng/dL (Quest testosterone, 2023).[11] However, in female disease conditions these levels can be much higher. Levels above this normal reference range are considered hyperandrogenism (figure 3).

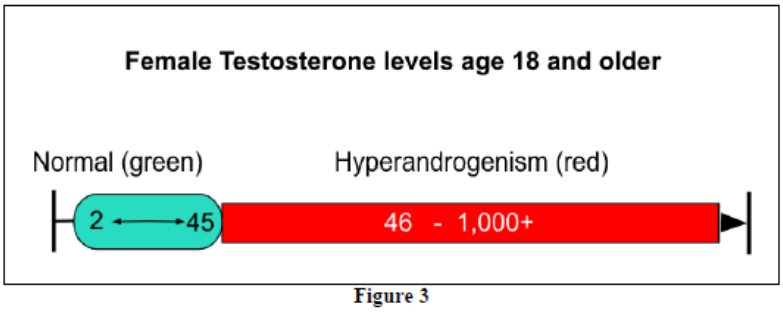

Figure 3

130. For example, in polycystic ovarian syndrome levels may range from 50 to 150 ng/dL.

131. I frequently diagnose and treat the hyperandrogen condition called polycystic ovarian syndrome (PCOS). These patients have elevated testosterone levels. These levels are mildly to moderately elevated and may range from 50-150. Hyperandrogenism found in PCOS has been associated with insulin resistance (Dunaif, 1989), metabolic syndrome (Apridonidze, 2005) and diabetes (Joham, 2014).

132. I also evaluate patients to rule out rare androgen producing tumors that generate very high levels of testosterone. These rare endocrine tumors can cause

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[11] For females aged 11-17 the reference range is <= 40 and below this age group, the range is even lower.

severely elevated testosterone levels in the 300-1000 range. Once the cause of a hyperandrogen condition is identified, treatments may be put in place to help bring the testosterone levels down to the normal reference range.

133. Recommendations from the Endocrine Society's clinical guidelines related to GAT are to ultimately raise female levels of testosterone to 320 to 1000 ng/dL[12] which is on the same order as dangerous endocrine tumors for women as described above (Hembree, 2017). A simple calculation shows this level for the adult may be anywhere from 6 to 100 times higher than native female testosterone levels. In doing so they are inducing severe hyperandrogenism. These extraordinarily high levels of testosterone are associated with multiple risks to the physical and mental health of the patient.

134. The following chart shows testosterone levels in the normal adult female range (blue), PCOS (gray), endocrine tumors (red), and gender affirmative therapy

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[12] In the Endocrine Society's Guidelines there is no grading of evidence for the rationale of using such high supraphysiologic doses of opposite sex hormones for the female or male. There seems to be an underlying assumption that because the person believes to be the opposite sex then they acquire the sex specific laboratory ranges of the opposite sex. "The root cause of this flaw in thinking about diagnostic ranges was exemplified in a response letter by Rosenthal et al claiming that gender identity determines the ideal physiologic range of cross-sex hormone levels (5). Thus, a psychological construct, the 'gender identity', is imagined to affect physical reality and change a person's sex-specific laboratory reference ranges. This is clearly not the case, otherwise there would be no serious complications of high-dose androgen treatment in transgender males" (Laidlaw et al., 2021).

(orange) as part of female to male (FtM) transition (figure 4).

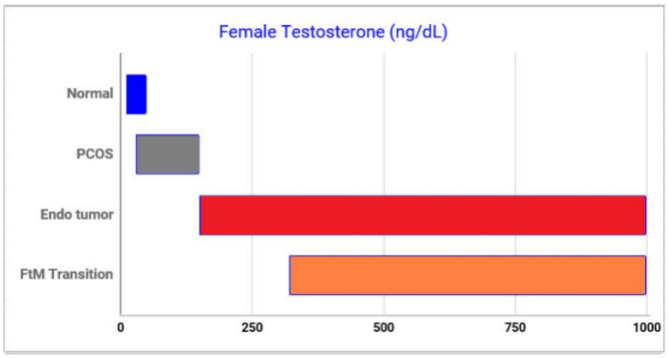

Image by Michael K Laidlaw. MD. Approximate total testosterone in ng/dL based on laboratory, etc. FtM transition from 2017 Endo Society Guidelines on Gender Dysphoria. With PCOS testosterone levels may be as high as 150. With endocrine tumors testosterone may be in the 150-1000 range. The recommendations of the Endocrine Society/WPATH are to bring levels into the 300-1000 range which is 6-100 times higher than normal endogenous adult female levels.

Figure 4.

b. Medical Problems Related to Hyperandrogenism

135. With respect to cardiovascular risk, "[s]tudies of transgender males taking testosterone have shown up to a nearly 5-fold increased risk of myocardial infarction relative to females not receiving testosterone" (Laidlaw et al.,2021; Alzahrani et al., 2019).

136. Permanent physical effects of testosterone therapy involve irreversible changes to the vocal cords. Abnormal amounts of hair growth which may occur on the face, chest, abdomen, back and other areas is known as hirsutism. Should the female eventually regret her decision to take testosterone, this body hair can be very difficult to remove. Male pattern balding of the scalp may also occur. I would expect these changes to occur to the plaintiffs taking testosterone to induce hyperandrogenism. Common sense suggests that changes of voice and hair growth could be psychologically trou-

bling should a patient decide to detranstition and attempt to reintegrate into society as female.

137. Changes to the genitourinary system due to hyperandrogenism include polycystic ovaries, clitoromegaly and atrophy of the lining of the uterus and vagina (Hembree, 2017). The breasts have been shown to have an increase in fibrous breast tissue and a decrease in normal glandular tissue (Grynberg et al., 2010). Potential cancer risks from high dose testosterone include ovarian and breast cancer (Hembree, 2017). I would expect some or all of these effects and risks to occur to the plaintiffs taking testosterone to induce hyperandrogenism.

138. Dr. Adkins states that "Though some effects of hormone therapy can be irreversible depending on the duration of the treatment, such as facial hair growth in patients on testosterone, many others are reversible once the treatment is stopped." (Adkins decl, p. 13). This is clearly misleading, as effects such as hirsutism, deepening of the voice, and clitoromegaly are permanent. The effects on fertility of starting an adolescent on puberty blockers in early puberty (Tanner stage 2 or 3) and then adding opposite sex hormones are unknown, but opposite sex hormones are likely cytotoxic to the immature gonads.

139. According to research, anabolic steroid abuse[13] has been shown to predispose individuals towards mood disorders, psychosis, and psychiatric disorders. The "most prominent psychiatric features associated with

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[13] Anabolic steroid abuse involves the deliberate creation of hyperandrogenism in the body as a result of high doses of testosterone or other androgens.

AAS [anabolic androgenic steroids, i.e. testosterone] abuse are manic-like presentations defined by irritability, aggressiveness, euphoria, grandiose beliefs, hyperactivity, and reckless or dangerous behavior. Other psychiatric presentations include the development of acute psychoses, exacerbation of tics and depression, and the development of acute confusional/delirious states" (Hall, 2005). Moreover, "[s]tudies . . . of medium steroid use (between 300 and 1000 mg/week of any AAS) and high use (more than 1000 mg/week of any AAS) have demonstrated that 23% of subjects using these doses of steroids met the DSM-III-R criteria for a major mood syndrome (mania, hypomania, and major depression) and that 3.4%-12% developed psychotic symptoms" (Hall, 2005).

c. Erythrocytosis as a Result of Hyperandrogenism

140. I regularly monitor patients who are receiving testosterone to evaluate for erythrocytosis. Erythrocytosis is a condition of high red blood cell counts. Prolonged hyperandrogenism such as occurs with the use of testosterone at supraphysiologic levels can cause erythrocytosis.

141. Males and females have different reference ranges for red blood cells (measured as hematocrit). For example the normal range of hematocrit for females over age 18 is 35.0-45.0% and males 38.5-50.0% (Quest Hematocrit, 2023). Levels above this range signify erythrocytosis (see figure 5).

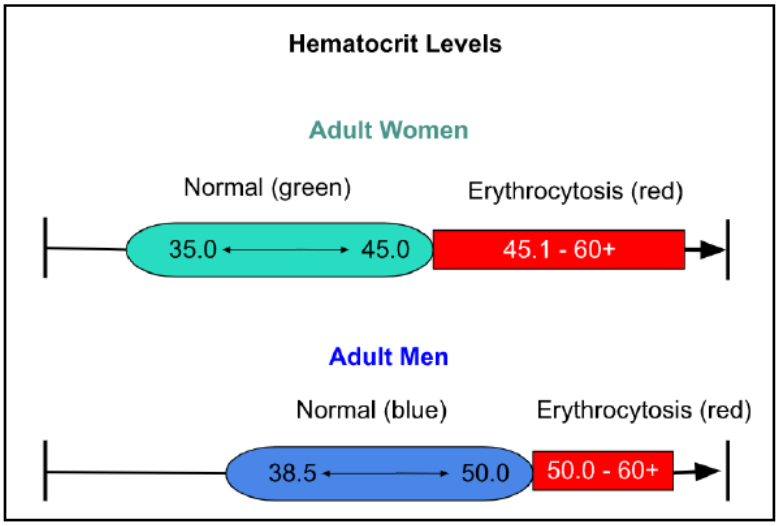

Figure 5.

142. As one can see, there is an overlap in the ranges of males and females such that levels between 45.1 and 50 are considered normal for the male. However for the female these levels are considered erythroctotic. Levels above 50 for the male are considered erythrocytosis and for the female severe erythrocytosis.

143. The Madsen study was a "20-year follow-up study in [1,073] adult trans men who started testosterone therapy and had monitoring of hematocrit at our center" (Madsen, 2021). In this study, 24% of trans men had hematocrit levels 50% at some time which would be considered severe erythrocytosis. Unfortunately, they did not examine the hematocrit range of 45-50. However one would presume that this would occur in at least the same percentage or higher as those who had developed severe erythrocytosis.

144. Any level of erythrocytosis in young women has been shown to be an independent risk factor for cardiovascular disease, coronary heart disease and death due to both (Gagnon, 1994).

2. Estrogen

145. Estrogen is the primary sex hormone of the female. Prescription estrogen may be used if a woman has low estrogen levels due to premature failure of her ovaries. Estrogen is prescribed to bring these levels back into a normal range for the patient's age. Another labeled use of estrogen is to treat menopausal symptoms. The use of estrogen to treat pediatric age males is experimental.

146. Hyperestogenemia is a condition of elevated blood estrogens such as estradiol. I regularly evaluate patients for hyperestrogenemia in my practice. Hyperestrogenemia in the male is harmful and can lead to various maladies.

147. In order to diagnose hyperestrogenemia, a laboratory blood test of estrogen is performed. In hyperestrogenemia, one will find estrogen levels elevated above the reference range.

148. For example, in an adult male the normal estrogen reference range is 60-190 pg/mL (Quest Estrogen, 2023). Levels above this range are consistent with hyperestrogenemia. See figure 6.

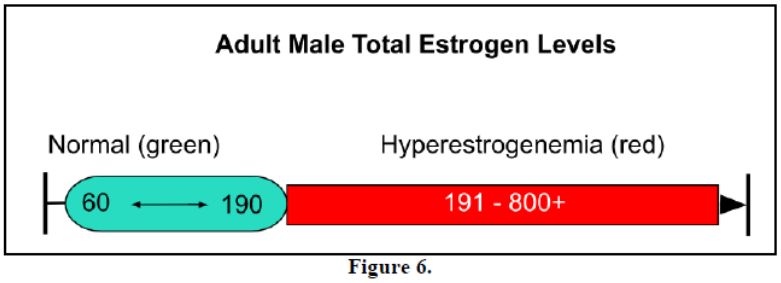

Figure 6.

149. There are medical conditions which can result in hyperestrogenemia. For example, "[t]he concentration of estrogen in cirrhotic patients is thought to increase by fourfold compared to individuals without cirrhosis" (Pagadala, 2023). Certain rare tumors for example of the adrenal gland can result in estrogen levels 3 to 10 fold higher than normal (Cavlan, 2010).

150. In gender affirmative therapy, the medical condition of hyperestrogenemia is being deliberately, medically induced by the off-label use of high doses of estrogen. Endocrine Society guidelines recommend raising estradiol levels to 2 to 43 times above the normal range.[14] The high doses are used in an attempt to primarily affect an increase of male breast tissue development known as gynecomastia. Gynecomastia is the abnormal growth of breast tissue in the male. I evaluate and treat patients with gynceomastia. I have prescribed medication and have referred patients for surgery for this condition.

151. Other changes of secondary sex characteristics may develop because of hyperestrogenemia such as sof-

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[14] Estradiol is a type of estrogen. Endocrine Society Guidelines recommend raising estradiol levels to 100-200 pg/mL (Hembree, 2017). The normal adult male estradiol range is 7.7-42.6 pg/mL (Labcorp Estadiol, 2023).

tening of the skin and changes in fat deposition and muscle development.

152. Long-term consequences of hyperestrogenemia include increased risk of myocardial infarction and death due to cardiovascular disease (Irwig, 2018). Also "[t]here is strong evidence that estrogen therapy for trans women increases their risk for venous thromboembolism[15] over 5 fold" (Irwig, 2018).

153. Breast cancer is a relatively uncommon problem of the male. However the risk of a male developing breast cancer has been shown to be 46 times higher with high dose estrogen (Christel et al., 2019).

154. Sexual dysfunction, including decreased sexual desire and decreased spontaneous erections, is another adverse effect of hyperestrogenemia (Hembree, 2017).

3. Opposite Sex Hormones and Infertility/Sterility

155. Dr. Adkins states, "Pubertal suppression on its own has no impact on fertility", which, as discussed above, is incorrect. (Adkins decl., p. 19). Dr. Adkins further states, "Hormone therapy can impact fertility but many transgender individuals conceive children after undergoing hormone therapy." (Id). Dr. Antommaria states, "While treatment for gender dysphoria with gender-affirming hormones may impair fertility, this is not universal and may also be reversible." (Antommaria decl, p. 19). While the statements of Drs. Adkins and Antommaria may be true for patients who have not had normal puberty blocked (and were therefore able to complete sexual development), this is not the case for

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[15] Venous thromboembolism is a blood clot that develops in a deep vein and "can cause serious illness, disability, and in some cases, death" (CDC, 2022).

patients whose normal pubertal development has been altered by puberty blockers and opposite sex hormones.

156. This is because the effects of starting an adolescent on puberty blockers in early puberty (Tanner stage 2 or 3) and then adding opposite sex hormones on ultimate fertility are unknown. There is no evidence so far as to whether, for example, a patient's testicles would continue to develop normally in order to produce an ejaculate with healthy, mature sperm capable of fertilization under those circumstances.

> Dr. Antommaria further states that "[t]ransgender men and women are also capable of producing eggs and sperm respectively both during and after the discontinuation of gender-affirming hormone treatment." (Antommaria decl., pp. 19-20). This is not the case for patients taking GnRH analogues because, as mentioned previously, these agents cause hypogonadotropic hypogonadism which, by definition, stops sperm production in men and ovulation in females. Similarly, high dose testosterone in natal females will stop normal pituitary communication with the ovary and will also stop or interfere with menstrual cycles and ovulation.

D. Surgeries

157. The fourth stage of gender affirmative therapy is surgical alterations of the body of various kinds in an attempt to somehow mimic features of the opposite sex. This is also important to note because transition surgeries, in particular mastectomies, are being performed on minors throughout the country.

158. Although endocrinologists do not typically perform surgery, we do refer patients for surgeries and

need to be aware of the risks, benefits, complications, and long term outcomes.

159. Individual surgical procedures can be a complex topic. It is helpful to first step back and consider conceptually what any surgery can and cannot accomplish.

160. In its basic form surgery is subtractive. In other words, a portion of tissue, an organ or organs are removed in order to restore health. For example, a diseased gallbladder may be surgically removed to help the patient get back to wellness. An infected appendix may be surgically removed to prevent worsening infection or even death. In both of these cases an unhealthy body part is surgically removed in order to restore health.

161. In some cases a diseased tissue or organ is removed so that a foreign replacement part may be substituted for an unhealthy organ or tissue. For example, a diseased heart valve may be replaced with a pig valve or a prosthetic heart valve. Another example is a failed liver may be replaced by liver transplant.

162. Though modern surgical techniques and procedures are astounding, there are very noteworthy limitations. Importantly, surgery cannot de novo create new organs. If a person's kidneys fail, the surgeon has no scientific method for creating a new set of kidneys that can be implanted or grown within the patient. This conceptual background is helpful when considering various gender affirming surgeries.

163. There are a variety of gender affirming surgeries for females. These may include mastectomies, metoidioplasty, and phalloplasty.

1. Mastectomy

164. Mastectomies are the surgical removal of the breasts. The procedure is used in GAT in an attempt to make the chest appear more masculine. The surgery results in a permanent loss of the ability to breastfeed and significant scarring of 7 to 10 inches. The scars are prone to widening and thickening due to the stresses of breathing and arm movement. Other potential complications include the loss of normal nipple sensation and difficulties with wound healing (American Cancer Society, 2022).

165. It is important to note that this operation cannot be reversed. The female will never regain healthy breasts capable of producing milk to feed a child (Mayo Clinic, Top Surgery, 2022).

166. Another important consideration is that compared to the removal of an unhealthy gallbladder or appendix, in the case of gender dysphoria the breasts are perfectly healthy and there is no organic disease process such as a cancer warranting their removal.

2. GAT Surgeries on the Male

167. GAT surgeries for the male include removal of the testicles alone to permanently lower testosterone levels. This is by nature a sterilizing procedure. Further surgeries may be done in an attempt to create a pseudo-vagina which is called vaginoplasty. In this procedure, the penis is surgically opened and the erectile tissue is removed. The skin is then closed and inverted into a newly created cavity in order to simulate a vagina. A dilator must be placed in the new cavity for some time so that it does not naturally close.

168. Potential surgical complications may include urethral strictures, infection, prolapse, fistulas and injury to the sensory nerves with partial or complete loss of erotic sensation (Mayo Clinic, Feminizing Surgery, 2022).

3. GAT Surgeries of the Female Pelvis and Genitalia

169. Other types of surgery for females include those of the genitalia and reproductive tract. For example, the ovaries, uterus, fallopian tubes, cervix and the vagina may be surgically removed. Removal of the ovaries results in sterilization.

170. Importantly, removing female body parts does not produce a male. Rather, the female has had sex specific organs permanently destroyed with no hope of replacement, while remaining biologically female.

171. There have also been attempts to create a pseudo-penis. This procedure is known as phalloplasty. It is not possible to de novo create a new human penis. Instead, a roll of skin and subcutaneous tissue is removed from one area of the body, say the thigh or the forearm, and transplanted to the pelvis. An attempt is made to extend the urethra or urinary tract for urination through the structure. This transplanted tissue lacks the structures inherent in the male penis which allow for erection, therefore erectile devices such as rods or inflatable devices are placed within the tube of transplanted tissue in order to simulate erection (Hembree, 2017). The labia may also be expanded to create a simulated scrotum containing prosthetic objects to provide the appearance of testicles.

172. Complications may include urinary stricture, problems with blood supply to the transplanted roll of

tissue, large scarring to the forearm or thigh, infections including peritonitis, and possible injury to the sensory nerve of the clitoris (Mayo Clinic, Masculinizing Surgery, 2022). A recent systematic review and meta-analysis of 1731 patients who underwent phalloplasty found very high rates of complications (76.5%) including a urethral fistula rate of 34.1% and urethral stricture rate of 25.4% (Wang, 2022).

III. The Lack of Evidence Supporting Gender-Affirming Therapy

173. There is not a medical consensus supporting the use of puberty blockers and cross-sex hormones for the treatment of gender dysphoria. In my opinion, there is insufficient evidence to conclude that any benefit of such treatment would outweigh the harm, particularly given the evidence of a rapid rise in cases of youth gender dysphoria, the high rates of coexisting mental health comorbidities, and naturally high rates of desistance.

A. The WPATH and The Endocrine Society

174. WPATH's Standards of Care 7 were produced over a decade ago in 2011. They were prepared within their advocacy organization and are purported to be a "professional consensus about the psychiatric, psychological, medical, and surgical management of gender dysphoria." (WPATH, 2022). However, the "professional consensus" exists only within the confines of its organization. Furthermore, their Standards of Care 7, unlike the Endocrine Society's guidelines, do not have a grading system for either the strength of their recommendations or the quality of the evidence presented.

175. Dr. Adkins references the Endocrine Society's 2017 guidelines to support the Assertion that ES has published "widely accepted guidelines for treating gender dysphoria." (Adkins decl, p. 6). However, the Endocrine Society never claimed that their guidelines were to be considered standard of care. Quite the opposite, the Endocrine Society states that their "guidelines cannot guarantee any specific outcome, nor do they establish a standard of care." (Hembree et al, 2017, p. 3895).

176. With respect to the makeup of authors of the ESG, nine out of ten authors were members of WPATH or worked on WPATH's scientific committees. Seven of those nine had at some time been in WPATH leadership including the WPATH presidency and board of directors.

177. In fact, with respect to the Endocrine Society's guidelines, the quality of evidence for the treatment of adolescents is rated "very low-quality evidence" and "low quality evidence". "The quality of evidence for [puberty blocking agents] is noted to be low. In fact, all of the evidence in the guidelines with regard to treating children/adolescents by [gender affirmative therapy] is low to very low because of the absence of proper studies." (Laidlaw et al., 2019).

178. Unlike some other recommendations for adolescent GAT, the Endocrine Society's guidelines do not include any grading of the quality of evidence specifically for their justification of laboratory ranges of testosterone or estrogen or for adolescent mastectomy or other surgeries.

179. Endocrinologists W. Malone and P. Hruz and colleagues have written critically of the Endocrine So-

ciety's (ES) guidelines: "Unlike standards of care, which should be authoritative, unbiased consensus positions designed to produce optimal outcomes, practice guidelines are suggestions or recommendations to improve care that, depending on their sponsor, may be biased. In addition, the ES claim of effectiveness of these interventions is at odds with several systematic reviews, including a recent Cochrane review of evidence, and a now corrected population-based study that found no evidence that hormones or surgery improve long-term psychological wellbeing. Lastly, the claim of relative safety of these interventions ignores the growing body of evidence of adverse effects on bone growth, cardiovascular health, and fertility, as well as transition regret." (Malone et al., 2021) (footnotes omitted).

180. In June of 2022, the Endocrine Society published "Enhancing the Trustworthiness of the Endocrine Society's Clinical Practice Guidelines" (McCartney et al., 2022). They wrote "In an effort to enhance the trustworthiness of its clinical practice guidelines, the Endocrine Society has recently adopted new policies and more rigorous methodologies for its guideline program." (Id.) They relate that in 2019, the ECRI Guidelines Trust "asked the Society for permission to include its guidelines in the ECRI Guidelines Trust database". However, after an evaluation by ECRI, the guideline related to osteoporosis "was the only guideline for which all recommendations were based on verifiable systematic evidence review with explicit descriptions of search strategy, study selection, and evidence summaries" (Id.). Therefore, we can conclude that with regard to the recommendations from the ESG 2017 on Gender Dysphoria/Gender Incongruence not all recommendations were "based on verifiable systematic evi-

dence review with explicit descriptions of search strategy, study selection, and evidence summaries". Furthermore, these ESG 2017 were highly subject to conflicts of interest. As related earlier, nine out of the 10 authors were members or worked on the scientific committees of the advocacy group WPATH. Additionally, the ESG 2017 document was endorsed by WPATH. The "Enhancing Trustworthiness" article recommends the opposite composition of authors for guidelines: "A majority (>50%) of non-Chair GDP members must be free of relevant C/DOI [conflict/duality of interest]" (McCartney et al., 2022).

181. Further problems with the Endocrine Society's guidelines are highlighted in a recent BMJ Investigation article. It reads "Guyatt, who co-developed GRADE, found 'serious problems' with the Endocrine Society guidelines, noting that the systematic reviews didn't look at the effect of the interventions on gender dysphoria itself, arguably 'the most important outcome.' He also noted that the Endocrine Society had at times paired strong recommendations—phrased as 'we recommend'—with weak evidence. In the adolescent section, the weaker phrasing 'we suggest' is used for pubertal hormone suppression when children 'first exhibit physical changes of puberty'; however, the stronger phrasing is used to 'recommend' GnRHa treatment. 'GRADE discourages strong recommendations with low or very low quality evidence except under very specific circumstances,' Guyatt told The BMJ. Those exceptions are 'very few and far between'" (Block, 2023).

182. In my opinion, neither WPATH7 nor the Endocrine Society's guidelines provide a standard of care that any physician should follow.

B. WPATH Standards of Care 8 is Flawed and Inherently Dangerous to Tennessee Youth

183. WPATH Standards of Care 8 (SOC 8) were published Sep. 6, 2022 (Coleman et al., 2022) and are endorsed by Dr. Adkins along with the Endocrine Society guidelines as "widely accepted" and "the best evidenced-based practice guidelines available for treating this condition." (Adkins decl, p. 6). However there are multiple serious problems with this document such that any clinician who follows its recommendations puts the youth of Tennessee at great risk.

184. In a correction to the SOC 8, all guidelines for minimum age of opposite sex hormones were removed (Correction IJTH, 2022). All guidelines for minimum age of surgery were also removed, meaning a minor of any age could be referred for any of the GAT surgeries listed previously (Id.).

185. The correction reads: "On page S258, the following text was removed:

'The following are suggested minimal ages when considering the factors unique to the adolescent treatment time frame for gender-affirming medical and surgical treatment for adolescents, who fulfil all of the other criteria listed above.

- Hormonal treatment: 14 years
- Chest masculinization: 15 years
- Breast augmentation, Facial Surgery: 16 years
- Metoidioplasty, Orchiectomy, Vaginoplasty,
- Hysterectomy, Fronto-orbital remodeling: 17 years

– Phalloplasty: 18 years'" (WPATH SOC 8 Correction, p. S261).

186. Of great concern is that the minimum age recommendations were retracted, it appears, in contradiction to the recommendation of their own expert consensus:

"On page S66, the following text was removed:

'Age recommendations for irreversible surgical procedures were determined by a review of existing literature and the expert consensus of mental health providers, medical providers, and surgeons highly experienced in providing care to TGD adolescents.'" [emphasis added] (WPATH SOC 8 Correction, p. S260).

Naturally, to remove age limits for hormones and surgeries which have life altering physical consequences should be done with the primary goal of obtaining the best possible health outcome for each patient. This should also be done with solid research and long-term studies justifying these treatments for young, developing persons.

However, WPATH's own statements show that liability and politics were their primary motivations. According to SOC8 author Dr. Tishleman the changes were made in order to help ensure that doctors would not be liable for malpractice suits if they deviated from their new standards (add ref). Additionally, WPATH's president said that to "propose" surgeries at newly set lower age recommendations would necessitate a "better political climate" (add ref).

187. Another concerning component of SOC 8 is a new chapter regarding eunuchs that gives recommendations for how to induce hypogonadism in men who have the eunuch "gender identity"[16] by either orchiectomy [testicle removal] or chemical castration such as with GnRH analogues (Coleman et al., 2022)[17].

188. The SOC8 also used an aberrant form of the GRADE approach for systematic reviews that removed the grading of quality of evidence (which should be categorized as very low, low, moderate, and high quality).[18] Instead any recommendation of "recommend" is automatically assigned as high quality of evidence. SOC 8 also failed to provide evidence profile tables which should include "an explicit judgment of each factor that deter-

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[16] The notion that there is a "eunuch gender identity" further invalidates the gender identity as a serious biological property of human beings: "Many eunuch individuals see their status as eunuch as their distinct gender identity with no other gender or transgender affiliation" (Coleman et al., 2022, p. S88).

[17] "Treatment options for eunuchs to consider include:

- Hormone suppression to explore the effects of androgen deficiency for eunuch individuals wishing to become asexual, nonsexual, or androgynous;
- Orchiectomy [testicle removal] to stop testicular production of testosterone;
- Orchiectomy with or without penectomy to alter their body to match their self-image;
- Orchiectomy followed by hormone replacement with testosterone or estrogen." (Id.)

[18] From SOC 8 "The [recommendation] statements were classified as:

- Strong recommendations ("we recommend") are for those interventions/therapy/strategies where:
- the evidence is of high quality" (Id., p. S250).

mines the quality of evidence for each outcome" (Guyatt et al., 2021).

189. Such a modification of GRADE is explicitly recommended against in the referenced GRADE document[19] and in so doing, in my opinion, invalidates all of the SOC 8 recommendations as being evidence-based.

190. For at least the reasons above, in my professional opinion WPATH SOC 8 represents a grave and immediate danger to minors, young adults, and adults and should not be followed by any physician, mental health care provider, or other medical professional.

C. Dr. Antommaria's Faulty Comparison of GAT to CPR

191. Dr. Antommaria states that "[g]uidelines issued by other professional associations concerning pediatric medical care rely on similar quality evidence" and uses as an example "the American Heart Association's (AHA's) guideline for Pediatric Basic and Advanced Life Support" (Antommaria, p. 14).

192. Dr. Antommaria fails to recognize that the purpose and use of hormones and surgeries in GAT is fundamentally different than cardiopulmonary resuscitation for life support. Dr. Antommaria also fails to distinguish the experimental use of sex hormones in GAT for adolescents compared to the FDA approved usage

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[19] From the GRADE guidelines: "Some organizations have used modified versions of the GRADE approach. We recommend against such modifications because the elements of the GRADE process are interlinked because modifications may confuse some users of evidence summaries and guidelines, and because such changes compromise the goal of a single system with which clinicians, policy makers, and patients can become familiar" (Guyatt et al., 2011).

of sex hormones as hormone replacement for hormone deficiencies (See also II.C.1).

193. The purpose of the American Heart Association's guideline is to restore normal "blood flow to vital organs" in order to "increase the likelihood of return of spontaneous circulation" (Topjian et al., 2020). In contrast to the restoration of normal function by the application of CPR, the purpose of the WPATH/Endocrine Society guideline for GAT is to intentionally disrupt normal endocrine function by generating the abnormal medical conditions of hypogonadotropic hypogonadism, hyperandrogenism, and hyperestrogenemia. It also advocates for the removal of healthy organs such as breasts, testicles, ovaries, penises, vaginas and uteruses in order to render these organs non-functional.

194. The purpose of chest compressions and the requirements of high-quality CPR are no different for adults compared to children and adolescents. The purpose of both are to "restore blood flow" to vital organs such as the heart and brain.[20] Likewise, what consti-

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[20] Pediatric guideline:

> "High-quality CPR generates blood flow to vital organs and increases the likelihood of return of spontaneous circulation (ROSC). The 5 main components of high-quality CPR are (1) adequate chest compression depth, (2) optimal chest compression rate, (3) minimizing interruptions in CPR (ie, maximizing chest compression fraction or the proportion of time that chest compressions are provided for cardiac arrest), (4) allowing full chest recoil between compressions, and (5) avoiding excessive ventilation.

"(Topjian et al., 2020).

Adult guideline:

tutes high-quality CPR (components such as proper rate and depth of chest compressions and avoiding overventilation) are the same in adults as they are in children and adolescents. Because the mechanisms of cardiopulmonary function are similar in adults and children it is logically inferred that the techniques used for CPR in adults will be fairly similar and have relatively similar effects in children and adolescents. Therefore guidelines of lower quality evidence in children and adolescents for CPR are acceptable because the purpose, what constitutes high quality CPR, and the ultimate outcomes are similar for both.

D. Flawed studies based on the problematic 2015 US Transgender Survey

195. There is much additional evidence that questions the long-term benefits of opposite sex hormones and gender reassignment surgery and in fact suggests serious harms.

196. I've already discussed the negative long-term risks in the De Vries studies as a pathway to sterilization and other damages from hormones.

197. The Smith et al. study of 2005 contained initially "325 consecutive adolescent and adult applicants for sex reassignment". However only 222 started hormone therapy and 34 dropped out of treatment alto-

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"For any cardiac arrest, rescuers are instructed to call for help, perform CPR to restore coronary and cerebral blood flow" (Panchal et al., 2020).

"A number of key components have been defined for high-quality CPR, including minimizing interruptions in chest compressions, providing compressions of adequate rate and depth, avoiding leaning on the chest between compressions, and avoiding excessive ventilation" (Id.).

gether. The study states that "Only data of the 162 adults were used to evaluate treatment" and not adolescents. So the study had a high drop-out rate and the limited remaining results were only applicable to adults.

198. With respect to the Turban et al. 2022 study, it was not a randomized controlled study nor a prospective observational study. Rather the study relied upon the 2015 US Transgender Survey (USTS), which has been severely criticized for its serious limitations and weaknesses.

199. D'Angelo et al. have written about the 2015 USTS survey as part of the criticism of another flawed study in the journal Pediatrics by Jack Turban in 2020 titled "Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation" (Turban, 2020). They write in their critique of the USTS that it is "a convenience sampling, a methodology which generates low-quality, unreliable data." (Bornstein, Jager, & Putnick, 2013). Specifically, the participants were recruited through transgender advocacy organizations and subjects were asked to 'pledge' to promote the survey among friends and family. This recruiting method yielded a large but highly skewed sample. Their analysis is compromised by serious methodological flaws, including the use of a biased data sample, reliance on survey questions with poor validity, and the omission of a key control variable, namely subjects' baseline mental health status." They also state that "[s]tigmatizing non-'affirmative' psychotherapy for GD [gender dysphoria] as 'conversion' will reduce access to treatment alternatives for patients seeking non-biomedical solutions to their distress." (D'Angelo et al., 2021).

200. Other published studies of GAT have been shown to have serious errors. For example, a major correction was issued by the American Journal of Psychiatry. The authors and editors of a 2020 study, titled "Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study" (Bränström study, 2020) retracted their original primary conclusion. Letters to the editor by twelve authors including myself led to a reanalysis of the data and a corrected conclusion stating that in fact the data showed no improvement in mental health for transgender identified individuals after surgical treatment nor was there improvement with opposite sex hormones ("Correction", 2020; Van Mol et al., 2020).

201. The initial reports of this study claimed that the authors found treatment benefits with surgery, and this was shared widely in the media. For example, ABC News posted an article titled "Transgender surgery linked with better long-term mental health, study shows" (Weitzer, 2019). An NBC news/Reuters headline reads "Sex-reassignment surgery yields long-term mental health benefits, study finds" (Reuters, 2019).

202. However, after twelve authors from around the world (including our team) investigated the study in detail, a number of serious errors were exposed leading to a retraction (Kalin, 2020; Anckarsäter et al., 2020).

203. In our letter to the editor which I co-wrote with former Chairman of Psychiatry at Johns Hopkins Medical School, Paul McHugh, MD, we noted key missing evidence in the original Branstrom report when compared to the previous body of knowledge yielded from the Swedish Dhejne study. We wrote that "[t]he study

supports only weak conclusions about psychiatric medication usage and nothing decisive about suicidality. In overlooking so much available data, this study lacks the evidence to support its pro gender-affirmation surgery conclusion" (Van Mol, Laidlaw, et al., 2020).

204. In another letter, Professor Mikael Landen writes that "the authors miss the one conclusion that can be drawn: that the perioperative transition period seems to be associated with high risk for suicide attempt. Future research should use properly designed observational studies to answer the important question as to whether gender-affirming treatment affects psychiatric outcomes" (Landen, 2020).

205. In another letter to the editor, psychiatrist David Curtis noted that "[t]he study confirms the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex. However, the Branstrom study does not demonstrate that either hormonal treatment or surgery has any effect on this morbidity. It seems that the main message of this article is that the incidence of mental health problems and suicide attempts is especially high in the year after the completion of gender-affirming surgery" (Curtis, 2020).

206. In yet another critical letter, Dr. Agnes Wold states that "[w]hether these factors involve a causal relationship (i.e., that surgery actually worsens the poor mental health in individuals with gender dysphoria) cannot be determined from such a study. Nevertheless, the data presented in the article do not support the conclusion that such surgery is beneficial to mental health in individuals with gender dysphoria" (Wold, 2020).

E. High Rates of Completed Suicide and Psychiatric Complications in GAT

207. The most comprehensive study of GAT of its kind is from Sweden in 2011. The authors examined data over a 30-year time period (Dhejne, 2011). The Dhejne team made extensive use of numerous Swedish database registries and examined data from 324 patients in Sweden over 30 years who had taken opposite sex hormones and had undergone sex reassignment surgery. They used population controls matched by birth year, birth sex, and reassigned sex. When followed out beyond ten years, the sex-reassigned group had nineteen times the rate of completed suicides and nearly three times the rate of all-cause mortality and inpatient psychiatric care compared to the general population of Sweden.

208. The recent study published by Chen and Olson-Kennedy et al. confirms the inherent danger of gender affirmative therapy found in the Dhejne study. The New England Journal of Medicine recently published "Psychosocial Functioning in Transgender Youth after 2 Years of Hormones" in which Dr. Johanna Olson-Kennedy is the principal investigator (Chen, Olson-Kennedy, et al., 2023). This arm of her study included 315 adolescents aged 12 to 20 years old who were taking high dose hormones of the opposite sex[21]. The study was

[21] "[T]he US Department of Health and the Food and Drug Administration reference approximate age ranges for these phases of life, which consist of the following: (1) infancy, between birth and 2 years of age; (2) childhood, from 2 to 12 years of age; and (3) adolescence, from 12 to 21 years of age. Additionally, Bright Futures guidelines from the American Academy of Pediatrics identify adolescence as 11 to 21 years of age, dividing the group into early (ages 11-14 years), middle (ages 15-17 years), and late (ages

not randomized and had no control group. The authors report that 2 out 315 subjects died by suicide. The authors also report "The most common adverse event was suicidal ideation" in 11 subjects.

209. Unfortunately, unlike the Dhejne study, the Olson-Kennedy study provides little other useful data about outcomes such as psychiatric hospitalizations, suicide attempts, or rates of comorbid psychiatric illness. The death by suicide of 2 out of 315 subjects equates to approximately 317 suicide deaths per 100,000 patient-years. If we compare this figure to that of the UK's largest gender identity service, Tavistock, the "annual suicide rate is calculated as 13 per 100,000" patient-years (Biggs, 2021). The death-by-suicide rate was approximately 24 times higher in Dr. Olson-Kennedy's study compared to the much larger Tavistock Clinic. In fact, Professor Biggs reports that two of the four suicide deaths from the Tavistock data were of patients who were on the waiting list and "would not have obtained treatment" (Id.). This strongly suggests that the use of high dose opposite sex hormones in Dr. Olson-Kennedy's study was associated with a much higher

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18-21 years) adolescence. The American Academy of Pediatrics has previously published a statement on the age limit of pediatrics in 1988, which was reaffirmed in 2012 and identified the upper age limit as 21 years with a note that exceptions could be made when the pediatrician and family agree to an older age, particularly in the case of a child with special health care needs. Recent research has begun to shed more light on the progression of mental and emotional development as children progress through the adolescent years into young adulthood. It is increasingly clear that the age of 21 years is an arbitrary demarcation line for adolescence because there is increasing evidence that brain development has not reliably reached adult levels of functioning until well into the third decade of life" (Hardin, 2017).

death rate. NIH produced the consent forms related to this study pursuant to a FOIA request my colleague submitted. I have reviewed them. Unfortunately, of the many side effects of hormone therapy listed on the study's consent forms, death by suicide (or by any cause) is not listed and was not disclosed to participants.

210. These facts would be useful to know to determine how high-dose opposite hormones and gender affirmative therapy affect overall health and their association with death by suicide. All of the data collected to date in Dr. Olson-Kennedy's publicly funded study the "The Impact of Early Medical Treatment in Transgender Youth" should be released to the public so that other researchers and clinicians can determine how puberty blockers, opposite sex hormones, and mastectomy surgeries affect adolescent physical and mental health.

211. While it is true that patients suffering from gender dysphoria have higher rates of suicidal ideation and completed suicide than the general population, studies have not definitively shown that providing hormones reduces rates of suicide, and in fact those interventions may be associated with increased rates.

F. An Increase in Cases of Gender Dysphoria

212. Gender Dysphoria has been a relatively rare condition in children and adolescents. However there have been very significant increases in referrals for this condition noted around the globe.

213. For example, in the UK, "The number of referrals to GIDS [Gender Identity Development Service] has increased very significantly in recent years. In 2009, 97 children and young people were referred. In 2018 that number was 2519" (Bell v Tavistock Judg-

ment, 2020). There is evidence that this increase may be in part due to social contagion and fueled by social media/internet use (Littman, 2018).

214. The French National Academy of Medicine wrote recently: "Parents addressing their children's questions about transgender identity or associated distress should remain vigilant regarding the addictive role of excessive engagement with social media, which is both harmful to the psychological development of young people and is responsible for a very significant part of the growing sense of gender incongruence" (SEGM, 2022).

215. In "a study of the Finnish gender identity service, '75% of adolescents [assessed] had been or were currently undergoing child and adolescent psychiatric treatment for reasons other than gender dysphoria' (Kaltiala-Heino, 2015). In fact, '68% had their first contact with psychiatric services due to other reasons than gender identity issues.' The same study also showed that 26% percent had an autistic spectrum disorder and that a disproportionate number of females (87%) were presenting to the gender clinics compared to the past" (Laidlaw in gdworkinggroup.org, 2018).

G. Desistance

216. Desistance is a term indicating that the child, adolescent, or adult who initially presented with gender incongruence has come to experience a realignment of their internal sense of gender and their physical body. "Children with [gender dysphoria] will outgrow this condition in 61% to 98% of cases by adulthood. There is currently no way to predict who will desist and who will remain dysphoric" (Laidlaw et al., 2019; Ristori & Steensma, 2016).

217. Because there is no physical marker to diagnose gender dysphoria, and because it is not possible to predict which child or adolescent will desist, it is not possible to know which young person will remain transgender identified as adults. Also, because the rate of desistance is so high, gender affirmative therapy will necessarily cause serious and irreversible harm to many children and adolescents who would naturally outgrow the condition if not affirmed.

218. Dr. Turban states "Once a transgender youth begins puberty, it is rare for them to later identify as cisgender." (Turban decl, p. 12). However, his statement is contradicted by the evidence from the following studies.

219. Puberty, which pertains to the physical development of the reproductive tract, breasts, and associated secondary sex characteristics, can begin as early as age 8 in girls and age 9 in boys. The studies which have examined desistance involved adolescents and children aged twelve and under. For example, table 1 in Ristori and Steensma 2016 shows multiple studies involving minors. For the three most recent—Singh (2012), Wallien & Cohen-Kettenis (2008), and Drummond et al. (2008)—these involved age ranges from 3 to 12 years old.[22] The desistance rate varied from 61 to 88%. Since

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[22] "This study provided information on the natural histories of 25 girls with gender identity disorder (GID). Standardized assessment data in childhood (mean age, 8.88 years; range, 3-12 years)" (Drummond et al., 2008). "We studied 77 children who had been referred in childhood to our clinic because of gender dysphoria (59 boys, 18 girls; mean age 8.4 years, age range 5-12 years)" (Wallien et al., 2008). " Standardized assessment data in childhood (mean age, 7.49 years; range, 3-12 years) and at follow-up (mean age, 20.58 years; range, 13-39 years) were used to evaluate gender iden-

the upper age was twelve, this would include children in the age range of 8-12 years old, many of whom were already adolescents going through puberty based a knowledge of the ages of initiation of puberty and were therefore not pre-pubertal.[23] Therefore we can see that a high proportion of adolescents do in fact desist, contrary to what Dr. Turban has stated.

H. Mastectomy Surgery for Minors

220. Any serious look at long-term effects of surgical treatment would follow subjects out at least ten years. For example, an article was published recently examining patients who had mild calcium disorders due to a gland called the parathyroid. They compared a group of patients who had surgical removal of the parathyroid to a control group who had not. They examined data ten years after surgery was completed and concluded that parathyroid surgery in this group "did not appear to reduce morbidity or mortality" in that patient group (Pretorius, 2022).

221. To my knowledge there exists no comparable studies of minors with gender dysphoria comparing those who had mastectomy surgery to a control group who had not. There are also no known studies of minors followed for 10 years or more to determine the long-

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tity and sexual orientation outcome. At followup, 17 participants (12.2%) were judged to have persistent gender dysphoria." (Singh, 2012).

[23] To my knowledge the desistance literature does not examine Tanner stages of puberty as part of their studies. However, one can infer based on the ages that many children had at least begun puberty (Tanner stage 2) or were at a more advanced stage of puberty

term risks and benefits of mastectomy for gender dysphoria.

222. Good quality studies specifically showing that mastectomy surgery is safe, effective, and optimal for treating minors with gender dysphoria do not exist. For example, there is a study titled "Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults Comparisons of Nonsurgical and Postsurgical Cohorts" (Olson-Kennedy, 2018). The study authors conclude that "[c]hest dysphoria was high among presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults." However, there are a number of problems with this study. First, the term "chest dysphoria" is a creation of the study authors and is not found as a diagnosis or even referenced in the DSM-5. Second the "chest dysphoria scale" is a measuring tool created by the authors, but which the authors state "is not yet validated." (*Id.*, p. 435) Third, the mastectomies were performed on girls as young as 13 and 14 years old and who thereby lacked the maturity and capacity of good judgment for truly informed consent for this life altering procedure. For this reason, in my professional opinion, the research and surgeries performed were flawed and unethical.

223. There exists another poorly designed study which suffers from similar methodological and ethical problems as the Olson-Kennedy study. A 2021 study published in Pediatrics examined females aged 13-21 recruited from a gender clinic. Thirty young females had mastectomy procedures and sixteen had not. The average age at surgery was 16.4 years (Mehringer, 2021). The follow up time after surgery was only 19 months and no data is provided or analyzed about key psychiatric information such as comorbid psychological illnesses,

self-harming behaviors, psychiatric hospitalizations, psychiatric medication use, or suicide attempts.

224. Information returned from the study surveys were all qualitative and included responses such as "[My chest dysphoria] made me feel like shit, honestly. It made me suicidal. I would have breakdowns". Another respondent stated, "I've been suicidal quite a few times over just looking at myself in the mirror and seeing [my chest]. That's not something that I should have been born with" (Mehringer, 2021). The omission of psychiatric data is a major flaw in the study and also irresponsible given the obviously dangerous psychological states that some of these young people were in.

225. Since such a high proportion of subjects were using testosterone (83%), some of the responses could be attributed to adverse effects of testosterone. For example, as related earlier, high dose testosterone can manifest in irritability and aggressiveness. One study subject responded, "I get tingly and stuff and it kind of makes me want to punch something" (Mehringer, 2022).

226. The testosterone labeling also indicates nausea and depression as adverse reactions which are described by another study subject "There's a feeling of hopelessness, of desperation, of—almost makes me feel physically sick" (Actavis Pharma, Inc., 2018; Mehringer, 2022).

227. The study appears to have been designed, at least in part, to justify insurance companies paying for mastectomy procedure for minors with GD, even though they have provided no long-term statistical evidence of benefit: "These findings . . . underscore the importance of insurance coverage not being restricted by age" (Mehrniger, 2021). This also appears to be part of

the aim of the flawed Olson-Kennedy study which stated "changes in clinical practice and in insurance plans' requirements for youth with gender dysphoria who are seeking surgery seem essential" (Olson-Kennedy, 2018). So these two studies, rather than being a thorough examination of the psychological and physical risks and benefits of mastectomy surgery over the long-term appear instead to exist, at least in part, to validate the need for insurance companies to insure the costs of these dubious procedures for minors.

I. Centers for Medicare and Medicaid Services

228. The Centers for Medicare and Medicaid Services ("CMS") has found "inconclusive" clinical evidence regarding gender reassignment surgery. Specifically, the CMS Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) (June 19, 2019) states: "The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population."

J. Nations and States Question and Reverse Course on GAT

229. Dr. Adkins and Dr. Janssen describe the WPATH "standards of care" and Endocrine Society guidelines as "widely accepted" in the medical community. (Adkins decl., p. 6; Janssen decl., p. 10). However, numerous nations are questioning and reversing course on the WPATH/Endocrine Society's low-quality gender affirmative therapy guidelines. For example, in the *Bell v. Tavistock* Judgment in the UK, regarding puberty blockers used in GAT, they concluded that "there is real

uncertainty over the short and long-term consequences of the treatment with very limited evidence as to its efficacy, or indeed quite what it is seeking to achieve. This means it is, in our view, properly described as experimental treatment." (*Bell v. Tavistock* Judgment, 2020).

230. The case was appealed and, although the medical decision making was returned to clinicians (rather than the courts), it was noted that great pains should be taken to ensure that the child and parents are properly informed before embarking on such treatments. In its conclusion, the appeals court stated that "[c]linicians will inevitably take great care before recommending treatment to a child and be astute to ensure that the consent obtained from both child and parents is properly informed by the advantages and disadvantages of the proposed course of treatment and in the light of evolving research and understanding of the implications and long-term consequences of such treatment. Great care is needed to ensure that the necessary consents are properly obtained." (*Bell v. Tavistock* Appeal, Judgment, 2021).

231. In the bulletin of the Royal College of Psychiatrists in 2021, a reevaluation of the evidence, Griffin and co-authors wrote, "As there is evidence that many psychiatric disorders persist despite positive affirmation and medical transition, it is puzzling why transition would come to be seen as a key goal rather than other outcomes, such as improved quality of life and reduced morbidity. When the phenomena related to identity disorders and the evidence base are uncertain, it might be wiser for the profession to admit the uncertainties. Taking a supportive, exploratory approach with gender-

questioning patients should not be considered conversion therapy." (Griffin et al., 2021).

232. In 2020, Finland recognized that "[r]esearch data on the treatment of dysphoria due to gender identity conflicts in minors is limited," and recommended prioritizing psychotherapy for gender dysphoria and mental health comorbidities over medical gender affirmation (Council for Choices in Healthcare in Finland, 2020). Additionally, "[s]urgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors." (Id.)

233. In 2021, Sweden's largest adolescent gender clinic announced that it would no longer prescribe puberty blockers or cross-sex hormones to youth under 18 years outside clinical trials (SEGM, 2021). "In December 2019, the SBU (Swedish Agency for Health Technology Assessment and Assessment of Social Services) published an overview of the knowledge base which 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. These treatments are potentially fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis. This makes it challenging to assess the risk / benefit for the individual patient, and even more challenging for the minors or their guardians to be in a position of an informed stance regarding these treatments." (Gauffen and Norgren, 2021). In 2022, the SBU stated, "The scientific basis is not sufficient to assess effects on gender dysphoria, psychosocial conditions, cognitive function, body measurements, body composition or metabolism of puberty-inhibiting or gender-opposite hormone treatment in children and ad-

olescents with gender dysphoria." (SBU, 2022). In 2023, a Swedish literature review concluded that the "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." The study emphasized various methodological weaknesses and the lack of randomized controlled trials and long-term studies regarding the outcomes of GAT for gender dysphoria. (Ludvigsson, 2023.)

234. Dr. Hilary Cass "was appointed by NHS England and NHS Improvement to chair the Independent Review of Gender Identity Services for children and young people in late 2020" (The Cass Review website, 2022). In her interim report dated February 2022, it states that "[e]vidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and internationally" (Cass, 2022). This led to the shutting down of their Tavistock child gender identity clinic.

235. In the nation of Norway, a report from the Norwegian Healthcare Investigation Board (Ukom) was released in March of this year. The report found "there is insufficient evidence for the use of puberty blockers and cross sex hormone treatments in young people, especially for teenagers who are increasingly seeking health services and being referred to specialist healthcare. Ukom defines such treatments as utprøvende behandling, or 'treatments under trial,' said Moen" (Block, "Norway", 2023).

236. In the State of Florida, effective March 6, 2023, the Florida Board of Medicine amended its "Standards

of Practice for Medical Doctors" to include the following:

"64B8-9.019 Standards of Practice for the Treatment of Gender Dysphoria in Minors.

(1) The following therapies and procedures performed for the treatment of gender dysphoria in minors are prohibited.

(a) Sex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics.

(b) Puberty blocking, hormone, and hormone antagonist therapies."

IV. Medical Concerns regarding the Three Minor Plaintiffs

A. L.W.

237. **[REDACTED]**

238. **[REDACTED]**

239. **[REDACTED]**

240. **[REDACTED]**

241. **[REDACTED]**

242. **[REDACTED]**

243. **[REDACTED]**

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247. **[REDACTED]**

248. **[REDACTED]**

249. **[REDACTED]**

250. **[REDACTED]**

251. **[REDACTED]**

252. **[REDACTED]**

253. **[REDACTED]**

254. **[REDACTED]**

255. **[REDACTED]**

256. **[REDACTED]**

a. **[REDACTED]**

b. **[REDACTED]**

c. **[REDACTED]**

d. **[REDACTED]**

257. **[REDACTED]**

B. Ryan Roe

258. **[REDACTED]**

259. **[REDACTED]**

260. **[REDACTED]**

261. **[REDACTED]**

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[24] "Most common related adverse reactions (>10%) in clinical trials were hot flashes/sweats, headache/migraine, decreased libido, depression/emotional lability, dizziness, nausea/vomiting, pain, vaginitis and weight gain." (Lupron Depot-Ped, 2022).

[25] In L.W.'s case, estrogen could be titrated down over the course of a few weeks. Lupron could be stopped immediately as it may take 6-18 months or longer for the pituitary gonadal axis to return to normal functioning.

262. **[REDACTED]**

263. **[REDACTED]**

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286. **[REDACTED]**

287. **[REDACTED]**

288. **[REDACTED]**

C. John Doe

289. **[REDACTED]**

290. **[REDACTED]**

291. **[REDACTED]**

292. **[REDACTED]**

293. **[REDACTED]**

294. **[REDACTED]**

295. **[REDACTED]**

296. **[REDACTED]**

297. **[REDACTED]**

298. **[REDACTED]**

V. Risks of GAT Outweigh the Benefits for the Three Minor Plaintiffs

299. **[REDACTED]**

VI. Conclusion

300. The gender affirmative therapy model suffers from serious deficiencies in logic and lacks scientific foundation. The deep error hidden in this model is that one cannot in fact change sex. One cannot acquire the deep characteristics of biological sex in order to gain the

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[26] **[REDACTED]**

[27] As of this writing, only limited medical records of the three plaintiffs are available for review.

complete sexual and reproductive functions of the opposite sex. This is not technologically possible.

301. Children and adolescents are of such immature minds that they are likely to believe that it is possible. In fact they may come to believe that their inherent, biologically necessary puberty is "terrifying" or needs to be stopped. Social transition serves to convince the child or adolescent that they can be the opposite sex. Puberty blockers sustain this state of mind by retaining a childlike state with respect to the genitalia and body habitus. High dose opposite sex hormones then cause medical conditions such as hirsutism and irreversible damage to the vocal cords in females and gynecomastia in males. These conditions serve to convince the young person that they are going through puberty of the opposite sex when in fact they are not developing sexually and are infertile.

302. There are known risks for both adults and minors, some of which I have described above, including cardiovascular disease, cancer, deficiencies in ultimate bone density, harms to sexual function, infertility, and for some permanent sterility. The child or adolescent cannot consent to these harms when they are not mature enough to fully comprehend what they mean. Long-term studies regarding the treatment effects specifically for minors with hormones and surgeries, using randomized controlled studies or even proper observational studies do not exist.

303. WPATH's newly released SOC 8 represents a grave and immediate danger to minors, young adults, and adults and should not be followed by any physician, mental health care provider, or other medical professional.

304. For the reasons set forth above, in my professional opinion as an endocrinologist, no child or adolescent should receive puberty blockers to block normal puberty, nor should they receive supraphysiologic doses of opposite sex hormones to attempt to alter secondary sex characteristics, nor should they have surgeries to remove or alter the breasts, genitalia or reproductive tracts as part of GAT. There exists insufficient evidence of benefit, but serious concerns for risk of harm. Therefore, I believe that the newly enacted Tenn. Code Ann. § 68-33-101, *et seq*., is based on sound medical principles for the protection of minors.

I declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury that the foregoing is true and correct. Executed 5/19/2023.

/s/ MICHAEL K. LAIDLAW, M.D.
MICHAEL K. LAIDLAW, M.D.

EXHIBIT 8

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
GEETA NANGIA, M.D.

TABLE OF CONTENTS

I, Geeta Nangia, MD, have been retained by counsel for the Defendants in connection with the above captioned litigation.

1. I have been asked by counsel for the Defendants to provide my expert opinion on the diagnosis and treatment of gender dysphoria in minors as it relates to Tennessee Senate Bill I.

2. I am over the age of 18. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion. I am being compensated at an hourly rate of $350.00 per hour for documentation and $550.00 per hour of testimony that I devote to this case. My compensation does not depend on the outcome of this litigation, the opinions that I express, or the testimony that I provide.

BACKGROUND AND QUALIFICATIONS

3. I am a Board-Certified Child and Adolescent Psychiatrist, and Board-Certified Adult Psychiatrist. I obtained my B.A. in Biochemistry and Molecular Biology from Boston University and my M.D. from Boston University School of Medicine. I graduated with the Ruth Hunter Johnson Prize in Psychiatry. My residency and fellowship training, in Psychiatry and Child and Adolescent Psychiatry, respectively, were at The Medical University of South Carolina (MUSC). I completed my fellowship in 2007.

4. I have been active in teaching medical students and residents throughout my career and received the Circle of Excellence in Teaching at MUSC. In recent years, my clinical lectures have focused on child and adolescent development.

5. I have worked in the field of Child and Adolescent Psychiatry as a community psychiatrist in a wide range of settings, providing comprehensive psychiatric services for children and families. I chose to work as a community psychiatrist because I desired to evaluate and treat a wide range of mental health disorders and wanted to see young people in the context of their families and community "systems" (e.g., schools, extracurriculars, local supports). Throughout my career I have worked in rural, urban, and suburban areas, and in outpatient, inpatient, partial, as well as residential care settings. I have been very active in school consultations and advocating on a community level for mental health accommodations for youths in school. I have worked toward providing access to mental health care for youths who are underfunded and lack services due to barriers of access and cost. I have provided psychiatric evaluations, psychotherapy, and medication management for children and adolescents, as well as family therapy. I have been a part of multiple interdisciplinary teams.

6. Much of my career has been spent educating, equipping, and supporting families of children who struggle with depression, anxiety, and other mental health issues by stressing the importance of attachment between parents and children. I believe that an attachment-centered approach to therapy helps children to find their homes as a safe place to connect, where they feel nurtured, supported, and loved. It is connection and secure attachment to safe caregivers that form the foundation for healthy childhood development, allowing a child to success-

fully progress through the developmental trajectory toward identity consolidation.

7. I continue to provide community mental health care through my private practice and am providing this opinion as a child psychiatrist working in private practice.

8. Over the course of my career, seeing a broad range of psychiatric disorders, I have treated many patients with active gender dysphoria or a history of gender dysphoria. Per my best reflection, I'd estimate that 550 of these have been minors. As discussed below, the modalities of care that I have utilized with minor patients who have gender dysphoria include supportive and exploratory (psychodynamic) therapy, family therapy, and psychopharmacology. The latter has only been used if children and adolescents are also struggling with mental health disorders such as depression or anxiety. I have collaborated with others in the community to garner a network of support for my patients, when deemed appropriate.

9. Given the nature of being a community child psychiatrist, I have the benefit of being involved with children's health care not only in my office, but also with their families, schools, and outside support systems. This provides me with the ability to have a more complete perspective on their development, and the interventions that produce the best outcomes for their overall wellbeing.

10. My medical opinion below is based upon my training and clinical experience as a Child and Adolescent Psychiatrist, my knowledge of child development, and review of the literature (including stand-

ards) on this subject. I may wish to supplement my opinions or the bases for them as new research is published or in response to statements made in my area of expertise.

11. My previous expert witness testimony has been regarding abuse and trauma, and interventions for children struggling with mental health disorders. I also submitted a written report in *Dekker v. Marstiller*, No. 4:22-cv-325-RH-MAF (N.D. Fla.) and *Boe v. Marshall*, No. 2:22-cv-0184 (M.D. Ala.).

12. For medicolegal purposes, I have also, throughout my career in mental health, served as a designated examiner for persons during inpatient hospitalizations, and as part of this process, I have performed numerous capacity assessments and presented them to courts.

GENDER DYSPHORIA

I. Diagnostic Criteria

13. Gender dysphoria in adolescents is defined by the DSM-5-TR as: A marked incongruence between one's experienced/expressed gender and assigned gender, of at least six months duration, as manifested by at least two or more of the following:

- A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
- A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a de-

sire to prevent the development of the anticipated secondary sex characteristics)

- A strong desire for the primary and/or secondary sex characteristics of the other gender
- A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
- A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)
- A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)

The condition is associated with clinically significant distress or impairment in social, occupational, and other important areas of functioning. (DSM-5, TR)

14. According to the American Psychiatric Association, gender dysphoria often begins in childhood, but some individuals may not experience it until puberty or much later. (DSM-5-TR)

15. The DSM-5-TR defines gender dysphoria in children as a marked incongruence between one's experienced/expressed gender and assigned gender, lasting at least six months, as manifested by at least six of the following (one of which must be the first criterion):

    - 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)

- 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.
- A strong preference for cross gender roles in make-believe play or fantasy play
- A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender
- A strong preference for playmates of the other gender
- 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
- A strong dislike of one's sexual anatomy
- A strong desire for the physical sex characteristics that match one's experienced gender As with adolescents and adults, the condition must also be associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning. (DSM-5-TR)

II. Prevalence

16. According to a 2022 study done by The UCLA School of Law Williams Institute, entitled "How Many Adults and Youth Identify as Transgender in the United States?" over 1.6 million adults and youth (13-17) identify as transgender in the U.S. Among youth ages 13-17, 1.4 percent identify as transgender. The data used was from the CDC's BRFSS and YBRS (Behavioral Risk Factor Surveillance System and the Youth Risk Behavior Survey). The BRFSS questionnaire asks, "Do you consider yourself to be transgender?" (Herman 2022)

17. Research shows that transgender individuals are younger on average than the U.S. population, and youth ages 13-17 are significantly more likely to identify as transgender than adults ages 65 and older. (Herman 2022)

18. At the state level, estimates from this same study show that 3.0% of youth ages 13-17 are identifying as transgender in New York as compared to 0.6% in Wyoming. (Herman 2022)

19. Per a 2022 report from Herman et al. and The Williams Institute, when comparing the current report with estimates made by The Williams Institute in 2016-2017, researchers found that the percentage and number of adults who identify as transgender has remained steady over time. The YRBS data shows that youth comprise a larger share of the transgender identified population than what was previously estimated, currently comprising 18.3% of the transgender identified population in the United States, up from 10 percent previously. (Herman 2022)

20. There are several contributing factors to the rise of gender dysphoria that I observe in my own patient population: 1) an increase in "pathologizing" of what I view—and what much of the reliable scientific literature has long viewed—as a normal part of childhood development, 2) shifts in cultural norms having to do with gender exploration in adolescence, 3) the advent of social media, 4) heightened vulnerability in youth, and 5) what some call "social contagion." These are explained below.

21. Increase in pathologization of a normal part of childhood development: When gathering a developmental history, it has been my experience that many parents and children describe a period of time, greater than six months, during which the child was a "tomboy" or "tomgirl" (per their own terminology). When discussing this further, most of these parents and children openly talk about how the child felt strongly that he/she wanted to be the opposite gender, preferred to play with stereotypical opposite gender toys, preferred to engage in opposite gender activities, wanted to only wear opposite gender clothing, preferred opposite gender playmates, rejected same gender toys/activities, and had significant associated distress. These are the first six out of eight criteria in the gender dysphoria diagnosis, and only six criteria and significant distress are necessary for the diagnosis. However, these children weren't ever diagnosed formally, their parents didn't label or pathologize their behavior, and the symptoms eventually passed and the children became comfortable with their natal sex.

22. In colloquial English, in decades past, society referred to children who had such symptoms as "tomboys" and "tomgirls." Gender-medicine experts today distinguish between tomboys or tomgirls and children with gender dysphoria. They state that the former display an outward expression of the opposite gender to the world, but feel an internal comfort with their birth gender. The latter, they say, have an internal psychological sense that they are of another gender. (DSM-5-TR)

23. The American Academy of Child and Adolescent Psychiatry uses the terms gender nonconformity versus gender discordance to make this same distinction. However, they acknowledge in their Practice Parameters that "there may be clinical difficulty distinguishing between gender nonconformity and gender discordance." (Adelson 2012)

24. In my clinical experience, I have had difficulty appreciating this distinction. First, this is because both parents and children, who describe such a period in the child's life of having been a "tomboy" or "tomgirl," most often retrospectively endorse the criteria that are necessary for the gender dysphoria diagnosis. Second, this assertion—that children with gender dysphoria have an "internal psychological sense" of their gender incongruence—implies that children are able to have consolidated identity. This is not congruent with what we know about identity formation and consolidation, a stage which doesn't occur until adolescence. While gender identity is in the process of forming in very early childhood, this formation continues to be influenced by multiple factors over many years, as the normal course of childhood development unfolds. It isn't

until adolescence that several key psychosexual and psychosocial development models show identity forming and becoming more fixed. In other words, children's sense of who they are, or their "identity," can and often does shift over time as part of normal development. It is not until they reach the end of adolescence, at the cusp of adulthood, when identity is said to consolidate. (Erikson 1998)

25. Still, this notion that children have an internal sense of gender and should be offered specialized care if they endorse the above criteria has led to the unnecessary pathologization of what otherwise has been considered a normal phase of development. This mistaken notion has contributed to an increase in gender dysphoria diagnoses. Many parents, who in the past simply would have not worried about their children who had the above "symptoms," are now compelled to consider a diagnosis of gender dysphoria and treat the child because of the fear that their child may suffer if they don't. Physicians, likewise, are acting quickly to usher these children into gender-affirming care, out of the same fear. This is in spite of the data showing that "cross-gender wishes usually fade over time and do not persist into adulthood." (Adelson 2012)

26. Shifts in cultural norms in adolescence and the advent of social media: Culturally, society has created a new "norm" of gender questioning and exploration in adolescence. This cultural norm of gender exploration also has been reinforced by the medical community. According to a recent *New York Times* article, "It's developmentally appropriate for teenagers to explore all facets of their identity—that is what teenagers do," stated Dr. Angela Goepferd,

medical director of the Gender Health Program at Children's Minnesota Hospital. "And, generationally, gender has become a part of someone's identity that is more socially acceptable to explore." (Ghorayshi 2022)

27. Hence, not only have cultural norms shifted due to information availability and social media, but they have also shifted due to physicians informing parents and children that gender exploration is healthy and appropriate. One can infer that if a child has never questioned their own gender previously, this new norm tells them that it is healthy to do so and encourages it as part of normal development.

28. Further, the advent and expansion of social media has created waves in what youth consider to be popular, acceptable, and normative. Youths are consuming more social media than ever before. Social media enables the spread of information pertaining to many issues, including those related to sexual development, sexual orientation, sexual activity and practices, and gender. There has been a dramatic increase in the global public discourse surrounding LGBTQA issues amongst youths. There has been widespread content circulating throughout society on gender exploration, incongruence, and dysphoria. This is generally accompanied by passionate advocacy that is highly regarded by youths of all ages. Celebrities have highlighted LGBTQA issues and have used various forms of social media, like TikTok, to promote and celebrate gender incongruence. On a local level, information sharing has led to the popularity of LGBTQA clubs at schools, community groups dedicated to raising awareness and acceptance, and enthusiastic support networks for

those who identify as LGBTQA. Many of these can easily be found online. With the spread of online information and cultural advocacy, the natural heightened propensity of youth to explore gender and see it as fluid has increased.

29. In a 2018 study on parent surveys of children with gender dysphoria, Littman writes: "Parents identified the sources they thought were most influential for their child becoming gender dysphoric. The most frequently answered influences were: YouTube transition videos (63.6%); Tumblr (61.7%); a group of friends they know in person (44.5%); a community/group of people that they met online (42.9%); a person they know in-person (not online) 41.7%." (Littman 2018)

30. Youths are more vulnerable to novel information streams. According to another article in *The New York Times*,

> Helana Darwin, a sociologist at the State University of New York at Stony Brook who began researching nonbinary identities in 2014, found that the social-media community played an unparalleled role in people's lives, especially those who were geographically isolated from other nonbinary people. . . . Her research found that social media is a gathering place for discussing the logistics of gender—providing advice, reassurance and emotional support, as well as soliciting feedback about everything from voice modulation to hairstyles. . . . Psychologists often posit that as children, we operate almost like scientists, experimenting and gathering information to make sense of our surroundings. Children use their available resources—generally limited to their immediate

environment — to gather cues, including information about gender roles, to create a sense of self.

(Wortham 2018)

31. In this same *New York Times* article, author Jenna Wortham asked Alison Gopnik, a renowned philosopher and child psychologist, "if it's possible that social media can function as a foreign country, where millions of new ideas and identities and habitats are on display—and whether that exposure can pry our calcified minds open in unexpected ways." Gopnik replied, "Absolutely. . . . Having a wider range of possibilities to look at gives people a sense of a wider range of possibilities, and those different experiences might lead to having different identities." Wortham continued:

When we dive into Instagram or Facebook, we are on exploratory missions, processing large volumes of information that help us shape our understanding of ourselves and one another. And this is a country that a majority of young adults are visiting on a regular basis. A Pew study from this year found that some 88 percent of 18-to-29-year-olds report using some form of social media, and 71 percent of Americans between ages 18 and 24 use Instagram. Social media is perhaps the most influential form of media they now have. They turn to it for the profound and the mundane—to shape their views and their aesthetics. Social media is a testing ground for expression, the locus of experimentation and exploration.

(Wortham 2018)

32. So, it would seem most plausible that the normalization and even encouragement of gender explora-

tion in adolescence combined with the emphasis on building awareness of gender dysphoria, particularly through social media, would lead to a heightened prevalence of the gender dysphoria diagnosis. More adolescents naturally are exploring gender, more have awareness of gender fluidity and gender dysphoria, and more are seeking out help or guidance.

33. For example, an adolescent natal female who has been bullied by female peers for years now has shifted to having mainly male friends, preferring male athletic clothing, and wanting a short haircut to fit in with them. She believes her emotions to be more in line with theirs and feels distress over this. Later, through exposure to transgender friends and information she finds online, she comes to believe that she has gender dysphoria and needs gender-affirming care, so she seeks help. Previously she may have viewed her feelings of distress and her behaviors to be a mere reflection of her vulnerability around females based on her negative experiences. In years past, such an adolescent natal female may not have interpreted that her feelings and negative experiences or the reactions of others had anything to do with a condition like gender dysphoria. But now, surrounded by widespread societal, cultural, and peer encouragement, she may contextualize those feelings and discomfort in ways that prompt her to inquire, first, into gender dysphoria as a concept, and then into riskier or more invasive and biologically systemic responses to her internal discomfort. Situations like this are common, in my experience, and I believe they have led to an increase in the diagnosis of gender dysphoria.

34. Heightened vulnerability: Youth today are also experiencing more vulnerability and a feeling of being disconnected, or not belonging. A new U.S. Department of Health and Human Services (HHS) study published in the American Medical Association's journal, *JAMA Pediatrics*, reports significant increases in the number of children diagnosed with mental health conditions. The study, conducted by the Health Resources and Services Administration (HRSA), finds that between 2016 and 2020, the number of children ages 3-17 years diagnosed with anxiety grew by 28.9% and those with depression by 26.7%. (Lebrun-Harris 2022)

35. Certainly, there has been a large increase in mental health disorders in the United States over the last several years, with COVID increasing the numbers of vulnerable children. Families have been struggling, and there has been an increased rate of family disruption. Stress and trauma have exponentially increased, and all these stressors impact youth vulnerability, and youth seeking out places where they fit and belong. In my experience with adolescents, many are drawn to LGBTQ clubs and online groups, and find them to be a kind respite where they are cared for, affirmed, and feel a sense of comradery with other peers who've faced social vulnerability and had a feeling of not belonging. Feeling embraced and accepted by friends whom they can relate to may lead them to consider that they, too, may be transgender. In my adolescent patients, this type of feeling is echoed often and lends to them endorsing gender-dysphoria criteria.

36. Social Contagion: Lastly, heightened prevalence of gender dysphoria may be attributed to a "band-

wagon effect" or, as others call it, "contagion." In my experience, adolescents presenting with gender dysphoria have often described being influenced by peers and social media to consider that they may be the opposite gender. Similar types of influence have been reported in the past with other mental health conditions in psychiatry. For example, a study showed self-harming behaviors were socially contagious in adolescents, and studies on eating disorders have shown similar patterns. (Riggio 2022; Dishion 2011)

III. Treatments

37. According to the American Academy of Child and Adolescent Psychiatry, principles that are important in the treatment of youth with gender discordance are as follows:

    1) A comprehensive diagnostic evaluation should include an age-appropriate assessment of psychosexual development for all youths

    2) The need for confidentiality in the clinical alliance is a special consideration in the assessment of sexual and gender minority youth.

    3) Family dynamics pertinent to sexual orientation, gender nonconformity, and gender identity should be explored in the context of the cultural values of the youth, family, and community.

    4) Clinicians should inquire about circumstances commonly encountered by youth with sexual and gender minority status that confer increased psychiatric risk.

5) Clinicians should aim to foster healthy psychosexual development in sexual and gender minority youth and to protect the individual's full capacity for integrated identity formation and adaptive functioning.

6) Clinicians should be aware of current evidence on the natural course of gender discordance and associated psychopathology in children and adolescents in choosing the treatment goals and modality.

7) Clinicians should be prepared to consult and act as a liaison with schools, community agencies, and other health care providers, advocating for the unique needs of sexual and gender minority youth and their families.

8) Mental health professionals should be aware of community and professional resources relevant to sexual and gender minority youth.

(Adelson 2012) The parameters also note, with regard to medical or surgical transition: "In general, it is desirable to help adolescents who may be experiencing gender distress and dysphoria to defer sex reassignment until adulthood, or at least until the wish to change sex is unequivocal, consistent, and made with appropriate consent." They go on to describe different treatment approaches when waiting until adulthood is not "feasible." One approach described is puberty suppression at age 12 followed by cross-sex hormones at age 16, and then gender reassignment surgeries at age 18. Another approach is waiting

until Tanner Stage 2 to initiate pubertal suppression, and then proceeding with options for cross-sex hormones and gender reassignment surgeries. A therapeutic group approach with families to help them offer support is described. While the authors report negative outcomes with conversion therapies, they repeatedly comment on the lack of controlled trials looking at other therapeutic (including psychodynamic therapy) approaches in children with gender discordance. (Adelson 2012)

IV. Medical Interventions and Associated Risks

38. Medical gender transition involves puberty blockers and subsequently cross-sex hormones. These interventions are frequently followed by surgeries that can include but not limited to breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery.

39. Puberty blockers (gonadotropic releasing hormone agonists or GnRHa) are a form of medication that block the physiological production of sex hormones and are given during the Tanner Stage 2 of development when puberty has just started. (Delemarre-van de Waal 2006)

40. Testosterone (in males) and estrogen (in females) are responsible for changes that occur in puberty. Puberty blockers stop the production of follicle-stimulating hormone (FSH) and luteinizing hormone (LH) from the pituitary, and this then prevents the production of sex hormones.

41. None of the puberty blockers are currently FDA-approved for use in gender dysphoria.

42. In gender dysphoria, puberty blockers are given "off-label" to postpone the changes that occur with puberty. The clinical reasoning behind this is that proponents say that it gives youth time to decide whether to "fully" transition, through a trajectory of cross-sex hormones and then surgeries, while preventing changes that may cause distress. (Delemarre-van de Waal 2006)

43. There is marked debate on the safety of puberty blockers, cross-sex hormones, and surgeries utilized in gender transition.

44. Some of the risks that are debated in the literature are the long-term effects of these medications on the endocrine system, reproductive system, bone growth, brain maturation, psychological functioning, and metabolic functioning.

45. I am generally familiar with the literature surrounding these debates. I have reviewed the report of Dr. James Cantor submitted in this case and agree with his conclusion that the existing studies of puberty-blockers and cross-sex hormones in minors provide no reliable evidence of effectiveness for improving mental health relative to mental health treatments that lack medical risk. I also agree with his conclusion that all existing systematic reviews of safety and effectiveness of these treatments have concluded that the evidence on medicalized transition in minors is of poor quality.

V. Clinical Experience with Gender Dysphoria

46. As part of an initial evaluation, I ask individuals how they identify in terms of sexual orientation and gender. When taking a developmental history dur-

ing an in-person assessment, I ask about an individual's social development, as well as questions pertaining to self-concept (how one views oneself). As part of this, I may delve into questions that deal with gender, in an age-appropriate manner, with the child, adolescent, and/or parent. Questions that I ask pertaining to gender identity include, but are not limited to:

- 1) How did you feel about your gender early on in your life?
- 2) Did you feel comfortable with your gender?
- 3) If not, did you identify with another gender?
- 4) How did this affect you, and the way that you saw yourself?
- 5) What types of play did you enjoy the most?
- 6) Were most of your friends of the same gender or opposite gender?
- 7) Do you remember feeling discomfort with your body in any fashion?
- 8) Did you prefer to ever dress as another gender?
- 9) If you previously felt more comfortable as another gender, or unsure of identifying with your birth sex, how long did this persist?
- 10) If you now feel comfortable with your natal sex, but previously did not, what led to you feeling comfortable?

47. The reason such questions are important in addressing self-concept—and gender as a part of self-

concept—is that, developmentally, an individual's early experiences and view of oneself in the context of a greater environment are important to understanding the individual's presenting clinical issues.

48. Since becoming a physician in 2002, I estimate that I've evaluated and treated 550 children and adolescents (and hundreds of adults) who have met criteria at some point in their lives for a "gender dysphoria" diagnosis. Of 550 adolescent patients, I approximate that 350 of these patients had a history of gender dysphoria, as discovered on evaluation or over the course of patient care. This was ascertained via parent or child retrospective report wherein they had met criteria for the diagnosis. For these children, the gender dysphoria resolved with age maturation alone prior to seeing me. Many of these children were referred to by their parents as having been a "tomboy" or "tomgirl," and their parents were not concerned. I discuss these terms above. I did not label or pathologize these children during the course of their mental health treatment as having had "gender dysphoria," despite the diagnostic criteria seeming to have been met. But for the purpose of this declaration, I am including them in the discussion of patients I have treated who have had gender dysphoria.

49. I estimate that I've seen close to 100 additional child patients who meet criteria for gender dysphoria on clinical interview during or over the course of treatment with me (as opposed to retrospective report). I have often observed that children's feelings regarding their own gender are a reflection of their perception of gender roles within their family unit and sphere of influence. I have had many female

child patients who enjoy climbing trees and playing "boy sports," playing with "boy toys," who have a strong desire to be boys like their brothers, play with only boys on the playground, reject "girly" toys and activities, and want to use the restroom standing up like boys do. These children often are emotional and experience some real distress for significant periods about having been born as girls and wanting to be boys in every imaginable way. I've had male child patients who do the opposite. With all these children, I have told their parents not to become anxious, and not to pathologize or characterize their child based on their observations.

50. In every case that I have observed, children grow out of such "gender dysphoria" and become comfortable with their natal sex. In fact, these children are naturally some of the most confident children I've seen over time. I have always attributed this to their parents being comfortable allowing them to explore and engage in free play without feeling any anxious desire to push them toward the toys and activities that are stereotypical of only one gender. They have not pathologized or seen their child's preferences for play and fun as something to be concerned about. Hence, their children learn confidence to explore the world around them, feel validated and affirmed by their parents, without any assumptions that their exploration is anything more than a normal part of growing up.

51. My experience has been that periods of gender incongruence and associated distress are normative and transient, with resolution as the child matures. I have provided these parents and children with

guidance; support; and, when needed, exploratory therapy.

52. I also estimate that I have seen just over 100 adolescents who have presented with gender dysphoria that has been more abrupt in onset. The majority of these are biological females, and these cases have grown increasingly frequent over recent years.

53. In these cases, adolescents and/or their parents reported at least one of the following issues as also being primary within their life "systems" (e.g., school, family, peer group, community): 1) a feeling of not fitting in with peers, or feeling "different" and not belonging, 2) an experience of gender roles within their own families, or within their peer groups, that has had a marked influence on their own perception of gender and gender identity, 3) a history of trauma, 4) a history of disruption of primary attachment, 5) a history of feeling vulnerable and emotionally unsafe, 6) a history of depression, anxiety, or social anxiety, 7) a history of an autism spectrum disorder, 8) an exposure to information on gender via social media, TV, or the internet, with a subsequent curiosity about gender exploration, 9) a feeling of vulnerability, followed by a search for belonging, or 10) a feeling of a good "fit" among peers who have also felt vulnerable in an LGBTQA group online or in school.

54. Almost all of the adolescent patients had taken steps to access additional information about their gender dysphoria from readily available online sources and social media, and many found friendship within LGBTQA clubs at school or online friends in the LGBTQA community. They described

feeling accepted, supported, and affirmed within these social groups. Some did not identify as the opposite gender, but rather stated they were "gender queer" or "non-binary."

55. For all of these youth, I provided exploratory therapy, supportive therapy, and family therapy, or I worked with a therapist who collaborated with me in treatment, to address these factors within the adolescent's life systems. I also provided medication management where needed for other mental health issues. Their treatment plans included crafting an individualized approach from the above therapies, harnessing community support, and providing guidance to parents in two key areas: 1) How to best be "present" and establish an emotionally safe environment at home, and 2) how to grow in connection and relationship with their child by loving them for who they are. Among these adolescents, the vast majority realigned with their natal sex over the period of treatment. Some stated, over time, that they were questioning their sexual orientation, and not their gender. All responded to these interventions positively such that, over time, regardless of whether they'd realigned with their natal sex or had a future plan to transition, they no longer experienced gender dysphoria and their mental health improved. Those who had continued gender incongruence felt that they wanted to see how they felt over time rather than pursuing options to medically transition as minors. They were appreciative of the support and therapy and found it helpful.

56. I've treated approximately 25 children/adolescents during their social and/or medical transition. I supported them where they were at on their journey,

through psychotherapy and medication management, and I respected their decision based on what treatment options had been afforded to them by other doctors. To clarify, I have never personally referred a minor for medical transition, as I don't believe the option should be given to minors based on reasons I explain below.

VI. The Role of Exploratory Therapy for Gender Dysphoria in My Practice

57. Minor patients with gender dysphoria benefit tremendously from therapy that explores their feelings and experiences within their "life systems," past and present. I have found that adolescents with gender dysphoria are generally very open to this. They voice that they feel supported and that they gain clarity in the process. Through therapy, just like most youth with presentations other than gender dysphoria, these patients improve in self-concept and mindfulness, becoming aware of how their experiences have affected them, and what defenses they employ when feeling challenged or stressed. They learn to identify their own values and what matters to them, which makes their choices and decisions clearer.

58. The primary modality of therapy that I have utilized in treating gender dysphoria is psychodynamic therapy, I have also utilized cognitive behavioral therapy, interpersonal therapy, and family therapy. I *do not* endorse conversion therapy and I believe it is detrimental. I have treated one adolescent who underwent conversion therapy as part of a religious school prior to seeing me, and she suffered significant trauma as a result. This patient

required specific therapy to help her process that trauma.

59. Psychodynamic therapy engages individuals in "free association." Free association is the idea that whatever is on a patient's mind guides the clinical session. The free association, or whatever the patient brings up, is deemed of importance and is used to spur exploration of the patient's past and how that past may be affecting the patient's present circumstances and feelings.

60. In this context, then, the therapist can help the patient identify how repressed feelings from the past may be influencing the patient's current decision making, relationships, and behaviors. Over time, this leads to natural "uncovering" of coping and defense mechanisms, fears, desires, and values that are rooted in a person's past experiences.

INFORMED CONSENT

61. To provide children the best-quality care, physicians should abide by the ethical standards that are universal to the practice of medicine. One of these standards is informed consent. Implicit to the informed consent process are related standards of medical ethics that are central to the practice of medicine, taught in medical school, and widely accepted.

I. Medical Ethical Standards

62. These universal ethical standards include beneficence, non-maleficence, autonomy, truth-telling, confidentiality, and justice.

63. Beneficence is the obligation of the physician to act for the benefit of the patient. In principle, the phy-

sician should support moral rules to protect and defend the rights of others, prevent harm, remove conditions which cause harm, help persons with disabilities, and rescue persons in danger. This means not simply avoiding harm, but actively seeking to promote the welfare of the patient. Beneficence is applied most often during clinical assessment, but also throughout treatment (Varkey 2020).

64. Non-maleficence is the obligation of the physician to not harm the patient. This is supported by moral rules (e.g., do not cause pain or suffering, do not kill, do not cause offense, or deprive others of the goods of life). Hence, the doctor must weigh the benefits of interventions with risks or burdens they may place on the patient. Nonmaleficence and beneficence are both part of the quality-of-life discussion between a doctor and patient. (Varkey 2020)

65. Autonomy is the supposition that all persons have intrinsic and unconditional value or worth, and therefore, should have the power to make moral choices and rational decisions, and to do so for self-determination. (Guyer 2003)

66. Autonomy does not extend to persons who lack capacity to act autonomously. Thus, children, adolescents, or individuals who have disorders that prevent capacity or competency lack autonomy. (Grisso 1998) Autonomy is at its most important as the doctor considers patient rights and preferences.

67. Truth-telling is the principle that doctors must not withhold information, nor misrepresent it, but rather provide information plainly and honestly to the patient, so that the patient or parent can, in turn, demonstrate full understanding in order to provide

voluntary consent. Informed consent is at its most important in discussing treatment options, and truth-telling is critical throughout patient care.

68. Confidentiality is maintaining the patient's privacy. This must apply to all domains of treatment.

69. Justice is the fair, equitable, and appropriate treatment of persons. Distributive justice is the equitable distribution of health care resources determined by justified norms. This standard is at its most important in the discussion of external forces and context for a patient, including their cultural, spiritual, religious, and economic beliefs and circumstances. (Fleischacker 2005; Varkey 2020)

70. In providing care for gender dysphoria, or for any other medical or mental health condition, these ethical standards must be adhered to.

II. Informed Consent as an Ethical Standard in Minors

71. The principle of informed consent rests upon the moral and legal premise of patient autonomy. In all populations, informed consent must balance the respect for patient autonomy with the protection of patient vulnerability. (Appelbaum 2007) This is particularly relevant as it applies to minors.

72. The informed consent process requires that certain criteria be met, and these are dependent on development (neurologic, cognitive, psychosocial) and experience. Informed consent involves the following principles: a) decisionmaking capacity, b) full disclosure of medical options, c) comprehension, and d) voluntary consent. (Grisso 1998) Voluntary consent is one's agreement to the intervention, without coercion or distress. Explanation of the

other principles, and the neurodevelopmental requirements for each, follows.

A. Decision-Making Capacity

73. To provide informed consent, one must have the ability to make the decision at hand. In a model of assessing decision-making capacity in children, Miller et al. identified cognitive development and experience as being pivotal. (Miller 2004)

74. In an article published in BMC Pediatrics, researchers expanded on this by undertaking a multidisciplinary approach to describing capacity in their research. Taking from neuroscience research concerning the developing brain, and other fields such as psychology and decision-making science and ethics, they highlighted the development necessary to meet the four standards for capacity. (Appelbaum 2001) They then identified certain neurodevelopmental skills and abilities that needed to be developed for each standard to be met. (Grootens-Wiegers 2017) These skills include:

    A. **The ability to communicate a choice:** This is the least rigorous standard for decision-making capacity. To consent to treatment, a person needs to be able to communicate that there is a choice to be made and a preference of treatment, via written or spoken language. This neurologic skill is "communication", either spoken or nonverbal. Nonverbal communication is an indication of dissent or implicit consent, but not legal consent. Hence, this standard depends on language development, which is initiated in early childhood. Children have a reasonable understanding of language by age five,

with refinement continuing until age nine. Further development of vocabulary and expression occurs throughout adolescence. (Shaffer 2007)

B. **The ability to understand:** In order to understand information presented about diagnosis and treatment options, and comprehend what choices for treatment are, and that a choice needs to be made, a person must be able to orient and direct attention to information. They must have sufficient intelligence, language proficiency to process the information, and memory and recall to integrate information beyond the short term. The foundation for this is laid down during infancy. Maturity in orientation and attention develops from ages seven to ten. (Rueda 2004) Memory increases between ages six and twelve, and then increases slightly during adolescence. (Thaler 2013)

C. **The ability to reason:** One must understand information, and then be able to reason regarding risks, benefits, and possible consequences of treatment. (Appelbaum 2007; Grisso 1997) To do this, one must have the "ability to engage in consequential and comparative reasoning and to manipulate information rationally." (Palmer 2016) Children, between the ages of six and eight years old, can engage in logical reasoning, and this ability grows from ages eight through eleven, as they use and access their own knowledge. (Markovits 1998) Complex reasoning, about alternative causal relations, develops into adulthood. Risk identification develops strongly between ages six through ten. (Hillier 1998) Although risk identification is

mature in late adolescence, adolescents are paradoxically more inclined toward risky behaviors due to the impulse control centers of their brains not having yet matured. (Casey 2015) This is further discussed below.

D. **The ability to appreciate:** This is the strictest standard of decisionmaking capacity. It requires that one understand the various options for treatment, and the relevance of those options to one's personal circumstances, values, and beliefs. Therein, one needs to have the ability to think abstractly and to understand the intangible consequences of a decision. This includes being aware that others have a mind of their own. (Appelbaum 2001) Many different areas of the brain are involved in this skill. Children start to recognize their own beliefs and desires, which contribute to their personal values and norms, between the ages of three and four. (Shaffer 2007) They begin to understand how these beliefs influence their actions. As an individual ages, due to the efficiency of working memory, one can think about more abstract and hypothetical things. (Markovits 2013; Pike 2010)

75. Capacity judgments should also take into consideration the factors, or circumstances and stressors, that affect minors in decision-making competency (competency being a legal decision). These are: personality (the child's predisposition to view information a particular way), emotional state (which can be seen as a motivator for information and preferences), and disease severity (which can affect un-

derstanding, retention of information, and reasons to consent).

76. Additionally, the minor's decision-making capacity for medical treatment should be assessed in the context of parental and clinician attitude and influence. (Miller 2004; Alderson 1992; Mann 1989)

77. Finally, the minor's capacity should also take into consideration the type and complexity of the decision, the setting, and the timing of the decision and time constraints.

78. Decision-making capacity can be considered in terms of neurodevelopment, psychosocial development, and cognitive development. Each is considered below.

79. **Neurodevelopment.** The MacArthur Competence Assessment Tool is often used to assess medical decision-making capacity. It was shown to be valid and reliable in children. (Palmer 2016; Appelbaum 2001) In a group of children six to eighteen years of age, it demonstrated that age limits for children to be deemed competent were estimated as early as 11.2 years old. (Hein 2014; Hein 2015) However, the authors point out that the cut off age of 11.2 years does not imply competence for any decision, in any situation. Rather, it is an age when, given favorable environmental factors, competency may be considered. (Hein 2014) Furthermore, with adolescence approaching, a child this age will continue to experience specific events in brain development that influence competency. (Appelbaum 2001) As noted by Hein et al. in a 2015 study, "[C] hildren may differ from adults by not having developed yet stable long term goals and values in life, meaning

that children may procedurally be classified as competent although their decisions are based on values that might change. This could imply that later on they might regret decisions based on those early-life values." (Hein 2015)

80. These specific events in adolescent brain development (Appelbaum 2001) contribute to a non-linear increase in decision-making competency from ages twelve to eighteen. During this adolescent stage of development the most significant changes in the brain have to do with processing rewards and risks, and self-regulation. Because of this, adolescence is often marked by risky behaviors, sensation seeking, and high prioritization of peer influences when making decisions. This also is the explanation for the higher rates of health issues and mortality in adolescents. (Steinberg 2004)

81. The increase in adolescent decision-making competency is non-linear due, in part, to "cross talk" between various brain structures during development. The three areas of the brain that are developing during adolescence and that pertain to decision making are the pre-frontal cortex (the brain's control system), the ventral striatum (the reward system), and the amygdala (the emotional center). The "cross talk" between these structures is not fully developed until early adulthood. (Steinberg 2013)

82. The prefrontal cortex is involved in impulse control and self-regulation. The ability to self-regulate develops significantly by age eighteen, and then further into early adulthood. The prefrontal cortex also is involved in functions that require control,

like paying attention, planning, organizing tasks, weighing risks and benefits, and processing more complicated decisions. (Gogtay 2004)

83. The ventral striatum is pivotal in the brain's reward system. It produces dopamine in response to rewards. During adolescence, the reward system is hyperresponsive. (Van Leijenhorst 2010) This means that the dopamine response to reward is much higher and is associated with increased reward seeking and sensation-seeking. This heightened responsiveness applies even to "small" rewards, making the positive effect of small rewards greater than in adults. Hence, "in a dilemma in which there is a small chance of reward, this reward may be attributed such a high value that the situation is no longer perceived a dilemma by the adolescent and there is only one path to choose." (Steinberg 2004)

84. The amygdala is involved in emotional processing and input to the reward system. The maturation of the amygdala stabilizes in late adolescence.

85. There is a mismatch in timing and pacing between the development of the amygdala, the ventral striatum, and the prefrontal cortex. The control system in the prefrontal cortex develops slowly and is last to complete maturation in early adulthood, whereas the reward system and emotional input system (ventral striatum and amygdala) begin change in early adolescence and complete maturation at a quicker pace. This accounts for the fact that even though adolescents can estimate risk or make responsible decisions, they often end up in precarious and risky situations and their behavior is not al-

ways consistent with their capacities. This also accounts for their often "too quick" decision making. Adolescents are prone to picking pathways with more immediate reward, regardless of consequences or consideration of other pathways. (Mills 2014; Steinberg 2013)

86. Consider, as a simple example, the "kid in a toy store" scenario. Children and adolescents are more likely to choose a flashy toy or item that they encounter first and feel instantly drawn toward rather than waiting to explore the rest of the store where they may find toys and items they like even more and that are more valuable. They seek out immediate gratification and pursue impulse-driven choices when confronted with reward stimuli rather than contemplating other options that carry the same or better reward but entail delayed gratification.

87. Steinberg puts it another way by discussing "hot" and "cold" contexts. An emotionally laden context is hot, whereas a minimally emotional context is cold. When emotions play a role in a situation, this can influence the decisionmaking process and the outcome. In adolescence, risk taking in a cold situation may be similar to that in children and adults. However, in hot situations, risk taking is increased, and this affects decision-making severely. This explains "the often-risky decisions adolescents make, seemingly only thinking about short term rewards, even though afterwards they can reasonably assess their 'leap in judgment.'" (Steinberg 2013; Metcalfe 1999)

88. These neurobiological models of adolescence are summarized in Appendix A. (Ernst 2006; McClure 2004; Metcalfe 1999; Casey 2008)

89. Johnson et al. also report similar conclusions in their work. The brain continues to mature into an individual's mid-20s. Functional MRI studies show that the prefrontal cortex is still maturing; this is the part of the brain involved with executive functioning and impulse control. Johnson et al. state that "[a]mong the many behavior changes that have been noted for teens, the three that are most robustly seen across cultures are: (1) increased novelty seeking, (2) increased risk taking, and (3) a social affiliation toward peer-based interactions." (Johnson 2009)

90. B.J. Casey confirmed this in her research on adolescent decision making. Her research concludes that the adolescent brain is more vulnerable when tasked with decision making in emotionally laden situations and in situations with peer involvement. (Casey 2008a; Casey 2008b; Casey 2010; Casey 2013; Chein 2011)

91. Casey's team studied adolescent response time when pairing stimuli with rewards and incentives. (Hare 2008, Appendix B and C). Naturally, without conscious awareness, people have quicker responses when they associate certain stimuli with positive outcomes or incentives. Individuals have slower responses to stimuli when there are fewer expected positive outcomes or rewards. (McClure 2004) Representation of rewards and incentives is found in the ventral striatum. Across development, studies show that adolescents activate this deeper region of

the brain more than young children and adults. When greater activity is seen in the ventral striatum, it is correlated with a higher degree of risk-taking behaviors or impulsivity. (Casey 2015)

92. Per Casey's research, the presence of peers also influences response time and accuracy for the adolescent. According to studies, when peers are present, adolescents make more errors in social cue interpretation and response time. They react more quickly to incentives and are more drawn to danger and risk taking or impulsive behaviors. Their brains are activated in the areas of the ventral striatum and the amygdala shows heightened activity relative to younger children and adults. (Casey 2015; Chein 2011)

93. Essentially, then, peers serve as reinforcers to influence behavior. (Chein 2011). Jones et al. (2014) developed a social reinforcement learning model to evaluate the degree to which peers reinforce behaviors from childhood to adulthood. The investigators manipulated the probability of the participant receiving positive social feedback from three virtual peers, who provided 33 percent, 66 percent, or 100 percent positive feedback. The results showed that different amounts of positive feedback enhanced learning in childhood through adulthood. However, based upon response latency measurement, it was concluded that all positive social reinforcement from peers equally motivated adolescents. Furthermore, adolescents, unlike children and adults, had an increase in premotor circuitry when receiving positive social feedback regardless of the expected outcome. (The premotor cortex communicates with other parts of the brain to cause motion.)

Hence, peer interactions appear to motivate adolescents toward action. (Jones 2014)

94. Casey concludes that adolescents show impairment in overriding impulses in emotionally charged situations. The imbalance appears to reflect earlier developing emotional centers in the brain and those involved in self-control. Lastly, she states that diminished self-control is transient and continues to develop in adulthood as these brain systems mature with experience. (Casey 2008; Casey 2015).

95. **Psychosocial development.** Children are developing human beings. Children go through several stages of psychosocial development according to Erik Erikson, a developmental psychologist whose theories are utilized across the fields of mental health and development. He stated that children enter the stage of "Industry vs. Inferiority" between ages five and twelve, wherein their major milestone is attaining the virtue of competence. (Erikson 1998)

96. During this stage, a child's peer group becomes more important. The child views his or her peers as being highly significant. The child's self-concept begins to form more closely around peer approval or disapproval. Children's reactions of feeling confident or proud, rejected and incapable, often form around their accomplishments and the responses of their peers. If their efforts are reinforced by praise and reward, they feel industrious (or "competent"). They exude a readiness to move past this stage and further along the developmental trajectory. If, however, they feel rejected or disapproved of, they feel inferior ("incompetent"), causing a halt in de-

velopment and an inability to move forward along the developmental trajectory. (Erikson 1998)

97. Adolescence, which is the next stage, is a time when youth develop the capacity to navigate social situations, and process social cues in more abstract ways. The ability to understand others' perspectives is expanding. Additionally, self-awareness is increasing into late adolescence and early adulthood, and modulating decision making as identity is consolidated.

98. According to Erikson, adolescents ages twelve to eighteen, who successfully moved forward from the former phase of development, enter the stage of "Identity vs. Role Confusion." During this stage, they are searching for a sense of self and identity. They experience intense exploration of personal values, beliefs, and goals. Adolescents begin to analyze and think more deeply about their own morality and ethics, and to determine their individual identities based upon their life experiences.

99. Body image is critical in this stage of development, and Erikson suggests that two identities are forming: "sexual" and "occupational." Erikson says that adolescents may feel discomfort with their bodies for some period until they can adapt and grow into the changes. Success in this stage leads to the virtue of "fidelity," which he defines as the ability to commit oneself to others on the basis of accepting them even where there are differences.

100. Adolescents have a desire to belong to society and to be productive. During this period, those adolescents who fail to form a sense of identity experience role confusion, feeling unsure where they fit into society in the long term.

101. Also, during this stage, youth are particularly impacted by peers, and are seeking to approve of themselves while being approved of by their peer group. Their exploration of their identities is ongoing throughout this stage and not solidified until they reach adulthood. (Erikson 1998)

102. **Cognitive development:** A model of cognitive development in children and adolescents was developed by Jean Piaget, another developmental psychologist.

103. Piaget described children between the ages of 2 to 7 as being in the "preoperational stage" of development. During this stage, children struggle with logic and have difficulty with the idea of constancy. They use their imagination and engage in pretend play but are concrete in the way they view their immediate surroundings. They also think symbolically and enjoy role play. Their cognitive skills (working memory, attention) are being developed.

104. He stated that between ages 7 through 11 (middle childhood through preadolescence), children entered the stage of "concrete operations." During this stage, children use logic in problem solving, and can engage in inductive (inferential) reasoning. However, they struggle with deductive reasoning, which involves the ability to use a general principle to predict an outcome. They are able to see another person's perspective. They lack the

ability to solve problems that deal with more abstract concepts, while they can solve concrete problems (actual objects or events). They have difficulty with understanding and utilizing common sense, and difficulty applying what they know to more hypothetical situations. (Santrock 2008)

105. Children in this stage also begin to think through social matters differently. Piaget's theory suggests that during the stage of concrete operations and on into the stage of formal operations, adolescents experience a feeling of uniqueness and invincibility. He refers to this as "imaginary audience" and "personal fable." Imaginary audience is evidenced by the adolescent always thinking others are watching, and personal fable is the adolescent's belief that he or she is exceptional in some way.

106. From age 11 through adulthood, adolescents go through "formal operations," the final stage in Piaget's theory. An adolescent during this stage is starting to engage more in deductive reasoning (Berger 2016), and is able to consider the hypothetical and "what if?" type of situations. The adolescent's metacognition is also developing, which is the awareness and understanding of their own thought processes.

107. Piaget's theories were rooted in observation and testing and are still utilized in our field. Neuroscientific developments through functional imaging have helped refine our understanding of his cognitive development theory.

108. To summarize, neurological, psychosocial, and cognitive development in the child and adolescent all

play a role in the determination of decision-making capacity.

B. Full Disclosure

109. To provide informed consent to treatment, a patient must be given full disclosure. (Varkey 2020) This must include: a) an explanation of the diagnosis and how it was arrived upon, b) information about the diagnosis and what is known regarding outcomes, c) the options that the patient has for treatment (including no treatment), d) the risks and benefits surrounding each treatment option, including those risks and benefits that are unknown, and e) the likelihood of the risks and benefits (occurring over the short and long term) for each treatment option.

110. Additionally, the physician must present details of the treatment options, including but not limited to, the preparation for the treatment that is necessary, and the follow up that should occur afterward for the best outcomes.

111. The physician should have knowledge of the subject area, and be objective in approach, placing the decision in the hands of the patient. The physician's role is to provide information and education to the patient based on expertise and to allow the patient to voluntarily consent.

C. Comprehension

112. Comprehension in the informed-consent process requires that the patient understand the diagnosis, the treatment options, and risks and benefits. To demonstrate comprehension, patients are asked to explain these things back to the physician in their

own words, indicating that they intellectually have grasped the content. Adolescents are developing the ability to engage in deductive reasoning as they grow toward adulthood. They can consider the hypothetical, which makes their ability to think about abstract consequences of treatments possible as they mature. However, it is important to note that the adolescent brain's ability to "appreciate" is evolving throughout adolescence and into adulthood. Hence, being able to fully appreciate outcomes of treatment, particularly those that are more abstract, is difficult through this period. Additionally, adolescents are still prone to impulse-driven decisions that end in more immediate gratification or reward, regardless of risk.

III. Parental Consent with Child Assent When Minor Informed Consent Is Unattainable

113. An adolescent's capacity and competency are not assumed in most cases, and parents are generally seen as medical decision makers for them. The rationale underlying this presumption is that "parents have what children lack in maturity, experience, and capacity for judgment when making difficult life decisions." (Diaz 2015).

114. There are exceptions to parents' ability to provide consent for the minor. In certain circumstances, a state may substitute its judgment that a medical procedure is in a child's best interests, even if parents do not consent. Likewise, a state may determine that a medical procedure is *not* in a child's best interest, even if parents attempt to give consent—an example being parents seeking to permit sterilization of their children.

115. As explained above, informed consent requires that a patient have decisionmaking capacity, which includes the ability to understand, reason, appreciate, and comprehend the information presented in a full disclosure of a diagnosis, its prevalence, available treatments, and the treatments' risks and benefits. There are at least two problems with this within the minor population when it comes to gender dysphoria.

116. First, patients must understand, reason through, and appreciate that the prevalence of gender dysphoria has been on the rise in adolescents, and there has been little research as to contributing factors. Additionally, there are a host of other co-occurring issues that need to be weighed in navigating treatment direction. Patients must understand that when these factors and co-occurring issues are brought to conscious awareness in therapy, gender dysphoria is often transient and remits. This is, at minimum, a difficult task for minors to understand.

117. Second, when considering treatment options for gender dysphoria, patients must be able to appreciate and weigh their options. The option of exploratory therapy inherently has far less risk than undergoing medical gender transition, but it takes time and considerable emotional investment as it explores the various systems in an adolescent's life. Albeit very fruitful and with minimal risks, it can still be emotionally taxing. Research confirms that adolescents devalue delayed outcomes relative to adults. (Huang 2017) Adolescents are less

inclined to plan ahead or anticipate the future consequences of their actions before acting. (Steinberg 2009).

118. Gender affirming care and medical transition may appear to be "quicker" answers to dysphoria and internal discomfort, as they aim to directly and immediately validate the adolescent's feelings about becoming the opposite gender, and they summarily dispense with any need to understand or explore causation. Considering both options, the impulse-prone adolescent is likely to find the latter far more rewarding.

119. In order for the minor to provide informed consent, the adolescent would need to be developmentally capable of appreciating the long-term consequences and risks of each option, and to be able to supersede impulse and desire for reward (to become the opposite gender), and attribute both options equal consideration. This requires complex deductive reasoning, planning, and thinking through future hypothetical life events like the desire to have children and potentially breastfeed. They would have to be able to fully comprehend and appreciate the debate over medical gender transition side effects, risks, benefits, and outcomes, and the issue of data quality. The complexity of the debate over the safety and outcome data is remarkable, and essential for the patient to understand as the potential risks involved can affect a minor patient's entire life. This particular task, in my opinion, is insurmountable for a minor patient.

120. These two barriers and necessary prerequisites to minor informed consent—(1) the requirement to understand, reason through, and appreciate that the prevalence of gender dysphoria has been on the rise in adolescents, that there has been little research as to both contributing factors, and the long-term effects of suggested medical interventions; and (2) that there can be a host of other co-occurring issues that need to be weighed in navigating treatment direction—are discussed further below. These details must be adequately and sensitively considered by all persons involved in the informed consent process to accurately ascertain and preserve the range of informed choices and effective options available to the patient. This more detailed discussion of these prerequisites and barriers will be followed by a discussion of why parental consent with minor assent should not be sufficient in the case of medical or gender transition.

I. Minor Gender Dysphoria Prevalence and Informed Consent

121. When the prevalence of a particular presentation increases, regardless of what presentation is, physicians must first ask themselves what factors are leading to the increased prevalence and what co-occurring issues are also presenting.

122. For example, if there were an increase in the prevalence of hypertension (high blood pressure) in teenagers, physicians would naturally craft a two-pronged response. One would be tailored to the potential factors that have led to the heightened prevalence, and the second would be tailored to any co-occurring conditions they see accompany-

ing the hypertension in the event that those are linked or causative. They would not simply advise all teens with hypertension to take medications that could carry associated risks. They would first take measures to address factors that may affect prevalence, like an increase in sugar consumption among youths, or an increase in cultural acceptance of childhood obesity. Second, they would also take measures to address co-occurring factors like obesity, stress, and sedentary lifestyles. Patients would be informed of these factors and co-occurring issues, and physicians would help each patient to appreciate them and to address them with education about the effects of obesity and too much sugar and about the need for improved diet, exercise, and stress-relieving measures. While these interventions may take time in comparison to medicines that relieve hypertension quickly, they would carry far less risk to the adolescent.

123. Second, when looking at increased prevalence of a presentation, physicians should ask themselves if the presentation is transient or continual over a meaningful span of time. Patients, in the informed-consent process, would need to know if their diagnosis is one that can resolve over time, if it is permanent, whether or not it requires immediate treatment, how soon it might require an intervention that entails proportionally significant risk, the relative likelihood or probabilities of all of the above, and how all of this information relates to the reliability of existing research and the current frontiers and limits of scientific inquiry.

124. For example, if teens were showing signs of mood lability through a particular stage of puberty, phy-

sicians would look at whether the lability was transient, and whether it would resolve completely on its own. If a known external cause was identified, they would seek to address it. If it were determined to be transient and a normal part of youth maturation, then physicians would likely provide support through that stage and see if the lability declined naturally. If not, they'd address it later.

125. Taking a second example, in mental health, if a five-year-old patient presented with difficulty with affect regulation, as well as trouble focusing and being still in the classroom, most physicians would not diagnose ADHD on initial assessment. The diagnosis and labeling of ADHD carelessly or prematurely can have negative implications for the child. Rather, they would investigate what other issues are happening in the child's life, and consider the child's development, family history, abilities according to a psychoeducational assessment, teacher input, the way the child learns, his classroom structure, social skills, and his stressors. Additionally, they would consider that children who are five years of age are in the developmental stage of initiative vs. guilt, and the milestone of this stage is "purpose." The child is learning to navigate social rules and gain self-regulation. From a neurodevelopmental perspective, the child's brain is presently at the stage in which impulse control centers, motor centers, and expressive language centers are not yet fully matured, and hence, his behavior may be merely a result of him needing to grow more. Any treatment interventions beyond parental guidance, teacher guidance, and therapeutic support may be unnecessary

or even detrimental as risk would likely outweigh benefit. Further time and observation would allow physicians to gain a better understanding as to whether the child will outgrow these behaviors, or whether they will be sustained once he grows and other factors resolve. The child and his parents, as part of informed consent, would need to know that these behaviors sometimes pass on their own with maturation. They would also need to understand the evidence (or lack thereof), risks, and benefits of all treatment options that are available if these behaviors did not resolve with maturation.

126. With regard to gender dysphoria, the heightened prevalence in recent years should cause physicians to identify possible contributing factors and co-occurring issues, and then craft a two-pronged response that addresses these, all prior to recommending medical transition which entails risk. Patients need to be able to understand, reason through, and appreciate these factors and cooccurring issues and have the opportunity to explore them prior to considering transition. The factors I've observed to contribute to the heightened prevalence of gender dysphoria are an increase in "pathologizing" of a normal part of childhood development, shifts in cultural norms having to do with gender exploration in adolescence, the influence of social media, heightened vulnerability in youth, and what some call "social contagion." Some co-occurring issues that I have observed are trauma, depression, anxiety, autism spectrum disorders, influential gender-role experiences, vulnerability and a lack of feeling socially accepted, and the influence of social media. These are iden-

tified and addressed as the patient goes through the therapeutic process and supports for the patient are also harnessed. As part of informed consent, patients should understand and appreciate that when these issues are addressed, frequently gender dysphoria is transient and remits. As stated above, this understanding and appreciation is an extremely difficult task for adolescents.

II. Minor Treatment Recommendations and Informed Consent

127. Major medical associations, including WPATH, have endorsed puberty suppression and cross-sex hormones as treatments for youth with gender dysphoria. Patients, in the informed-consent process, need to be able to understand, reason through, and appreciate the limits of medical knowledge and the issues that are of ongoing debate regarding gender transition, including the debate over long-term outcomes, safety, and potential risks.

128. The WPATH SOC-8, in its adolescent chapter, states: "We recommend health care professionals working with gender diverse adolescents undertake a comprehensive biopsychosocial assessment of adolescents who present with gender identity-related concerns and seek medical/surgical transition-related care, and that this be accomplished in a collaborative and supportive manner."

(Coleman 2022, Recommendation 6.3) It goes on to state:

> ***The following recommendations are made regarding the requirements for gender-***

affirming medical and surgical treatment (All of them must be met):

6.12—We recommend health care professionals assessing transgender and gender diverse adolescents only recommend gender-affirming medical or surgical treatments requested by the patient when:

6.12.a—the adolescent meets the diagnostic criteria of gender incongruence as per the ICd-11 in situations where a diagnosis is necessary to access health care. . . .

6.12.b—the experience of gender diversity/incongruence is marked and sustained over time.

6.12.c—the adolescent demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment.

6.12.d—the adolescent's mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed.

6.12.e—the adolescent has been informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility, and these have been discussed in the context of the adolescent's stage of pubertal development.

6.12.f—the adolescent has reached [T]anner [S]tage 2 of puberty for pubertal suppression to be initiated.

6.12.g—the adolescent had at least 12 months of gender-affirming hormone therapy or longer, if

> **required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.**

(Coleman 2022, Recommendation 6.12)

129. On page S5 of the WPATH SOC-8 guidelines, the Introduction presents the guidelines as reliable, comfort-oriented, safety-oriented, and evidence based. "The overall goal of the . . . (SOC-8) is to provide clinical guidance to health care professionals to assist transgender and gender diverse (TGD) people in accessing safe and effective pathways to achieving lasting personal comfort with their gendered selves with the aim of optimizing their overall physical health, psychological well-being, and self-fulfillment." The introduction continues: "WPATH envisions a world wherein people of all gender identities and gender expressions have access to evidence-based health care, social services, justice, and equality." In the next paragraph, WPATH assures readers that "[o]ne of the main functions of WPATH is to promote the highest standards of health care for individuals through the Standards of Care (SOC) for the health of TGD people," and that "[t]he SOC-8 is based on the best available science and expert professional consensus." The Abstract itself, in the Methods paragraph, expressly offers the following assurance:

> The SOC-8 is based on the best available science and expert professional consensus in transgender health. International professionals and stakeholders were selected to serve on the SOC-8 committee. Recommendation statements were developed based on data derived from independent systematic literature reviews, where available, background reviews and expert opinions. Grading of recommendations was based on the available evidence supporting interventions, a discussion of risks and harms, as well as the feasibility and acceptability within different contexts and country settings.

(Coleman 2022)

130. Reading these statements, the natural assumption of patients, parents, caregivers, and many physicians is that the factors contributing to gender dysphoria have been well established and that based on those factors, "seek medical/surgical transition-related care." (Coleman 2022, Recommendation 6.3) It is further assumed that when the recommendations above are followed with minors who have gender dysphoria—directing the patient to gender-affirming care, then on toward medical suppression of puberty, cross sex hormones, and gender reassignment surgeries.—these interventions will automatically be the best course of treatment. Furthermore, the WPATH recommendations leave ample room for physicians, patients, and parents to erroneously assume that recommendations for medical and surgical gender are evidence-based, that is, founded in rigorous scientific inquiry through randomized controlled trials and long-term follow-up studies that

affirmatively show positive medical and psychological outcomes and established safety records. Lastly, the physician and the patient (and parent) might naturally assume that the quality of the studies must be high, given that altering the natural course of development in youth is a significant measure; that it is relatively new; that it is not something that the medical community has engaged in historically; and that common sense would indicate that such major interventions generally would only be justified on the basis of thorough deliberation, ample and solid research, and strong evidence.

131. However, there is remarkable controversy and debate over these recommendations and the data that supports them.

132. While physicians can understand and appreciate the controversies that follow below, in my view adolescents are not developmentally able to do so. Their neurodevelopment and proneness to impulse-driven decisions make it highly possible that they will disregard or undervalue the critical issues of controversy and debate and move forward with assent/consent to medical or surgical transition, all to achieve the perceived reward of achieving secondary sex characteristics of the opposite gender.

133. I believe that several issues must be fully considered and appreciated by patients in order for them to be able to provide appropriate informed consent. However, many of the most vital issues cannot be sufficiently appreciated in adolescence. These issues are listed below:

- The Dutch Studies have been foundational in the formation of the WPATH recommendations but are suspect in terms of their quality and their applicability to the patient population currently presenting in America. "Several recent international systematic reviews of evidence have concluded that the practice of pediatric gender transition rests on low to very low quality evidence—meaning that the benefits reported by the existing studies are unlikely to be true due to profound problems in the study designs." (Abbruzzese 2023)
- Gender dysphoria is the only diagnosis that I am aware of for which an alteration of bodily integrity is being clinically advised for the purpose of affirming identity.
- There is debate over the quality of data used in studies assessing links between suicide rates and gender dysphoria, including the change in suicide rates post-transition.
- The WPATH recommendations state that only one comprehensive psychological assessment should be required for minors in order to proceed to transition. (Coleman 2022) Patients should understand that such co-occurring health concerns and issues accompanying gender dysphoria take time to identify, and one comprehensive assessment is not sufficient to do so for any practically condition in mental health.
- The WPATH recommendations state that decision-making capacity has to be determined in each adolescent wanting to undergo gender transition based on each adolescent's develop-

ment. (Coleman 2022) But WPATH elides the crucial issue: both patients and parents/guardians should understand that it is not well established that adolescents can *ever* meet such requirements for decision-making capacity when they are offered non-emergent treatments that substantially affect bodily integrity and that have potentially life-long irreversible consequences on reproduction and multiple other bodily systems.

- There is significant debate about whether the majority of children and adolescents with gender dysphoria realign with their birth sex with time and maturation.
- There is debate as to the lack of studies that evaluate the factors that are leading to the heightened prevalence of gender dysphoria.
- Patients and their parents must understand that while gender medicine experts claim minimal risk with puberty blockers, this is highly controversial. They should also understand that almost one hundred percent of those taking puberty blockers go on to receive cross-sex hormones. Hence, even if puberty blockers themselves were of low risk, the trajectory of medical gender transition includes cross-sex hormones, which render a patient infertile.
- There is additional debate over the long-term side effects and consequences of the medical transition trajectory, including but not limited to potential problems with bone growth, brain maturation, metabolic function, endocrine

function, sexual health, psychological function, and reproductive capacity.

- There is debate as to whether minors can appreciate the potential impact that infertility can have on an individual's psyche should they one day desire to have children.
- There is insufficient data on detransitioners, and there is literature that states that those who detransition may not access adequate follow up or support.
- The interplay between gender dysphoria and common co-occurring conditions, and how treating those conditions may affect an individual's gender dysphoria, have not been adequately studied.
- Alternative approaches to treating gender dysphoria have not been adequately studied.

134. In my experience, the task of understanding, reasoning through, appreciating, and comprehending the above matters is insurmountable for adolescents.

135. Furthermore, I don't believe that parents should be able to provide medical consent with minor assent for medical gender transition. This is because the debate that exists has to do with the safety of treatments that affect the bodily integrity of the minor, and there is debate as to the long-term outcomes of such treatments. Many of these debated outcomes would stand to permanently affect the quality of life of the minor, in multiple arenas such as romantic relationships, marriage, sexual intimacy, childbirth, child rearing, self-concept, social

and workplace relationships, potential adversity due to discrimination, and long-term psychological and medical health. In my opinion, for a parent to provide consent to non-emergent treatments that stand to affect the rest of a minor's life in every arena, and to do so without the minor's full ability to appreciate the above debate and potential long-term ramifications, violates the minor's future right to autonomy.

TRAUMA AND GENDER DYSPHORIA

136. Children and adolescents with gender dysphoria who have been through trauma may have an even greater difficulty with appreciating and weighing the various treatment options for gender dysphoria. Trauma affects how children and adolescents process the world around them, how they interact and engage in relationships, how they perceive various events and situations, and how they react and behave. Trauma influences the way individuals perceive their own bodies. Their sense of bodily safety and how they feel about their outward appearance is often significantly affected. The risk in offering medical or surgical transition to adolescents who have gender dysphoria and a history of trauma is that they may find gender transition to be appealing and a "quick fix" to their complex internal emotions and feelings about their bodies. This may stand in contrast to a child or adolescent's perception of trauma-focused therapy modalities that are directed at helping an individual work through, process, and recover from trauma, as these treatments take an extensive amount of time (months to years) and are emotionally very difficult. While trauma-focused therapies are

data-driven and effective and allow an individual to experience healing and then to make more consequential life decisions, the child or adolescent may not give them consideration when perceiving that medical or surgical transition would help them to feel better faster by changing how they feel about their body. It may prove tempting to try and resolve internal woundedness by changing external appearance, but an adolescent is likely to experience regret after transition if the internal woundedness is not first addressed through the therapeutic process.

137. Trauma can be due to a number of different experiences. Trauma arises when there is a "failure of the natural physiologic activation and hormonal secretions to organize an effective response to threat." In early childhood development, the orbitofrontal and limbic structures in the brain mature in response to the caregiver. Dysfunctional associations in this relationship between caregiver and child result in permanent physicochemical and anatomical changes which impact the child's developing personality and behaviors. Children who have been exposed to ongoing stress lose the ability to use their own emotions to guide effective actions. They often cannot recognize their own feelings, and so they are not able to respond appropriately to stressors. The inability to identify emotional states also often affects the child's ability to recognize others' emotions. Due to difficulty in regulating their own internal state, they become very reactive to their environment. They respond with emotion and impulsivity, behaviors that are

often an externalization of the chaos and stress they feel inside. (Trauma Recovery Institute)

138. Trauma can occur outside the parent-child relationship. Exposure to domestic violence, abuse, neglect, animal abuse, poverty, substance abuse, bullying, disasters, loss of a loved one, or parental illness can cause similar psychological and physiological responses in children. Some forms of trauma, particularly interpersonal trauma and abuse, place children and other survivors at increased risk of future trauma because past experiences of victimization are associated with an increased risk of subsequent victimization. (Jaffe 2019)

139. Trauma can cause:

- Loss of self worth
- Heightened Reactivity (e.g., explosivity and anger outbursts)
- Hyperarousal
- Withdrawal from others or avoidance
- Difficulty with trusting others
- Shame
- Loss of danger cues
- Loss of a sense of self
- Poor self-esteem
- Hypervigilance
- Confusion or feelings of being lost
- Depression and anxiety

- Impulsivity
- Negative body image and desire to hide body or change appearance
- Oversexualized behavior or sexual avoidance
- Dissociation
- Hallucinations or Re-experiencing
- Flooding
- Frequent somatic symptoms
- Enuresis (bedwetting)/encopresis (soiling)
- Body inflammation or repeated infections, autoimmune problems

140. Trauma impacts every system in the body: gastrointestinal, genitourinary, endocrine, cardiovascular, neurologic, and immune systems. (Heim 2008) With regard to neurodevelopment, functional neuroimaging of children and adolescents exposed to maltreatment has shown executive, attentional, and affective emotional dysregulation. (Mueller 2010).

141. Children do not generally disclose trauma on initial assessment. Disclosure can take months and sometimes years. Children must experience safety within the therapeutic relationship, which takes time and patience to establish. As therapy continues, children will disclose trauma when they feel safe enough to do so and trust the examiner's response.

142. Trauma treatment (psychodynamic therapy and trauma focused cognitive behavioral therapy) focuses on a) education surrounding trauma; b) iden-

tification of feelings and emotions; c) understanding safety and practicing mindfulness, relaxation, and the ability to calm the sympathetic nervous system; d) exploration and processing of the trauma and its effects through a trauma narrative in a safe therapeutic setting; e) harnessing family/loved one support and validation; f) clarification where appropriate; g) building a healthy self-concept; h) a reorientation to the environment through awareness that trauma can impact all arenas of life; and i) continued support. The goal in recovery is for the individual to heal emotionally, to have internal and external ability to self-regulate and respond to stress appropriately, and to be able to engage in relationships in a healthy fashion. This type of treatment takes time, as there must be patient-therapist rapport and adequate trust laid down as a foundation.

143. Due to the effects of trauma on all bodily systems, and its effects on self-concept and body image and appearance, it is critical to realize that it can contribute to gender dysphoria. Explorative (psychodynamic) therapy and Trauma Focused Cognitive Behavioral Therapy is important to help the patient identify, process, and work through trauma in order to ensure that the patient is not experiencing gender incongruence due to the trauma itself. This information is valuable to patients as they navigate and chart their own courses through their unique, individual processes of healing and growth.

144. Research suggests relatively higher levels of reported trauma among children with gender dysphoria and among transgender and gender-non-

conforming adults. In one study that considered relational trauma up to age 14 within primary relationships:

> Results showed that 10% of GD participants had not experienced any early adversity, 13% had experienced one form of trauma, 8% had experienced two forms, 13% had experienced three forms and 56% had experienced four or more forms. In the control group, 30% of participants had not experienced any form of trauma, 37% had experienced one form of trauma, 16% had experienced two forms, 9% had experienced three forms and 7% had experienced four or more forms.

(Giovanardi 2018) Another study reported similar findings. (Schnarrs 2019)

145. Timely and compassionate assessment, diagnosis, and trauma-informed treatment is likely to meaningfully improve long-term outcomes for children with gender dysphoria, whether they come to identify with their natal sex or whether they persist in their transgender identity.

146. It has been my clinical experience that when youths with gender dysphoria are treated with psychodynamic therapy, and a history of trauma is identified and subsequently treated, gender dysphoria often remits or resolves. In other cases, youths have gained clarity about how trauma has affected them and can move forward as adults with the ability to make mindful decisions surrounding gender dysphoria treatments. Each of these children deserves the option to achieve this clarity,

treatment, education, and support, regardless of which options they ultimately choose.

147. Because actual patient cases cannot be discussed in this report, I have provided four hypothetical situations based on my experiences to illustrate how trauma affects gender incongruence and gender dysphoria, and when treated, can result in its resolution or provide clarity for future treatment decisions.

    a. A female teen describes gender dysphoria. She wants to be called "she/her" and not change pronouns yet because she is worried that her grandmother may find out about her gender dysphoria and be angry. On initial assessment, it becomes clear that she experienced maternal abandonment at a young age.

       Over the course of therapy, she says has a vivid recollection of her mother leaving her at her grandmother's home and not returning. Her grandmother is emotionally and physically abusive toward her often and a child protective report has to be filed. She has remarkable difficulty in trusting others and isolates herself socially due to fear of not being accepted. She has been bullied by female peers. She says that she is unsure of others' responses and fears rejection. Inside, she feels persistently anxious, struggles to enjoy normal activities for girls her age, and describes feeling uneasy. She expresses that she identifies as male. When her perception of gender roles is ex-

plored further, she talks about women being angry, uncaring, and harsh. She describes wishing she'd had a father who had protected her and kept her safe. She says she always thinks about how she could have kept herself safe and struggles with guilt and shame associated with the abuse because she believes she allowed it to happen.

As trauma-focused treatment is provided, she learns about the effects of trauma and what emotions survivors struggle with. After working through her trauma narrative, she realizes that her identification with male gender is due to an unconscious desire to protect herself from abuse, and to be strong enough to "fight it," and to not feel anything in common with the females in her life who have been neglectful, abusive, and wounding. This conscious awareness allows her to begin recovering. She learns new ways to feel in control and safe and learns to identify her feelings and process them and use logic alongside emotion in decision making and in relationships. Over the course of many months, and ongoing support and psychodynamic therapy, she realigns with her natal sex. She says she feels safe and in control of her own body now.

b. A male teen is nonbinary and prefers to be called "they/them." On initial assessment, they report having been bullied at school and not fitting in since a very young age. They have suffered from ADHD related

impulsivity and reactivity and often got in trouble in elementary school. Peers were unkind and often refused to eat with them at lunch or play with them at recess. Due to ADHD medication side effects, they reported being very thin and feeling awkward. As other kids developed and boys became more athletic, and girls developed breasts, they described feeling uncomfortable in their body because they remained thin, lanky, and of short stature through middle school. Last year, while being online playing video games, they met a couple of transgender peers online. They began to get to know one another and establish friendships. This was the first time they felt connected and safe. Engagement with them during daily gaming became routine, and they got to know one another and built friendships. They began to learn more about gender incongruence online and began to feel that they were nonbinary and that maybe this was why they never fit it and felt so anxious socially. They discussed this with their friends online, and friends supported gender exploration and made statements that they "knew the feeling" and "were there for them."

In exploratory therapy, they discuss several incidences of bullying that were traumatic and caused marked emotional harm. Trauma focused-therapy is initiated, and they are able to bring to conscious awareness past feelings of being trapped, of be-

ing unwanted, being unworthy, and being unloved by others. They also identify fear of bodily harm due to bullying and wanting to go unnoticed by peers at school to preserve a sense of safety. As they learn ways to identify and work through the intense emotion that accompanies memories of past trauma, they begin to realize that being gender nonbinary has allowed them to feel safer. It has been a way to describe a deep feeling of discomfort with their own body and a feeling of being different. Having made strong friendships with transgender peers who also had gone through similar feelings, they realize that identifying as nonbinary allowed them to also feel closer to their friends. Over time, they begin to feel more positively about their own self-concept and friendship making ability, and to use coping skills to work through memories of past trauma. They begin to want to be referred to as "he" and describe realigning with natal sex. He is able to process and understand trauma and its impact on feelings about bodily appearance, bodily safety, and a need for secure relationships.

c. A female teen has gender dysphoria. She describes wanting to be called "he/him." He talks about wanting to medically transition and denies any past history of psychiatric issues. He describes having a good relationship with his mom, and not knowing where his father is, who left their home

when he was ten years old. He describes having a history of urinary tract infections, enuresis (bedwetting), and constipation. Medical records are consistent with his description. Throughout early therapy, he talks about his relationship with his mother and how she is dating someone new. He says he doesn't mind, but becomes more uncomfortable when mom's partner moves in. He begins to have difficulty with sleep, and his mother reports that he is very reactive and at times hostile toward her partner. He begins to have enuresis again and also stomachaches.

Over the course of therapy, he eventually discloses that his father had touched his (female) privates several times and shown him naked pictures of girls. Trauma-focused therapy is initiated. He learns about trauma, its impacts, and normal feelings that children experience when victimized. He learns how to calm himself and self-regulate intense emotion through progressive muscle relaxation and deep breathing. He engages in developing a trauma narrative and is able to detail what happened to him over the upcoming many weeks. He talks about past fear of his father that turned into rage and fantasies of fighting his father and making sure that he could never harm anyone again. This brings to his conscious awareness that identifying as male allowed him to feel power over his abuser and to feel a sense of control. When think-

ing of being in a male body, he felt safer, and he didn't have to feel the fear and feeling of being trapped that he used to in a female body. Over the course of a couple of years, as he begins to recover from the sexual trauma he'd suffered, through ongoing therapy and support, he begins to come in wearing female clothes. He wants to be called "she/her" and says that she feels more comfortable being female now. She feels safe and in control in her own body.

d. A male teen is struggling with gender dysphoria and prefers to be called by "she/her." She talks about being raised by her single adoptive mother since age four. Her dad was not active in her life. She struggled with ADHD and anxiety throughout elementary and middle school. She struggled with academics and didn't feel like she fit in. She began experiencing gender dysphoria at the age of eleven when she began to develop body hair and sweat and feel "gross." She talks about male features (like her broad shoulders) having made her feel angry when she looked in the mirror.

   Through explorative therapy, she began to talk about how she often wondered about her birth family and why she was given up. She wondered if she looked like her birth father, and she said this thought made her physically ill. She said she'd have panic attacks when looking at her shoulders widening and at hair in her armpits and private

areas. As therapy progressed, she talked about having been told her birth father had been in jail and was a drug addict. She wondered if she'd be like him, and this caused her to have tremendous anxiety. She is able to bring to conscious awareness that she felt more comfortable as a female because she didn't want to grow to up be like her birth father, because he abandoned her and was a "criminal."

Through additional work with a therapist specializing in adoptions, she is able to understand that she suffered trauma as a child due to separation from her birth mother, regardless of being moved to a safer adopted home. She is able to learn about the feelings that children who've experienced adoption often go through and understand that her feelings are reasonable and normal. She is able to bring to conscious awareness that her feelings about not wanting to be like her birth father are a normal part of processing her past and considering who she wants to be in the future. She learns from her therapist about neurodevelopment and how the adolescent brain is still developing. With good support from her family in place, she continues in her social transition, but also continues therapy for support and ongoing processing of her stressors. She decides to medically transition as an adult, and says she feels her decision making is clearer as she has been able to understand her gen-

der identity, come to terms with how trauma has affected her, and be confident in her ability to provide informed consent as an adult with a lesser risk of regret.

CONCLUSIONS

148. In my clinical experience, informed consent is remarkably difficult with minors. Even when prescribing a psychiatric medication, adolescents are most often unable to appreciate the long-term risks, nor are they able to comprehend the details of full disclosure. I find this is secondary to their psychosocial and neurodevelopmental stage of development. They can communicate a choice. They can understand the diagnosis and treatment options to an extent. However, they are less able to comprehend and appreciate the implications of the diagnosis and treatment options long term. Generally, they are focused on "feeling better" and choosing the treatment pathway that leads to feeling better quickly regardless of treatment side effects or risks. Once they have identified the path they want to take, they most often lose sight of other treatment options that may take longer, though they are just as effective at helping them feel well, and with lesser risk. In the setting with outside influences, this push to choose the path with the immediate reward while devoting less attention to other options, is even more evident.

149. For this reason, with very rare exceptions, I employ parental consent with minor assent in the process of prescribing treatments to minors, and only after weighing the risk/benefit ratio of treatment interventions and providing full disclosure.

150. If there are insufficient evidence-based benefits to treatment, and if benefits do not substantially outweigh risks of treatment, I do not prescribe medication.

151. In the event, that parental consent and minor assent is provided for a medication, but there is an issue of the growing child or adolescent's future autonomy being affected, I do not prescribe, unless there is medical necessity to treat due to an imminent risk to the child's safety or to others if the child is not treated.

152. Individuals with gender dysphoria deserve compassionate care that is not only equitable, but also well thought out, well researched, and well executed. In the matter of medical and surgical gender transition in minors, the overarching questions I ask myself regarding my own patients and the informed consent process, when reviewing all the literature and processing my own clinical experience, are:

    - Can youths understand, reason through, appreciate, and comprehend all of the issues with the present data, the ethical dilemmas that are present, and the debate in the medical community?
    - Can youths appreciate the future risks that medical gender transition entails, particularly regarding circumstances that only present later in life (like the desire to bear children and breastfeed)?

- Can they understand, appreciate, and comprehend the unknown risks of treatment on brain maturation?
- Can they appreciate and comprehend that there is debate as to whether suicidality improves or worsens post-transition?
- Can they understand the significance of the paucity of data on detransitioners?
- Can parents provide consent (with minor assent) for treatments that affect bodily integrity, that are appropriately considered experimental due to lack of quality data, that carry marked long-term medical and psychological risk, for which long-term safety and efficacy is unproven, and that have the potential to create irreversible consequences such as infertility? All for the purpose of affirming an identity that has not yet solidified, based on what we know about the developing adolescent?

My answer to all these is, "Absolutely not."

153. With this context, I draw three primary conclusions:

I. Informed Consent Is Not Attainable for Medical or Surgical Transition in Minors

154. Minors lack decision-making capacity for medical and surgical transition. In my opinion, due to a lack of full neurologic, psychosocial, and cognitive developmental maturation, adolescents are unable to understand, reason through, appreciate, and comprehend the impact of the shortcomings of the present data, the lack of FDA indication for puberty blockers, the long-term risks and conse-

quences of transition, and the low-grade rating of studies that have been used to support medical and surgical transition. Hence, they lack decision-making capacity.

155. As discussed in the section above regarding neurodevelopment and psychosocial development, when there is perceived reward with one pathway, despite long-term risks associated with that pathway, adolescents will generally select it rather than consider that there are alternative pathways with fewer long-term risks. With medical gender transition, adolescents are likely to perceive reward (in this case, reduced dysphoria) with the pathway of puberty blockers and cross-sex hormones and hence, they are likely to choose this path rather than considering other paths (such as engaging in exploratory or supportive therapy, socially transitioning, and waiting until adulthood for medical transition). Additionally, as peer and cultural influences are more significant in adolescence, adolescents may make more impulsive decisions to pursue medical transition without considering risks. This also factors into a capacity judgment.

156. The risks associated with puberty blockers and cross-sex hormones are difficult for adolescents to comprehend and appreciate. First, the near certainty of infertility on the transition pathway is likely to not be appreciated until the age during which most individuals consider having children. The debate over impacts on hormonal shifts, bone density, cardiovascular risk, and brain maturation are simply too difficult for minors to grasp. Furthermore, effects of transition on more abstract

situations that the adolescent may face decades later, such as effects on intimate relationships, sexual gratification, reproduction, breastfeeding, child rearing, family relationships, and self-concept are even more difficult to fully realize. Adolescents have not fully developed the ability to appreciate the treatment options in this context of "later life", which is part of decision-making capacity. Their deductive reasoning is developing, but not yet complete.

157. Furthermore, while parental consent and adolescent assent is possible for other medical interventions, it is insufficient in the matter of gender transition in minors. First, the risks to the growing adolescent are remarkable, including infertility, irreversible changes to secondary sex characteristics, potential issues with bone density, cardiovascular risks, metabolic function, endocrine function, reproductive capacity, psychological and medical health, and brain maturation. Second, a parent is unable to determine whether their child will realign with his or her natal sex. This presents inherent risk. Third, the present data supporting the benefit of transition in adolescence is rated "very low quality." There is no reliable long-term data on safety or efficacy of these treatments.

158. For this reason, I believe that parental consent with adolescent assent for medical gender transition is problematic and can result in long-term detriment to the adolescent that later cannot be reversed. Parental consent may be deemed in the short term to be preserving the adolescent's autonomy by prioritizing the adolescent's desire to self-actualize and reduce dysphoria. However, in the

long term, there is remarkable intrusion on the growing adolescent's autonomy as an adult. When the adolescent matures to adulthood and can't reverse consequences (e.g., fertility) of interventions that the parent consented to without the adolescent having had full capacity to appreciate, psychological repercussions are likely to be profound.

159. Regarding other medical diagnoses, where bodily integrity is challenged as a result of treatment, such as with cosmetic surgery in minors, informed consent has been a central issue.

160. In 2005, in the *AMA Journal of Ethics*, pertaining to teens who desire cosmetic surgery, authors cited The American Society of Plastic Surgeons statement against breast augmentation for patients under 18. In the absence of longitudinal research, they said,

> [I]t is impossible for physicians to warn patients, or their parents, about the risks of performing cosmetic surgery on bodies that have not reached maturation, the operative complications and long term physical effects of these surgeries and the psychological implications of surgery on developing body image, or the extent to which distorted body image common among adolescence may result in the pursuit of plastic surgery.

(Zuckerman 2005)

161. During the FDA hearings on breast augmentation, several physicians noted that obtaining meaningful informed consent from teenagers and their parents can often be difficult. According to one speaker,

this difficulty is largely related to the fact that the kind of information being given to potential breast implant surgery patients is largely "probabilistic information" and "probabilistic thinking is the most abstract kind of thinking and the last one to develop in the range of skills and capacity that we have." Several physicians in attendance agreed. Dr. Charles Bailey noted that, "with respect to interacting with the patients, it's not uncommon to be sitting in front of a very young patient where you feel like nothing that you're saying is being heard." This is the exact sentiment echoed by physicians who are opposed to medical and surgical gender transition in minors, an area in which data is even more controversial and the long-term risks of far greater magnitude. (Cohen Cooper 2014)

162. Furthermore, within my own clinical experience, I cannot envision a circumstance with my own patients wherein parental consent and minor assent would be sufficient for medical or surgical gender transition based on the above explanation. The justification of imminent risk to the child's safety or others around the child is not present. Additionally, not only could proceeding to medical or surgical gender transition profoundly affect the child, but also the parent-child relationship, which is of remarkable concern to me as a child psychiatrist.

II. A Better and More Compassionate Approach is Provision of Therapy Until Adulthood When Consent Can be Provided

163. Gender dysphoria can be a normal part of childhood development, as discussed in the section on

my clinical experience above. It should not be labeled or pathologized, as it is most often transient, making a "watch and wait" approach sensible.

164. A compassionate approach to gender dysphoria in adolescents entails: a comprehensive assessment, individual and family therapy, and harnessing a support network for the patient. I have used this approach for years and have found it to be beneficial and far less risky. The child patients I've treated that meet criteria for gender dysphoria realign with their birth sex with maturation (children) and a "watch and wait" approach. Adolescents most often realign with their natal sex with maturation, therapy, and support. Further, my patients who have decided to transition as adults have been grateful that they waited and that therapy helped them to be sure of their choice. They have felt positively about their decision-making capacity as adults.

165. This approach takes into consideration that medical and psychological risks are far too great to risk providing unproven treatment to a substantial number of minors who would otherwise realign with their natal sex.

166. Additionally, this compassionate approach adheres to ethical standards in the field of medicine, while medical and surgical transition for minors, individually and in combination, substantially risks violating those standards.

167. As an example, beneficence requires that the physician actively promote the welfare of the patient and protect the patient from harm. Regardless of positive intentions to provide relief for the minor

with gender dysphoria, when a physician is seeking to use controversial treatments for a diagnosis 1) that has an increasing prevalence 2) for which contributing factors have not yet been adequately identified 3) for which alternative treatment pathways with less risk may not have not been well studied 4) that may resolve in children without any intervention or respond to very low risk supportive interventions in adolescence and 5) could be intertwined with co-occurring conditions that could be treated with low risk interventions first, there should be concern over whether the physician violates the standards of beneficence and nonmaleficence. That is especially true when the risky treatments 1) have marked effects on a minor's bodily integrity, 2) carry significant long-term risks, 3) are unsupported by reliable long-term data about safety and efficacy, and 4) are recommended based on evidence deemed to be of very low quality by systematic reviews.

168. The physician seeking to recommend medical transition to a minor also risks violating the principle of informed consent, considering the minor patient lacks decision-making capacity.

169. If all of the above issues of debate and controversy have not been fully disclosed to the minor patient, and comprehended, the standard of truth telling is also not met.

170. And, lastly, the standard of distributive justice may be violated if the minor patient has not been meaningfully offered available resources such as exploratory therapy, family therapy, and supportive mental health care that may be offered to oth-

ers in this same situation, given these are low in risk and likely high in benefit.

III. Tennessee Senate Bill I Appropriately Protects Minors

171. Individuals with gender dysphoria deserve compassionate care that is not only equitable, but also well thought out, well researched, and well executed.

172. They deserve to not be subjected to experimental treatments that, to date, lack high-quality studies, long-term outcome measures, and proven psychological benefit. Instead, they should all be afforded well-researched options that entail less risk and are more likely to be effective. They should also receive the time and patience and ongoing support necessary in order to pursue those options.

173. They deserve to have methodologically and scientifically sound research conducted on all possible pathways of treatment, so that they can make well informed decisions as adults about which pathway of treatment they'd like to choose.

174. They deserve to be supported, cared for, and shown that they are valued, as all individuals should.

175. Minor patients with gender dysphoria deserve to be treated with respect for their vulnerability and their stage of development, which makes them unable to provide informed consent. They deserve for their future autonomy to be protected.

176. While their immediate desire for relief needs to be addressed, they also need their desire for long-

term happiness honored, as growing members of society. They deserve to have the capacity to make their own decisions about treatments that would systemically alter their bodies and thereby affect their future relationships, their ability to have children, their ability to breastfeed, their ability to experience and feel positively about sexual intimacy, and their ability to feel well about themselves. This capacity cannot be reached until adulthood.

/s/ GEETA NANGIA
GEETA NANGIA

May 19, 2023

EXHIBIT 11

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, PLAINTIFFS

v.

JONATHAN SKRMETTI, ET AL., DEFENDANTS

DECLARATION OF CHLOE COLE

I, Chloe Cole, declare as follows:

1. I am 18 years old and am not a party to this action. I have actual knowledge of the following facts and, if called upon to testify to them, could and would do so competently. I am submitting this Declaration in support of Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction.

2. Tennessee's law prohibiting medical procedures performed on minors "for the purpose of: (A) Enabling a minor to identify with, or live as a purported identity inconsistent with the minor's sex, or (B) Treating purported discomfort or distress from a discordance between the minor's sex and asserted identity," Tenn. Code Ann. § 68-33-101, *et seq*., is a necessary and potentially life-saving regulation to protect vulnerable young people from the heartbreaking regret, irreversible physical changes, and emotional pain I have experienced.

3. I am a detransitioned woman from California who medically transitioned as a child. I grew up with ideal conditions for transitioning. I lived in an area where medical transition was easily accessible, had the support of family and a group of friends, and started treatment as young as possible. Yet, my transitioning was still a failure.

4. I began puberty very young, no older than 8 or 9. I had a lot of discomfort around my developing body. I was afraid to grow from a girl into a woman and experience things like periods, childbirth, and menopause. I only hear about how scary and painful being a woman was from other girls and older women. I never really had any strong female role models, and I never felt like I fit in with other girls, but I had a tomboyish streak influenced by my older brothers.

5. At the age of 12, I began to believe that I was transgender. I became obsessed about the idea of becoming a boy. I believed that my insecurities and anxieties about being a hypersexualized and vulnerable girl would magically disappear if I transitioned. At school, I also had trouble making friends but saw the praise that coming out as "trans" gave people on Instagram and social media. I started socially transitioning from a girl into a male identity.

6. Soon after, I was diagnosed with gender dysphoria by a "gender specialist." The gender specialist told my parents that children know their gender from a young age, and I know what's best for myself. The mental health professionals did not try to dissuade me from my beliefs. At no point did anyone explore why I did not want to be a girl.

7. The doctors treated me like an adult who could make informed lifelong decisions. Yet, I was in 8th grade. I had no concept of what it would mean to me as an adult to have children someday. But this decision would affect every area of my life, from socialization and relationships to sexual function, and my ability to have children. I cannot imagine a doctor asking a child this and expecting them to make a mature judgment.

8. When speaking to my parents, the gender specialist cited the suicide rate, stating, "If you don't affirm your child, she will commit suicide." The provider asked, "Would you rather have a dead daughter or live son?" They did not present any other option to treat my dysphoria to me or to my parents. My distraught parents wanted me alive, so they listened to my doctors. However, I wasn't suicidal until I underwent treatments.

9. Like many dysphoric children, I suffered from several mental health conditions, such as ADHD, and comorbidities, including undiagnosed autism and body dysmorphia.

10. Because I am autistic, I have more masculine behaviors and am more object-oriented than most girls. I have some social, cognitive, and sensory processing differences that made school and going through puberty a little more difficult. These struggles were all normal but were misrepresented as problems having to do with my gender.

11. Six months after my gender dysphoria diagnosis, I started puberty blockers. A month later, I was put on testosterone. I stayed on puberty blockers for a year and on testosterone for three years. When I received the hormones, the endocrinologist cited some of the

risks, including vaginal atrophy and the inability to have children. However, I did not really understand what that would mean and didn't realize that it could involve other pelvic structures.

12. After I started the hormones, I began having severe hot flashes, like those in menopause. My entire body got very itchy. After a while I would sometimes hear loud cracks in my neck and back. The hormones caused an atrophy of my urinary tract. I suffered from urinary tract infections and blood clots in my urine. I also developed digestive problems. I also experienced a very heightened libido which was very difficult to deal with at such a young age. This caused me to make a lot of regrettable sexual decisions. However, I did not want to discontinue testosterone because I wanted to continue to be treated as a boy.

13. At 13, I started binding my breasts. A classmate groped me in 8th grade, and I never wanted it to happen again. After two years of binding, I began seeking a mastectomy to have my breasts removed. This process took only six months and did not require a psychological evaluation. I was simply referred to a surgeon by a gender specialist.

14. At 15, just after my sophomore year of high school ended, I had a double mastectomy. I had serious complications from the surgery. I have to wear bandages over my chest every day because the areola grafts on my mastectomy started to fail and leak fluid two years postop.

15. About 11 months after my surgery, I began experiencing grief. I realized this was a mistake, that I had lost a part of my body. I won't be able to breastfeed my future children. While doctors warned me about

this, no teenager can grasp what that really means. I will never be able to bond in an important way with any future children. I might not be able to have children.

16. I became extremely depressed to the point of my grades and school attendance dropping, and I experienced severe paranoia and suicidal ideation. I had to drop out of high school several times. The longer I was on my medications, the worse my mental health became. I felt alienated and started to become suicidal for the first time. Although I did not act on my thoughts, they were taking a toll on me.

17. I broke down one night as it all came to a head and made the decision to stop the testosterone. I also dropped the male identification and began to identify again as female.

18. At first some things got worse. I had more UTIs, blood clots and sometimes tissue in my urine, and worse digestive issues. That has since gone away, but I still experience frequent urination, dehydration, and occasionally infections.

19. I was very emotionally volatile, and my suicidal ideation got worse. I became very sick and lost a lot of weight. My overall mental health got worse. I had to drop out of school and get a GED because I couldn't perform at school.

20. Over time my body began to readjust. My features resoftened. The fat in my body and body shape began to return to a female form and I have regained the weight.

21. Currently, my mental health is stable. The treatments were just band aids for my mental health issues.

I still struggle, but my depression and anxiety have improved.

22. It should not have been an option for me to be prescribed hormone treatments that caused me harm and may have affected my fertility, or to have my healthy breasts removed at the age of 15.

23. The complications from puberty blockers, testosterone, and surgery still impact my day-to-day life in ways that I didn't even know were possible. The puberty blockers gave me joint and back pain, and the testosterone caused me to develop issues in my urinary tract. The status of my fertility is currently unknown.

24. I still experience gender dysphoria to this day. The only thing that has improved it long term was simply living in my body with no intervention or medication.

25. Tennessee's law banning these treatments is a crucial step in protecting children and their right to grow up into healthy adults who are able to live fulfilling lives.

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

Executed on May 19, 2023.

/s/ CHLOE COLE
CHLOE COLE

EXHIBIT 12

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, PLAINTIFFS

v.

JONATHAN SKRMETTI, ET AL., DEFENDANTS

DECLARATION OF HELENA KERSHNER

I, Helena Kershner, declare as follows:

1. I am 24 years old. I have actual knowledge of the following facts and if called upon to testify to them could and would do so competently. I am submitting this Declaration in support of Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction and Complaint.

2. I am a detransitioned female from Ohio who would have transitioned as a minor if my mother consented to "gender affirming" medical treatment: giving me testosterone. Thankfully, she did not. Tennessee's law prohibiting minors' medical transitioning is a necessary regulation that will allow kids to grow up and mature before changing their bodies forever.

3. I was conventionally feminine when I was young and had no discomfort with being a girl. However, I was

an introvert, and found it difficult to fit in with other girls.

4. My home life was challenging. My mom worked many hours, so my aunt became my main caretaker. After my aunt moved out of the country, I spent more time surrounded by babysitters than family. I struggled with depression and started seeing a therapist.

5. When I was 13, I started using the social media site Tumblr and spent a lot of time online. On Tumblr, I became completely immersed in the "topics" I read about. As a socially struggling teen, this had a big effect on me. When I read about self-harm, I started to self-harm. When I read about eating disorders, I developed an eating disorder.

6. Around the time I turned 14, I found Tumblr's "social justice" communities that harshly stigmatized people who were straight, white, and not transgender. I found myself in an environment where being a cis-white female was the absolute worst form of human, and being trans was normal. I read that if a person did not like their body and if they suspected that they might be trans, they are probably trans.

7. Based on the content I saw and the materials I read, I started to interpret my social, emotional, and body image difficulties as signs of gender dysphoria. I believed that by becoming trans, I could become a desirable, accepted, not evil white cis-person that caused all of the pain of the world. Soon, I began to identify as nonbinary.

8. When I was 15, I started to identify as transgender. I started socially transitioning, changing my pronouns, cutting my hair, and changing my clothing. I

received more positivity and encouragement than I had ever experienced. With each change, I received positive affirmation on the internet.

9. By age 17, I identified as a "trans boy" and was fully convinced that my only chance at living a happy life would be to take hormones and undergo surgeries to change my body. I became obsessed with my weight and believed that taking testosterone would transform my body into the ideal I dreamed I could become: thin, tall, sporty, androgynous.

10. My school counselor and therapist both agreed with my beliefs. The psychologist told my mother that I was at risk of suicide if she would not agree to testosterone treatments. Thankfully, my mom did not allow it.

11. I went to a Planned Parenthood clinic in Chicago a few weeks after my 18th birthday and asked for testosterone to medically transition. No clinician asked me what was behind my desperation to change my body. The clinician prescribed me testosterone that day without any blood work or medical evaluation because I seemed "so sure" about my decision. I told the clinicians that I wanted a high dose so I would see more changes in my body. They agreed and prescribed me 100mg of testosterone per week.

12. The mental health effects of testosterone were profound. I began experiencing uncontrollable episodes of rage and paranoia, where I was a danger to myself and others. I self-harmed more and became suicidal. Due to this, I was hospitalized twice. No prescribing ever mentioned these side effects of testosterone. Instead, I was prescribed a litany of psychiatric

drugs. This time was so dark that it caused me to question the original promises of a joyful trans life.

13. In February 2018, I stopped taking testosterone and began the journey of detransitioning. My mysterious mental illness went away soon after and has never returned.

14. I am grateful that I spent only a short time on testosterone and am fortunate I haven't experienced any obvious physical injuries. But the impact this experience has had on my life cannot be understated. I became a danger to myself and others under the influence of testosterone. I struggled to process my new reality and face these mental health issues.

15. I am very thankful that my mother did not consent to giving me testosterone as a teenager. If I had transitioned as a minor, I could have spent a lot more time taking it. Because of her decision, I can now have a healthy relationship with my body.

16. Tennessean children are lucky that its legislature has seen these dangers of "gender affirmation" and created a law to allow kids to grow into their natural bodies first before making a life-altering decision.

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

Executed on May 19, 2023.

/s/ HELENA KERSHNER
HELENA KERSHNER

EXHIBIT 13

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

Case No. 3:23-cv-00376

L.W., ET AL., PLAINTIFFS

v.

JONATHAN SKRMETTI, ET AL., DEFENDANTS

DECLARATION OF PRISHA MOSLEY

I, Prisha Mosley, declare as follows:

1. I am a 25-year-old woman who has suffered severe and lasting injuries because I was subjected to so-called "gender-affirming care" as a minor. This "care" included medical intervention to make my body appear as that of a male.

2. I support the legislation under challenge in this case known as Senate Bill 1.

3. If legislation like Senate Bill 1 had been in place when I was a minor in my home state of North Carolina, I would have been protected from the healthcare providers who irreversibly harmed my body in order to make it look more like a boy's.

4. As a teenager, I suffered from a number of mental health issues, including anorexia, obsessive-compulsive disorder, borderline personality disorder, anxiety, and depression. I also engaged in self-harm and suffered trauma from sexual assault.

5. At age 17, after meeting with me for a matter of minutes, a counselor told me that I was actually a boy and that changing my body to be more like a boy's would fix my mental health issues. Around that same time, a doctor prescribed testosterone for me as "gender-affirming care" to make my body look more like a boy's body.

6. Less than six months later, while I was still 17, a surgeon familiar with breast reduction surgery for women met with me and expressed eagerness in performing gender-affirming "top surgery" on me. At age 18, the surgeon performed a double mastectomy, removing my healthy breasts.

7. These healthcare providers, whom I trusted to take care of me, misled me into believing that changing my body to look more like a boy's body would solve my mental/psychological problems.

8. As a result of these healthcare providers' actions, I have suffered severe and lasting injuries. These injuries are both psychological and physical in nature.

9. My body did not develop the way it should have and does not function normally. I am unable to nurse a child and I do not know if I will be able to conceive and give birth to a child.

10. I suffer from chronic pain and a host of additional medical issues and psychological and emotional anguish as a result of the medical and surgical abuse that I was led into by the healthcare providers who were supposed to take care of me.

11. I feel strongly that what happened to me should not have happened, and it should not happen to anyone else. That is why I support Senate Bill 1.

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

Executed on ___05/19/2023_____.
Date

/s/ PRISHA MOSLEY
PRISHA MOSLEY

EXHIBIT 14

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, PLAINTIFFS

v.

JONATHAN SKRMETTI ET AL., DEFENDANTS

DECLARATION OF BARBARA F.

I, Barbara F.,[1] declare as follows:

1. I am over the age of 18 years and am not a party to this action. I have actual knowledge of the following facts and, if called upon to testify to them, could and would do so competently. I am submitting this Declaration in support of Defendants' opposition to Plaintiffs' Motion for a Preliminary Injunction.

2. Tennessee recently passed a law prohibiting hormonal and surgical procedures "for the purpose of: (A) Enabling a minor to identify with, or live as a purported identity inconsistent with the minor's sex, or (B) Treating purported discomfort or distress from a discordance between the minor's sex and asserted identity," Tenn. Code Ann. § 68-33-101, *et seq*. This Act will protect parents against confused children, ex-spouses, and provid-

[1] Declarant is submitting this Declaration using a pseudonym to protect the privacy of her children and other family members.

ers' coercive tactics to obtain consent to medical interventions "affirming" a child's professed discordant gender identity—through methods such as threatening alienation or loss of a child through suicide.

3. There is no such parent and child-protective law in my home state, where "gender-affirming" providers and clinicians have blatantly disregarded my decisions related to my child's medical and mental health. Tennessee's law will prevent its parents and children from suffering harm like mine and my daughter's.

4. When my daughter, B, was young, her father (my ex-husband) gave B's brother preferential treatment. B's father also ridiculed her for having traits similar to mine, such as the way we both laugh.

5. When B was 11 years old, she told me she identified as a boy and wanted me to call her by a male name she had chosen. B's father championed her new "male" identity and harassed me for not affirming it. He accused me of emotional abuse and called child protection services against me. B's father convinced B to avoid visiting me under our custody agreement unless I affirmed the discordant identity.

6. Shortly after B announced that she identified as a boy, I acted on the advice of our family physician and took B to a gender clinic. I naively believed that the clinic's psychologist would evaluate and provide counseling to discuss B's sudden identification as a boy before medical intervention to "affirm" her choice.

7. When we arrived at the clinic, the staff psychologist did an evaluation. However, the psychologist also said she did not have time to see B regularly for more in-depth psychological help. I told the clinic staff that B

needed psychological counseling before starting any medical interventions (i.e., seeing an endocrinologist). As a parent, I was confused why there were two different offices: Why would we visit with an endocrinologist if the psychologist (as a gatekeeper) isn't prioritizing seeing my child regularly? I was instantly troubled by the clear lack of any regard for my child's underlying comorbidities. I could picture my child on a conveyor belt, as if she was just one more coin in their purse.

8. That same day, the clinic left me alone in a room for 2 hours. While I waited, I thought the psychologist was talking to my child, and then my ex-husband. However, it turned out that B and her father secretly met with the clinic's endocrinologist without my knowledge or consent to discuss starting her puberty blockers. After their secret meeting, the endocrinologist returned to my room to speak with me and my daughter to "get me on board" with the treatment.

9. I had researched puberty blockers and cross-sex hormone therapy and was concerned about their unproven safety and efficacy. When I raised these concerns, the endocrinologist said no studies show that the drugs aren't safe. She also told me in front of my daughter that I needed "to get on board if I don't want my daughter to commit suicide."

10. My ex-husband and I have shared decision-making authority for our children's medical care. I have repeatedly notified clinic staff, orally and in writing, that I do not consent to them treating B. The clinic staff ignored my directions.

11. The clinic and B's father have continued with regular consultations with my daughter without my consent. I have reviewed documents from the clinic

where staff noted that they plan to "convince me" to consent to the medical interventions. The notion of "informed consent" or parental decision-making was nonexistent.

12. The availability and promotion of "gender-affirming" medical intervention for minors were used to drive a wedge between B and me, preventing B from receiving counseling for underlying mental health issues and exposing her to unknown long-term medical and mental health consequences without my consent.

13. Tennessee's Act prevents such coercive manipulation and potential harm against its vulnerable children and should be upheld to protect children and their families.

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

Executed on May 18, 2023.

/s/ BARBARA F.
BARBARA F. (pseudonym)

EXHIBIT 16

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, PLAINTIFFS

v.

JONATHAN SKRMETTI ET AL., DEFENDANTS

DECLARATION OF KELLIE C.

I, Kellie C.,[1] declare as follows:

1. I am over the age of 18 years and am not a party to this action. I have actual knowledge of the following facts and, if called upon to testify to them, could and would do so competently. I am submitting this Declaration in support of Defendants' opposition to Plaintiffs' Motion for a Preliminary Injunction.

2. Tennessee recently passed a law prohibiting medical procedures performed on minors "for the purpose of: (A) Enabling a minor to identify with, or live as a purported identity inconsistent with the minor's sex, or (B) Treating purported discomfort or distress from a discordance between the minor's sex and asserted identity," Tenn. Code Ann. § 68-33-101, *et seq*. This Act will provide parents with necessary protections against ma-

[1] Declarant is submitting this Declaration using a pseudonym to protect the privacy of her children and other family members.

nipulation and coercion on the part of health care providers, ex-spouses, and confused children to comply with demands for medical and surgical interventions aimed at "affirming" a child's professed discordant gender identity under threats of alienation or loss of a child to suicide.

3. No such parent and child-protective law exists in my home state. Providers have used coercion and manipulation to obtain my consent or blatantly disregarded my decisions for my child's medical and mental health. Tennessee's Act will prevent its parents and children from suffering similar harm. It will restore the rights of all parents, not just those who agree with demands for "gender-affirming" medical interventions, to make medical and mental health care decisions for their children following their natural, healthy development.

4. My daughter, D., became involved in fan fiction at age 11, around the time she began puberty. By age 13, D. had diagnosed herself with gender dysphoria and began identifying as a 17-year-old male character from Harry Potter. For several years, D. celebrated the birthday of the fictional identity and, at age 17, identified as a 23-year-old male.

5. D. underwent a psychiatric evaluation which found that she is delusional and incapable of caring for herself. She is on the autism spectrum and has OCD and possibly ADHD, but she is not psychotic. The evaluation team admits that D. identifies as a 23-year-old man and proclaims that she has Dissociative Identity ("multiple personality") Disorder. The psychiatric team does not believe she has DID, but that D. has researched DID and is using it as a maladaptive coping tool for

working through the childhood trauma of being sexually assaulted at age 13 or 14.

6. D. is in a residential treatment center. The treatment team has not engaged in therapy with D. to address her underlying issues. Instead, they have embraced her delusion that she is a 23-year-old fictional male character with a transgender identity. The therapists reiterate that they want D. to feel "safe," so they will not address any underlying issues unless D. brings it up on her own.

7. D. has asked for puberty blockers and testosterone. Despite her myriad comorbidities and unaddressed sexual trauma, the treatment team said that D. is ready for "gender-affirming" medical interventions. The therapists and psychologists have told me that if I do not consent, I "will have a dead daughter instead of a 'live son.'" The providers constantly tell me I must "get on board" with what D wants.

8.qThe therapists and D.'s father told her that my refusal to consent was the only thing standing in the way of her getting those treatments. As a result, my daughter has alienated me, and I have been banned from knowing her medical status.

9. Today, D. is 19. As far as I know, D. never received puberty blockers or cross-sex hormones. Five months ago, D's younger brother, age 17, told me that D. no longer identifies as the 17-year-old fictional character from Harry Potter. Now, D bounces back and forth to multiple characters, calling herself "AND-I." It's expected that everyone embraces D.'s ever-changing pronouns and various personas, including the "transgender" aspect of any given character.

10. Tennessee's Act protects its vulnerable children by making these medical interventions unavailable. The Act will also prevent the harm inflicted on parents who fight to defend their mentally disturbed children from irresponsible healthcare providers. It is a necessary regulation that should be upheld for the protection of children and their families.

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

Executed on May 18, 2023.

/s/ KELLIE C.
KELLIE C. (pseudonym)

EXHIBIT 19

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, PLAINTIFFS

v.

JONATHAN SKRMETTI ET AL., DEFENDANTS

DECLARATION OF JOHN NOAKES

I, John Noakes,[1] declare as follows:

1. I am over the age of 18 years and am not a party to this action. I have actual knowledge of the following facts and, if called upon to testify to them, could and would do so competently. I am submitting this Declaration in support of Defendants' opposition to Plaintiffs' Motion for a Preliminary Injunction.

2. Tennessee recently passed a law prohibiting hormonal and surgical procedures "for the purpose of: (A) Enabling a minor to identify with, or live as a purported identity inconsistent with the minor's sex, or (B) Treating purported discomfort or distress from a discordance between the minor's sex and asserted identity," Tenn. Code Ann. § 68-33-101, *et seq*. This Act will protect parents against confused children, ex-spouses, and provid-

[1] Declarant is submitting this Declaration using a pseudonym to protect the privacy of his children and other family members.

ers, whose coercive tactics to obtain consent to medical interventions "affirming" a child's professed discordant gender identity include threatening alienation or loss of a child through suicide.

3. I am a resident of the State of Tennessee, along with my 20-year-old daughter, B, who recently identified as transgender. However, B had never suggested that she had issues with her gender before. She was a "girly girl." She did gymnastics and ballet, and happily wore a pink tutu.

4. Growing up, my daughter, B, and I had a good relationship. However, my relationship with B changed after her mother and I divorced. B was about 13 years old at this time. Initially, visitation was regular and normal. However, as time went on, I did not see her as much due to the distance created by the divorce.

5. After B turned 16, I saw her only a handful of times the following year. It became increasingly difficult for B to deal with her mother whenever she visited me.

6. I invited B over right before she was about to turn 17 years old to celebrate her birthday. It was the first time I had seen her in months. When B arrived, I was completely shocked. She had given herself a buzz cut and was dressed like a boy.

7. B announced that she was transgender. She told me that she identified as a boy and wanted me to call her by a new name she had chosen. This was the first time I learned that B was experiencing issues with her gender identity.

8. B handed me papers from the Vanderbilt University Medical Clinic ("VUMC"). She had been to

VUMC's gender clinic and saw Dr. Cassandra Brady. My ex-wife had taken her and had not informed me about the appointment. B's mother supported her new male gender identity.

9. B told me she wanted me to sign these papers, giving my consent and approval for her to receive testosterone shots from Vanderbilt. Her request overwhelmed me, and I wanted to speak with her doctor.

10. B and my ex-wife pressured me to sign immediately. Dr. Brady had told them about the risk of suicide if they chose not to administer medical treatments. They both told me that if B committed suicide, it would be all my fault. However, I needed more information before signing. My gut told me that something was not right. B and her mother said everything would make sense once I talked to Dr. Brady.

11. So, I called Dr. Brady at VUMC. Dr. Brady told me she was "so sure" that B was a good candidate. Dr. Brady said that kids as young as 5 to 7 years old come to the clinic and that the physicians know right away if the kids are good candidates for medical treatments.

12. Dr. Brady said that kids question their gender as early as 5 to 7 years old, and when these kids come into the clinic, the physicians know right away if the kids are good candidates for medical treatments. The concept that a child would know they are transgender that young was completely absurd. Still, I challenged Dr. Brady's suggestion and told her that when B was younger, she never acted like a boy, did girly things, and never suggested she was uncomfortable in her body. I ended the call when it became clear that Dr. Brady did not care about my experiences with and observations of B as a child that clearly identified as female.

13. Ultimately, I could not agree to the medical treatments. I was concerned about the permanent harm it might have on her body. I wanted to wait for her at least to turn 18 so she could have more time to develop. The possibility that she might change her mind was very real. This change happened so quickly that she could easily change her mind.

14. Dr. Brady's promotion of "gender-affirming" medical intervention for minors was used to drive a wedge between me and my daughter. For the next year, until B turned 18, B and her mother harassed me for not affirming her gender or consenting to the treatments. B has since completely alienated me from her life. I have no idea if she has received medical treatments or continues to visit VUMC.

15. Tennessee's law will prevent its parents from suffering harm like mine. It will also help prevent coercive manipulation and potential harm against its vulnerable children and should be upheld to protect children and their families.

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

Executed on May 19, 2023.

/s/ JOHN NOAKES
JOHN NOAKES (pseudonym)

EXHIBIT 20

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, PLAINTIFFS

v.

JONATHAN SKRMETTI ET AL., DEFENDANTS

DECLARATION OF JAMIE REED

I, Jamie Reed, declare as follows:

1. I am an adult, I am under no mental incapacity or disability, and I know that the following facts set forth are true because I have personal knowledge of them. I am submitting this Declaration in support of Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction and Complaint.

2. Tennessee's law prohibiting hormonal and surgical procedures "for the purpose of: (A) Enabling a minor to identify with, or live as a purported identity inconsistent with the minor's sex, or (B) Treating purported discomfort or distress from a discordance between the minor's sex and asserted identity," Tenn. Code Ann. § 68-33-101, *et seq.*, is necessary to support children's health and welfare and to protect the medical profession's integrity and public respect.

3. I hold a Bachelor of Arts in Cultural Anthropology from the University of Missouri St. Louis and a Master of Science in Clinical Research Management from Washington University. I have worked at Washington University for seven years. I initially worked with HIV-positive patients, caring for many transgender individuals. From 2018 until November 2022, I worked as a case manager at the Washington University Pediatric Transgender Center ("the Center") at St. Louis Children's Hospital. My duties included meeting with patients two to three days a week and completing the screening triage intake of patients referred to the Center.

4. I have experience and expertise working with transgender individuals and pediatric populations. I accepted the job at the Center because I firmly believed I could provide quality care for children there. Instead, I personally witnessed children experience shocking injuries from puberty blockers and cross-sex hormones, which often were prescribed to them without complete informed parental consent or an accurate assessment of the child's needs. To my knowledge, the Center did not track patients' adverse outcomes post-discharge. I left the Center in November 2022 after having raised concerns internally for years.

5. During my time at the Center, I was required to schedule patients to the Endocrinology or Adolescent Medicine practice based on their age and stage of puberty. Generally, Psychology was primarily only available to write patients' letter of support for medical transition treatments instead of ongoing therapy. Psychiatry was limited to patients "not too severe" to avoid the already overburdened emergency room for patients suf-

fering suicidal ideations and self-harm or requiring inpatient eating disorder treatment.

6. On my own initiative, I tracked certain patients on a case-by-case basis. I was concerned that Center doctors were prescribing cross-sex hormones and puberty blockers to children who were not good candidates. I created a "red flag" list of children where other staff and I had concerns. Ultimately, Center doctors sent these children to our in-house therapists, and those therapists inevitably provided letters to the doctors. Center doctors told me I had to stop raising these concerns, and I was no longer allowed to maintain the red flag list. I also wanted to track the number of our patients who detransitioned, attempted suicide, or committed suicide. The Center would not make these tracking systems a priority.

7. From 2020 to 2022, the Center initiated medical transition for more than 600 children and adolescents. Approximately 74% of these patients were assigned female at birth. One biologically female patient on cross-sex hormones called the Center after having sexual intercourse and experiencing severe vaginal lacerations as a result. Patient bled through a pad, pants, and a towel wrapped around their waist. Ultimately, Patient required surgical treatment in St. Louis Children's Hospital emergency room. I have heard from minor patients given testosterone that their clitorises have grown so large that they now constantly chafe against their pants, causing them pain when they walk.

8. Nearly all children and adolescents who came to the Center presented with severe comorbidities, including autism, ADHD, depression, anxiety, PTSD, trauma histories, OCD, and eating disorders. Many were pre-

scribed puberty blockers or cross-sex hormones. For example:

a. Patient came to the Center identifying as a "communist, attack helicopter, human, female, maybe nonbinary." Patient was in poor mental health and reported early on that they had no idea of their gender identity. The Center prescribed Patient cross-sex hormones. Patient subsequently reported that their mental health worsened.

b. Patient was in a residential sex offender treatment facility in state custody. Patient had previously sexually abused animals and had stated that they would do so again when released. There were questions about the consistency of gender history. The Center prescribed Patient cross-sex hormones.

c. Patient had severe Obsessive Compulsive Disorder and threatened to self-harm their genitals. Patient did not have a trans or other incongruent gender identity. The Center prescribed Patient cross-sex hormones to reduce libido and sexual arousal chemically.

d. Patient had a history of sexual abuse and notified the psychologist of this. Documented in the letter of support were Patient's concerns about the changes that testosterone would cause to their genitals. The Center prescribed Patient testosterone.

e. Patient had severe mental health concerns and was prescribed psychiatric medications. Patient failed to take these prescriptions. The Center

nonetheless prescribed Patient cross-sex hormones.

f. Patient had significant autism with unrealistic expectations, struggled to answer questions, and wanted questions provided ahead of time. The Center prescribed Patient feminizing hormones.

g. Patient had a mental health history that included violent tendencies. Parent forced Patient to cross-dress. The Center prescribed Patient feminizing hormones.

h. Patient was on cross-sex hormones and had decompensating mental health, outlandish name changes, and a self-diagnosis of multiple personalities. The Center continued prescribing Patient cross-sex hormones.

i. Patient believed that their prescribed testosterone was poisoning them and stopped for a period. Patient had significant serious mental health issues. The Center continued prescribing Patient testosterone.

j. A 17-year-old Patient arrived at the Center with non-relative man who had been living with Patient. One year later, the Center prescribed Patient hormones. Patient's mental health deteriorated. Patient visited the Emergency Department and disclosed that the non-relative man that had brought them to the clinic had been sexually and physically abusing them. The Center continued Patient's medical transition treatment.

k. Patient was in residential facility, in foster care. The Center convinced the facility staff to allow Patient to start testosterone. Patient ran away numerous times from the facility and began having unprotected intercourse while on testosterone. The Center continued prescribing Patient testosterone.

l. Patient admitted that their parent encouraged them to start taking testosterone at 11-years-old because they were moving to a state that the parent believed would restrict Patient's care in the future. Patient had desisted in male identity to a vague nonbinary. Patient changed their name numerous times and struggled with thoughts about desistence, even saying they wanted breast development. The Center continued prescribing Patient testosterone.

m. Patient on cross-sex hormones was evaluated for OCD and a somatization disorder with "seizure" activity. The Center continued prescribing Patient cross-sex hormones.

n. Patient on cross-sex hormones stopped taking their schizophrenia medications without consulting a doctor. The Center continued prescribing Patient cross-sex hormones.

9. I witnessed puberty blockers worsen patients' mental health. Several children that had never contemplated suicide attempted suicide after taking puberty blockers. Similarly, many patients with depression and anxiety symptoms became more severe after starting cross-sex hormones. The Center did not require children to continue with mental health care after they prescribed cross-sex hormones or puberty blockers. The

Center continued treatment despite patients reporting worsening mental health.

10. The Center had four basic requirements to place a child on puberty blockers or cross-sex hormones: age or puberty stage, therapist letter, parental consent, and a clinical visit. In practice, every patient who met these minimum criteria was prescribed cross-sex hormones or puberty blockers.

11. First, the Center required that the child be at a certain age or stage of puberty. Puberty stages were measured according to the Tanner Stage system. When I was at the clinic, the World Professional Association for Transgender Health ("WPATH") Standard of Care Version 7 recommended that children be at least 16 years old before starting cross-sex hormones. The Center routinely prescribed cross-sex hormones to children as young as 13.

12. Second, the Center required the child to have a therapist referral letter authorizing medical treatment. Supposedly, this requirement ensured that two independent professional clinicians agreed that medical transition was appropriate before giving the child medication. The Center would recommend therapists it knew would offer children a letter supporting medical transition. If the child did not receive a letter from an outside therapist authorizing puberty blockers or cross-sex hormones, we would send the patient to the Center's in-house therapists. I was instructed to draft and send language to the therapists for them to use for letters supporting medical transition. Most therapists had a template letter drafted by the Center. Many therapists on the Center's list would return letters supporting medical transition after 1-2 hours with a patient.

13. Third, the Center required parental consent. But parents routinely said they felt they were pressured to consent. I was present during visits where Center doctors obtained consent by telling the parent of a child assigned female at birth, "You can either have a living son or a dead daughter," or parents of a child assigned male at birth, "You can either have a living daughter or dead son."

14. The Center did not inform parents or children of all known side effects before placing children on cross-sex hormones or puberty blockers. Center doctors knew that many of its former patients had stopped taking cross-sex hormones and were detransitioning. Doctors did not share this information with parents or children. The Center nurse and I expressed concerns about one patient's intellectual function and ability to provide informed consent. Patient attended a school district for special education needs, could not identify where they lived, and could not explain what kind of legal documents or identification they possessed. The provider dismissed our concerns and prescribed hormones. In a follow-up appointment, Patient stated that they were possibly interested in having biological children. Patient never saw the fertility department and the Center never discussed fertility questions with Patient.

15. Fourth, the Center required that the child attend a consultation with the Endocrinology or Adolescent Medicine practices. On several occasions, I witnessed Center doctors mention that they did not have time in the meeting to discuss everything they would have liked to.

16. During my four years working at the clinic, I witnessed only two instances where doctors chose not to

prescribe cross-sex hormones or puberty blockers for a child who met the four basic criteria. Both cases involved patients with severe developmental delays. In one of those cases, the doctors did not prescribe cross-sex hormones or puberty blockers, despite recommending the medications, solely because the parents would not agree to monitor the child's medication administration.

17. Toward the end of my time at the Center, I saw a large increase in children seeking transition treatment. When I started in 2018, the Center received between 5 and 10 calls a month. When I left, the Center had received more than 40 calls a month. Many children reported that they learned of their gender identities from TikTok.

18. Center doctors would prescribe puberty blockers or cross-sex hormones even if the child had severe comorbidities or was influenced by social media.

19. Children had come into the clinic using pronouns of inanimate objects like "mushroom," "rock," or "helicopter;" asking for hormones because they do not want to be gay; changing their identities on a day-to-day basis; and under clear pressure by a parent to identify in a way inconsistent with the child's actual identity.

20. In hundreds of other cases, Center doctors regularly issued puberty blockers or cross-sex hormones despite concerns raised by the child's individual circumstances. For example:

a. Patient's gender identity shifted day-to-day. Patient changed preferred name and at one point changed to non-binary identity. Center

doctors continued prescribing Patient cross-sex hormones.

b. 19-year-old Patient, initially seen as a minor, had a mastectomy at St. Louis Children's Hospital. Three months after the surgery, Patient contacted the surgeon and asked for their breasts to be "put back on."

c. Doctors placed a biologically female patient on cross-sex hormones. Later, I discovered that Patient desired cross-sex hormones only to avoid becoming pregnant.

d. I witnessed a call between an outside psychiatrist and the Center's endocrinologist. Psychiatrist recommended that Patient not start cross-sex hormones due to the child's serious mental health issues. Patient had threatened to commit suicide by jumping off a roof. The Center's endocrinologist yelled at the psychiatrist and spoke down to this provider.

e. At intake, Patient identified as "blind," even though vision tests revealed that the child could see. Patient also identified as transgender. The Center dismissed the child's blindness claim as a somatization disorder but accepted Patient's statement about gender. The Center prescribed that child drugs for medical transition without confirming the length or persistence of the condition. The Center provided no concurrent mental health.

21. I have personally witnessed staff say they were uncomfortable with how the Center requested that they code bills sent to publicly funded insurance programs.

I witnessed staff ask providers for clarification on billing questions and have providers dismiss the concerns and prioritize patients' coverage. I personally witnessed staff report that they were aware that patients had been coded incorrectly, coding for precocious puberty for a puberty blocker prescription when the child did not have the condition.

22. In my role we had direct ties to the Vanderbilt Gender Center in Nashville, Tennessee, early in my tenure. We were aware of a program that Vanderbilt started called the TransBuddy Program. We extensively researched this program, one of my students had contact with a staff member at Vanderbilt and we worked for a period to pilot the same program at St Louis Children's Hospital. We were interested in piloting this program in part because we knew that Vanderbilt's gender program was very similar in practice to our own program. We were similarly embedded in a university research-based hospital system and shared the same structural values in treating transgender children. The TransBuddy program itself is based on the same fundamental principles that transgender children require special medical care that is kept protected from any medical staff questions or true assessment. It is my assessment having spent hours working to reproduce the program that Vanderbilt created that the same or very similar systematic issues, ethical concerns, and maltreatment would be found in both centers.

23. Washington University School of Medicine's Pediatric Transgender Center at St Louis Children's Hospital is not an outlier in its practices. It is just like the vast majority if not all other pediatric gender centers in the United States. I know this to be true for the following reasons:

a. Our clinical co-director was trained in gender care by Dr. Steven Rosenthal, the Medical Director of the Children and Adolescent Gender Center at the University of California San Francisco at Benioff Children's Hospital. UCSF is known as a leading institution in pediatric gender care. UCSF recently hosted the 2023 National Transgender Health Summit. Our clinical co-director, Dr. Chris Lewis continued to seek out Dr. Rosenthal's clinical expertise on a regular basis through my tenure at the center and would state that he wanted to discuss cases with his mentor. Even after those discussions clinical decisions like I described above were made.

b. Our center's multidisciplinary team attended numerous national conferences. We attended as a group the Philadelphia Trans Wellness Conference at the Mazzoni Center. We also attended as a group the Gender Odyssey Conference in San Diego. In these conference sessions we were never challenged with any information or clinical practices that demonstrated that our clinical practices were outside of the norm. If anything, we were presented with information that demonstrated that our clinical care was potentially more conservative than the prevailing norms at the coastal centers. For example, the conference in San Diego had an entire session on the use of the cancer drug bicalutamide and our provider, Dr. Chris Lewis, was using this drug on a regular basis. This drug was not found in any WPATH or Endocrine Society formal 'guidelines' and yet was clearly being used by other gender centers treating children around the country.

c. Our center's multidisciplinary team was active in an online email national group that linked together pediatric gender care providers. Although I never completed the steps to join that group, in part because I already had enough email to manage, I heard from the providers comments that our practices were actually more conservative than what they were seeing on the group chats. Casey Lofquest, our center's nurse practitioner even commented once to me about this chat saying that if I think our center is going too far and not following the 'guidelines' that I would be appalled at some of the other clinical practices who do not even know that 'guidelines' even exist.

d. We had patients who transferred their care to our center from centers in other states. Upon reviewing the records from other centers I found that other centers did not even attempt to determine who the legal guardians are for children in their care. I found that other centers did not even request a letter of support at all before starting children on cross sex hormone treatment. I also found in one case that a child transferred to our center who was started on testosterone at the age of 11. It was apparent that other centers, within the United States, were operating well outside of any standard of care.

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

Executed on May 18, 2023

/s/ JAMIE REED
JAMIE REED

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

AND

UNITED STATES OF AMERICA, PLAINTIFF-INTERVENOR

v.

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

DECLARATION OF SAMANTHA WILLIAMS IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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

1. I have personal knowledge of the facts set forth in this Declaration and could and would testify competently to those facts if called as a witness.

2. On July 1, 2023, the law prohibiting access to gender affirming health care for transgender adolescents like my daughter L.W. is set to go into effect.

3. On March 14, 2023, we were informed by L.W.'s medical providers at Vanderbilt University that they will be discontinuing treatment beginning on July 1, 2023 because of the law. Although the law allows for

providers to treat existing patients with a titrated form of care between July 1, 2023 and March 31, 2024, this will not be an option for L.W. at Vanderbilt.

4. When I first found out that Vanderbilt is cutting off care starting July 1st as a result of the law, I was terrified. Receiving that message from Vanderbilt made clear to me that we had to move a lot faster to find a provider out of state given how important it is to our family to secure continuity of care for L.W. It takes L.W. time to adjust to and feel comfortable with new providers, and she has finally built that rapport with Dr. Brady at Vanderbilt. Dr. Brady encouraged us to try to find a provider out of state after July 1 but agreed to continue providing care to L.W. until then in anticipation of the difficulties of finding a new provider. Our last appointment at Vanderbilt is in June.

5. In the last few months, I have contacted eight institutions out of state to make appointments for L.W. to continue accessing gender affirming care. I reached out to a hospital in Atlanta, Georgia, and they told us that they do not accept our insurance. I contacted three hospitals in Illinois, one of which communicated that they are currently not taking out of state patients but were able to place us on a waitlist, and the other two told us that they do not accept our insurance. I reached out to a hospital in Charlottesville, Virginia but they are not able to give L.W. an appointment by the next time she will require her medication. I reached out to a clinic in Asheville, North Carolina and they have not yet given us an appointment.

6. I contacted a clinic in Cincinnati, Ohio, and they were able to give us an appointment for June. I was also able to schedule an appointment with a clinic in Char-

lotte for the middle of July. Although we were able to make appointments at the Cincinnati and Charlotte clinics, we are not guaranteed that L.W. will be able to access her medication at that appointment, nor are we guaranteed that the clinic will be able to continue seeing L.W. given the capacity of those clinics to see out-of-state patients.

7. We are not able to make appointments at institutions that do not accept our insurance because going out-of-network would double our deductible cost (from $3,000 to $6,000), and our out-of-pocket maximum amount would double as well (from approximately $5,000 to $10,000). Between the salaries of my husband Brian and I, we are not able to bear that financial burden.

8. Cincinnati is a 4 hour drive one-way from our home. To see a provider in Cincinnati and get her prescriptions filled, L.W. will need to miss at least two days of school, and Brian and I would have to take off two days from work. We would have to stay overnight at a hotel, given that we do not have family or friends in Ohio to host us. Should an appointment become available at the hospital in Chicago, our family would need to travel by plane given that a one-way drive is approximately 8 hours from our home. That travel would similarly require L.W. to miss at least two days of school, and Brian and me to miss two days of work.

9. Traveling out of state will come at a great personal and financial burden to our family, given the disruption to our school and work schedules, and the cost of travel and accommodation for each visit. Brian and I are very worried about how this disruption and these

costs will impact our ability to take care of our family, especially both of our children, in the long-term.

10. As July 1st approaches, L.W. has been much more anxious and has been speaking to Brian and me more frequently about our back-up plan and what the future of accessing care for her will look like. This care is so important to L.W., and it is hard to describe the stress of worrying that our options for receiving care out of state might be further limited by states—like Ohio—that might pass their own healthcare bans and worrying about when we will even be able to get an appointment with a provider that accepts our insurance in a state like Illinois. We will not stop searching for alternative means of getting our daughter the treatment that has allowed her to live authentically. There is no other option for us.

* * *

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

Dated: May [30], 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

AND

UNITED STATES OF AMERICA, PLAINTIFF-INTERVENOR

v.

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

DECLARATION OF JANE DOE IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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

1. I have personal knowledge of the facts set forth in this declaration and could and would testify competently to those facts if called as a witness.

2. I previously testified about the effect that the July 1, 2023 effective date of Tennessee's ban on gender-affirming care will have on my son and our family, and submit this declaration to offer additional and clarifying information.

3. Our last appointment with John Doe's pediatric endocrinologist, Dr. Cassandra Brady, was in February

2023. During that February 2023 appointment, 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. As a result, she encouraged us to look for out-of-state providers. This would allow John to continue his current treatment regimen, which Dr. Brady believes is medically necessary for him. We discussed alternatives for finding care outside of Tennessee. We have an appointment to see Dr. Brady one final time before the law takes effect, at which point we will get updated information from her about alternatives for accessing care and work on finalizing our plans.

4. But we have done some additional research in advance and the prospects feel daunting. Dr. Brady mentioned Atlanta, Georgia as an alternative place to seek care, but Georgia has since passed its own ban on gender-affirming care for adolescents. We also discussed Cincinnati, Ohio as an option, but she reported that their wait list was already two-to-three months long because of the demand from states like Tennessee. We also discussed Minnesota since we have family there, but that requires even lengthier travel.

5. As I testified previously, having to travel to access this care would be disruptive, costly, and time-consuming. I would need to miss work, and John would need to miss school for each appointment. Based on my research, I do not believe there is any location where we could realistically access this care without needing to travel with at least one overnight stay for each trip.

6. We are frustrated and upset at the sacrifices this would require just to access this essential care for John. Both my husband and I are invested in John's medical treatment, and we prefer to attend important medical

appointments together. Given the travel required to seek care out of state, that will make it extremely difficult for us both to miss the required amount of work to both attend and participate in the appointments.

7. John's father, James Doe, and I are both planners, and the lingering uncertainty, and hardship required to travel to access this care, causes us an incredible amount of stress. Even more importantly, we are profoundly upset by the need to disrupt the continuity of care that has served John so well throughout the course of this treatment.

8. Because we have been able to maintain long-term relationships with John's providers, he has been able to see the same pediatrician, therapist, and endocrinologist his entire life, and those same three providers have been involved in Jack's care for gender dysphoria at varying points since he was approximately seven years old. The same nurse at John's pediatric office who weighed him as an infant also administers John's puberty-delaying injections today. The thought of establishing care out of state, when we have network of providers here that we trust and who know John deeply, is frightening to us because the last thing we want to do is leave the longstanding safety net we have had here—especially where something as serious as medical care is concerned. One simply cannot create that kind of trust and bond with new providers overnight. Worrying about the need to start all over with new providers out of state, and the ongoing uncertainty about the disruption, cost, and difficulty of accessing this care keeps me up at night.

* * *

Dated: May [29], 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 REBECCA ROE IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELMINARY INJUNCTION

I, REBECCA ROE, pursuant to 28 U.S.C § 1746, declare as follows:

1. I have personal knowledge of the facts set forth in this Declaration and could and would testify competently to those facts if called as a witness.

2. On July 1, 2023, the law prohibiting transgender adolescents like my son from accessing gender affirming health care is set to go into effect.

3. Though the law allows for providers to wean patients off current medications between July 1, 2023, and March 31, 2024, we were informed by Ryan's medical providers at Vanderbilt University that they will be discontinuing treatment beginning on July 1, 2023 because of the law.

4. The only provider that I am aware of in the state that will continue treatment of transgender adolescents with gender dysphoria between July 1, 2023 and March 31, 2024 is CHOICES in Memphis. But CHOICES only treats adolescents patients with gender dysphoria beginning at age 16. Ryan is only 15 years old. I called CHOICES to see if we could get an appointment with them but Ryan is too young and his 16th birthday is too far off for CHOICES to even schedule a future appointment.

5. With care being cut-off at Vanderbilt on July 1st as a result of the law and Ryan's 16th birthday not until October, there are no in-state options for treatment for my son.

6. I have spent hours researching and calling clinics in other states to try and get an appointment for Ryan. I have set up two appointments for Ryan for treatment for his gender dysphoria out of state for June. One appointment is in Asheville, North Carolina and the other is in Cincinnati, Ohio. Asheville is 4.5 hours by car each way and Cincinnati is 4 hours by car each way. We are preparing to potentially spend 8-9 hours driving for each appointment to access treatment for Ryan. This will mean missing work and school and driving long distances, potentially waiting overnight and missing additional time at work and in school. Disrupting Ryan's treatment is not an option, however, which means that we will have to make these sacrifices if the law is allowed to take effect.

7. I am worried that if Ohio or North Carolina pass similar laws, we will have to travel even further to access treatment and at greater expense. Though the Asheville Clinic has a sliding scale model for payment,

I am not sure how we will afford treatment at the Ohio clinic in the long-term. We are already experiencing the emotional and financial burdens resulting from the law and are concerned about the future impact of this ongoing travel.

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

Dated: [5/28/23] /s/ REBECCA ROE
REBECCA ROE

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

AND

UNITED STATES OF AMERICA, PLAINTIFF-INTERVENOR

v.

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

REPLY 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. One aspect of my practice is treating transgender patients ages 16 and up with hormone therapy for gender dysphoria.

3. I currently have 14 adolescent patients whose treatment will be subjected to the Health Care Ban's prohibition on treating gender dysphoria with hormone therapy beginning on March 31, 2024.

4. Given that it is dangerous to abruptly terminate hormone therapy, should the Ban not be enjoined by July 1, 2023, I will have to disrupt those patients' ongoing and needed medication and begin to titrate their hormone dosages down prior to March 31, 2024.

5. Additionally, I have a few patients who are relatively new to hormone therapy and have appointments scheduled every three months so that I can monitor their hormone levels and adjust their care as indicated by their lab work. Should the Health Care Ban take effect, I am concerned that it will prevent me from providing quality care to my patients based on their individual circumstances given the prohibition on modifying current treatment.

6. I am concerned for the health and well-being of my transgender patients should they not be able to access this life-saving care, and I do not want to withhold or modify care in a way that would both jeopardize the well-being of my patients and go against my best practice as a physician.

7. Should the Court grant a preliminary injunction prohibiting enforcement of the Ban, I would continue provide care for my existing patients, and any new patients, as I currently do—in accordance with the standards of care that guide my ordinary practice, and without having to titrate my adolescent patients down from therapeutic doses of their hormone therapy.

* * *

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

Executed on this 31st day of May 2023 I Memphis, Tennessee.

/s/ 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

AND

UNITED STATES OF AMERICA, PLAINTIFF-INTERVENOR

v.

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

EXPERT REBUTTAL DECLARATION OF DEANNA ADKINS, MD

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 in this declaration and have collected and cite to relevant literature concerning the issues that arise in this litigation in the body of the report.

3. My credentials are set forth in my initial declaration filed with the Court at ECF No. 29.

4. I have reviewed the declarations of Drs. Stephen Levine, Paul Hruz, James Cantor, Michael K. Laidlaw, Sven Román, and Geeta Nangia. Here, I respond to some of the central points in those declarations. I do

not specifically address each study or article cited, or each point made, but instead explain the overall problems with some of the conclusions that the Defendants' experts draw and provide data showing why such conclusions are in error. I reserve the right to supplement my opinions if necessary as the case proceeds.

TREATMENT PROTOCOLS FOR ADOLESCENTS WITH GENDER DYSPHORIA

5. Defendants' experts suggest that gender clinics routinely provide medical interventions to adolescents without proper mental health assessments and without informing patients and their parents of the potential risks of treatment. I cannot speak to the practice of every gender clinic in the country but both the Endocrine Society Clinical Practice Guideline (the "Endocrine Society Guideline") and the World Professional Association of Transgender Health Standards of Care (the "WPATH SOC") require rigorous mental health assessments and informed consent processes before any medical treatment is initiated. In my experience treating over 600 youth with gender dysphoria during my tenure at the Duke Center for Child and Adolescent Gender Care (the "Duke Gender Care Clinic"), each patient undergoes an extensive psychological assessment and, if medical interventions are deemed medically appropriate, an extensive informed consent process before such interventions are provided.

6. In my practice, I regularly communicate with practitioners who treat adolescents with gender dysphoria. The assessment and informed consent process that we utilize at the Duke Gender Care Clinic is comparable to the processes used at gender clinics across the country as I understand them. If providers are fore-

going assessments and informed consent such practice would be outside the recommended guidelines for care.

7. It is not the case that we encourage any patient to initiate gender-affirming care as some of the Defendants' experts suggest. *See, e.g.*, Hruz ¶ 64; Levine ¶ 122. Consistent with the WPATH SOC and the Endocrine Society Guideline, each patient is met first by providers who explore the patient's medical and mental health history and identity. Under the standards of care, no patient is rushed into medical treatment, and no treatment is initiated without appropriate evaluation and an informed consent process. Gender clinics use a multidisciplinary team approach and thus the decision to initiate gender affirming care is made by a team including the providers, the patient and their parents with informed consent.

8. It appears to be the position of the Defendants' experts that waiting until a patient turns 18 years of age before initiating medical treatment for gender dysphoria would not cause harm to minor patients. *See, e.g.*, Levine ¶ 238; Nangia ¶ 176. This is wrong. Many physiological changes that happen during endogenous puberty cause severe distress for patients with gender dysphoria and can be difficult, if not impossible, to reverse with subsequent treatment. Based on my clinical experience, patients with severe dysphoria who are able to receive treatment prior to age 18 experience substantial mental health improvements from gender-affirming medical interventions.[1]

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[1] Lane, A., & Wilson, T. A. (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(1). https://doi.org/10.1186/

9. Dr. Levine critiques WPATH because it is "a voluntary membership organization" and "attendance at its biennial meetings has been open to trans individuals who are not licensed professionals." Levine ¶ 62. The fact that non-professionals can attend meetings does not undermine the scientific rigor of WPATH's Standards of Care. Only licensed professionals participate in the drafting of the Standards of Care. Defendants' experts also attempt to discredit WPATH by referring to it as an advocacy organization. This critique is also misplaced. Like many medical associations, WPATH both advocates for patients and pursues rigorous scientific research. This is not a new phenomenon in medicine. The American Diabetes Association, for example, is a professional association that both advocates for patients with diabetes and is a scientific organization. Additionally, rigorous papers are presented at the WPATH meetings and well-funded scientific research is reported on. Similarly, the American Heart Association has scientific meetings, community engagement and advocacy arms.

SAFETY AND EFFICACY OF TREATMENTS

Safety and Efficacy of Puberty Blockers

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s13633-020-00078-2; llen, 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. https://doi.org/10.1037/cpp0000288; Becker I, Auer M, Barkmann C, Fuss J, Möller B, Nieder TO, Fahrenkrug S, Hildebrandt T, Richter-Appelt H. A Cross-Sectional Multicenter Study of Multidimensional Body Image in Adolescents and Adults with Gender Dysphoria Before and After Transition-Related Medical Interventions. Arch Sex Behav. 2018 Nov;47(8):2335-2347. doi: 10.1007/s10508-018-1278-4. Epub 2018 Aug 7. PMID: 30088234.

10. Puberty blockers have been used to treat patients with gender dysphoria since at least 2004 in the United States. We have almost 20 years of data showing the safety and efficacy of this treatment for patients with gender dysphoria. We have over 30 years of data about the safety of this treatment based on data from treating children with precocious puberty. It is therefore not accurate to suggest that little is known about the effects of puberty blockers.[2]

11. Though Defendants' experts warn about delaying puberty, use of puberty blockers in transgender youth does not delay puberty beyond the typical age range. Pubertal development has a very wide age variation among individuals. Puberty in individuals assigned male at birth typically begins anywhere from age nine to age fourteen, and sometimes does not complete until a person's early twenties. For those individuals assigned female at birth, puberty typically occurs sometime within the ages of eight to 17, generally beginning between the ages of eight and 13. Protocols used to treat adolescents with gender dysphoria would tend to put them in the latter third of typical pubertal age ranges but nothing outside of the typical range.[3] Though

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[2] Federica, et al. Management of Endocrine Disease: Long-term outcomes of the treatment of central precocious puberty. *European Journal of Endocrinology*. 2016; 174(3): R79–R87. doi: https://doi.org/10.1530/EJE-15-0590.

[3] Hembree, W.C., Cohen-Kettenis, P.T., Gooren, L., et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*. 2017; 102(11): 3869-903; Euling, S.Y., Herman-Giddens, M.E., Lee, P.A., et al. Examination of U.S. Puberty-Timing Data from 1940 to 1994 for Secular

some peers of a patient on puberty blockers to treat gender dysphoria may undergo pubertal changes earlier than the gender dysphoric patient, many peers will have comparably timed or later puberty. In fact, one of the reasons WPATH SOC 8 has eliminated strict age guidelines for hormone therapy was so that patients moving from puberty blockers to hormones could have an individualized assessment about when initiating puberty is appropriate. There is no data to support the assumption of Defendants' witnesses that delaying puberty within these normal age ranges will have negative short- or long-term social and developmental consequences.

12. In my clinical experience, puberty blockers can be an essential tool to improve the health and well-being of some transgender adolescents with gender dysphoria. Where medically indicated, puberty blockers effectively prevent the worsening distress that is common among adolescents with gender dysphoria upon the onset of puberty. In addition to preventing this worsening distress, puberty blockers allow an adolescent and their family time to assess future treatment options. Accordingly, when the time comes for these patients to make a choice about stopping puberty blockers or going onto gender affirming hormones, they have had time to process with themselves, their parents, and their clinical team what their life will look like if they undergo the puberty that does not match their sex assigned at birth. This allows a thorough understanding of the benefits and potential side effects of this course of treatment. In my clinical experience, their mental health improves

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Trends: Panel Findings. *Pediatrics*. 2008; 121 (Supplemental 3): S172-S191.

with lower levels of anxiety, improvement in depression, more interactivity at school and with their peers. Their school performance often improves as well due to the improvements in their mental health overall.

13. In his declaration, Dr. Hruz claims that patients treated with puberty blockers will experience a range of health consequences. *See, e.g.*, Hruz ¶¶ 73-79. For example, he says that patients treated with puberty blockers will be at an elevated risk of lower bone mineral density. Hruz ¶ 74. During the course of treatment, patients may have reduced bone mineral density relative to their peers who are progressing through puberty which naturally increases bone mineral density at a faster rate than the bone density accrual that occurs pre-puberty. The data available shows that most keep a stable density, but when compared to peers, who are adding more density, their Z scores (density compared to those of the same age and gender) are lower. There are a number of issues in this area that may lead to false comparisons as it is not clear which gender norm should be used. Many studies don't correct for bone age, pubertal stage, or height, all of which confound the DXA measurements. In addition, the studies available, even with these limitations, show that after two to three years on gender affirming hormone therapy (or endogenous puberty), the patient's bone structure and strength increases.[4] Additionally, studies have shown no changes

[4] Some transgender women do not return to their baseline before treatment within this short window. However, their baseline bone densities are frequently low to start. The cause of this is not clear. Some scientists suspect it has to do with a decreased level of activity seen in transgender women in general. This has been shown in research and also has been my experience with patients. *See* van der Loos, M.A., Hellinga, I., Vlot, M.C., et al. Development of Hip Bone

in bone mineralization among patients with central precocious puberty treated with puberty blockers for a period of three years.[5] Dr. Hruz raises the issue of risk of fracture later in life, but we have been using puberty blockers to treat patients with precocious puberty for over 30 years and have not observed these long-term effects. Hruz ¶ 91. As with all of the risks of puberty blockers, the risks related to bone mineralization and the state of the evidence are discussed with patients and their parents during the informed consent process and

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Geometry During Gender-Affirming Hormone Therapy in Transgender Adolescents Resembles That of the Experienced Gender When Pubertal Suspension Is Started in Early Puberty. *Journal of Bone and Mineral Research*. 2021; 36(5): 931-41. doi: https://doi.org/10.1002/jbmr.4262; Schagen SEE, Wouters FM, Cohen-Kettenis PT, Gooren LJ, Hannema SE. Bone Development in Transgender Adolescents Treated With GnRH Analogues and Subsequent Gender-Affirming Hormones. J Clin Endocrinol Metab. 2020 Dec 1;105(12):e4252-63. doi: 10.1210/clinem/dgaa604. PMID: 32909025; PMCID: PMC7524308.

Dr. Hruz focuses on a study by Klink that reported some reduction in bone density at age 22 among 15 transgender women treated with blockers during adolescence. *See, e.g.*, Hruz ¶ 79. But the authors concluded that "[t]he contribution of GnRHa treatment is at best tentative," as they noted other factors that could explain the results, such as lower bone density among the transgender women before commencement of treatment, possibly due to their discomfort engaging in sports. Klink, D., Caris, M., Heijboer, A., et al. Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria, *The Journal of Clinical Endocrinology & Metabolism*. 2015; 100(2): E270-E275, at E274. doi: https://doi.org/10.1210/jc.2014-2439.

[5] Park, H.K., Lee, H.S., Ko, J.H., et al. The effect of gonadotrophin-releasing hormone agonist treatment over 3 years on bone mineral density and body composition in girls with central precocious puberty. *Clinical Endocrinology*. 2012; 77(5): 743-48.

are weighed against the risks of not providing treatment.

14. With respect to Dr. Hruz's claim about weight gain, there is no consistency in the data on weight gain or loss in transgender individuals and, in my clinical experience, these outcomes most often relate to factors such as socioeconomic status, ability to participate in sports, and living in a food desert, as opposed to their hormonal status. This correlates with findings in my cisgender patients as well. I have observed much more significant weight gain in patients on certain antidepressants such as aripiprazole compared to patients being treated with hormones.

15. Additionally, Dr. Hruz suggests that patients on puberty blockers will have slower rates of growth in height. Hruz ¶ 119. Their rate is normal for those not in puberty. For transgender girls, there is some overall reduced height growth, but the reduced height is both consistent with the gender-affirmation aspect of the care (*i.e.*, a transgender girl's treatment will aim to align her physiological characteristics, including height, consistent with what is typical for girls generally) and still within the expected overall range for the patient's height based their mid parental average. For transgender boys, puberty blockers would lead to increased height growth, which is likewise consistent with the gender-affirmation aspect of the care and also still within the expected overall range for what their adult height would be.

16. Dr. Hruz's claim that brain development occurring during puberty may be negatively affected by puberty blockers is not accurate. *See* Hruz ¶¶ 76-78. Patients with gender dysphoria who are treated with pu-

berty blockers undergo hormonal puberty with all the same brain and other development.[6] There is no research suggesting that treatment has negative impact on brain development or executive functioning and I have not seen this in my practice at all.

17. Dr. Hruz's claim is inaccurate for the additional reason that some people never go through hormonal puberty, such as patients with Turner Syndrome, and still have normal brain development with respect to cognition and executive function. He also seems to imply that youth with gender dysphoria have their puberty delayed beyond the typical age range, *see* Hruz ¶ 75, but, as I discussed above, this is not accurate. He also implies that gender dysphoric youth treated with puberty blockers remain on them longer than those treated for precocious puberty. This is also not accurate. The longest my patients with gender dysphoria are treated with puberty blockers before the introduction of pubertal hormones is around three years. By contrast, many pa-

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[6] Staphorsius, A. S., Kreukels, B. P., Cohen-Kettenis, P. T., et al. Puberty suppression and executive functioning: An fMRI-study in adolescents with gender dysphoria. *Psychoneuroendocrinology*. 2015; 56: 190-99. doi: https://doi.org/10.1016/j.psyneuen.2015.03.007; Schneider MA, Spritzer PM, Soll BMB, Fontanari AMV, Carneiro M, Tovar-Moll F, Costa AB, da Silva DC, Schwarz K, Anes M, Tramontina S and Lobato MIR (2017) Brain Maturation, Cognition and Voice Pattern in a Gender Dysphoria Case under Pubertal Suppression. *Front. Hum. Neurosci*. 11:528. doi: 10.3389/fnhum.2017.00528; Nienke M. Nota, Baudewijntje P.C. Kreukels, Martin den Heijer, Dick J. Veltman, Peggy T. Cohen-Kettenis, Sarah M. Burke, Julie Bakker, Brain functional connectivity patterns in children and adolescents with gender dysphoria: Sex-atypical or not?, Psychoneuroendocrinology, Volume 86, 2017, Pages 187-195, ISSN 0306-4530, https://doi.org/10.1016/j.psyneuen.2017.09.014.

tients with precocious puberty are treated with puberty blockers for five to seven years.

Safety and Efficacy of Hormone Therapy

18. Hormone therapy is safe, effective, and essential for the well-being of many transgender adolescents. For example, boys who are transgender treated with puberty blockers and gender affirming hormones will receive the same amount of testosterone during puberty that non-transgender boys generate with their testes. They will grow darker and thicker facial and body hair, experience fat distribution away from the hips, have decreased breast growth, and develop lower vocal pitch. Likewise, girls who are transgender and treated with puberty blockers and gender affirming hormones will receive the same amount of estrogen during puberty that non-transgender girls generate endogenously. They will develop breast tissue, fat will be distributed to their hips, their skin will soften, and their vocal pitch will not deepen further. My patients who receive medically appropriate hormone therapy and who are treated consistent with their gender identity in all aspects of life experience significant improvement in their health.

19. Dr. Hruz claims that the risks of hormone therapy "include disfiguring acne high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease." Hruz ¶ 91. In my clinical experience, I have rarely seen these side effects in my patients. Although a high percentage of transmasculine individuals have acne, the severity is highly variable. Most often we see more acne in those who have a strong family history of significant pubertal acne. Most of my transgender patients have mild acne requiring only routine washing. The natural

history of the acne during testosterone use in transmasculine patients is that is increases in the first six months and then improves by around one to two years of treatment. Only a few have it to the point where there may be scarring in my clinical experience. In my practice, we have patients start on a preventive regimen of acne wash from the beginning of treatment and provide them with the standard acne treatment that many teens use if the issue arises. Of the alleged risks identified by Dr. Hruz, the most common would be "cardiovascular disease" in transgender women, but this is likewise usually only present when a patient is denied care and self-administers the treatment without appropriate clinical supervision.[7] Blood pressure measurements have been documented to increase with a statistical significance, but no clinical significance. Transgender men do not have more cardiovascular disease like stroke or heart attack than similar cisgender men. Transgender women have reported increase in stroke when on older formulations of estrogen. When their blood pressure levels are higher than the normal physiologic range, close monitoring can ameliorate these potential issues as it can with high blood pressure in transgender men. In my clinical experience, patients only develop high blood pressure when there is a strong family history of high blood pressure. In my extensive practice, I have only had to treat two transgender patients for hypertension even though I routinely treat many of my cisgender patients for hypertension.

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[7] Weinand, J.D. & Safer, J.D. Hormone therapy in transgender adults is safe with provider supervision; A review of hormone therapy sequelae for transgender individuals. *Journal of Clinical and Translational Endocrinology*. 2015; 2(2): 55-60. doi: https://doi.org/10.1016/j.jcte.2015.02.003.

20. When treating patients with hormones, we closely monitor dosing and circulating hormone levels to minimize any risk of adverse effects. This is true for patients with gender dysphoria and any other conditions requiring hormonal treatment. In the past, some of the estrogens used to treat patients did increase thrombovascular risks, but with current forms of medication and appropriate monitoring and dosing, we are not seeing these side effects. In addition, estradiol via patch has been used to treat cisgender men with prostate cancer and that use has not shown an increase in cardiovascular effects. For transgender men treated with testosterone, it is uncommon to see red blood cell counts that are atypical for males, and data have not shown [8] increased risk of cardiovascular disease for transgender men treated with testosterone.

21. Defendants' claim that hormone therapy is harmful because adolescents receive, what they call, "high, supraphysiologic doses" of hormones. But this is not accurate. Each patient is treated individually and their hormones are managed based on their physiological and clinical needs. The guidelines recommend that the hormone levels be kept in the normal physiologic range for their gender identity, not their sex assigned at birth. The levels are thus in the physiologic range for their gender identity. ECF No. 112, pp. 12-13.

22. Defendants seem to suggest that hormone treatment is harmful because it leads to a "lifetime" of continuing to receive such therapy. *See, e.g.*, Cantor ¶¶ 224;

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[8] Wierckx K., Mueller, S., Van Caenegem, E., et al. Long-term evaluation of cross-sex hormone treatment in transsexual persons. *The Journal of Sexual Medicine*. 2012; 9(10): 2641-51. doi: https://doi.org/10.1111/j.1743-6109.2012.02876.x.

Levine ¶¶ 121; Laidlaw ¶¶ 54. For some patients this is not the case as they may undergo hormone treatment for a period of time and then discontinue the treatment if dysphoria is well-managed and the changes from the hormone therapy have adequately addressed the underlying dysphoria. For those who do remain on maintenance doses of hormone therapy for their lifetimes, the risks of ongoing hormone therapy can be well-managed and are not unlike risks associated with those present for other patients who undergo long-term hormone therapy for different conditions like hypothyroidism, Kleinfelter's Syndrome, Turner Syndrome, patients who have to have their ovaries or testicles removed due to cancer, torsion or other cause as well as those with hypopituitarism. Many endocrine conditions are lifelong and require lifelong use of hormone replacement including hypothyroidism (congenital hypothyroidism requires treatment from birth to death), Type 1 diabetes, which requires insulin for life. Additionally, adrenal insufficiency is a lifelong condition whether its cause is a hereditary enzyme deficiency which presents at birth, or, an autoimmune condition, an infection or an injury (these present later in life). These patients require lifelong steroids. Ultimately, many conditions are treated with lifelong medical management—including hormone therapy—and that does not pose an inherent risk to patient health. In fact, the lifelong management improves patient health and extends life.

23. Defendants' experts also discuss the fertility implications of gender-affirming care. Levine ¶ 189; Hruz ¶¶ 89-90. Dr. Levine's sweeping suggestion that hormone therapy affects fertility for all patients is simply incorrect. Many transgender individuals conceive chil-

dren after undergoing hormone therapy.[9] Pregnancy among trans men after undergoing testosterone therapy is very common.[10] A recent eight-year study found that four months after stopping testosterone treatment, transgender men had comparable egg yields to non-transgender women.[11]

24. Going directly from puberty blockers to gender-affirming hormones does affect fertility. For these patients, and any patients treated with estrogen, who are concerned about the impact of estrogen on fertility, fertility preservation remains an option. More generally, many medical interventions necessary to preserve a person's health and well-being can impact an individual's fertility, but we proceed with the treatment after informed consent.

25. Defendants' witnesses also critique an update to the WPATH SOC, which no longer sets more rigid age

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[9] Light A.D., Obedin-Maliver J., Sevelius J.M., et al. Transgender men who experienced pregnancy after female-to-male gender transitioning. *Obstetrics Gynecology*. 2014; 124(6): 1120-27; Maxwell S., Noyes N., Keefe D., Berkeley A.S., et al. Pregnancy Outcomes After Fertility Preservation in Transgender Men. *Obstetrics Gynecology*. 2017; 129(6):1031-34; Neblett M.F. & Hipp H.S. Fertility Considerations in Transgender Persons. *Endocrinology and Metabolism Clinics*. 2019; 48(2): 391-402.

[10] *See, e.g.*, Moseson, H., Fix, L., Hastings, J., et al. Pregnancy intentions and outcomes among transgender, nonbinary, and gender-expansive people assigned female or intersex at birth in the United States: Results from a national, quantitative survey. *International Journal of Transgender Health*. 2020; 22(1-2): 30-41. doi: https://doi.org/10.1080/26895269.2020.1841058.

[11] Leung, A., Sakkas, D., Pang, S., et al. Assisted reproductive technology outcomes in female-to-male transgender patients compared with cisgender patients: a new frontier in reproductive medicine. *Fertility and Sterility*. 2019; 112(5): 858-65.

limitations around the initiation of hormone therapy. This allows for flexibility in caring for patients who have a need to access hormones earlier due to early puberty or earlier onset and severity of dysphoria. We still counsel families about the risks and benefits of the treatments and the limitations of data available for younger adolescents. Generally speaking, this is how the practice of medicine works—we use the best available evidence from research and clinical experience to tailor treatment for each individual.

26. Ultimately, in my clinical experience, gender-affirming medical care drastically improves the health and well-being of adolescents with gender dysphoria for whom the care is medically indicated. And contrary to the suggestions made by the Defendants' experts, my clinical experience has shown that adolescents who access needed gender-affirming medical treatment have improved social and romantic relationships and are able to develop peer relationships with cisgender and transgender people alike.

27. For patients for whom these medical interventions are indicated, taking them off of their puberty blockers or their GAHT is likely to cause severe harms and no discernible benefits. The physical consequence to stopping GnRH (puberty blockers) in transgender patients can be permanent change in the secondary sex characteristics which can lead to future severe and/or worsening dysphoria. An increase in dysphoria can increase depression, anxiety, self-harm, hospitalizations, and suicidality in transgender adolescents. These permanent changes can lead to future surgeries that would not have been required had the patient remained on treatment. These permanent changes can also make it more difficult for transgender adolescents to navigate

society in both adolescence and adulthood as they can make it harder for people to be perceived as cisgender thereby increasing the potential for harassment and violence. I have personally witnessed the differences for my patients who are able to begin treatment early in puberty when compared to patients who undergo their endogenous puberty. Early intervention dramatically affects a patient's ability to "pass" as cisgender, which can have many practical and mental health benefits.

28. Titrating down hormone therapy can be done but is not medically recommended and is not consistent with my practice. It will lead to transgender individuals experiencing physiological changes in their bodies that are consistent with their assigned sex at birth, including but not limited to menstrual cycles, facial hair, body hair, change in body shape. These physiological changes will once again lead the individual back into dysphoria and worsen their mental health. And because adolescence is such a critical time with respect to these permanent changes, even titrating down the hormone therapy to a non-therapeutic dose could lead to permanent physical changes that will affect a patient for their lifetime.

29. As the Director of a transgender health clinic in North Carolina, I see patients who live out-of-state, and I am acutely aware of the difficulties that families endure in accessing gender-affirming care, including long wait times and barriers associated with insurance and travel. The longer the patient is unable to access their medically necessary care, the worse their suffering will be. In addition, transgender youth are often wary of medical providers and can take longer to develop a therapeutic and trusting relationship with their provider.

This change in providers can set them back in their care and can have lasting physical and mental health effects.

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

* * *

Executed on: May 31, 2023.

/s/ DEANNA ADKINS, MD
DEANNA ADKINS, MD

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

AND

UNITED STATES OF AMERICA, PLAINTIFF-INTERVENOR

v.

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

EXPERT REBUTTAL 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 the expert declarations of James Cantor, PhD, Paul W. Hruz, MD, PhD, Stephen B. Levine, MD, Dr. Sven Román, Michael K. Laidlaw, MD, and Geeta Nangia, MD, filed

by the Defendants in this case in opposition to Plaintiffs' Motion for Preliminary Injunction.

4. In this reply declaration, I explain how these experts inaccurately characterize the role of patients' symptoms in diagnosis, mischaracterize gender-affirming medical care as experimental, inaccurately represent European policies on this topic, inaccurately portray the informed consent process, and underestimate parents' and adolescents' medical decision-making capacity. Further, my review of the Defendants' experts' declarations has not provided me reason to change my opinion that there is no sound medical or ethical basis to prohibit healthcare professionals from providing gender-affirming medical care to minors.

Diagnosis of Gender Dysphoria and Other Medical Conditions

5. Medical care is greatly informed by patients' reports of their symptoms. As a pediatrician, when a patient's reports are unavailable, for example, a toddler with a limp or an adolescent with static encephalopathy (permanent brain damage) who is crying, diagnosis can be substantially more difficult.

6. Contrary to the Defendants' experts' claims,[1] the fact that the diagnosis of gender dysphoria relies on patients' reports of their symptoms and is not confirmed by laboratory or radiographic testing does not undermine its validity as a medical condition. In addition to the fact that most mental health conditions have this characteristic, the diagnosis of some non-mental health

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[1] Cantor 38, 283, Hruz 56, 95, Levine 218, 236, and Laidlaw 16-21, 49, 78. All references are to paragraphs in the Defendants' experts' reports unless specifically noted, e.g, Page or Footnote.

conditions also relies on patients' reports of their symptoms and are unable to be confirmed by laboratory or radiographic testing. The diagnosis of migraine headaches, for example, depends on individuals' report of the number, duration, and characteristics of their headaches. These characteristics include the headaches' location, quality, intensity, and aggravating factors as well as the presence of nausea and/or vomiting, and light and sound sensitivity.[2] Like gender dysphoria, there are no confirmatory laboratory or radiographic studies for the diagnosis of migraine headaches. Radiographic studies and electroencephalograms (EEG) are only used if the history and physical examination suggest that the headache is caused by another condition, e.g., meningitis or subarachnoid hemorrhage.[3] Clinical trials of migraine treatments, including randomized, double-bind, placebo-controlled trails, rely on participants' daily headache diaries.[4]

Gender-Affirming Medical Care
Including Clinical Practice Guidelines

7. The Defendants' experts characterize gender-affirming medical care as experimental.[5] To the extent

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[2] Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211.

[3] Steiner TJ, Jensen R, Katsarava Z, et al. Aids to management of headache disorders in primary care, 2nd edition. *J Headache Pain*. 2019;20(1):57.

[4] Powers SW, Coffey CS, Chamberlin LA, et al. Trial of amitriptyline, topiramate, and placebo for pediatric migraine. *N Engl J Med*. 2017;376(2):115-124; Ailani J, Lipton RB, Goadsby PJ, et al. Atogepant for the preventive treatment of migraine. *N Engl J Med*. 2021;385(8):695-706.

[5] Cantor 282, Hruz 115, 145, and Levine 14.

that they provide definitions of experimental, these definitions are erroneous. Dr. Cantor, for example, contends, "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 evidence (165)."[6] Dr. Cantor does not provide any references to support his claim. If this definition were correct, which it is not, many widely accepted medical treatments would be classified as experimental, including ones that the Defendants' experts accept are not experimental. The use of gonadotropin-releasing hormone (GnRH) analogs to treat central precocious puberty, for example, was approved by the U.S. Food and Drug Administration (FDA) and is accepted as the standard of care based on observational studies and not RCTs.[7] Dr. Cantor's definition of experimental appears to be based on the conclusion that gender-affirming medical care is experimental, rather than as serving as the independent basis for this conclusion.

8. Dr. Laidlaw's contention that "Dr. Antommaria fails to recognize that the purpose and use of hormones

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[6] See also "GnRH analogue medications have not been FDA approved for this use. The use of GnRH analogue medication for this purpose in adolescents is experimental as there have been no randomized controlled trials for this specific use case (Levine 75)."

[7] HIGHLIGHTS OF PRESCRIBING INFORMATION. May 2017. Accessed February 26, 2023. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020263s042lbl.pdf; Mul D, Hughes IA. The use of GnRH agonists in precocious puberty. *Eur J Endocrinol*. 2008;159(Suppl 1):S3-8; Carel JC, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009; 123(4):e752-762.

and surgeries in [gender-affirming treatment] is fundamentally different than cardiopulmonary resuscitation for life support (192)" entirely mises the point. I cited the American Heart Association's guideline for Pediatric Basic and Advanced Life Support in my expert report as an example of the limited high- and moderate-quality evidence available in pediatrics. The purpose of gender-affirming medical care and cardiopulmonary resuscitation is irrelevant to the level of evidence that supports these practices.

9. The Defendants' experts emphasize the results of systematic reviews of the literature.[8] The Cochrane Collaboration defines systematic reviews as follows: "A systematic review attempts to collate all empirical evidence that fits pre-specified eligibility criteria in order to answer a specific research question. It uses explicit, systematic methods that are selected with a view to minimizing bias, thus providing more reliable findings from which conclusion can be drawn and decisions made."[9] Key characteristics of systematic reviews include grading the quality of the evidence. Systematic reviews have many critical roles including identifying future research priorities.[10] In contrast to clinical practice guidelines, they do not, however, make treatment

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[8] Cantor 70-87, Hruz 120, 133, Levine 134-137, 176, 228-236, and Laidlaw 179.

[9] The Cochrane Collaboration. "What is a systematic review?" in *Cochrane Handbook for Systematic Reviews of Interventions.* Version 5.1.0. ed. Higgins JPT, Green S. March 2011. Accessed May 26, 2023. Available at https://handbook-5-1.cochrane.org/chapter_1/1_2_2_what_is_a_systematic_review.htm.

[10] Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *BMJ*. 2021;372:n71.

recommendations.[11] Dr. Laidlaw's statement that the conclusions of systematic reviews done by Sweden, Finland, the United Kingdom, and McMasters University "agree that the risks of puberty suppression and cross-sex hormones outweigh the possible benefits (176)" inappropriately confuses systematic reviews and clinical practice guidelines.

10. The quality of the evidence, as defined by a grading system, is only one factor considered in clinical practice guidelines when making recommendations and rating their strength. The other factors are the balance between the desirable and undesirable outcomes, the confidence in values and preferences and variability, and resource use.[12] Dr. Cantor's purported scientific expertise (9-15) is not sufficient for developing and rating treatment recommendations; clinical expertise is necessary to understand the potential benefits, risks, and patients' values and preferences, and to balance the potential benefits and risks from the patients' perspective.

11. Dr. Cantor states that individuals who provide care to patients with gender dysphoria have conflicts of interest (260, 292, 297). They do not have conflicts of interest in the relevant sense. If treatment were hypothetically to change, providers would continue to be compensated for providing this new treatment or treat-

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[11] National Heart, Lung, and Blood Institute. About systematic evidence reviews and clinical practice guidelines. Accessed May 26, 2023. Available at https://www.nhlbi.nih.gov/node/80397.

[12] 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.

ing patients with other conditions. It is unclear who Dr. Cantor expects to write clinical practice guidelines if not experts in the field. Professional organizations have mechanisms to screen potential authors of clinical practice guidelines for real conflicts of interest such as compensation from or equity interest in pharmaceutical manufacturers.

12. Several of the Defendants' experts cite comments made by Gordon Guyatt regarding the Endocrine Society's and World Professional Association for Transgender Health's (WPATH's) clinical practice guidelines.[13] These comments appear in a features article[14] written by an independent journalist[15] rather than in a peer reviewed article written by Dr. Guyatt himself. One of the potential criticisms is that the Endocrine Society's clinical practice guideline makes strong recommendations based on low- or very low-quality evidence. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach does not, however, preclude this from being done and identifies 5 situations in which it is appropriate.[16] The Defendants' experts have not shown that none of these criteria apply to the Endocrine Society's guideline. They instead seem to categorically dismiss this guideline based on allegations about its methods or results that also apply to

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[13] Hruz 98-99.

[14] Block J. Gender dysphoria in young people is rising-and so is professional disagreement. *BMJ*. Feb 23 2023;380:382.

[15] Jennifer Block. Bio. Accessed May 21, 2023. Available at http://jenniferblock.com/bio/.

[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.

clinical practice guidelines unrelated to gender dysphoria. Table 1 (Exhibit B) of my expert declaration shows that 26 of the American Heart Association's 130 recommendations (20%) in its Guideline for Pediatric Basic and Advanced Life Support are strong recommendations based on limited data.[17]

13. Several of the Defendants' experts cite disclaimers that appear in the Endocrine Society's and WPATH's clinical practice guidelines and systematic reviews accompanying WPATH's clinical practice guideline.[18] The disclaimers in the guidelines emphasize that clinicians must use their judgment in applying the guideline's recommendations to individual patients. When Dr. Levine emphasizes that "The 2017 Endocrine Society Guidelines themselves expressly state that they are *not* 'standards of care (80, italics in original),'" he inappropriately relies on the differences between the colloquial use of the term "standard of care" and its technical meaning in malpractice litigation. A provider who deviates from the guidelines does not inherently commit malpractice, i.e., violate the standard of care. The disclaimer on the systematic review reinforces the independence of the review from WPATH, the type of independent evaluation for which Dr. Cantor calls (4).

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[17] Topjian AA, Raymond TT, Atkins D, et al. Part 4: Pediatric basic and advanced life support: 2020 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation. 2020;142(16_suppl_2):S469-S523. These clinical practice guidelines use different terminology than the GRADE approach for describing the quality of the evidence and the strength of recommendations.

[18] Cantor 92-93, 254, Levine 80, and Laidlaw 175.

European Statements

14. The Defendants' experts reference the reports and decisions of European agencies.[19] Most importantly, no European country has banned gender-affirming medical care as has Tennessee. The experts' appeals to this material do not undermine the Endocrine Society's and WPATH's clinical practice guidelines for several reasons including (i) the sources are frequently not available in official English translation, (ii) the experts misrepresent or incompletely report this material, and (iii) they hold this material to a different standard.

15. No European country has banned gender affirming medical care as has Tennessee. The only categorical prohibition of a form of gender-affirming medical care appears to be the Finnish Council for Choices in Health Care's statement, "Surgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors." Pubertal suppression and gender affirming hormone treatment are nonetheless permitted for minors in Finland.[20] Furthermore, Tennessee appears to not only ban gender-affirming medical care but also the research on gender-affirming medical care for which the Defendants' experts and these European countries call.

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[19] Cantor 16-33, Hruz 131, Roman 7, 18, and Levine 77. Cf., Laidlaw 229.

[20] Palveluvalikoima. Summary: Medical treatment methods for dysphoria associated with variations in gender identity in minors —recommendations. June 16, 2020. Accessed May 21, 2023. 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.

16. Much of the material on which the Defendants' experts rely is not available in official English translations. Dr. Cantor, for example, references two Finnish documents, Pasternack 2019 (22) and COHERE Recommendation 2020 (24), quoting from the latter. These documents are in Finnish and there are not official English translations, not even of a summary.[21] Dr. Cantor's Curriculum Vita, Appendix 1, does not indicate that he has reading competency in Finnish. There are sound reasons to believe Google Translate is unreliable to translate medical documents.[22] Drs. Hruz (Footnotes 306, 315, 316) and Román (Footnote 10) reference documents posted on the Society for Evidence Based Gender Medicine's website and translated by the organiza-

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[21] Pasternack I, Söderström I, Saijonkari M, Mäkelä M. Lääketieteelliset menetelmät sukupuolivariaatioihin liittyvän dysforian hoidossa. Systemaattinen katsaus. May 15, 2019. Accessed May 21, 2023. Available at https://palveluvalikoima.fi/documents/1237350/22895008/Valmistelumuistion+Liite+1.+Kirjallisuuskatsaus.pdf/5ad0f362-8735-35cd-3e53-3d17a010f2b6/Valmistelumuistion+Liite+1.+Kirjallisuuskatsaus.pdf?t=1592317703000; Palveluvalikoima. Palveluvalikoimaneuvoston suositis: Alaikäisten sukupuoli-identiteetin variaatioihin liittyvän dysforian lääketieteelliset hoitomenetelmät. Accessed May 21, 2023. Available at https://palveluvalikoima.fi/documents/1237350/22895008/Alaik%C3%A4iset_suositus.pdf/c987a74c-dfac-d82f-2142-84f8ddead64/Alaik%C3%A4iset_suositus.pdf?t=1592317701000. See also Roman's (21) reference to Trysell K. De flesta har skärpt rutiner för ny hormonbehandling hos minderåriga. September 9, 2021. Accessed May 21, 2023. Available at https://lakartidningen.se/aktuellt/nyheter/2021/08/de-flesta-har-skarpt-rutiner-for-nyhormonbehandling-hos-minderariga/.

[22] Cornelison BR, Al-Mohaish S, Sun Y, Edwards CJ. Accuracy of Google Translate in translating the directions and counseling points for top-selling drugs from English to Arabic, Chinese, and Spanish. *Am J Health Syst Pharm*. 2021;78(22):2053-2058.

tion. This is an advocacy organization[23] and it does not provide documentation that the translations were performed by a certified translator.[24] Other documents have broken links[25] or original sources are not specified.[26] It, therefore, is difficult to evaluate the Defendants' experts' claims and one must question how they are able to make them in the first place.

17. With respect to the experts' characterization of these materials, they are frequently inaccurate or incomplete. Dr. Cantor, for example, asserts "These range from medical advisories to outright bans on the medical transition of minor (16)." As described above, no European county has banned the medical transition of minors. Some experts reference the British High Court opinion in *Bell v. Tasistock* without acknowledg-

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[23] Society for Evidence Based Gender Medicine. About Us. Accessed May 21, 2023. Available at https://segm.org/about_us.

[24] See, for example, Palveluvalioima. SEGM unofficial translation: Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland). Accessed May 21, 2023. Available at https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation_0.pdf.

[25] The link to Swedish Socialstyrelsen Support 2022 (Cantor 25), https://www.socialstyrelsen.se/globalassets/sharepointdokument/artikelkatalog/kunskapsstod/2022-2-7774.pdf, resulted in a 404 error when I attempted to access the page on May 21, 2023.

[26] Cantor quotes from "a new policy statement" from the Karolinska Instiute, Karolisnka 2021, but does not provide a source for this statement in his references or clarify who translated it. See also Ukom 2023. While this document does appear to be available on the internet, it is only available in Norwegian. Ukom. Pasientsikkerhet for barn og unge med kjønnsinkongruens. March 9, 2023. Accessed May 21, 2023. Available at https://ukom.no/rapporter/pasientsikkerhetfor-barn-og-unge-med-kjonnsinkongruens/sammendrag.

ing that this ruling was overturned on appeal[27] or incorrectly stating that it is still being appealed.[28] Finally, some experts emphasize that these countries constrain the provision of gender-affirming medical care to research protocols[29] without acknowledging that this research need not be randomized controlled trials. For example, the Swedish National Board of Health and Welfare (NBHW) states, "To ensure that new knowledge is gathered, the NBHW further deems that treatment with GnRH-analogues and sex hormones for young people should be provided within a research context, which does not necessarily imply the use of randomized controlled trials (RCTs)."[30] This undermines

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[27] Roman 7, 18. Cf., Cantor 18 and Laidlaw 229-30. See Bell v. The Tavistock and Portman NHS Foundation Trust [2021] EWCA Civ 1363 Appeal No. C1/2020/2142. September 17, 2021. Accessed May 22, 2023. Available at https://www.judiciary.uk/judgments/bell-and-another-v-the-tavistock-and-portman-nhs-foundation-trust-and-others/. Also relevant and unmentioned is a separate case involving the Trust in which the High Court ruled that parents can consent to the use of GnRH analogues if their child does not dissent. See AC v. CD [2021] EWHC 741 (Fam) Case No. FD21P00063. March 26, 2021. Accessed May 22, 2023. Available at https://www.judiciary.uk/judgments/ac-v-cd-and-ors/.

[28] Levine 77. See The Supreme Court. Permission to appeal. Accessed May 22, 2023. Available at https://www.supremecourt.uk/news/permission-to-appeal-april-may-2022.html.

[29] Cantor 20, 21.

[30] Socialstyrelsen. Care of children and adolescents with gender dysphoria: Summary. Accessed May 21, 2023. Available at https://www.socialstyrelsen.se/globalassets/sharepointdokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf. See also, The Cass Review. Independent review of gender identity services for children and young people: Interim report. February 2020. Recommendation 8, Page 22. Accessed May 21, 2023. Available at https://cass.independentreview.uk/publications/interim-report/.

Dr. Cantor's claim that randomized controlled trials are feasible (286).

18. None of these documents meet the standards to which the Defendants' experts hold the Endocrine Society and WPATH. The Swedish National Board of Health and Welfare summary of its December 2022 National Guidelines for the care of children and adolescents with gender dysphoria, for example, does not clearly enumerate its recommendations. Some, but not all, of its recommendations are bulleted and bullets are also used to denote reasons for the recommendations. This makes it difficult to identify the recommendations. The quality of the evidence supporting each recommendation and the strength of the recommendation is not consistently specified. Finally, it does not appear from the summary that a systematic review of the literature was conducted in the formulation of each and every recommendation.[31] The Defendants' experts appear to hold materials which they believe supports their position to a lower standard.

19. Finally, it should be noted that the Defendants' experts do not provide a systematic review of European policies; they selectively reference policies that they believe support their position.

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[31] Socialstyrelsen: The National Board of Health and Welfare. Care of children and adolescents with gender dysphoria: Summary of national guidelines. December 2022. Accessed May 22, 2023. Available at https://www.socialstyrelsen.se/globalassets/sharepointdokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf

Informed Consent for Gender-Affirming Medical Care

20. The Defendants' experts inappropriately focus on adolescents', rather than their parents', consent.[32] Dr. Levine, for example, states "Given the considerable risk of harms, which include premature death and other less obvious problems discussed in this report, the question of whether minors may provide consent for medical and surgical treatments quickly arises (137, reference omitted)." Except in exceptional circumstances, for example, a minor has been emancipated by the court, the consent of parents or legal guardians is required for gender-affirming medical care for minors.

21. Dr. Nangia's claim "I don't believe that parents should be able to provide medical consent with minor assent for medical gender transition (135, see also 158)" highlights the ban's inconsistent treatment of different medical conditions. Dr. Nangia argues that "for a parent to provide consent to non-emergent treatment that stand to affect the rest of a minor's life in every area, and to do so without the minor's full ability to appreciate the above debate and potential long-term ramifications, violates the minor's future right to autonomy (135)."[33] The ban however permits other medical treatments to which this statement would apply; the ban permits the performance or administration of medical procedures to treat a minor's congenital defect which includes differences of sex development (DSD) 68-33-103(b)(1)(A).

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[32] Levine 237 and Nangia 71.

[33] Dr. Nangia's claim is inapplicable to gender-affirming medical care because this medical care is not "non-emergent"; delaying gender-affirming medical care permits the development of secondary sexual characteristics inconsistent with an individual's gender identity that are irreversible.

Non-emergent medical procedures, to which parents can consent, to treat DSD which have similar long-te ramifications include feminizing genioplasty and gonadectomy. The ban treats different medical conditions inequitably and Defendants' experts' claims highlight the lack of justification for the differential treatment.[34]

22. Claims that parents and legal guardians are inadequately informed or coerced lack empirical evidence. Dr. Levine, for example, asserts without supporting evidence that "Many affirmative care clinicians, because they don't understand the vital differences between suicidality and suicide, provide unethical coercive guidance commonly summarized as, 'Would you rather have a trans daughter than a dead son (205)?'" Although he refers to minors, Dr. Hruz also makes an unsubstantiated empirical claim regarding informed consent: "Using 'affirming' treatment on minors violates this essential principle by using experimental treatments on vulnerable population without properly informing them of the actual risks and limitations of treatment (114)." He provides no evidence that parents or their adolescent children are not properly informed. Even if these claims were true, and I am not conceding that they are, there are other less restrictive means to address inadequate informed consent than banning

[34] Dr. Nangia also provides cosmetic surgery in minors, specifically breast augmentation for patients under 18 years old, as an example of a procedure for which it is difficult to obtain meaningful informed consent (159-161). This procedure, however, also appears to be permitted under the ban if it is not performed as part of gender-affirming medical care.

gender-affirming medical care. Such means include credentialing,[35] licensing,[36] and malpractice litigation.[37]

23. Claims that parents cannot understand the relevant information is also without foundation. Dr. Levine, for example, claims, "[parents] cannot be expected to understand the limitations of the science pointed out by the Swedish systemic review (237)."[38] Why not? Parents can understand that gender-affirming medical care might not have the benefits predicted and that it might have future risks that have not yet been proven such as effects on executive function. When parents enrolled their children in clinical trials of COVID-19 vaccines, for example, they understood that the vaccine might not be effective and that there were potentially unknown side-effects. This is in the context of an irreversible intervention; a vaccine cannot be removed once administered. Even after COVID-19 vaccines were authorized by the FDA for pediatric age groups, there remained uncertainty about side-effects both because the vaccines were tested on relatively small groups of children and because follow up had been for a limited time. The FDA issued an Emergency Use Authorization for the Pfizer-BioNTech vaccine for children 5 to 11 years of age based on studies of approximately 4,700 children

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[35] Patel R, Sharma S. Credentialing. *StatPearls*. October 30, 2021. Accessed May 22, 2023. Available at https://www.ncbi.nlm.nih.gov/books/NBK519504/.

[36] Federation of State Medical Boards. About Physician Discipline. Accessed May 22, 2023. Available at https://www.fsmb.org/u.s.-medical-regulatory-trends-and-actions/guide-to-medicalregulation-in-the-united-states/about-physician-discipline/.

[37] Dobbs D, Hayden P, Bublick E. Liability of health care providers. *Hornbook on Torts*. 2nd ed. West Academic Publishing; 2016.

[38] See also Hruz 111.

and examined the risk of contracting COVID-19 7 days after the second dose.[39] Decisions parents make regarding gender-affirming medical care are comparable to other decisions that they make for their children, which the Defendants' experts do not appear to challenge.

24. Dr. Nangia asserts that the tasks necessary for a minor to provide informed consent for gender-affirming medical care are insurmountable (119, see also 132-134, 152-156, 168).[40] She, however, acknowledges that the MacArthur Competence Assessment Tool (MacCAT) has been shown to be valid and reliable in children (79). Lieke J.J.J. Vrouenraets and colleagues used the treatment version of this tool to assess the capacity of transgender adolescents, who had completed their diagnostic evaluation and were ready to start puberty suppression, to consent. (Individuals who were not yet Tanner Stage 2 or who had serious psychiatric conditions or psychopathology that would interfere with treatment were appropriately not included in this study.) Seventy-three adolescents participated. Their mean age was 14.71 years old, and their ages ranged from 10.63 to 18.34. Sixty-six (89.2%) of the participants were judged to have medical decision-making capacity using this tool.

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[39] U.S. Food & Drug Administration. FDA authorizes Pfizer-BioNTech COVID-19 vaccine for emergency use in children 5 through 11 years of age. October 29, 2021. Accesses May 21, 2023. Available at https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizerbiontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age.

[40] See also Cantor 235, Hruz 107, Levine 28, 202, and Laidlaw 302.

25. Dr. Nangia does not discuss this study and the potential reasons for the significant discrepancy between her opinion and this evidence. One potential confounder is her belief in the efficacy of exploratory therapy (117) and her view that "impulse-prone" adolescents are more likely to choose gender-affirming medical care because they perceive it to be "quicker" (118). Dr. Nangia, however, does not present evidence for the efficacy of what she characterizes as exploratory therapy to treat gender dysphoria. Dr. Levine, one of the Defendants' other experts, states, "To my knowledge, there is no evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boy, adolescents, and men, or return to female identification for genetically female girls, adolescents, and women (45)." Dr. Cantor would emphasize that this is one of the lowest, if not the lowest, levels on the Pyramid of Standards of Evidence (Figure 1, Page 18).

26. The logical conclusion of some of the experts' views is that the age of majority should be increased until individuals have completed their neurological development in their mid-20s. Dr. Román, in fact, claims, "It is my opinion that the irreversible measure of sterilization should not be carried out until the age of 25 [when the frontal lobe matures], and it is therefore appropriate to have the same age limit for gender reassignment treatment for gender dysphoria (39)." The ban does not however prohibit all sterilizing procedures on minors, demonstrating again the inequitable treatment of gender-affirming medical care and other forms of medical treatment. Although sterilization is not the intent of gender-affirming medical care and the potential infertility caused by pubertal suppression and gender-affirming

hormones is not universal or always permanent, treatments permitted by the law, including gonadectomy in minors with DSD, cause permanent infertility.

Conclusion

27. My review of the Defendants' experts' reports has not provided me reason to change my opinion that "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: May 29, 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

AND

UNITED STATES OF AMERICA, PLAINTIFF-INTERVENOR

v.

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

EXPERT REBUTTAL DECLARATION OF ARON JANSSEN, M.D.

I, Aron Janssen, M.D., hereby declare and state as follows:

1. I am over 18 years of age, of sound mind, and in all respects competent to testify.

2. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation. The opinions expressed in this declaration are my own and do not express the views or opinions of my employer.

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

4. I incorporate as part of this rebuttal declaration my opinions and qualifications set forth in the expert declaration I filed in this matter dated April 17, 2023. Since that date, I have testified as an expert at trial or by deposition in: *Dekker v. Weida*, No. 4:22cv325 (M.D. Fla.) (trial).

5. I submit this rebuttal declaration to respond to the expert declaration by Geeta Nangia, M.D., dated May 19, 2023, which Defendants have submitted in this case.

SUMMARY OF OPINIONS

6. Based on her declaration and curriculum vitae, Dr. Nangia does not appear to have a sufficient clinical basis for offering expert opinions regarding the diagnosis and treatment of gender dysphoria in children and adolescents, or the assessment and informed consent process involved when treating adolescents with gender dysphoria with gender affirming care. Her declaration appears to be based on a series of hypothetical assumptions about how other mental health practitioners are diagnosing minors with gender dysphoria and recommending treatment—without any direct experience doing so herself, and without any apparent knowledge of how care is actually provided by others.

7. Dr. Nangia's wildly implausible claim to have treated "550 children and adolescents (and hundreds of adults) who have met criteria at some point in their lives for a 'gender dysphoria' diagnosis," Nangia Decl. ¶ 48, reflects a profound misunderstanding of how gender dysphoria is diagnosed and an inability to distinguish between people with gender dysphoria—a medical condition requiring clinically significant distress or impairment in social, occupational, or other important areas of

functioning—and people who are simply gender non-conforming.

8. While Dr. Nangia speculates that people are being misdiagnosed with gender dysphoria because they are tomboys, or have co-occurring medical conditions, or have experienced trauma, those speculations appear to be based on her own misunderstanding of how gender dysphoria is properly diagnosed.

9. Dr. Nangia also appears to assume that mental health providers working with transgender youth are not explaining risks and benefits and are unfamiliar with principles of informed consent and assent. Once again, that speculation appears to be based on her own misunderstanding of how care is actually provided by specialists in the field.

10. Dr. Nangia also does not appear to have an expert basis for her speculation that an increasing number of youth are being diagnosed with gender dysphoria as a result of factors such as "social media" or "social contagion." None of Dr. Nangia's speculation is supported by actual evidence, and her personal opinions do not reflect the common views of experts in the field.

EXPERT OPINIONS

A. Dr. Nangia Lacks Experience or Familiarity with Properly Diagnosing Gender Dysphoria.

11. I have significant questions about Dr. Nangia's actual experience working with transgender youth. Dr. Nangia implausibly claims to have evaluated and treated "550 children and adolescents (and hundreds of adults) who have met criteria at some point in their lives for a 'gender dysphoria' diagnosis," including 350 patients who "had a history of gender dysphoria, as discovered

on evaluation or over the course of patient care," and "close to 100 additional child patients who meet criteria for gender dysphoria on clinical interview during or over the course of treatment with [her]" and "just over 100 adolescents who have presented with gender dysphoria that has been more abrupt in onset." Nangia Decl. ¶¶ 48-49, 52. While claiming that these 550 children and adolescents met criteria for gender dysphoria, Dr. Nangia does not claim to have provided any actual treatment for that condition.

12. Dr. Nangia appears to derive her claim to have worked with "550 children and adolescents who have met criteria at some point in their lives for a 'gender dysphoria' diagnosis," based on patient case histories that she thinks could have hypothetically supported a gender dysphoria diagnosis. But a proper diagnostic evaluation requires more than reviewing a simple case history. As Dr. Nangia herself notes "in mental health, if a five-year-old patient presented with difficulty with affect regulation, as well as trouble focusing and being still in the classroom, most physicians would not diagnose ADHD on initial assessment," and would instead evaluate those symptoms within the context of other psychosocial developments in the child's life, while keeping in perspective what we know about the typical emotional and neurological development of children that age. Nangia Decl. ¶ 125. Just as most physicians would not immediately diagnosis a 5-year-old child with difficulty in affect regulation as having ADHD, most physicians would not claim to have worked with 550 patients who had ADHD based on the fact that those patients reported having trouble sitting still when they were 5 years old. Nor would most physicians claim to

be experts in treating ADHD based on those case histories.

13. Dr. Nangia's assumption that 550 of her patients *could* have been diagnosed with gender dysphoria also reflects a failure to distinguish between people who have gender dysphoria and people who are simply gender nonconforming. Most critically, Dr. Nangia fails to appreciate that a diagnosis of gender dysphoria in children or adolescents requires "clinically significant distress or impairment in social, occupational, and other important areas of functioning." DSM-5-TR

14. Dr. Nangia concedes she has "difficulty appreciating th[e] distinction" between gender nonconformity and gender discordance. Nangia Decl. ¶ 24. But to be qualified to make a diagnosis, one must understand what that diagnosis is. That is why mental health providers making a gender dysphoria diagnosis should have the training and experience to provide a thorough and comprehensive evaluation that can distinguish gender non-conforming behaviors from a core incongruence of identity with associated distress. Treating patients with gender dysphoria also involves educating patients and their parents and caregivers about the difference between preferred play, dress, and playmates and core identity concerns.

15. Here and elsewhere, Dr. Nangia inexplicably assumes that mental health providers somehow disregard everything else they know about adolescent development and identity formation when they make a gender dysphoria diagnosis. In reality, when assessing adolescents for gender-affirming medical care, providers engage in a comprehensive assessment that takes precisely these considerations into account. Understand-

ing potential reinforcers of identity and challenging patients' assumptions with an aim of developing a nuanced sense of self is a core component of the diagnostic assessment.

16. Dr. Nangia speculates that people with symptoms of gender dysphoria are not being assessed to see if they have suffered other trauma. Like other mental health providers, mental health providers who specialize in gender dysphoria are familiar with treating traumatized youth. We assess patients for trauma, and we assess for how trauma informs identity or complicates a gender dysphoria diagnosis. If an adolescent's identity questions are secondary to trauma, that patient would not meet criteria for the diagnosis of gender dysphoria. But transgender adolescents may experience trauma and still have gender dysphoria that independently requires gender-affirming care to be treated properly.

17. Dr. Nangia also speculates that transgender youth are being misdiagnosed when they have other co-occurring mental health conditions. I have extensive clinical and research experience working with transgender youth who have co-occurring mental health diagnoses. The WPATH Standards of Care specifically recommend that providers who assess adolescents for gender-affirming care should have experience and training to distinguish between gender dysphoria and other mental health conditions or developmental anxieties. But the existence of a co-occurring mental health diagnosis is not—by itself—a reason to withhold care for gender dysphoria. It is important that co-occurring conditions are treated. And if co-occurring conditions impair the individual's capacity to understand the interventions in question, we have to treat those conditions before any medical care for gender dysphoria would be

initiated. But there is no evidence that treating co-occurring mental health conditions resolves gender dysphoria. In the same way that we would not expect that treating anxiety is going to get rid of ADHD, treating anxiety, for example, is not going to get rid of gender dysphoria.

B. Dr. Nangia Lacks Familiarity With Procedures for Informed Consent to Gender-Affirming Care.

18. As with her other speculations, Dr. Nangia wrongly assumes that other mental health providers are not explaining risks and benefits of medical interventions for gender dysphoria or are unfamiliar with principles of informed consent and assent. But a fundamental part of assessment for gender-affirming care is determining whether the minor can understand and articulate to the best of their ability the risks, benefits, and alternatives of that intervention, and determining whether parents can provide consent for that intervention. The risks and benefits associated with gender-affirming care are not more difficult to understand than those associated with other mental health conditions.

19. Dr. Nangia asserts that adolescents have developing brains that cannot think about long-term consequences. But a decision to receive pubertal suppression or hormone therapy for gender dysphoria is not a spur-of-the-moment decision. For gender dysphoria care, it is inherent to our assessment that we are evaluating an individual's cognitive capacity, capacity to understand, and ability to think through potential consequences. These are discussions and assessments that occur longitudinally over time, and these are decisions that adolescents and family are making over a long period and not in a moment.

20. In my psychiatric practice, I have seen a tremendous benefit from these interventions. I have seen individuals who blossom when they are able to express and live their lives according to their experienced gender after receiving medical intervention to treat gender dysphoria. And I have seen so much joy and improvement in functioning when adolescents receive the care that is clinically indicated.

C. Dr. Nangia's Speculations About Social Causes of Gender Dysphoria Are Not Based on Any Apparent Expert Knowledge and Lack Scientific Support.

21. Access to medical care for transgender youth with gender dysphoria has dramatically improved over the past 20 years. Instead of attributing an increase in the number of gender dysphoria diagnoses to increased access to care, Dr. Nangia speculates about other phenomena that she views as causes. But none of Dr. Nangia's speculation is supported by actual evidence, and her personal opinions do not reflect the common views of others in the field.

22. Dr. Nangia speculates that children and adolescents are being diagnosed with gender dysphoria because of an "[i]ncrease in pathologization of a normal part of childhood development." Nangia Decl. ¶ 21. Dr. Nangia acknowledges that "[g]ender-medicine experts today distinguish between tomboys or tomgirls and children with gender dysphoria," but she speculates without any evidence that "[m]any parents, who in the past simply would not have worried about their children" who are tomboys or tomgirls "are now compelled to consider a diagnosis of gender dysphoria" and that "[p]hysicians likewise, are acting quickly to usher these children into gender-affirming care." Nangia Decl. ¶¶ 22,

25. There is no evidence that these sorts of misdiagnoses are occurring in significant numbers by practitioners experienced in providing gender-affirming care. In fact, what we see is the opposite. In clinical care, parents are less likely to be concerned by stereotypical non-conforming behaviors than in the past.

23. Dr. Nangia also attributes gender dysphoria diagnoses to social media. But there is no evidence to suggest that social media has led to an increase in youth identifying as transgender. Nor is this a widely-held belief of most child psychiatrists in my experience.

24. Expertise in a field means drawing from the relevant literature. While not commenting on the quality of the New York Times as a news source, it is not a reference from which psychiatrists should make assertions about their clinical practice. And yet, in quoting from the Wortham 2018 article in the New York Times (Nangia Decl. ¶ 30), Dr. Nangia seems to misunderstand the underlying scientific literature being discussed. The study by Helana Darwin discussed in the New York Times article actually contradicts Dr. Nangia's assertions that social media leads to an increase in gender dysphoria. Darwin, H. (2017), Doing Gender Beyond the Binary: A Virtual Ethnography. Symbolic Interaction, 40: 317-334. In that article, individuals who already had a non-binary identity sought out online spaces of support. It was not the online space that created the identity.

25. Although Dr. Nangia divides her speculation into different headings of "social media," "heightened vulnerability" and "social contagion," all of these sections reflect the same speculation that more people are identifying as transgender because of social influences. The

only evidence Dr. Nangia cites in support of this speculation is a highly controversial article that purported to survey parents who believe their children experienced what the parents view as "rapid onset gender dysphoria," which is not an actual diagnostic term or concept. See Littman, L. (2018). Parent reports of adolescents and young adults perceived to show signs of a raid onset of gender dysphoria. PLoS ONE, 13(8), e0202330. Although purporting to provide a basis for Dr. Nangia's speculations, the study was based on an anonymous survey, allegedly of parents, about the etiology of their child's gender dysphoria. Participants were recruited from websites promoting this social-contagion theory, and the children were not surveyed or assessed by a clinician. Those serious methodological flaws render the study unreliable. The only conclusion that can be drawn from that study is that a self-selected sample of anonymous people recruited through websites that predisposed participants to believe that transgender identity can be influenced by social factors believe those social factors influence children to identify as transgender.

26. It is a normal developmental process for adolescents to seek out peers with shared experiences. This is not unique to transgender and gender-diverse young people. All types of minoritized youth tend to seek out affinity groups with those that share their experiences. In my experience, transgender youth also seek out those social connections. It is not the social connections that leads to the identity, but it is the identity that leads to seeking out these social connections.

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

Executed this 30th day of May 2023.

/s/ ARON JANSSEN
ARON JANSSEN, M.D.

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

AND

UNITED STATES OF AMERICA, PLAINTIFF-INTERVENOR

v.

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

EXPERT REBUTTAL DECLARATION OF JACK TURBAN, MD, MHS

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. My background and credentials are outlined in my initial declaration.

4. I reviewed the declarations of Drs. Cantor, Hruz, Levine, Roman, Laidlaw, and Nangia. Here, I respond to some of the central points in those declarations. I do not specifically address each study or article cited, but instead explain the overall problems with some of the conclusions that Defendants' experts draw and provide

data showing why such conclusions are in error. I reserve the right to supplement my opinions if necessary as the case proceeds.

DEFENDANTS' EXPERTS' CLAIM THAT TENNESSEE'S BAN ON GENDERAFFIRMING MEDICAL CARE FOR ADOLESCENT GENDER DYSPHORIA IS "IN LINE WITH INTERNATIONAL CONSENSUS" IS NOT ACCURATE

5. Defendants' experts rely on reports from a handful of European countries and imply that Tennessee's ban on gender-affirming medical care is in line with "international consensus." This is not accurate. Of note, the vast majority of these reports were not peer-reviewed. Some of these reports are older and do not include the most recent research demonstrating the efficacy of the banned treatments. And others do not include all of the relevant literature. Most importantly, though, Defendants' experts fail to emphasize that none of these countries have banned gender-affirming medical care for adolescents with gender dysphoria as Tennessee does. Rather, the select countries referenced have changed the way in which gender-affirming care is being delivered (e.g., moving care to settings where more data can be collected, as in Sweden, or creating several regional clinics instead of one centralized clinic, as in the United Kingdom). Rather than put it in line with "international consensus," Tennessee's broad ban on gender-affirming medical care for adolescent gender dysphoria puts the law squarely outside of mainstream medical views and policies around the world. In the United States, the major relevant expert medical organizations (e.g., the American Medical Association, the American Academy of Pediatrics, the American Psychi-

atric Association, and the American Academy of Child & Adolescent Psychiatry) explicitly oppose such bans.[1]

THOUGH RANDOMIZED CONTROLLED TRIALS OFTEN REPRESENT HIGHER QUALITY EVIDENCE THAN OTHER STUDY DESIGNS, THEY ARE NOT ETHICAL IN THE REALM OF GENDER-AFFIRMING CARE FOR ADOLESCENT GENDER DYSPHORIA AND EXISTING RESEARCH PROVIDES VALUABLE INFORMATION ON QUESTIONS OF CORRELATION VERSUS CAUSATION

6. Defendants' experts spend a great deal of time focusing on randomized controlled trial study designs and questions of correlation versus causation. It is true that randomized controlled trials provide valuable information that other studies do not; however, as noted in my initial declaration, they are not considered ethical in this area and would not be approved by an Institutional Review Board. For this reason, experts in this field look at the body of a literature as a whole to address certain questions.

7. As Dr. Cantor notes in his declaration, there are three possibilities when a study finds a correlation between two variables X and Y: "that X causes Y [causation], that Y causes X [reverse causation], or that there is some other variable Z, that causes both X and Y [confounding effect]." (Cantor Decl. ¶ 59). In this case, the question is whether gender-affirming medical care (X)

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[1] For a list of statements from major medical organizations opposing legislative bans on gender-affirming medical care for adolescent gender dysphoria, 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), 2251-52.

causes improved mental health outcomes for adolescents with gender dysphoria (Y).

8. The question of "reverse causation" (*i.e.*, the notion that improved mental health causes one to access gender-affirming medical care rather than the reverse, that gender-affirming medical care leads to better mental health) has been examined in the literature. For example, in a recent major publication in *The New England Journal of Medicine*, Chen et al. used a technique called parallel process modeling and found that improvements in mental health tracked along with improvements in appearance congruence over time (a measure of the degree to which study participants' bodies aligned with their gender identities), suggesting that gender-affirming medical care was the cause of the improvements in mental health, and arguing against the notion of reverse causation.[2]

9. The question of "confounding effect" has also been examined in several ways. For instance, a 2022 paper from my research group assessing the relationship between treatment with gender-affirming medical interventions and improved mental health adjusted for a range of potentially confounding variables including age, gender identity, sex assigned at birth, sexual orientation, race/ethnicity, level of family support for gender identity, relationship status, level of education, employment status, household income, having ever received pubertal suppression, having ever been exposed to gender identity conversion efforts, and having expe-

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[2] 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), 240-50.

rienced any harassment based on gender identity in school.[3] Even after adjusting for these potential confounding factors, the study found that treatment with gender-
affirming medical care during adolescence was associated with lower odds of adverse mental health outcomes.

10. Another potential confounder that Defendants' experts raise is whether or not participants received supportive psychotherapy in addition to gender-affirming medical care. Of note, there is no evidence-based psychotherapy that treats gender dysphoria itself, so such therapy is generally aimed at supporting the patient in general with their mental health. At least two studies provide evidence against the notion that mental health improvements were due to supportive psychotherapy rather than gender-affirming hormone treatment. Achielle et al. ran regression analyses in order to separate out the impacts of gender-affirming medical interventions from the impact of counseling and psychiatric medications.[4] Though the sample size made it difficult to detect differences, they nonetheless found that pubertal suppression was associated with better scores on the Center for Epidemiology Studies Depression Scale,

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[3] 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.

[4] Achille, C., Taggart, T., Eaton, N. R., Osipoff, J., Tafuri, K., Lane, A., & Wilson, T. A. (2020). Longitudinal impact of gender-affirming endocrine intervention on the mental health and wellbeing of transgender youths: preliminary results. *International Journal of Pediatric Endocrinology*, *2020*(1), 1-5.

which was a statistically significant finding.[5] Costa et al. examined two cohorts of adolescents with gender dysphoria. Both cohorts received six months of supportive psychotherapy for the initial six months of the study. For the next six months, one group continued to receive supportive psychotherapy alone, while the other received supportive psychotherapy *and* pubertal suppression. The group that received pubertal suppression in addition to psychotherapy experienced statistically significant improvement in global functioning over that second course of six months, while the group that received supportive psychotherapy alone did not.[6]

DEFENDANTS' EXPERTS' DISCUSSION OF CHILDHOOD VERSUS ADOLESENT ONSET OF GENDER DYSPHORIA DOES NOT SUPPORT BANNING GENDER-AFFIRMING MEDICAL CARE

11. Defendants' experts draw a distinction between those who first come to experience gender dysphoria in early childhood and those who first come to experience gender dysphoria in adolescence (i.e., after the onset of puberty). They imply that those who first recognize

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[5] It is important to note that in statistics, a statistically significant finding tells you that a finding is likely to represent a true effect and the finding wasn't due to random chance. In contrast, the lack of a statistically significant finding doesn't tell you one way or another if there is an effect. I would caution against over-interpreting non-statistically significant findings. Lack of a statistically significant finding doesn't mean that no effect exists, it simply means the analysis in question does not tell the researchers one way or another if an effect exits.

[6] Costa, R., Dunsford, M., Skagerberg, E., Holt, V., Carmichael, P., & Colizzi, M. (2015). Psychological support, puberty suppression, and psychosocial functioning in adolescents with gender dysphoria. *The Journal of Sexual Medicine*, *12*(11), 2206-14.

gender dysphoria in adolescence will not continue to hold a gender identity different from their sex assigned at birth later in life. There is no evidence to support this claim. Additionally, it is important to note that Tennessee's ban on gender-affirming medical care is a broad ban on all gender-affirming medical care, regardless of whether the patient experienced childhood-onset gender dysphoria or adolescent-onset gender dysphoria.

12. It is true that some past studies on the benefits of gender-affirming medical care were limited to patient populations who first knowingly experienced gender dysphoria in early childhood (e.g., deVries et al. 2014). However, these are not the only studies documenting improved mental health from treatment. Other studies have similarly shown improved mental health for adolescents with gender dysphoria treated with pubertal suppression and gender-affirming hormones in contexts where the studied population was not limited to those experiencing early childhood onset gender dypshoria. Correspondingly, the clinical guidelines do not recommend that those who first experience gender dysphoria in adolescence be ineligible for gender-affirming medical care. The WPATH Standards of Care 8, for instance, highlight that those with an absence of gender incongruence during the prepubertal childhood period may warrant "a more extended assessment process," but are still candidates for care. Likewise, a recent publication from our group found that it is not uncommon for transgender people to first come to understand their transgender identity in adolescence or later.[7] In this

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[7] Turban, J. L., Dolotina, B., Freitag, T. M., King, D., & Keuroghlian, A. S. (2023). Age of Realization and Disclosure of Gender

sample of over 27,000 transgender adults, 40.8% reported first coming to realize their transgender identity during adolescence or adulthood. Though one's transgender identity has a strong biological basis, as described later in this declaration, it can take some time for individuals to ascribe language to their transgender identity or gender dysphoria, and it can also take a substantial period of time to overcome the stigma associated with a transgender identity to be able to openly accept one's transgender identity. Thus, a lack of expressed early childhood gender incongruence does not necessarily indicate less severe gender dysphoria, or that gender-affirming medical care will not be effective.

13. Dr. Cantor raises "particular concern" that adolescent-onset gender dysphoria may actually represent borderline personality disorder (BPD). (Cantor Decl. ¶ 160). There is no evidence to support this theory. Existing guidelines emphasize the importance of a comprehensive biopsychosocial mental health evaluation, designed to differentiate other mental health conditions (e.g., BPD or body dysmorphic disorder from gender dysphoria), prior to initiating gender-affirming medical care. Of further note, a recent peer-reviewed paper in *The Harvard Review of Psychiatry* emphasized the ways in which certain potential indicators of other conditions, like BPD, can be differentiated from gender

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Identity Among Transgender Adults. *Journal of Adolescent Health*, *72*(6), 852-59.

dysphoria.[8] It also noted that it is rare for BPD to lead to a transgender identity through "identity diffusion."[9]

DR. CANTOR FALSELY CLAIMED THAT I MADE AN ERROR IN MY CHARACTERIZATION OF HOW DIAGNOSTIC CRITERIA CHANGED FROM DSMIV TO DSM-5

14. In my initial declaration, I explained that the DSM-IV diagnosis of "gender identity disorder in children" did not require a child to identify as a gender different from their sex assigned at birth, an issue that was remedied with the DSM-5's "gender dysphoria" diagnosis. Dr. Cantor claimed that the DSM-5 diagnosis of gender dysphoria did not require one to identify with a gender different from their sex assigned at birth and the DSM-IV diagnosis of "gender identity disorder in children" did. (Cantor Decl. ¶ 308). However, he failed to note, despite pasting the DSM-5 criteria into his declaration, that the DSM-5 gender dysphoria diagnosis states that the criterion A1 is required for the diagnosis: "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." The prior DSM-IV diagnosis of "gender identity disorder in children" did not require this, and one could qualify for the diagnosis by meeting criterion A2-A5, none of which require a gender identity different from one's sex assigned at birth, creating the potential for cisgender

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[8] Goldhammer, H., Crall, C., & Keuroghlian, A. S. (2019). Distinguishing and addressing gender minority stress and borderline personality symptoms. *Harvard Review of Psychiatry*, *27*(5), 317-25

[9] *Id.*

"tomboys" or cisgender males with "feminine interests" to meet those old diagnostic criteria.

DEFENDANTS' EXPERTS' ASSERTION THAT SOCIAL TRANSITION AND/OR GENDER-AFFIRMING MEDICAL CARE INTENSIFY GENDER INCONGRUENCE IS NOT SUPPORTED BY EVIDENCE

15. The Defendants' experts spend a considerable portion of their declarations discussing social transition. This refers to when a transgender person adopts a gender expression (i.e., a name, pronouns, clothes, etc.) that aligns with their gender identity. This does not involve any of the medical interventions banned by the Tennessee law at issue in this case. Nevertheless, it is worth noting that the assertions made by the Defendants' experts about this issue are not supported by evidence. For example, Dr. Levine states: "Social transition of young children is a powerful psychotherapeutic intervention that radically changes outcomes, almost eliminating desistence." (Levine Decl. ¶ 122). This assertion is premised on the presumption that a social transition will make a child identify more strongly as transgender and therefore be less likely to ultimately "desist" and maintain a cisgender identity. However, research has shown that gender identification is not significantly different before and after a social transition.[10] Rae et al. *Psychological Science* 2019 makes clear that this association—between prepubertal social transition and transgender identity—is because those who undergo a pre-pubertal social transition had stronger discordance between their sex assigned at birth and their

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[10] Rae, J. R., Gülgöz, S., Durwood, L., DeMeules, M., Lowe, R., Lindquist, G., & Olson, K. R. (2019). Predicting early-childhood gender transitions. *Psychological Science*, *30*(5), 669-81.

gender identity to begin with, and that social transition itself does not increase gender discordance. Defendants' experts proceed to point to studies showing that over 98% of transgender adolescents who start pubertal suppression go on to start gender-affirming hormones, in order to suggest that pubertal suppression increased these adolescents' gender incongruence. It is a logical fallacy to infer that a study showing that 98% of adolescents on puberty blockers proceeding on to gender-affirming hormones is evidence that puberty blockers increase the likelihood of persistence; rather, it is just as possible, and in my opinion more likely, that, given the biopsychosocial mental health assessment that is done prior to starting gender-affirming medical interventions under current guidelines, the adolescents who started pubertal suppression were those who were, through medical and mental health screening, determined, prior to starting pubertal suppression, to have a low likelihood of future desistence.

DEFENDANTS' EXPERTS' SUGGESTION THAT GENDER-AFFIRMING TREATMENT SHOULD NOT BE AVAILABLE BECAUSE GENDER DYSPHORIA IS THE RESULT OF "SOCIAL CONTAGION" AND "RAPID ONSET GENDER DYSPHORIA" IS WITHOUT BASIS

16. Defendants' experts suggest that gender-affirming medical care should be banned because, they claim, peer influence is responsible for adolescents seeking gender-affirming medical care that they will later come to regret. They assert that "social contagion" is the driver of gender dysphoria and that there is a phenomenon of "rapid-onset gender dysphoria" or ROGD. For instance, Dr. Roman states, "My view is that gender dysphoria in children and young adults is largely ex-

plained as a social contagion." (Roman Decl. ¶ 28). Such a view is not supported by evidence.

17. Several of Defendants' experts allude to the term "rapid onset gender dysphoria"—failing to note that this is not a recognized mental health condition.[11] The term "rapid onset gender dysphoria" entered the literature in 2018 through a publication by Dr. Lisa Littman.[12] Soon after the initial publication of Dr. Littman's article, a correction was published.[13] The correction noted, "Rapid onset gender dysphoria (ROGD) is not a formal mental health diagnosis at this time . . . This report did not collect any data from the adolescents and young adults (AYAs) or clinicians and therefore does not validate the phenomenon."[14] The correction goes on to say "the term should not be used in any way to imply that it explains the experiences of all gender dysphoric youth. . . . " Despite this, Defendants' experts repeatedly cite this article to make unsubstantiated claims.

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

[12] Littman, L. (2018). Rapid-onset gender dysphoria in adolescents and young adults: A study of parental reports. *PLoS One*, *13*(8).

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

[14] A recent study by Bauer et al. in *The Journal of Pediatrics* examined some of the associations that would be consistent with the existence of "rapid-onset gender dysphoria" and concluded that their results "did not support the rapid onset gender dysphoria hypothesis." Bauer, G. R., Lawson, M. L., Metzger, D. L., & Trans Youth CAN! Research Team. Do Clinical Data from Transgender Adolescents Support the Phenomenon of" Rapid Onset Gender Dysphoria"?. *The Journal of Pediatrics*, S0022-3476

For example, Dr. Laidlaw states, "there is evidence that this increase [in referrals to gender clinics] may be in part due to social contagion and fueled by social media / internet use (Littman, 2018)." (Laidlaw Decl. ¶ 213). Dr. Levine states, "there is evidence among adolescents that peer social influences through "friend groups" (Littman 2018) or through the internet can increase the incidence of gender dysphoria or claims of transgender identity." (Levine Decl. ¶ 33).

18. The Littman study was an anonymous online survey of the parents of transgender youth, recruited from websites where this notion of "social contagion" leading to transgender identity is popular. The anonymous survey participants were asked what they thought was the etiology of their children's transgender identity. Some of these parents believed that their children became transgender as a result of watching transgender-related content on websites like YouTube and having LGBTQ friends. The alternative interpretation, and in my opinion more likely interpretation, is that these youth sought out transgender-related media and LGBTQ friends because they wanted to find other people who understood their experiences and could offer support. The parent respondents also noted that, from their perspective, their children became transgender "all of a sudden," hence the term "rapid onset." Once again, the problem here is that the study did not interview the adolescents themselves, nor their healthcare providers. It is common for transgender (as with gay, lesbian, and bisexual) children and adolescents to conceal their identity from their parents for long periods of time. In a recent study from our research group, transgender people who first understood their gender identity in childhood waited a median 14 years before

sharing this with another person.[15] In my experience working with transgender youth and adults, the reasons for this tend to be out of fear of negative repercussions (rejection, being kicked out of the house, or even physical assault) were their parents to find out that they are transgender. Children often learn to conceal their gender non-conforming behaviors and transgender identity early, particularly if their parents have strong negative reactions to them exhibiting gender non-confirming behavior.

19. Dr. Cantor attempts to add credence to this 2018 Littman study by stating that it was "independently replicated by another study." (Cantor Decl. ¶ 136). The "replicated" study (the "Diaz Study")[16] referenced by Dr. Cantor used the same methodology as the original Littman study of recruiting participants from websites where the idea of "social contagion" is popular, and thus carries the same limitations. Specifically, the Diaz Study used an identical methodology to the one used by Dr. Littman in her paper, and recruited participants from a website called "ParentsofROGDKids.com." Once again, the only thing that this study shows is that a number of people online have the belief that the politicized notion of ROGD is true. Due to this biased methodology, the Diaz Study referenced by Dr. Cantor likewise does not establish that ROGD is a valid mental health diagnosis. Furthermore, after publication, the

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[15] Turban, J. L., Dolotina, B., Freitag, T. M., King, D., & Keuroghlian, A. S. (2023). Age of Realization and Disclosure of Gender Identity Among Transgender Adults. *Journal of Adolescent Health*, *72*(6), 852-59.

[16] Diaz, S., & Bailey, J. M. (2023). Rapid Onset Gender Dysphoria: Parent Reports on 1655 Possible Cases. *Archives of Sexual Behavior*, *52*(3), 1031-43.

Diaz Study was updated with a notification from the journal stating, "readers are alerted that concerns have been raised regarding methodology as described in this article. The publisher is currently investigating this matter an a further response will follow the conclusion of this investigation."[17] The author of the paper subsequently announced that the paper was retracted, stating: "I have just been notified that my paper with Susanna Diaz will be retracted by the publisher due to concerns about the lack of informed consent."[18] Also of note, the original paper contains a notation that the first author "Susanna Diaz" is a pseudonym—an unusual practice in peer-reviewed journals.

20. Defendants' experts assert that the increase in referrals to gender clinics over the past few decades supports a "social contagion" theory. It does not. The increase in referrals has coincided with increased visibility of transgender people in society and greater awareness of gender dysphoria and access to medical care to treat it. Whereas parents in the past may have had limited literacy regarding gender diversity in adolescents, today more Americans, as well as people abroad, have greater understanding of the experiences of transgender youth. This fact has undoubtedly increased the number of parents bringing their adolescents to gender clinics for evaluation. Additionally, insurance coverage of gender-affirming medical interventions has improved drastically, meaning that more families are able to afford care, which results in an increase

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[17] *Id.*

[18] Blanchard, R. Statement on Twitter May 23, 2023. Available at: https://twitter.com/profjmb/status/1661022522446610434?s=20. Accessed: May 28, 2023.

in referrals for evaluation. Of note, not all adolescents who present for treatment ultimately go on to receive gender-affirming medical interventions.[19] In fact, in a large study from a Netherlands gender clinic, the percentage of patients who presented for evaluation who actually started any kind of gender-affirming treatment has decreased over time.[20] As the authors of that study note, "this finding may be explained by the fact that in the past it was harder to find information about [gender dysphoria] and its treatment, and only people with extreme types of [gender dysphoria] managed to visit our gender identity clinic for treatment. Currently, owing to media attention and the internet, it is easier to access information about our gender identity clinic, making the threshold lower to search for help." This shows that while more people may be coming in for evaluation, the criteria for diagnosis and treatment remain stringent and a smaller percentage of patients are actually being diagnosed with gender dysphoria and referred on for medical treatment.

21. Defendants' experts point to changes in sex ratios of patients at some clinics (where "birth-assigned females" are appearing in greater numbers relative to "birth-assigned males" than in the past), and claim that this assertion supports their "social contagion" theory. However, there are many potential explanations for a change in sex ratio that do not involve social contagion. One likely possibility is that more birth-assigned fe-

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[19] 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.

[20] *Id.*

males are being referred to gender clinics by their pediatricians due to greater understanding among pediatricians that birth-assigned females can have gender dysphoria. In the past, physicians thought of gender dysphoria as something that primarily impacted birth-assigned males. This likely led to many cases of gender dysphoria among birth-assigned females being undiagnosed or "missed." In recent years, literacy regarding gender dysphoria among birth-assigned females has increased among physicians. As fewer birth-assigned females go undiagnosed, the sex ratio in gender clinics has shifted away from predominantly birth-assigned males. This is similar to a pattern that has been seen in autism spectrum disorder. For example, a large study found that with increasing awareness that autism spectrum disorder can impact birth-assigned females as well as birth-assigned males, the sex ratio shifted more toward birth-assigned females, from 5.1:1 (birth-assigned males to females) to 3.1:1.[21] The same study saw the sex ratio for the related diagnosis of Asperger's syndrome similarly shift from 8.4:1 to 3.0:1.

22. Furthermore, if the Defendants' experts' theory that sex ratios have shifted due to social contagion and that there exists a unique susceptibility among people assigned female at birth were true, one would expect not just a shift in the sex ratios among those referred to gender clinics, but a shift in the sex ratio of adolescents identifying as transgender among the general popula-

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[21] Jensen, C. M., Steinhausen, H. C., & Lauritsen, M. B. (2014). Time trends over 16 years in incidence-rates of autism spectrum disorders across the lifespan based on nationwide Danish register data. *Journal of Autism and Developmental Disorders*, *44*(8), 1808-18.

tion. A recent study from our research group,[22] utilizing data from the Center for Disease Control and Preventions Youth Risk Behavior Survey, and including 91,937 adolescents in 2017 and 105,433 adolescents in 2019, found that in both years the sex ratio was close to 1:1, slightly favoring those assigned male at birth.[23] This study also examined the hypothesis that adolescents may be coming to identify as transgender in an attempt to flee the stigma of being cisgender and gay. The results did not support that hypothesis.

23. Some have raised the question that if decreased stigma were driving the higher rates of adolescents openly identifying as transgender, we should be witnessing a parallel in documentable rise in gender dysphoria among, say, middle-aged adults. However, transgender middle-aged adults have endured decades of stigma for their transgender identities that, despite improvements in contemporary social attitudes, make them far less likely to come out as transgender. The "gender minority stress" model explains that these decades of exposure to unaccepting environments leads to expectations of future rejection and internalized transphobia (i.e., internalization of society's negative mes-

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[22] Turban, J. L., Dolotina, B., King, D., & Keuroghlian, A. S. (2022). Sex assigned at birth ratio among transgender and gender diverse adolescents in the United States. *Pediatrics*, *150*(3).

[23] As with many papers in this field, this study garnered a great deal of attention, including a letter to the editor questioning the methodology. We responded to these concerns with additional analyses that reaffirmed the study's conclusions, and this paper was not retracted: Turban, J. L., Dolotina, B., King, D., & Keuroghlian, A. S. (2022). Author Response to: Science and Public Health as a Tool for Social Justice Requires Methodological Rigor. *Pediatrics*, *150*(6), e2022059680.

sages about transgender people leading to hate of oneself for being transgender), as well as identity concealment.[24] These factors make it less likely for middle-aged transgender adults to come out, despite the recently observed increase in societal acceptance for transgender people in the United States. Transgender youth are, for the first time, growing up in environments where transgender identity is not as stigmatized, making it easier for them to come out when compared to transgender adults plagued by anxiety due to decades of living in societies where being transgender was not recognized or accepted.

DR. LEVINE'S STATEMENT THAT TRANSGENDER IDENTITY IS NOT BIOLOGICALLY BASED IS NOT ACCURATE

24. Dr. Levine's assertion that transgender identities are not biologically based is not accurate. There is a substantial body of peer-reviewed scientific evidence showing that transgender identity has a strong biological basis. One of the strongest lines of evidence comes from so-called "twin studies" that allow researchers to look at the differential impact of environment (presumed to be similar for twins) and innate genetic factors (similar for identical twins but different for fraternal twins). Researchers have examined identical twins (with the same DNA) and fraternal twins (with different DNA) and found that identical twins of transgender people are far more likely to be transgender than fraternal twins of transgender people, pointing to a strong

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[24] Hendricks, M. L., & Testa, R. J. (2012). A conceptual framework for clinical work with transgender and gender nonconforming clients: An adaptation of the Minority Stress Model. *Professional Psychology: Research and Practice*, *43*(5), 460.

genetic link.[25] Functional neuroimaging studies have shown that transgender adolescents have patterns of brain activation most similar to non-transgender adolescents with their same gender identity rather than those of their sex assigned at birth.[26] Sophisticated gene sequencing studies have suggested that genes involved in estrogen processing play a role in the development of gender identity among transgender people.[27] Though the precise etiology of gender identity has yet to be identified, these studies together all establish that there is a strong innate biological basis for transgender identities.

DEFENDANTS' EXPERTS' CLAIMS THAT "SELF-REPORT" AND "SURVEY" DATA ARE NOT VALID REPRESENTS A MISUNDERSTANDING OF PSYCHIATRIC RESEARCH

25. Clinical psychiatry relies heavily on self-report and data collected via questionnaires. Defendants' experts' claims that self-report and "survey" data are not valid represent a broad misunderstanding of psychiatry. Clinical psychiatry and clinical psychiatric research almost always involve patient reports of their symptoms. Because psychiatric conditions (e.g., generalized

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[25] See, for example, Coolidge, F. L., Thede, L. L., & Young, S. E. (2002). The heritability of gender identity disorder in a child and adolescent twin sample. *Behavior Genetics*, *32*(4), 251-57.

[26] Burke, S. M., Cohen-Kettenis, P. T., Veltman, D. J., Klink, D. T., & Bakker, J. (2014). Hypothalamic response to the chemo-signal androstadienone in gender dysphoric children and adolescents. *Frontiers in Endocrinology*, *5*, 60.

[27] Theisen, J. G., Sundaram, V., Filchak, M. S., Chorich, L. P., Sullivan, M. E., Knight, J., . . . & Layman, L. C. (2019). The use of whole exome sequencing in a cohort of transgender individuals to identify rare genetic variants. *Scientific Reports*, *9*(1), 1-11.

anxiety disorder, major depressive disorder, schizophrenia, obsessive compulsive disorder, and gender dysphoria, among many others) do not have laboratory tests, diagnosis is made largely based on patient reports of their symptoms. At times these may be supplemented by reports from parent and clinician observations, particularly for establishing a diagnosis; however, they are not considered standard or necessary in clinical trials that track symptoms over time or compare the mental health of those receiving treatment to those not receiving treatment. The studies cited throughout my initial declaration utilize commonly used and validated self-report psychometric measures including the Kessler-6 measure of past-month severe psychological distress,[28] Beck Depression Inventory II,[29] and self-report measures from the National Institutes of Health Toolbox Emotion Battery.[30] These self-report instruments are standard in psychiatric research.

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[28] Kessler, R. C., Green, J. G., Gruber, M. J., Sampson, N. A., Bromet, E., Cuitan, M., . . . & Zaslavsky, A. M. (2010). Screening for serious mental illness in the general population with the K6 screening scale: results from the WHO World Mental Health (WMH) survey initiative. *International Journal of Methods in Psychiatric Research*, *19*(S1), 4-22

[29] Beck, A. T., Steer, R. A., & Brown, G. (1996). Beck depression inventory-II. *Psychological Assessment*.

[30] Slotkin, J., Nowinski, C., Hays, R., Beaumont, J., Griffith, J., Magasi, S., & Gershon, R. (2012). NIH Toolbox scoring and interpretation guide. *Washington (DC): National Institutes of Health*, 6-7.

DEFENDANTS' EXPERTS' VIEWS DO NOT ALIGN WITH MAINSTREAM PSYCHIATRY OR PSYCHOLOGY

26. As noted in my initial declaration, bans on gender-affirming medical care for adolescent gender dysphoria are opposed by all relevant major medical organizations including 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, among others.[31] Defendants' experts, which include experts in unrelated fields (e.g., Dr. Cantor is a pedophilia researcher, having never published original data in the field of child or adolescent gender dysphoria research, and has stated under oath that he has not treated any child or adolescent for gender dysphoria),[32] present views that do not align with mainstream psychiatry or medicine, as it pertains to the treatment of adolescents with gender dysphoria. Their reliance on non-peer-reviewed reports from various countries in Europe (e.g., Sweden, Finland, the United Kingdom, etc.), none of which have banned gender-affirming medical care for adolescents with gender dysphoria, represent an attempt to circumvent the actual peer-reviewed literature and expert consensus in the field.

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[31] 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), 2251-52.

[32] *Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131 (M.D. Ala. 2022)

CONCLUSION

27. In summary, the reports from the Defendants' experts do not provide justification for banning gender-affirming medical care for adolescents with gender dysphoria. Their view, that gender-affirming medical care for adolescents with gender dysphoria should be legislatively banned, is a fringe view, not consistent with mainstream medicine or science.[33] None of the European countries they cite have banned care. All major medical organizations in the United States disagree with the views expressed by Defendants' experts about the banned treatment.[34]

28. Under current guidelines, medical interventions for adolescents with gender dysphoria are only provided following a comprehensive biopsychosocial evaluation, consent is provided by legal guardians, assent is provided by the patient, and all stakeholders (patient, guardians, mental health professional, prescriber) are in agreement that the benefits outweigh the risks for a given adolescent.

29. As I have outlined above and in my initial declaration, there is a substantial body of literature showing that gender-affirming medical care results in better mental health outcomes for adolescents with gender dysphoria. This research is consistent with the decades of clinical experience from around the world of improved mental health outcomes from these interven-

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[33] For a list of statements from major medical organizations opposing legislative bans on gender-affirming medical care for adolescent gender dysphoria, 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), 51-2252.

[34] *Id.*

tions. Furthermore, there are no evidence-based alternatives for treating gender dysphoria. While Defendants' experts critique the literature regarding the benefits of gender-affirming medical care, the studies they present on rapid-onset gender dysphoria and social contagion meet none of their proposed bars for what research they would consider valid. Though they repeatedly advocate for "psychotherapy" alternatives to gender-affirming medical care, they fail to cite a single study showing that such strategies are effective. The Tennessee ban would leave physicians, adolescents, and their parents without any evidence-based treatments for adolescent gender dysphoria, a condition that can cause immense suffering.

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

Executed on: May 31, 2023

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

EXHIBIT D

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

No. 4:21CV00450 JM

DYLAN BRANDT, ET AL., PLAINTIFFS

v.

LESLIE RUTLEDGE, ET AL., DEFENDANTS

Nov. 28, 2022
Little Rock, Arkansas
8:57 AM

TRANSCRIPT OF BENCH TRIAL—VOLUME 5
BEFORE THE HONORABLE JAMES M. MOODY, JR.,
UNITED STATES DISTRICT JUDGE

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INDEX—VOLUME 5 (11/28/22)

[780]

(Proceedings continuing in open court at 8:57 AM.)

THE COURT: Are y'all ready?

MR. JACOBS: Your Honor, Defendants are ready to call, I guess, our next witness, not our first witness. One thing I wanted to check in on. So Dr. Regnerus is prepared to testify remotely tomorrow, and I wanted to ask at what time the Court could begin tomorrow with the hope that it could begin I guess as early as we can make it happen. Because Dr. Regnerus is testifying late in the evening from where he's located, so just to avoid him having to run into testifying in the wee hours of the early morning, if we could start as early as we can. I recognize that—

THE COURT: I expect this will likely make everybody cringe, but courthouse opens at 7:30.

MR. JACOBS: Could we—I think he'd be available to start at like 8:00.

THE COURT: That's fine. That would give everybody time to get in the building and get settled and we could make sure stuff is up.

MR. JACOBS: Okay. That's all the preliminary matters that we have.

THE COURT: So with an asterisk, you've got my entire week. What are your thoughts on how long you're going to take?

MR. JACOBS: Our witnesses will be done Thursday and [781] we'll rest on Thursday.

THE COURT: I've got two sentencings, one at 1:00 and one at 2:00 on Wednesday. Those usually last 30

minutes, so we're probably going to work a little later into lunch on Wednesday.

MR. JACOBS: That won't be a problem, Your Honor.

THE COURT: And then it looks like I've got a lunch hearing on the 1st. Okay. That's what is on my schedule other than you guys. So are we ready to jump back in?

MR. JACOBS: We're ready, Your Honor. Defendants will call Dr. Stephen Levine.

THE COURT: Sir, if you could come on the far side of that silver rail. Good morning.

STEPHEN LEVINE, DEFENDANTS' WITNESS, DULY SWORN

DIRECT EXAMINATION

BY MR. CANTRELL:

Q Good morning, Dr. Levine.

A Good morning.

Q Can you state your name and spell it for the record.

A Stephen, S-t-e-p-h-e-n, Barrett, B-a-r-r-e-t-t, Levine, L-e-v-i-n-e.

Q Thank you. Dr. Levine, can you tell us what academic and clinical positions that you currently hold?

A I am clinical professor of psychiatry at Case Western Reserve University. I'm a staff psychiatrist in a group * * *

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[897]

Q. And switching back to adults, you've written letters of authorization for adults seeking gender-affirming surgeries. Is that correct?

A. I have.

Q. And you've done that as recently as the past two years.

A. I have.

Q. And you've also written letters authorizing hormone therapy for adult patients with gender dysphoria.

A. I have.

Q. And these are letters they can take to the endocrinologist. Is that right?

A. Yes.

Q. And you have written such letters approving hormone therapy for minors under 18 in a few cases within the past five years, haven't you?

A. I don't think in the past five years.

Q. Okay. Can we turn to Dr. Levine's deposition, page 78?

I would like you to read along with me starting on line 3. So between you and Mrs. Novak, there have been a handful of cases in the past, say, five years where you have approved hormone therapy for minor. Is that right?

These are particularly fraught difficult circumstances, yes.

[898]

A. Yes.

Q. Mrs. Novak is someone who works in your medical practice—or your psychiatry practice?

A. She's a younger colleague of mine.

Q. That was your testimony.

A. I'm sorry?

Q. That was your testimony that I read correctly.

A. Yes. I'm just not sure today whether it's five years or six years now. And in generally, there have been a few very fraught cases where we felt that this is a very reasonable thing given the severity, the complexity of the case, and that we would—we, along with parents, would hold our breath that this would be of help.

Q. And you have cosigned letters for hormone therapy for minors written by Mrs. Novak, again, approving some minors for hormone therapy. Is that right?

A. Yes, but this has not occurred very recently, Ms. Cooper.

Q. You would not write a letter supporting hormone therapy for a minor if you did not believe the patient had gender dysphoria, correct?

A. Correct.

Q. And you would not write a letter approving a minor for hormone therapy without first determining that they had a longstanding, stable gender identity. Is that [900] much more cautious. We will give adolescents hormones, but not as quickly as the Standards of Care would like.

That was your testimony in Keohane.

A. I have to say yes.

Q. And just to clarify, the Standards of Care you're referring to in the 7th Edition, is that the WPATH's Standards of Care 7th Edition?

A. Yes.

Q. When you were deposed in May of this year in this case, the Brandt case, you testified, did you not, that going forward you have not made a decision to no longer write letters approving hormone therapy for patients under 18 years of age.

A. Indulge me a minute. In the previous thing you put up, my deposition of adolescents was not the definition I gave to the Judge earlier this morning. It was my definition of an adolescent is somebody 19 years of age. And so if you reread that, it would include 18-year-olds and 19-year-olds.

So would you repeat the last question you asked me?

Q. Sure. When you were deposed this past May in this case in Arkansas, you testified that, going forward, you have not made a decision to categorically not write letters approving hormone therapy for patients under 18, correct?

[901]

A. I don't remember saying that, but if you have that, I trust you.

Q. Yeah. I think we want to put that in the record.

Can we look at deposition page 227?

And if you go to line 3, part way through beginning with the words, "Have you made a decision." Are you with me? It's highlight.

Have you made a decision to no longer consider hormone therapy for anybody who has not reached their 18th birthday since you provided those letters?

Answer: I've made a decision to be very cautious and to put a period of time in therapy between me and the letter.

You go on to say more, which you're welcome to read if you would like, but I want to continue on to another passage that picks up rather than taking the Court's time reading a lot of discussion in between.

If we could turn to page 228, line 3. Let me know if you want to review there.

MR. CANTRELL: Your Honor, I would like to just, if we could, take a look at the intervening testimony, glance at that.

MS. COOPER: Sure. We can post that. Absolutely.

THE COURT: I thought you were in the [902] deposition, Mr. Cantrell, but go ahead.

BY MS. COOPER:

Q. Do you have that in front of you now, Doctor? If you look at line 3 and read along with me.

So I'm not sure if that answers my question. Have you made a decision to no longer provide letters?

Answer: Oh, I'm sorry. No, I haven't made that decision.

Question: So would it be a case-by-case basis if there were a patient that you felt it was appropriate for you—appropriate for, you would consider doing it, say, a 17-year-old or a 16-year-old?

Mr. Cantrell: Object to form.

Answer: I don't have a—yes. The answer to your question is yes.

I'm not going to ask you if that was your testimony again—

A. Thank you.

Q. —since I see how you love those questions.

Now, today you testified that you would not recommend hormone therapy for patients under 18. Do you mean you would not generally recommend hormone therapy as a general matter?

A. Yes.

Q. So there may be exceptional cases where you would [903] still consider it appropriate.

A. Yes. These are very fraught circumstances. I think all of us all over the world recognize that we are under very difficult circumstances sometimes. We don't know what to do and we eventually go along with the patient's sincere desire to try hormones.

Q. Now, you talked on direct about an article you wrote called, Reconsidering Informed Consent for Trans-identified Children, Adolescents, and Young Adults.

And I just want to ask you a couple of questions about that article.

In this article, you recommend informed content process that you think providers should undertake before authorizing medical or surgical transition for minors, correct?

A. Yes.

Q. I'd like to pull up a passage from that article to show you. If we can look at page 2. And I have some material highlighted. Actually, I would like you to skip to—sorry. I wasn't in front of the mic. I would like to skip to the second highlighted paragraph.

A. I know what you're you talking about.

Q. We over highlighted. If you'll read along with me in the second paragraph there.

Social transition, hormonal interventions, and * * *

* * * * *

[964]

MS. TEMPLIN: Apologies.

MR. JACOBS: That's what we would suggest. Dr. Lappert is willing to change around his travel to make that work. I think we went a little bit longer with Dr. Levine than we anticipated. We hoped to be able to do both today. So long as the Court has tomorrow afternoon available, so long as there's not any objections on that end, I think we could switch those and get everything done.

THE COURT: The only thing I have in my week that's in y'all's way is the one o'clock 30 minute and the two o'clock 30 minute on Wednesday, then the noon hour on Thursday.

MR. JACOBS: Neither of those will be problems on our end, Your Honor. If that's acceptable to everybody, I think we will proceed with Dr. Regnerus tomorrow when we get everything set and then proceed with Dr. Lappert.

THE COURT: If we get both of them done tomorrow, how late do you anticipate going on Thursday?

MR. JACOBS: On Thursday, Your Honor, it could be a full day on Thursday. I just don't know whether it's going to be sort of an early day out on Thursday or not at this point.

THE COURT: I'm just curious.

MR. JACOBS: Regardless of this, we'll still be totally done on Thursday with our witnesses. That won't impact this at all.

THE COURT: All right. Court is in recess until [965] eight o'clock tomorrow.

MR. JACOBS: Yes, Your Honor.

(Overnight recess at 4:19 p.m.)

REPORTER'S CERTIFICATE

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/s/ Elaine Hinson, RMR, CRR, CCR
United States Court Reporter

Date: December 4, 2022