EXHIBIT 6

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISIVLLE DIVISION

Electronically filed

DOE 1, *et al.*
Plaintiffs

v.

THORNBURY, *et al.*
Defendants

and

COMMONWEALTH OF KENTUCKY, *ex rel.* ATTORNEY GENERAL DANIEL CAMERON
Intervening Defendant

Civil Action No. 3:23-CV-00230-DJH

EXPERT DECLARATION OF MICHAEL K. LAIDLAW, M.D.

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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 the Intervening Defendant, Commonwealth of Kentucky, *ex rel.* Attorney General Daniel Cameron (the Commonwealth), in the above-captioned lawsuit to provide an expert opinion on the efficacy and safety of sex reassignment treatment, including the trustworthiness of proposed standards of care or treatment guidelines promulgated by medical organizations.

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

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; (4) my review of the various declarations submitted by Plaintiffs; and (5) 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 Plaintiffs' motion for preliminary injunction and its exhibits, including the expert and plaintiff declarations, DN 17, 17-1,17-2, 17-3, 17-4, 17-5, 17-6, and 17-7, a copy of Senate Bill 150, and the medical associations' tendered amicus brief, DN 19-2.

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:

11. United States District Court for the Middle District of Tennessee, 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, Case no. 3:23-cv-00376; United States District Court for the Middle District of Alabama Northern Division, BRIANNA BOE, et al., Plaintiffs, UNITED STATES OF AMERICA, Intervenor Plaintiff, v. HON. STEVE MARSHALL, in his Official capacity as Attorney General, of the State of Alabama, et al., Defendants, Case No. 2:22-cv-184-LCB; 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; 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. NO. D-1-GN-22-002569, 2022; JULIANA PAOLI v. JOSEPH HUDSON et al.,

[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.

Superior Court of State of California, County of Tulare, 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 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.

12. 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.

13. 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

14. 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.

15. 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.

16. 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.

17. Dr. Shumer states, "Sex is comprised of several components, including, among others, internal reproductive organs, external genitalia, chromosomes, hormones, gender identity, and secondary sex characteristics (IOM, 2011)" (Shumer decl, par 24, emphasis added). Dr. Shumer is incorrect to include "gender identity" as a component of sex. What he states contradicts the Diagnostic and Statistical Manual of Mental Disorders (DSM-5 TR), which states that "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" (DSM-5 TR, emphasis added). Note that gender identity is not a component of biological sex as defined by the DSM 5.

18. 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.

19. 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 "[t]here are no laboratory, imaging, or other objective tests to diagnose a 'true transgender' child" (Laidlaw et al., 2019).

20. 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 the 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.

21. This is in contrast to endocrine disorders which have a measurable physical change in either hormone levels or gland structure which 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).

22. Dr. Shumer goes on to say in par 28 of his declaration: "Scientific research and medical literature across disciplines demonstrates that gender identity, like other components of sex, has a strong biological foundation...In one such study, the volume of the bed nucleus of the stria terminalis (a collection of cells in the central brain) in transgender women was equivalent to the volume found in cisgender women." The study that Dr. Shumer references, Chung et al., 2002, involved autopsies of 50 deceased person's brains to examine the tissue. This sort of examination obviously cannot be done on living persons and has not been validated in any way to confirm the gender identity. Likewise, there has been no imaging (such as an MRI or CT scan of the brain) to examine the nucleus of the stria terminalis that has been validated to confirm the gender identity of a patient. In any event, 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 gender identity.

23. Dr. Shumer states that "[t]win studies have shown that if an identical twin is transgender, the other twin is much more likely to be transgender compared to fraternal twins, a finding which points to genetic underpinnings to gender identity development" (Shumer decl, par 29). However, if gender identity is actually determined by genes, we would expect that identical twins would profess having the same gender identity nearly 100 percent of the time. This is not the case. In fact, the largest transexual twin study ever conducted included seventy-four pairs of identical twins (Diamond, 2013). They were studied to determine in how many cases both twins would grow up to identify as transgender. In only twenty-one of the seventy-four pairs (28 percent) did both identical twins identify as transgender. This is consistent with the fact that multiple factors play a role in determining gender identity, including psychological and social factors. This study suggests that those factors are more important than any potential genetic contribution.

Furthermore, no genetic studies have ever identified a transgender gene or genes. And again, none of the five minor plaintiffs have presented evidence of genetic testing that was performed to verify the gender identity.

24. 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).

25. Dr. Shumer states: "There is also ongoing research on how differences in fetal exposures to hormones may influence gender identity. This influence can be examined by studying a medical condition called congenital adrenal hyperplasia" (Shumer decl, par 30). Congenital adrenal hyperplasia is a DSD. None of the plaintiffs have described a diagnosis congenital adrenal hyperplasia or any other DSD. Dr. Shumer also provides no evidence that any of the plaintiffs suffered from fetal exposure to opposite sex hormones.

B. Human Sexual Development

1. Embryologic Development

26. 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.

27. 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).

28. 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

exclusively 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.)

29. 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.).

30. 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

31. 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.

32. In early childhood, some low level of sex hormones are 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.

33. Dr. Shumer states that "[p]uberty is a process of maturation heralded by production of sex hormones—testosterone and estrogen—leading to the development of secondary sex characteristics" (Shumer, par 57). Dr. Shumer presents a very limited view of puberty. Puberty is an essential part of human development. Its purpose is to achieve full adult sexual function and reproductive capacity.

34. 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.

35. 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

36. 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.

37. 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).

38. 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). For males, 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

39. 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.

40. 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 resuscitate these ducts and continue development of opposite sex structures.

41. 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.

42. In fact, as I will discuss, gender affirming therapy can lead to infertility and potential sterilization.

C. Endocrine Disorders

43. 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.

44. 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.

45. 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.

46. 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.

47. 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.

48. 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.

49. 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.

50. 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 thyroid cancer, a surgical procedure known as a thyroidectomy may be performed to remove the diseased thyroid gland in order to treat the cancer.

51. 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, or 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

52. Gender dysphoria, on the other hand, is not an endocrine diagnosis. It is a psychological diagnosis. Gender dysphoria is the persistent state of distress that stems from the feeling that one's gender identity does not align with one's physical sex (DSM-5 TR). It is diagnosed purely by psychological methods of behavioral observation and questioning. The criteria for diagnosis is found in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5 TR).

53. Drs. Shumer and Kingery advocate for the use of the Endocrine Society's Guideline (ESG) on gender dysphoria. The Guideline discusses the importance of a psychological evaluation by a qualified clinician. It states: "GD/gender incongruence may be accompanied with psychological or psychiatric problems. 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, citations omitted).

54. 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

55. In the section that follows I discuss four interventions (social transition, blocking normal puberty, opposite sex hormones, and surgery) that some physicians 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 GAT it is more likely the patient will continue on to surgery (de Vries et al,, 2011; 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: if I did not understand these harms, I could not advise patients of the risks associated with GAT.

56. 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.

57. 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.

58. The application of this medical therapy to minors[2] is a fairly new intervention and is associated with a number of harms both known and unknown. GAT suffers 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

59. 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 to socially

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[2] "[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).

transition. A girl may cut her hair short and wear clothes from the boys' section of a department store.

60. Social transition of the child has been noted by an 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 Guideline states 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).

61. 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. At this age, the child likely has 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.

62. 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.

63. In fact, it would appear that in the minds of children and adolescents that they are 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 That Block Pubertal Development

1. Background

64. 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).

65. In order 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.

66. 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.

67. 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.

68. 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.

69. 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.

70. 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

71. There are a variety of uses for GnRH agonists. The use and outcome can be very different for different applications.

72. For example, the initial development of the medication called Lupron was for the treatment of 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.

73. 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[3], say age four, to begin pubertal development. In order to halt puberty which has begun at an abnormally early time, a GnRH agonist may be used. 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.

74. 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.

75. 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.

76. 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.

77. Dr. Shumer states that "[o]ptions for treatment after the onset of puberty include the use of gonadotropin-releasing hormone agonists ('GnRHa') for purposes of preventing progression of pubertal development, and hormonal interventions such as testosterone and

[3] "The traditional definition of precocious puberty is the development of secondary sexual characteristics before 8 years of age in girls and 9 years in boys" (Kota and Ejas, 2023).

estrogen administration. These treatment options are based on robust research and clinical experience, which consistently demonstrate safety and efficacy" (Shumer decl, par 44). However, he doesn't provide any evidence of studies that have short term or longitudinal data on safety and efficacy for the treatment of adolescents with gender dysphoria.

78. 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. Nor is there sufficient evidence to conclude that the effects of puberty blockers when used in this manner are reversible.

3. Hypogonadotropic Hypogonadism

79. 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.

80. 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.

81. 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.

82. 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].

[4] Levels will be similarly low for adolescents, though the normal reference range is different.

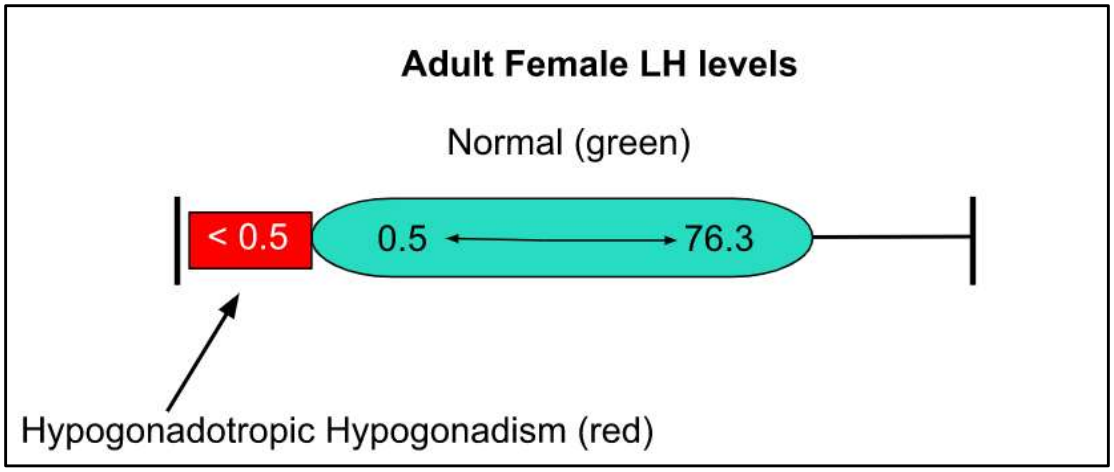

Figure 1.

83. 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-puberty or beyond, it will cause the cessation of normal sperm production.

84. As an endocrinologist, I would confirm the condition of hypogonadotropic hypogonadism based on laboratory results and then treat this medical condition.

85. 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.

86. 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

87. There are a number of serious health consequences that occur as the result of blocking normal puberty. The first problem is infertility.

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[5] The primary sex hormones being estrogen for females and testosterone for males.

88. Dr. Shumer states that "[i]n transgender youth, it is most typical to use GnRHa [puberty blockers] from the onset of puberty (Tanner Stage 2) until mid-adolescence" (Shumer decl, par 64). This is correct. However, he also states "GnRHa have no long-term implications on fertility" (Id.). That statement is incorrect. As I explain below, GnRHa have profound implications for fertility.

89. The Endocrine Society Guideline recommends beginning puberty blockers as early as Tanner stage 2. As discussed earlier, this is the very beginning of puberty. Fertility development happens later, generally in Tanner stage 4. Thus, if the developing person is blocked at Tanner stage 2 or 3, as advocated by the guidelines, this is prior to the patient becoming fertile. The gonads will remain in an immature, undeveloped state.

90. If the patient remains 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 doses of opposite sex hormones may permanently damage the immature sex organs leading to sterilization. Certainly, the removal of the gonads by surgery will ensure sterilization.

91. 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[6]. 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.

92. Although procedures to preserve fertility are available for patients in late pubertal stages (Tanner 4 and 5), studies show that less than 5% of adolescents in North America receiving GAT even attempt fertility preservation (FP) (Nahata, 2017). Moreover, for those in early pubertal stages (Tanner 2 and 3), "ovarian tissue cryopreservation is still considered experimental in most

[6] 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.).

centers and testicular tissue cryopreservation remains entirely experimental[7]. 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).

93. Dr. Kingery states that "[d]ecades of data on the use of puberty blockers as treatment for precocious puberty has demonstrated that puberty blocking medication does not have long-term implications for fertility" (Kingery decl, par 58). This statement fails to recognize the very different effects of PB medication in early childhood versus during adolescence.

94. 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, say at age 12, have the puberty blocker discontinued and at that point normal pubertal development will be allowed to proceed. Therefore, when the child is no longer taking the medication, he or she will gain natural fertility.

95. In contrast, puberty blocking medication given to minors as a part of GAT occurs during the time for natural puberty and is—precisely the time that the adolescent person would have otherwise gained reproductive function. The effects of puberty blocker on the adolescent are to prevent sperm production in the male and ovulation in the female, which produces the infertile condition. Importantly, so long as the minor continues PB, he or she will thus remain infertile. And should the patient continue on to opposite sex hormones as part of GAT, then the patient 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

96. 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.

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[7] "Once testicular tissue has been cryopreserved, future options for its use may include in vitro maturation or germ cell transplant, which at this time are theoretical in nature" (Klipstein et al., 2020).

97. 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"[8] (TLC, accessed 2022).

c. Negative Effects of Hypogonadotropic Hypogonadism on Bone Density

98. 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).

99. 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 can lead to an inability to attain peak bone density.[9]

100. 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.

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[8] Jazz's age is somewhere in the mid-teens during this episode.

[9] In the Amicus Brief of the AAP et al, they state that "[t]he risks of any serious adverse effects from these treatments [puberty blockers] are exceedingly rare when provided under clinical supervision" (AAP et al Amicus Brief, p. 13). However, they provide scant evidence which is not supportive of such a definitive statement. They offer a footnote referring to two articles in support of their statement. One of the articles simply refers to a case study of a single 15 year old "Nonbinary Teenager" (Pang et al., 2020). Moreover, this article does not report on a randomized controlled trial, an observational study or even a case series of patients who have been given GnRHa and followed up for adverse events. The AAP's footnote regarding this study implies that it shows an "exceedingly low risk of delayed bone mineralization from hormone treatment", however the article says no such thing (FN 39). It actually says that "EF's bone density has already fallen to the lowest 2.5 percentile," and that "[i]t can be expected to continue falling" while taking puberty blocking medication. The second article to support the idea of "exceedingly rare adverse effects" is a study that examined only the effects of GnRHa on the brain's executive functioning (Staphorsius et al., 2015). Although it appears to show no apparent negative effect due to GnRHa, the study says nothing about other effects on critical functions of the brain such as intelligence, memory and judgement. More importantly, neither of these two studies discuss the adverse risks on fertility, sexual function, suicidal ideation, depression or other serious risks of GnRHa.

101. 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.

102. 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).

103. 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.

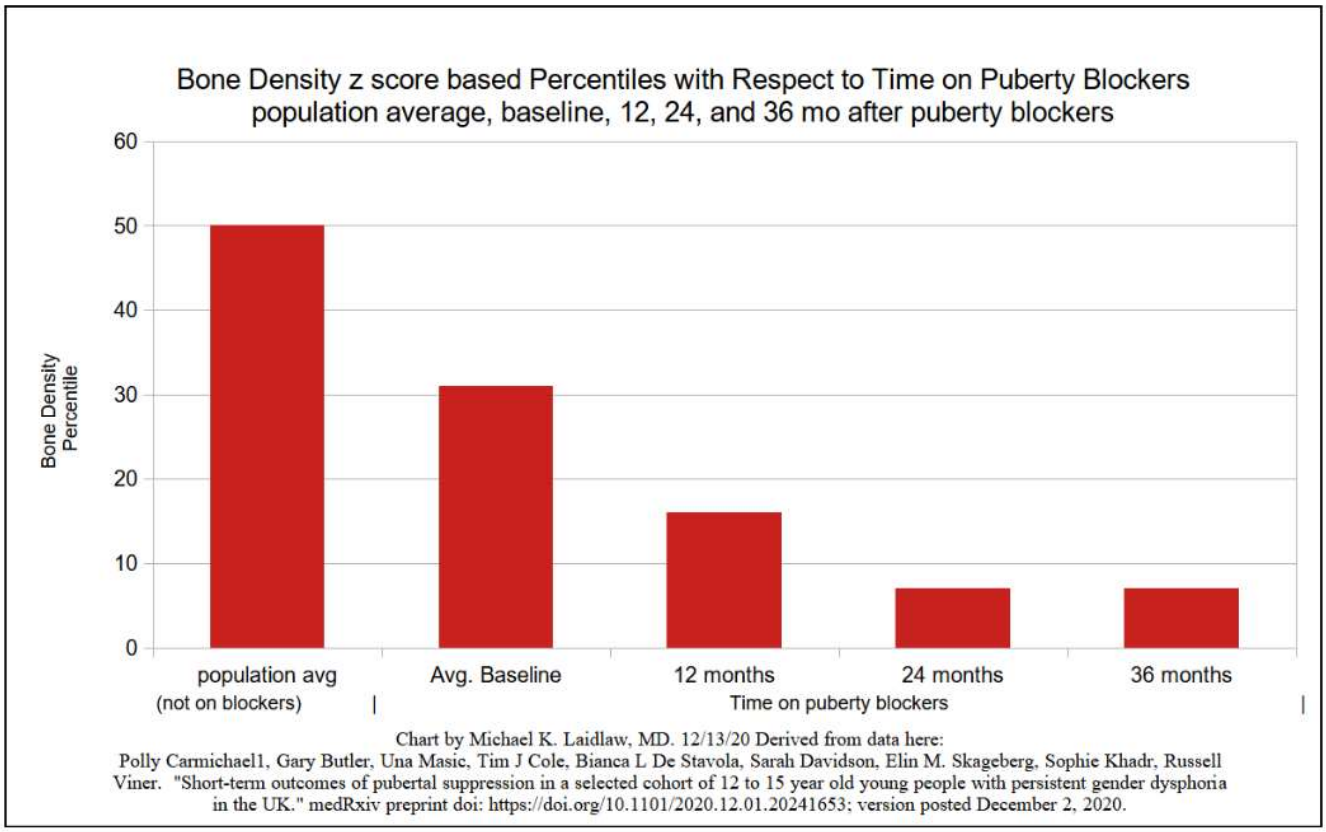

Figure 2

104. 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.

105. In natal females, hypogonadotropic hypogonadism leads to amenorrhea, meaning the absence of menstrual periods. Amenorrhea is detrimental to bone health: "In addition to this[10] 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) (emphasis added).

106. Dr. Shumer states "The treatment [puberty blockade] works by pausing endogenous puberty at whatever stage it is at when the treatment begins, limiting the influence of a person's endogenous hormones on their body" (Shumer decl, par 62). Dr. Kingery states that "[t]he temporary halt to puberty can be completely reversed if [puberty blocking] medication is stopped" (Kingery decl, par 30). In actuality, allowing a "pause" or a "halt" 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.

107. Dr. Kingery states that "[t]o address the risk of lower bone mineral density that can be associated with prolonged use of puberty blockers, we advise adequate intake of Vitamin D and calcium..., regular weight-bearing exercise, and limit the number of years a patient is on puberty blocking medication" (Kingery decl, par 58). However, Dr. Kingery provides no evidence that the measures she describes can allow a developing adolescent's bone density to adequately recover from the harms of GnRHa described above.

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 actually unknown. However, "sex hormones including estrogen, progesterone, 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.

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[10] "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."

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[11]. 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 development. 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).

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[11] "The other concern often used as a rationale for treatment is negative psychosocial consequences of precocious puberty, particularly in girls" (Eugster, 2019, emphasis added).

C. Opposite Sex Hormones

113. 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.

114. 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

115. 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.

116. I prescribe testosterone to men for testosterone deficiency. The state of testosterone deficiency can cause various problems including problems of mood, 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.

117. Contrast the FDA approved use of testosterone in males versus its experimental use 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.[12] 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

[12] "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, emphasis added).

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).

118. Regarding the potential for abuse, the labeling for testosterone 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, emphasis added)

119. Adverse events with respect to the nervous system include: "Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia." (Actavis Pharm, 2018)

120. 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.

121. 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.

122. "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).

123. 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, non-negligible 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).

124. 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

125. 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.

126. In order to diagnose hyperandrogenism, a laboratory blood test of testosterone is done. In hyperandrogenism, one will find testosterone levels elevated above the reference range.

127. For example, for females aged 18 or older, the normal reference range is 2-45 ng/dL (Quest testosterone, 2023).[13] However, in female disease conditions these levels can be much higher. Levels above this normal reference range are considered hyperandrogenism (figure 3).

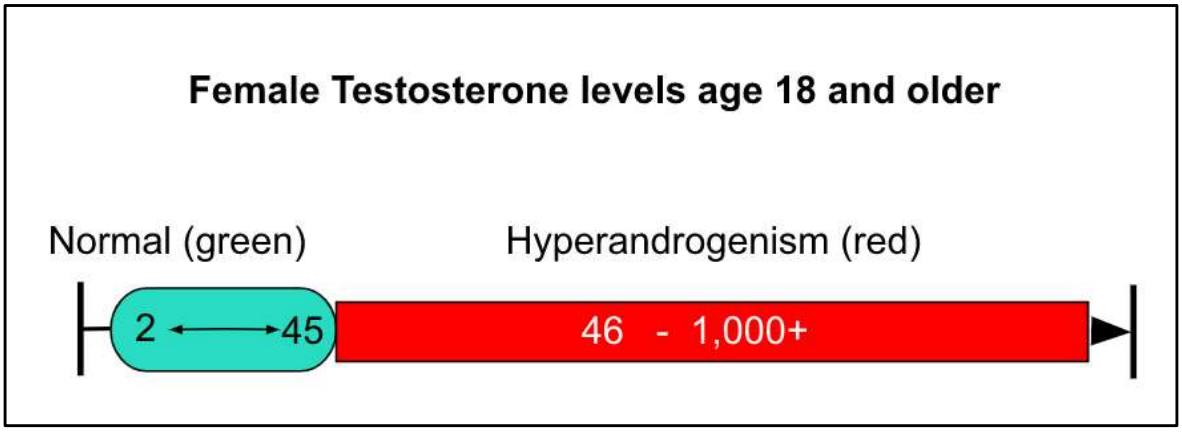

Figure 3

128. For example, in polycystic ovarian syndrome levels may range from 50 to 150 ng/dL.

129. 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

[13] For females aged 11-17 the reference range is <= 40 and below this age group, the range is even lower.

been associated with insulin resistance (Dunaif, 1989), metabolic syndrome (Apridonidze, 2005) and diabetes (Joham, 2014).

130. I also evaluate patients to rule out rare androgen producing tumors that generate very high levels of testosterone. These rare endocrine tumors can cause 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.

131. 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[14] 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.

132. The following chart shows testosterone levels in the normal adult female range (blue), PCOS (gray), endocrine tumors (red), and gender affirmative therapy (orange) as part of female to male (FtM) transition (figure 4).

[14] 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).

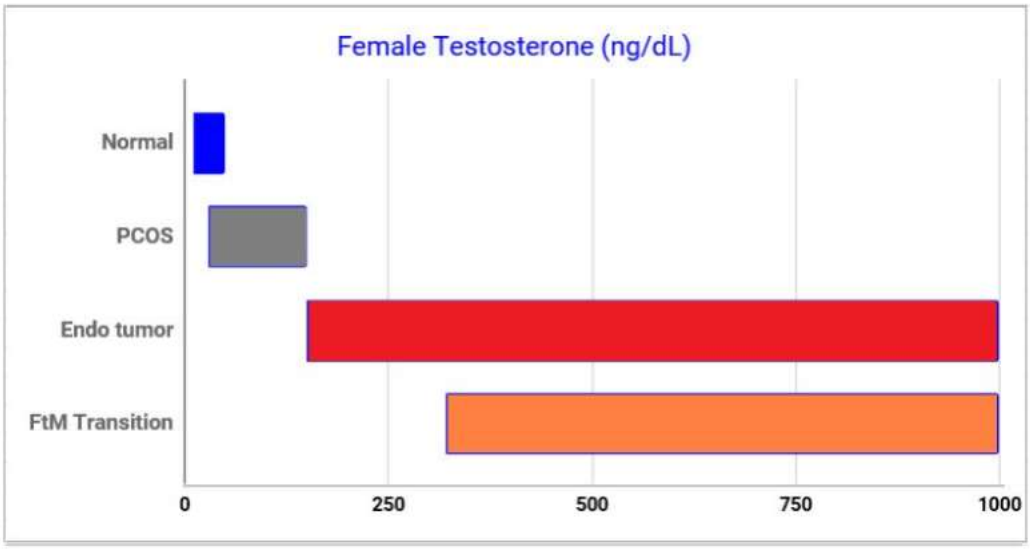

Image by Michael K Laidlaw. MD. Approximate total testosterone in ng/dL based on laboratory, etc. FtM transition from 2017 Endo Society Guidelines on Gender Dysphoria. With PCOS testosterone levels may be as high as 150. With endocrine tumors testosterone may be in the 150-1000 range. The recommendations 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

133. 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).

134. 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 troubling should a patient decide to detransition and attempt to reintegrate into society as female.

135. 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.

136. The long-term effects of starting an adolescent on puberty blockers in early puberty (Tanner stage 2 or 3) and then adding opposite sex hormones on ultimate sterility are unknown in the sense that we do not have studies showing precisely what happens, but based on what we do know, it seems safe to say that opposite sex hormones are likely cytotoxic to the immature gonads.

137. According to research, anabolic steroid abuse[15] has been shown to predispose individuals towards mood disorders, psychosis, and psychiatric disorders. The "most prominent psychiatric features associated with 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

138. 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.

139. 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).

[15] Anabolic steroid abuse involves the deliberate creation of hyperandrogenism in the body as a result of high doses of testosterone or other androgens.

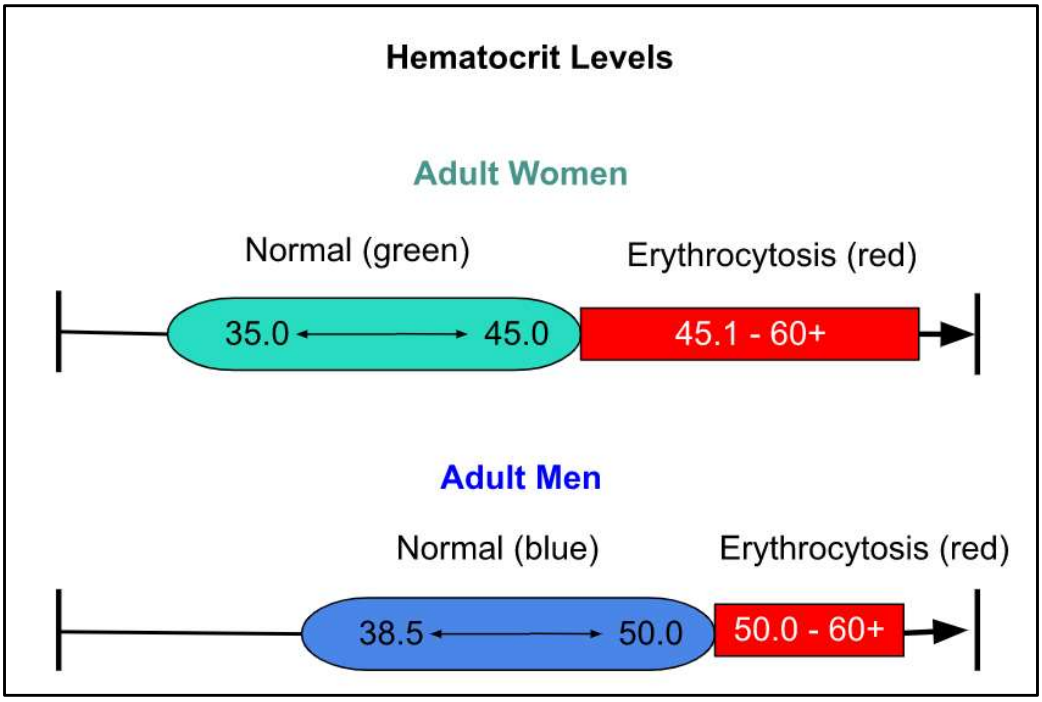

Figure 5.

140. 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.

141. 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 transgender 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.

142. 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

143. 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.

144. 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.

145. 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. 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.

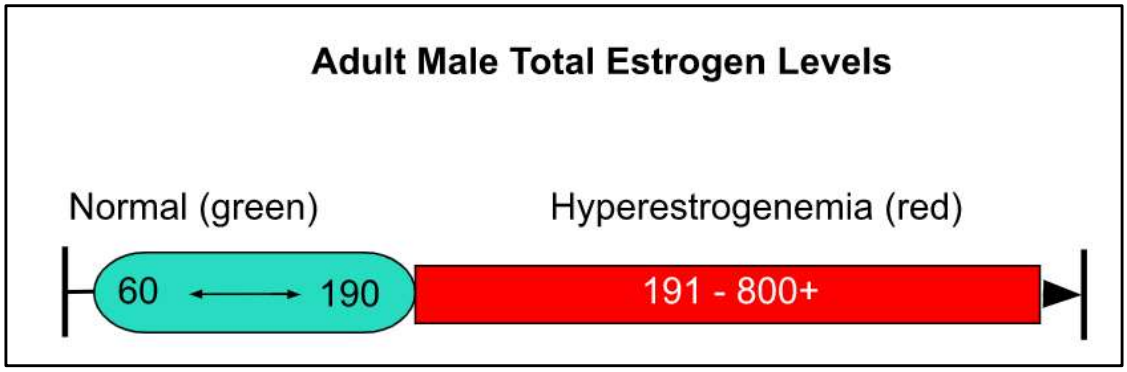

Figure 6.

146. 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).

147. In gender affirmative therapy, the medical condition of hyperestrogenemia is being deliberately, medically induced by the off-label use of high doses of estrogen. The Endocrine Society guideline for treating gender dysphoria recommends raising estradiol levels to 2 to 43 times above the normal range.[16] 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

[16] Estradiol is a type of estrogen. The Endocrine Society Guideline recommends 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).

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.

148. Other changes of secondary sex characteristics may develop because of hyperestrogenemia such as softening of the skin and changes in fat deposition and muscle development.

149. 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[17] over 5 fold" (Irwig, 2018).

150. 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).

151. 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

152. Dr. Shumer introduces the unproven idea that those adolescents who received puberty blockers in early puberty and then take opposite sex hormones (which will lock them in early puberty) may be able at some point as adults stop the hormones and then advance through their normal physiologic puberty. He states, "If attempting fertility after previous treatment with GnRHa followed by hormone therapy is desired, an adult patient would withdraw from hormones and allow pubertal progression. Assistive reproduction could be employed if needed (T'Sjoen, et al., 2013)" (Shumer decl, par 77). However, the reference from T'Sjoen that Dr. Shumer provides describes treatment for natal females as merely theoretical: "*in theory*, there are three options available to preserve fertility: oocyte banking, embryo banking and banking of ovarian tissue" (T'Sjoen, et al., 2013) (emphasis added). For natal males, it is even worse, "[i]n trans women, the best option to preserve gametes is cryopreservation of sperm by preference initiated before starting hormonal therapy" (Id.)(emphasis added). By definition, in the early puberty of natal males, sperm are not being produced therefore making sperm preservation as described by T'Sjoen impossible.

[17] 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).

D. Surgeries

153. 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.

154. Dr. Shumer states that "The transition process in adolescence typically includes (i) social transition and/or (ii) medications, including puberty-delaying medication and hormone therapy" (Shumer decl, par 56). However, Dr. Shumer neglects to describe surgeries as a part of the transition process. This is important to note because although endocrinologists like him and I 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. This is also important to note because transition surgeries, in particular mastectomies, are being performed on minors throughout the country.

155. 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.

156. 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.

157. 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.

158. 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.

159. There are a variety of gender affirming surgeries for females. These may include mastectomies, metoidioplasty, and phalloplasty.

1. Mastectomy

160. 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).

161. 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).

162. 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

163. 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; that procedure 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.

164. 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

165. 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.

166. 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.

167. 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.

168. 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

169. 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 Endocrine Society, WPATH, and Other Pro-Affirmation Organizations

170. Dr. Shumer cites the WPATH Standards of Care and the Endocrine Society's 2017 Guideline (ESG) stating that the "clinical practice guidelines and standards of care published by these organizations provide a framework for treatment of gender dysphoria in adolescents" (Shumer decl, par 45). I will address each in turn.

1. WPATH

171. Dr. Janssen is a member of WPATH, has worked on their "Standards of Care Revision" beginning in 2018, and is "a contributing author to the Child and Adult Mental Health chapters" for their Standards of Care 8 (WPATH website; Janssen decl, par 7).

172. WPATH has functioned primarily as an advocacy organization for promoting social and political activism rather than as a strictly scientific organization. Unlike a scientific organization that must allow for internal debate to clarify issues of uncertainty, WPATH has

actively sought to stymie such debate. As an example, Dr. Kenneth Zucker, whom I cited earlier, is a psychologist who led the Child Youth and Family Gender Clinic in Toronto, which was "one of the most well-known clinics in the world for children and adolescents with gender dysphoria" (Singal, 2016). He also led the group which wrote the DSM's gender dysphoria section. (Id.)

173. Zucker has been a longstanding member of WPATH. In fact, his work was cited 15 times in the 2012 WPATH Standards of Care 7 (Bazelon, 2022). Dr. Zucker discovered over the course of nearly forty years of clinical research "that most young children who came to his clinic stopped identifying as another gender as they got older" (Id.).

174. Dr. Zucker was invited to speak to the USPATH's 2017 inaugural conference. During his presentation, protestors disrupted his talk and made demands of WPATH. "That evening, at a meeting with the conference leaders, a group of advocates led by transgender women of color read aloud a statement in which they said the 'entire institution of WPATH' was 'violently exclusionary' because it 'remains grounded in 'cis-normativity and trans exclusion.' The group asked for cancellation of Zucker's appearance on a second upcoming panel. Jamison Green, a trans rights activist and former president of WPATH, said the board agreed to the demand. 'We are very, very sorry,' he said." (Bazelon, 2022).

175. As an example of WPATH's one-sided political advocacy, consider also the recent inflammatory message by WPATH president Marci Bowers, MD in a letter to members. Writing about laws like Kentucky's that seek to protect vulnerable minors from experimental procedures, Bowers wrote: "Ultimately, what terrifies conservatives most is that gender diversity is a force of nature that can no longer be contained by religious conscription or enforcement of a gender binary." Bowers concluded: "Anti-trans legislation needs to be fought with every voice, every thought, every inclination by all who know it. We need to make anti-trans legislation a losing political issue." (Bowers 2023). These statements are social-political advocacy statements and rallying cries, not scientific arguments. They reduce any disagreement or concern regarding the safety and efficacy of GAT for minors to "anti-trans" religious-based bigotry, and they leave no space for those who are concerned that, based on current scientific knowledge, the risks of GAT for minors outweigh their known benefits. In my experience, these statements are sadly indicative of WPATH's primary role as a political and social advocacy organization, not a scientific one.

176. As for WPATH's Standards of Care 8 (SOC 8), these were published Sep. 6, 2022 (Coleman et al., 2022) and are endorsed by Dr. Shumer as representing an "expert consensus for

clinicians related to medical care for transgender people, based on the best available science and clinical experience" (Shumer decl, par 46). However, there are multiple serious problems with this document such that any clinician who follows its recommendations puts the youth of Kentucky at great risk.

177. 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.).

178. 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).

179. 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.'" (WPATH SOC 8 Correction, p. S260, emphasis added).

180. 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.

181. 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 (Davis 2022). Additionally, WPATH's president said that to "propose" surgeries at newly set lower age recommendations would necessitate a "better political climate" (Ghorayshi 2022).

182. 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"[18] by either orchiectomy (testicle removal) or chemical castration such as with GnRH analogues (Coleman et al., 2022)[19].

183. 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).[20] 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 determines the quality of evidence for each outcome" (Guyatt et al., 2021).

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[18] 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).

[19] "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.)

[20] 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).

184. Such a modification of GRADE is explicitly recommended against in the referenced GRADE document[21] and in so doing, in my opinion, invalidates all of the SOC 8 recommendations as being evidence-based.

185. For at least the reasons above, in my professional opinion WPATH SOC 8 is the work of advocacy, not science, and should not be followed by any physician, mental health care provider, or other medical professionals.

2. Endocrine Society

186. As for the Endocrine Society Guideline, it is notable that the Endocrine Society itself never claimed that its guideline should be considered standard of care. In fact, quite the opposite. The Endocrine Society (ES) states that its "guidelines cannot guarantee any specific outcome, nor do they establish a standard of care" (Hembree et al, 2017, p. 3895, emphasis added).

187. Dr. Kingery stated that in order to develop their Guideline the ES used "an Endocrine Society-appointed task force whose Clinical Practice Guidelines were published in The Journal of Clinical Endocrinology & Metabolism in 2017" (Kingery decl, FN 2). What she fails to disclose is that nine out of ten authors of the Endocrine Society Guideline were members of WPATH or worked on WPATH's scientific committees. According to WPATH's website, seven of those nine had at some time been in WPATH leadership, including the WPATH presidency and board of directors.

188. 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).

189. 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.

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[21] 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).

190. Endocrinologists William Malone and Paul Hruz and other colleagues have written critically of the Endocrine Society's 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 well-being. 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).

191. In June of 2022, the Endocrine Society published "Enhancing the Trustworthiness of the Endocrine Society's Clinical Practice Guidelines'' (McCartney et al., 2022). It 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.) The document relates 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.). It follows that the recommendations from the ESG 2017 on Gender Dysphoria/Gender Incongruence were not all recommendations "based on verifiable systematic evidence 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, WPATH was a cosponsoring organization of the 2017 Guideline. 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).

192. 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).

193. It is clear that with respect to the subject of gender dysphoria, the Endocrine Society has acted as a vassal organization of WPATH's social-political advocacy group rather than an independent medical society generating its own scientific opinions. In my opinion, the Endocrine Society's guidelines do not provide a standard of care that any physician should follow.

3. Social-Political Advocacy in Organizations Supporting Gender Affirmation

194. It is concerning that organizations purporting to establish medical guidelines and standards of care for gender dysphoria are often in the political advocacy role for numerous social positions which have little direct relation to the practice of medicine. For example, WPATH issued a statement on race relations.[22] The American Medical Association[23] has weighed in on affirmative

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22 https://www.wpath.org/media/cms/Documents/Public%20Policies/2020/FINAL%20WPATH%20USPATH%20EPATH%20BLM%20Statement%20Approved%20Jun%2018%202020.pdf

23 The AMA is hardly representative of the majority of physicians of the United States. Business Insider wrote that "it counts fewer than 25 percent of practicing physicians as members, down from 75 percent in the 1950s." https://www.businessinsider.com/doctors-american-medical-association-2016-12

action,[24] climate change,[25] immigration,[26] gun control,[27] nuclear weapons,[28] the conflict in Ukraine,[29] whether lifetime imprisonment for minor felons is cruel and unusual punishment,[30] and whether biological males should play on female sports teams.[31] The American Academy of

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[24] https://searchltf.ama-assn.org/case/documentDownload?uri=%2Funstructured%2Fbinary%2Fcase%2FCase-Summary_Fisher-v-Univ-TX-Austin.pdf; https://searchltf.ama-assn.org/case/documentDownload?uri=%2Funstructured%2Fbinary%2Fcase%2FStudents_for_Fair_Admissions_v__Harvard_and_UNC.pdf

[25] https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-policy-declaring-climate-change-public-health-crisis

[26] https://searchltf.ama-assn.org/case/documentDownload?uri=%2Funstructured%2Fbinary%2Fcase%2FCase-Summary_Trump-v-Hawaii.pdf

[27] https://searchlf.ama-assn.org/case/documentDownload?uri=%2Funstructured%2Fbinary%2Fcase%2FWebber_v__Armslist_LLC.pdf; https://searchlf.ama-assn.org/case/documentDownload?uri=%2Funstructured%2Fbinary%2Fcase%2FNew_York_State_Rifle___Pistol_Assn__v__Bruen.pdf

[28] https://www.ama-assn.org/delivering-care/public-health/ama-urges-elimination-nuclear-weapons

[29] https://www.ama-assn.org/delivering-care/public-health/senseless-war-ukraine-sparks-physician-aid-response

[30] https://searchltf.ama-assn.org/case/documentDownload?uri=%2Funstructured%2Fbinary%2Fcase%2FCase-Summary_Graham-v-FL.pdf. Interestingly, the AMA argued that when it comes to imprisonment, courts should consider that the adolescent brain differs from the adult brain "and how such differences are likely to affect children's personalities and ability to make considered judgments." *Id.* When it comes to transitioning treatments for minors, though, the AMA appears to argue that adolescents are perfectly capable of consenting to care that may leave the child infertile and with impaired sexual function.

[31] https://searchlf.ama-assn.org/case/documentDownload?uri=%2Funstructured%2Fbinary%2Fcase%2FHecox_v__Little.pdf

Pediatrics has advocated on issues such as affirmative action,[32] climate change,[33] gun control,[34] immigration,[35] same-sex marriage,[36] and nuclear weapons.[37] And the Endocrine Society has issued statements on "eradicating racism"[38] and climate change.[39] Regardless of whichever views they have taken, these organizations' advocacy for primarily political issues brings into question whether their views are based on a full debate of the scientific evidence, or another example of them wanting to be on a particular side of a social issue of the day.

B. Retraction of the Flawed Bränström study Conclusion

195. 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

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[32] https://www.supremecourt.gov/DocketPDF/20/20-1199/232119/20220728171113348_20-1199%20and%2021-707%20Amicus%20Brief%20for%20Association%20of%20American%20Medical%20Colleges%20et%20al.pdf

[33] https://publications.aap.org/pediatrics/article/136/5/992/33836/Global-Climate-Change-and-Children-s-Health?autologincheck=redirected

[34] https://www.aap.org/en/advocacy/state-advocacy/universal-background-checks-for-gun-purchases/; https://www.aap.org/en/advocacy/state-advocacy/waiting-periods-for-firearms-purchases/

[35] https://www.abp.org/sites/abp/files/pdf/immigration_eo_statement.pdf

[36] https://publications.aap.org/pediatrics/article/118/1/349/69577/The-Effects-of-Marriage-Civil-Union-and-Domestic; https://publications.aap.org/pediatrics/article/131/4/827/31789/Promoting-the-Well-Being-of-Children-Whose-Parents

[37] https://publications.aap.org/pediatrics/article/121/5/e1430/73491/Taking-a-Stand-Against-Nuclear-Proliferation-The

[38] https://academic.oup.com/jcem/article/107/5/1205/6505234?login=false

[39] https://academic.oup.com/jcem/article/106/12/3381/6410138; https://www.supremecourt.gov/DocketPDF/20/20-1530/211345/20220125165209968_ELJC_WestVAvEPA_PublicHealthAmicus.pdf

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).

196. 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).

197. 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).

198. 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).

199. In another letter, Professor Mikael Landen wrote 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).

200. 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).

201. In yet another critical letter, Dr. Agnes Wold stated 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).

B. High Rates of Completed Suicide and Psychiatric Complications in GAT

202. Dr. Janssen claims that "[r]esearch shows that gender transition significantly improves the mental health of transgender young people, bringing their mental health profiles into alignment with their non-transgender peers" (Janssen decl, par 32). This is incorrect as research shows that key mental health outcomes such as psychiatric hospitalization, mortality, and completed suicide are significantly worse for those undergoing GAT than the general population.

203. For example, 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.

204. 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," for 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. The study was 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.

205. 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 death rate. NIH produced the consent forms related to this study pursuant to a FOIA request my colleague submitted. I have reviewed them and provided them to counsel for the Defendants. 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.

206. 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. 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.

207. 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 shown that providing hormones reduces rates of suicide, and in fact those interventions may be associated with increased rates.

C. An Increase in Cases of Gender Dysphoria

208. 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.

209. 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* Judgment, 2020). There is evidence that this increase may be in part due to social contagion and fueled by social media/internet use (Littman, 2018).

210. 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).

211. 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).

D. Desistance

212. 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).

213. 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.

214. Dr. Shumer states "data and personal experience shows that children whose gender dysphoria persists into adolescence are highly likely to be transgender" (Shumer decl, par 58). However, Dr. Shumer's statement is contradicted by the evidence from the following studies.

215. 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[40]. The desistance rate varied from 61 to 88%. Since 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 on a knowledge of the ages of initiation of puberty and were therefore not pre-pubertal.[41] Therefore we can see that a high proportion of adolescents do in fact desist, contrary to what Dr. Shumer stated.

E. Centers for Medicare and Medicaid Services

216. 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" (CMS.gov, 2016).

F. Mastectomy Surgery for Minors

217. 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).

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[40] "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 identity and sexual orientation outcome. At follow-up, 17 participants (12.2%) were judged to have persistent gender dysphoria" (Singh, 2012).

[41] 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.

218. 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-term risks and benefits of mastectomy for gender dysphoria.

219. 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.

220. 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.

221. 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.

222. 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).

223. 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).

224. 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 that "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.

G. Nations and States Question and Reverse Course on GAT

225. Dr. Kingery states that "[c]omprehensive standards of care and clinical practice guidelines directing this treatment [GAT] have been developed by the World Professional Association for Transgender Health (WPATH) and the Endocrine Society" (Kingery decl, par 25). She describes the WPATH as producing "[i]nternationally accepted Standards of Care" (Kingery decl, FN 1) (emphasis added).

226. 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 in GAT, the court 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, emphasis added). 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.

227. In the bulletin of the Royal College of Psychiatrists in 2021, in a reevaluation of the evidence, Griffin and co-authors write, "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).

228. 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".

229. 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).

230. 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.

231. 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).

232. 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."

(Florida Department of Health, Board of Medicine, 2023).

233. Very recently, in the peer reviewed journal Acta Pediatrica, Swedish authors published a systematic review of the data for hormone treatment with puberty blockers and opposite sex hormones on children. They wrote that of the studies they reviewed "[n]o 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" (Ludvigsson et al., 2023) (emphasis added). They concluded that "evidence to assess the effects of hormone treatment" in gender dysphoric children "is insufficient" (Id.) (emphasis added).

IV. Medical Concerns Regarding Plaintiffs

A. John Minor Doe 1

234. John Minor Doe 1 (JM1) was born a natal female and was 12 years old at the time of mother's declaration (Jane Doe 1 decl, par 4).

235. Dr. Shumer stated that "[p]ersistence or intensification of gender dysphoria as puberty begins is used as a helpful diagnostic tool as it becomes more predictive of gender identity persistence into adolescence and adulthood" (Shumer decl, par 60).

236. JM1's mother, Jane Doe 1, describes JM1 as a "transgender boy" who "'came out' as transgender when he was about eleven". However, Jane Doe 1 goes on to say that JM1 also came out "as nonbinary a few years previous, and as a lesbian before that" (Jane Doe 1 decl, par 5).

237. These statements suggest JM1 having had at least three different gender identities: 1) a transgender male, 2) a non-binary person, and 3) a female attracted to other females. Therefore, JD1 has not expressed a longstanding persistent belief in a specifically male gender identity.

238. This also contradicts Dr. Janssen's statement that "gender identity cannot be altered, either for transgender or for non-transgender individuals" (Janssen decl, par 20).

239. Jane Doe 1 reports that JM1 "became suicidal during and around his periods. In Spring 2022, after his second period, my husband and I hospitalized JM Doe 1 because he told a classmate that he wanted to die" (Jane Doe 1 decl, par 6). Further evaluation of JM Doe's mental health history is necessary, as these are very concerning signs of underlying mental illness.

240. Jane Doe 1 went on to say that "[t]hat fall, JM Doe 1 was diagnosed with gender dysphoria" (Jane Doe 1 decl, par 7). Dr. Shumer stated that "[i]n children and adolescents, a comprehensive biopsychosocial assessment is typically the first step in evaluation, performed by a mental health provider with experience in gender identity" (Shumer decl, par 41). However, JM Doe 1's biopsychosocial assessment has not been made available for review.

241. Jane Doe 1 stated that "[i]n November 2022, JM Doe 1 began taking puberty blockers to stop his periods" (Jane Doe 1 decl, par 8). Dr. Kingery stated that prior to starting puberty blockers "the adolescent must: (i) have been informed of the effects and side effects of treatment (including potential impacts on fertility if the individual subsequently continues with life-long sex hormone treatment) and options to preserve fertility; and (ii) has given informed consent and the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process" (Kingery decl, par 37). At present, no medical record evidence has been provided showing that any of these criteria have been fulfilled. Additionally, Dr. Kingery stated that the adolescent must have "sufficient mental capacity to give informed consent to this (reversible) treatment" (Kingery decl, par 36). It is not clear that JM1 had sufficient mental capacity and understanding to make an informed consent decision before starting puberty blockers, not only because of young age, but also because of the mental health hospitalization for suicidal ideation that occurred prior.

242. To summarize there are multiple concerns with GAT being used to treat JM1:

a) JM1 has not presented with a persistent, stable gender identity.

b) JM1 developed changes in gender identity at an early age and would be most likely to desist if not provided the medical intervention of puberty blockade.

c) JM1 has been hospitalized for suicidal ideation and it is not clear that JM1's underlying mental health condition(s) have been adequately assessed.

d) Because JM1 is taking puberty blockers to stop normal menstrual function, JM1 has had impairment of the normal rapid increase in bone development during adolescence because of the medication is causing the medical condition of hypogonadotropic hypogonadism and is therefore has an increased risk for development of osteoporosis as an adult.

e) JM1 will remain infertile while taking puberty blockers and this will persist if JM1 goes on to take testosterone.

234. Based on the available evidence, JM1's health would benefit from stopping gender affirmative therapy and by being seen by clinicians who do not follow the gender affirmative care treatment model.

B. John Minor Doe 2

235. John Minor Doe 2 (JM2) was born a natal female and was 15 years old at the time of father's declaration (John Doe 2 decl, par 4).

236. John Doe states that "[w]hen JM Doe 2 was in the first grade he would occasionally ask to be called by a male name and male pronouns", and that "JM Doe 2 'came out' as a boy at home and at school in about the seventh or eighth grade" (John Doe 2, par 4 & 6).

237. JM2's father goes on to describe JM2's social transition: "[a]s part of his coming out process, JM Doe 2 cut his hair and began using male pronouns. He recently even obtained a legal name change" (Id.). As discussed earlier, social transition is an active psychological intervention that has made JM2 more likely not to follow a natural desistance pattern[42].

238. John Doe 2 states that "[w]hen JM Doe 2 began puberty and started menstruating, he felt depressed and distressed by the mismatch between his body and gender identity," and that "[a]fter many evaluations and careful discussions regarding the risks and benefits of treatment, JM

[42] See II.A.

Doe 2 began receiving gender-affirming medications. He first began using birth control pills to cause amenorrhea or the complete cessation of menstrual function. He then began testosterone treatment" (John Doe 2 decl, par 6-7).

239. As mentioned earlier in my report, amenorrhea is detrimental to bone health, causing conditions "such as premature bone demineralization or inadequate bone formation, [which] are likely to put amenorrheic women at high risk for osteoporosis and fracture" (Santoro, 2011).

240. Dr. Shumer stated that "[i]n children and adolescents, a comprehensive biopsychosocial assessment is typically the first step in evaluation, performed by a mental health provider with experience in gender identity" (Shumer decl, par 41). However, no such biopsychosocial assessment has been made available to review if it occurred. Further, no mental health records have been provided to describe how JM2's feeling depressed and distressed have been evaluated by mental health professionals. None of the records of the "numerous healthcare professionals" or the "therapist" that John Doe reports to have seen with JM2 have been provided for review (John Doe 2 decl, par 7).

241. Dr. Kingery described a number of mental health criteria that need to be fulfilled prior to starting testosterone treatment as part of GAT: "For a transgender adolescent to be eligible for hormone therapy, the Endocrine Society Guideline directs that a qualified mental health professional confirms: (i) the persistence of gender dysphoria; (ii) any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start hormone therapy; and (iii) the adolescent has sufficient mental capacity to estimate the consequences of this treatment, weigh the benefits and risks, and give informed consent to this treatment" (Kingery decl, pae 39). No medical record evidence has been provided to confirm that these criteria have been fulfilled.

242. With respect to fertility, informed consent, and professional care, Dr Kingery stated that "[f]urther, the adolescent needs to have: (i) been informed of the effects and side effects of treatment (including options to preserve fertility); (ii) given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process. And lastly, a pediatric

endocrinologist or other clinician experienced in pubertal induction: (i) agrees with the indication for hormone therapy; and (ii) has confirmed that there are no medical contraindications to hormone therapy" (Kingery decl, par 39-40). Again, no medical record evidence has been provided that these recommendations have been followed.

243. In summary, the risks of GAT for JM2 are of great concern as high dose testosterone will lead to the condition of severe hyperandrogenism. This in turn leads to an increased risk of risk of heart disease[43].

244. JM2 is also at risk for permanent physical effects of hyperandrogenism including irreversible changes to the vocal cords, male pattern balding, clitoromegaly and hirsutism or abnormal hair growth which may occur on the face, chest, abdomen, back and other areas. Changes to the reproductive system due to hyperandrogenism include polycystic ovaries and atrophy of the lining of the uterus and vagina (Hembree, 2017). Potential cancer risks from high dose testosterone include ovarian and breast cancer (Hembree, 2017).[44] I would expect some or all of these effects and risks to occur to JM5 by continuing to take high dose testosterone as part of GAT.

245. Finally, it is concerning that high dose testosterone may have detrimental effect on JM2's previously described depressive symptoms and may result in a major depressive episode.

246. Based on the available evidence, JM2's health would benefit from stopping gender affirmative therapy, including tapering off of hormones, and by being seen by clinicians who do not follow the gender affirmative care treatment model.[45]

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[43] See II.C.1.b.

[44] Additionally, the ESG state that the natal female patient taking testosterone should be prepared for a potential future total hysterectomy for cancer prevention: "Although there is limited evidence for increased risk of reproductive tract cancers in transgender males, health care providers should determine the medical necessity of a laparoscopic total hysterectomy as part of a gender affirming surgery to prevent reproductive tract cancer," including ovariectomy "after the completion of hormone transition" (Hembree et al., 2017, p. 3892, 3890).

[45] The Plaintiffs' attorneys state that "[j]ust as the harm caused by a prohibition on diabetes treatment would not be mitigated by tapering a diabetic child off insulin, this irreparable harm is not mitigated simply because SB 150 allows some transgender adolescents to be tapered off their medicines." (Plaintiffs motion, p. 10).

247. Additionally, given the patient's age of fifteen, JM2 is still undergoing brain development, and as such is immature with respect to intellect, emotion, judgment, and self-control.

C. Jane Minor Doe 3

248. Jane Minor Doe 3 (JM3) was born a natal male and was 11 years old at the time of father's declaration (John Doe 3 decl, par 4).

249. According to father's declaration, JM3 began socially transitioning at the beginning of least fifth grade (John Doe 3 decl, par 7).[46]

250. John Doe 3 went on to state: "My wife and I identified a psychologist for JM Doe 3 after extensive research and consultations. JM Doe 3 now receives mental health care for gender dysphoria and generalized anxiety disorder. JM Doe 3's psychologist diagnosed her with gender dysphoria in Spring of 2022" (John Doe 3 decl, par 8-9). JM Doe 3's psychologistreferred JM Doe 3 to a pediatric endocrinologist. John Doe 3 does not state the lapse of time between seeking psychologialcare and then receiving the psychologist's referral.

251. John Doe 3 relates that JM3 was seen by a pediatric endocrinologist for a consultation which lasted over two hours. (John Doe 3 decl, par 10-11). The medical record of that visit has not been made available for review. According to the declaration, less than a year after first seeking psychiatric care, JM3 went on to see a surgeon to have a surgical procedure to implant a device that would release puberty blocking medication. Medical records for the surgical consultation and procedure have not been made available for review.

However, they make several fundamental errors in their assertion. Type 1 diabetes is an objectively verifiable condition in which insulin deficiency and high glucose levels (both of which can be measured in the lab with high degrees of certainty) lead overtime to ill-health and even death without the administration of the hormone insulin. Gender dysphoria on the other hand has no objective biological measure, has a very low probability of persistence from childhood, and withholding hormonal therapy does not lead to ill-health or death due to any physical cause. Minors with gender dysphoria who also have suicidal ideation and self-harming behaviors need proper mental health care for psychological comorbidities just as any other minor does with these conditions.

[46] Other aspects of social transition such as growing out hair and not using JM3's birth name occurred at ages 8 and 9 (John Doe 3, decl par 5). This occurred at an age when JM3 would have had a very high probability of desisting by adulthood had this psychological intervention of GAT not been employed. See III.D.

252. Dr. Kingery provided a list of criteria to be fulfilled before starting puberty blocking medication including information about the negative impact on fertility, the need from informed consent on the part of the parents and minor child, and that the adolescent must have "sufficient mental capacity to give informed consent to this (reversible) treatment" (Kingery decl, par 36 & 37). However, medical record evidence has not been provided to show that these criteria were fulfilled. Furthermore, it's unlikely that JM3 had sufficient mental capacity and understanding to make an informed consent decision before starting puberty blockers, not only because of young age, but also because of the mental health condition of anxiety.

253. To summarize my medical concerns for JM3:

a) JM3 has had an impairment of the normal rapid increase in bone development during adolescence because of the surgically implanted puberty blocking medication causing the condition of hypogonadotropic hypogonadism. Continued use of this medication can lead to an increased risk of osteoporosis and fractures as an adult.

b) Hypogonadotropic hypogonadism had caused JM3's genitalia to remain frozen in an undeveloped state while taking puberty blockers, causing sexual dysfunction and infertility.

c) The normal development of the brain under the influence of testosterone has been prevented in JM3 due to blocking normal puberty.

d) Based on the available evidence, JM3's health would benefit from stopping gender affirmative therapy and by being seen by clinicians who do not follow the gender affirmative care treatment model.

D. John Doe Minor 5

254. John Minor Doe 5 (JM5) was born a natal female and was 16 years old at the time of mother's declaration (Jane Doe 5 decl, par 4).

255. JM5 began aspects of social transition including using a "male name and male pronouns" in the seventh grade (Jane Doe 5 decl, par 7). JM5 went on to see a gynecologist because of "extreme distress" due to menstruation (Jane Doe decl, par 8). JM5 was prescribed a hormonal treatment (birth control pills) to cause amenorrhea or the complete cessation of normal menstrual function. No medical records regarding this evaluation and treatment have been made available for review.

256. As mentioned earlier in my report, amenorrhea is detrimental to bone health, causing conditions "such as premature bone demineralization or inadequate bone formation, [which] are likely to put amenorrheic women at high risk for osteoporosis and fracture" (Santoro, 2011).[47]

257. Jane Doe went on to say that "a physician recommended that JM Doe 5 take testosterone," and that after considering risks "[m]y husband and I... consented to the treatment and JM Doe 5 began taking testosterone in January 2023" (Jane Doe 5 decl, par 9). Neither the records of these visits; the concentration, dosage, timing, method of delivery (e.g. injections, topical gel, etc) of testosterone; nor the blood levels of testosterone or any other lab results have been made available for review. Furthermore, it is not clear if JM5 assented or consented to the treatment.[48]

258. Again, Dr. Kingery described a number of mental health criteria that need to be fulfilled prior to starting testosterone treatment as part of GAT including that a qualified mental health professional confirms 1) the persistence of gender dysphoria, 2) recognizes any coexisting psychosocial or medical problems that would interfere with testosterone treatment, 3) and that "the adolescent has sufficient mental capacity to estimate the consequences of this treatment, weigh the benefits and risks, and give informed consent to this treatment" (Kingery decl, par 39). No medical record evidence has been provided to confirm that these criteria have been fulfilled.

259. Dr. Kingery also stated that the adolescent needs to 1) be informed of the side effects of treatment including fertility preservation options, 2) be given informed consent, 3) and that a pediatric endocrinologist or other clinician experienced with GAT agrees with the indication for testosterone and has confirmed that there are no medical contraindications to high dose testosterone treatment (Kingery decl, par 40). No medical record evidence has been provided to confirm that these criteria have been fulfilled.

260. JM5 has been prescribed high dose testosterone as part of GAT which causes the medical condition of hyperandrogenism. I would expect JM5 to be at increased risk of cardiovascular disease due to hyperandrogenism from high dose testosterone.[49] JM5 is also at risk

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[47] See II.B.4.c.

[48] JM5 also sees a therapist, however these records have not been made available for review (Jane Doe 5 decl, par par 9).

[49] See II.B.4.c.

for permanent physical effects of hyperandrogenism including irreversible changes to the vocal cords, male pattern balding, clitoromegaly and hirsutism.

261. Changes to the reproductive system due to hyperandrogenism include polycystic ovaries and atrophy of the lining of the uterus and vagina (Hembree, 2017). Potential cancer risks from high dose testosterone include ovarian and breast cancer (Hembree, 2017).[50] I would expect some or all of these effects and risks to occur to JM5 by continuing to take high dose testosterone as part of GAT. JM5 is also at risk for mood disorders, psychosis, and other psychiatric disorders due to high dose testosterone.

262. Based on the available evidence, JM5's health would benefit from stopping gender affirmative therapy, including tapering off of hormones, and by being seen by clinicians who do not follow the gender affirmative care treatment model.

V. Conclusion

263. 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 complete sexual and reproductive functions of the opposite sex. This is not technologically possible.

264. 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 likely infertile.

265. There are known risks from GAT 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 (or assent) 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

[50] See footnote 43 regarding the need for hysterectomy to mitigate cancer risk.

hormones and surgeries, using randomized controlled studies or even proper observational studies do not exist.

266. WPATH's SOC 8 should not be followed by any physician, mental health care provider, or other medical professional. Neither does the Endocrine Society's Guideline provide a standard of care incumbent upon physicians and clinicians to follow.

267. 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 SB150 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 this 9th day of June, 2023.

Michael K. Laidlaw, M.D.

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Endocrinology, Diabetes, and Metabolism
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Rocklin, CA 95677
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EMPLOYMENT

2006-Present	Michael K Laidlaw, MD Inc. Private Practice – Endocrinology, Diabetes, and Metabolism. Rocklin, CA

EDUCATION

2004-2006	Endocrinology and Metabolism Fellowship - Los Angeles County/University of Southern California Keck School of Medicine
2001-2004	Internal Medicine Residency - Los Angeles County/University of Southern California Keck School of Medicine
1997-2001	University of Southern California Keck School of Medicine Doctor of Medicine Degree May 2001
1990-1997	San Jose State University Bachelor of Science Degree in Biology with a concentration in Molecular Biology, Cum Laude

LICENSURE

California Medical License – Physician and Surgeon: # A81060: Nov 6, 2002. Exp 5/31/2024.

PROFESSIONAL AFFILIATIONS

Endocrine Society 2006-2023
American Board of Internal Medicine - Endocrinology, Diabetes, and Metabolism – 2006
American Board of Internal Medicine - Internal Medicine - 2005
National Board of Physicians and Surgeons - Endocrinology, Diabetes, & Metabolism 2018-2024
National Board of Physicians and Surgeons - Internal Medicine 2018-2024

HONORS AND RECOGNITION

2010	Endocrine Society Harold Vigersky Practicing Physician Travel Award
2004-2005	Vice President - Joint Council of Interns and Residents
2002-2004	Council Member – Joint Council of Interns and Residents
1996, 1997	Dean's Scholar, San Jose State University
1995	Golden Key National Honor Society

RESEARCH AND PUBLICATIONS

2021 Publication – Michael K Laidlaw, Andre Van Mol, Quentin Van Meter, Jeffrey E Hansen. Letter to the Editor from M Laidlaw et al.: "Erythrocytosis in a Large Cohort of Trans Men Using Testosterone: A Long-Term Follow-Up Study on Prevalence, Determinants, and Exposure Years." The Journal of Clinical Endocrinology & Metabolism, Volume 106, Issue 12, December 2021, Pages e5275–e5276, https://doi.org/10.1210/clinem/dgab514

2020 Publication – Van Mol A, Laidlaw MK, Grossman M, McHugh P. "Correction: Transgender Surgery Provides No Mental Health Benefit." Public Discourse, 13 Sep 2020. https://www.thepublicdiscourse.com/2020/09/71296/

2020 Publication – VanMol A, Laidlaw MK, Grossman M, McHugh P.. "Gender-affirmation surgery conclusion lacks evidence (letter)". Am J Psychiatry 2020; 177:765–766.

2020 Publication – Laidlaw MK. "The Pediatric Endocrine Society's Statement on Puberty Blockers Isn't Just Deceptive. It's Dangerous." Public Discourse. 13 Jan 2020. https://www.thepublicdiscourse.com/2020/01/59422/

2019 Speech to the U.K. House of Lords – Laidlaw MK. "Medical Harms Associated with the Hormonal and Surgical Therapy of Child and Adolescent Gender Dysphoria". Parliament, London, U.K. 15 May 2019.

2019 Publication – Laidlaw MK, Cretella M, Donovan K. "The Right to Best Care for Children Does Not Include the Right to Medical Transition". The American Journal of Bioethics. Volume 19. Published online 20 Feb 2019. 75-77. https://doi.org/10.1080/15265161.2018.1557288

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2018 Publication – Laidlaw MK. "Gender Dysphoria and Children: An Endocrinologist's Evaluation of 'I am Jazz'". Public Discourse, 5 Apr 2018. https://www.thepublicdiscourse.com/2018/04/21220/

2013 Abstract – Poster presentation Jun 2013. Endocrine Society Annual Meeting. A 12 Step Program for the Treatment of Type 2 Diabetes and Obesity.

2011 Abstract – Poster presentation Nov 2011. Journal of Diabetes Science and Technology. A Video Game Teaching Tool for the Prevention of Type 2 Diabetes and Obesity in Children and Young Adults.

2011 Abstract – Journal of Diabetes Science and Technology. A Web-Based Clinical Software Tool to Assist in Meeting Diabetes Guidelines and Documenting Patient Encounters.

2008 Abstract - Accepted to Endocrine Society Annual Meeting 2008. Hypercalcemia with an elevated 1,25 dihydroxy-Vitamin D level and low PTH due to granulomatous disease.

2005-2006 Clinical Research - University of Southern California – Utility of Thyroid Ultrasound in the Detection of Thyroid Cancer. Study involving the use of color flow/power doppler ultrasound and ultrasound guided biopsy to detect the recurrence of thyroid cancer in patients with total thyroidectomies.

2005 Certification - Certification in Diagnostic Thyroid Ultrasound and Biopsy – AACE 2005

2003 Certification - Understanding the Fundamentals: Responsibilities and Requirements for the Protection of Human Subjects in Research. University of Southern California. 29 Sep 2003 - 29 Sep 2006

2002-2005 Clinical Research - University of Southern California - Determining the Role of Magnesium in Osteoporosis. Study involved collecting and analyzing patient data related to patient characteristics, laboratory results, bone mineral density exams, nutrition analysis, and genetic analysis in order to determine a link between magnesium deficiency and osteoporosis.

1996 Research Assistant - San Jose State University - Role of the suprachiasmatic nucleus pacemaker in antelope ground squirrels.

1995-1996 Research Assistant - San Jose State University/NASA. Acoustic tolerance test and paste diet study for space shuttle rats.

EXPERT WITNESS WORK AND AMICUS BRIEFS

2023 Expert Witness – Laidlaw MK. United States District Court for the Northern District of Oklahoma. PETER POE, et al., Plaintiffs, v. GENTNER DRUMMOND, et al., Defendants. Case No. 23-cv-00177-JFH-SH.

2023 Expert Witness – Laidlaw MK. United States District Court for the Western District of Kentucky. JANE DOE 1, et al., Plaintiffs, v. WILLIAM C. THORNBURY, JR., MD, in his official capacity as the President of the Kentucky Board of Medical Licensure, et al., Defendants. Case No. 3:23-cv-00230-DJH.

2023 Expert Witness – Laidlaw MK. United States District Court for the Middle District of Tennessee Nashville Division. L.W., by and through her parents and next friends, Samantha Williams and Brian Wil-liams, et al. Plaintiffs, v.

JONATHAN SKRMETTI, in his official ca-pacity as the Tennessee Attorney General and Reporter, et al., Defendants. Case No. 3:23-cv-00376.

2022-2023 Expert Witness – Laidlaw MK. 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. Report October 3, 2022. Testified in court October 12, 2022. Expert Report February 17, 2023. Rebuttal March 10, 2023.

2022 Expert Witness Report – Laidlaw MK. 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 Expert Witness Report – Laidlaw MK. DISTRICT COURT OF TRAVIS COUNTY, TEXAS 459th JUDICIAL DISTRICT. PFLAG, INC., ET AL., Plaintiffs, v. GREG ABBOTT, ET AL., Defendants. NO. D-1-GN-22-002569. 3 July 2022.

2022 Expert Witness Report #2 – Laidlaw MK. 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. 24 Jun 2022. (Sealed under Protective Order).

2022 Expert Witness Report – Laidlaw MK. United States District Court for the Middle District of Alabama Northern Division. REV. PAUL A. EKNES-TUCKER, et al., Plaintiffs, v. KAY IVEY, in her official capacity as Governor of Alabama, et al., Defendants. Civil Action No. 2:22-cv-184-LCB. 2 May 2022.

2021 Brief of Amicus Curiae – Bursch, John J., McCaleb, Gary S., Van Meter, Quentin L., Laidlaw, Michael K., Van Mol, Andre, Hansen, Jeffrey E. Brief of Amicus Curiae. United States Court of Appeals for the Eight Circuit. DYLAN BRANDT, et al., Plaintiffs-Appellees v. LESLIE RUTLEDGE, in her official capacity as the Arkansas Attorney General, et. al. Defendants-Appellants. 23 Nov 2021.

2021 Expert Witness – JULIANA PAOLI v. JOSEPH HUDSON et al. heard in THE SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF TULARE. CASE NO. 279126. 2021.

2021 Brief of Amicus Curiae – Bursch, John J., McCaleb, Gary S., Grossman, Miriam, Van Meter, Quentin L., Laidlaw, Michael K., Van Mol, Andre, Hansen, Jeffrey E. Brief of Amicus Curiae. United States Court of Appeals for the Eleventh Circuit. DREW ADAMS, Plaintiffs-Appellee v. SCHOOL BOARD OF ST. JOHNS COUNTY, FLORIDA, et. al. Defendants-Appellant. 26 Oct 2021.

2020 Expert Witness Affidavit 1 & 2 – Laidlaw MK. Supreme Court of British Columbia. File No. S2011599, Vancouver Registry. Between A.M. Plaintiff and Dr. F and Daniel McKee Defendants. 11/23/20 & 11/25/20.

2020 Brief of Amicus Curiae – Wenger, Randal L., McCaleb, Gary S., Grossman, Miriam, Laidlaw, Michael K., McCaleb, Gary S., Van Meter, Quentin L., Van Mol, Andre. Brief of Amicus Curiae. United States Court of Appeals for the Ninth Circuit. LINDSAY HECOX and JANE DOE, with her next friends Jean Doe and John Doe, Plaintiffs-Appellees v. BRADLEY LITTLE, in his official capacity as Governor of the State of Idaho, et. al. Defendant-Appellant. 19 Nov 2020

2020 Expert Witness Report – Laidlaw MK. 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. 27 Sep 2020.

2019 Expert Witness Affidavit – Laidlaw MK. Court of Appeal File No. CA45940, Vancouver Registry. B.C. Supreme Court File No. E190334, between A.B. Respondent/Claimant, and C.D. Appellant/Respondent, and E.F. Respondent/Respondent. 24 Jun 2019.

2018 Brief of Amicus Curiae – Alliance Defending Freedom, Campbell, James A., Grossman, Miriam, Laidlaw, Michael K., McCaleb, Gary S., Van Meter, Quentin L., Van Mol, Andre. Brief of Amicus Curiae. United States Court of Appeals for the Eleventh Circuit. Drew Adams, Plaintiff-Appellee, v. School Board of St. Johns County, Florida, Defendant-Appellant. 12/27/2018.

PERSONAL

Languages: Conversational Spanish, French
Tutor: Biochemistry, computer science, High School mentor
Computers: Ruby, Rails, Javascript, C++, C, Java, and HTML programming

EXHIBIT 7

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISIVLLE DIVISION

Electronically filed

DOE 1, *et al.*
Plaintiffs

v.

THORNBURY, *et al.*
Defendants

and

COMMONWEALTH OF KENTUCKY, *ex rel.* ATTORNEY GENERAL DANIEL CAMERON
Intervening Defendant

Civil Action No. 3:23-CV-00230-DJH

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 an inmate identifying as transgender 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 inmates adopting a transgender identity 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 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 complaint filed by the plaintiffs and the expert declarations of Susan Kingery, M.D., -Daniel Shumer, M.D., and Aron Janssen, M.D.

13. I am being compensated for my time spent in connection with this case at a rate of $400.00 per hour for review, document preparation, and consulting and $500 per hour for preparing for and delivering live or deposition testimony. My compensation is not dependent upon the outcome of this litigation or the substance of my opinions.

II. SUMMAR

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, socioeconomic 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 response results in the best long-term outcomes for affected individuals. The scientific basis for medical transition through puberty blockers and cross-sex hormones 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. (Section V.A.)

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. (Sections VI.A., VI.B.)

g. "Social transition"—the active affirmation of transgender identity—in young children is a powerful social intervention that will substantially reduce the number of children "desisting" from transgender identity. Therefore, the profound implications of an "affirmative" approach —which includes taking puberty blockers and cross-sex hormones— must be taken into account where social transition is being considered. (Sections VII.A,, VII.B.)

h. Administration of puberty blockers is not a benign "pause" of puberty, but rather a powerful medical and psychological 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" approach to 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 medically transitioning young children to a transgender identity 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. (Sections VIII.B., VIII.C.)

k. In light of what is known and not known about the impact of medical transition 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 expresses 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 life-long after-care; alienation of family and romantic relationships; elevated mental health risks of depression, anxiety, and substance abuse. (Section X.)

III. BAC GROUND 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. At its core, the sex of a human individual 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 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, cis-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 individual adopting a transgender identity 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.

In contrast to these well-established, time-honored, pervasively understood basic facts of biology, the plaintiffs' experts, Drs. Shumer, Janssen, and Kingery, promote a different view: Gender identity, like sex, is innate and largely biologically determined. They make no reference to the differing ages of patients declaring binary or nonbinary gender identity—in childhood, adolescence, early adulthood, middle age and older age. Nor do they acknowledge the idea that every aspect of personality is shaped by post-natal processes including family dynamics, individual psychological development, interpersonal relationships, and cultural forces. The evolution of gender identity is no exception. As explained below, noted instances of detransition are inconsistent with the plaintiffs' concepts of biological determination of gender identity.

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 cross-gender 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 identify as 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 adopt a transgender identity.

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 sub-threshold 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 absence of breasts, or the primary

anatomical sex organs of testes, ovaries, penis, or vagina—should be removed to alleviate the illness. Under this paradigm, these interventions are promised to cure the gender dysphoria. The plaintiffs' experts subscribe to this paradigm and believe that the mental distress of gender dysphoria is a serious medical condition that should be treated medically with hormones, puberty blockers and eventually surgery. But this approach neglects the origins or etiological influences on gender dysphoria's development. Such wrong thinking makes it easier for these advocates to change healthy anatomy and physiology contrary to the time-honored ethical principle: Above All Do No Harm.

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 that some attempt to treat first with the interruption of normal pubertal processes and then 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. People who identify as transgender 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 a 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 a person's sense of his or her gender. Some advocates assert that a transgender identity is biologically caused, fixed from early life, and eternally present in an unchanging manner. As I address 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 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

[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.

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 gender dysphoria and their ideal treatments exist. These current disagreements might have been minimized if persons who identify as transgender were carefully followed up to determine long term outcomes of any interventions they received. 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 VI.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 asserted gender identity in children to naturally evolve— that is, take its course from forces within and surrounding the child. Watchful waiting has two versions:

m. 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

n. 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 males who adopt a transgender identity, 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. An assertion of transgender 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 asserted 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 systematic 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 individual 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. When plaintiffs' experts note that some of their patients benefit from medical interventions, this, too constitutes anecdotal reports. 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 model therapists did not recommend psychotherapy before encouraging hormonal treatment (Littman, (2021). *See 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). Dr Shumer, a pediatric endocrinologist, asserts that there is no effective treatment for gender dysphoria other than medical transition requiring puberty blockers, cross-sex hormones and eventually surgery. He and Dr. Janssen, who is a psychiatrist, invoke the research of Dr. Turban to pejoratively label any attempt to understand the etiological influences on the development of gender dysphoria as "conversion therapy" even though all three of the plaintiffs' experts praise the requirement for a comprehensive slow psychiatric evaluation of the patients and the patients' families. Several of

these experts (Kingery and Janssen) emphasize that based on this process, some patients are directed to other forms of psychiatric intervention, either because they do not meet criteria for the diagnosis or that they are perceived to be too mentally ill. Nowhere do they acknowledge that psychotherapy, as opposed to psychiatric evaluation, can possibly address underlying developmental adversities that enable the minor to identify as a transgendered person. Rather, the purported destructiveness of psychotherapy is emphasized, despite that psychotherapy is the usual treatment for all other emotional disorders of minors, along with medications for some."

3 The affirmation 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 the child's claimed transgender identity. They argue that the child should be comprehensively re-socialized 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 asserted transgender identification as inappropriate. They may not recognize the child's ambivalence. They assume that observed psychological co-morbidities 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 asserted 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 VIII below, and suicide in Section IX 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. This study followed 55 of the original 70 patients until the maximum age of 21, providing no information about how these individuals fared thereafter. 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 affirmation 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 United Kingdom failed to demonstrate psychological benefits claimed by the Dutch studies. (Carmichael et al 2021). The plaintiffs' experts claim that the two deVries papers establish the effectiveness of affirmation. They make no mention of the obvious limitations of this work—an uncontrolled experiment that selected emotionally healthy minors who had been cross gender identified since childhood who were simultaneously treated with psychotherapy. Today's youth are heavily skewed towards pubertal onset of gender dysphoria among a preponderance of natal females who identify as non-binary. Thus, plaintiffs' experts ignore these limitations that even deVries herself has pointed out.

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 an asserted 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 gender dysphoric 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. The plaintiffs' experts emphasize the need for a comprehensive psychiatric assessment which takes a considerable amount of time. Dr. Kingery suggested months. Each expert points to WPATHs high standards for careful evaluation. However, the devil is in the details. I have had many experiences with patients who received hormones after meeting a specialist during the first visit. And, the multidisciplinary team that is so heavily emphasized by the plaintiffs' experts all act in concert in reliance on the mental health professionals, who are variously educated and experienced, to provide a letter of clearance assuring the hormone prescriber or surgeon that the patient is ready for the body changing intervention. Once again, the mental health professional's role is to ethically assure the other professionals that someone has justified the treatment. None of the plaintiffs' experts stated that the mental health professional was responsible for suggesting the vulnerabilities of the minor that led to assuming a new gender identity. Rather their role was to determine the diagnosis, the minor's cognitive maturity to consent to treatment, and to provide an opinion that medical intervention would be helpful. Nothing is said about providing care for the minor's autism, school avoidance, bonding problems, self-harm, eating disorders, and other of the common co-morbidiites. The mental health professional has to assure the endocrinologist that the co-morbidities are under reasonable control,

a concept that is never defined. This represents a rejection of the developmental paradigm of gender dysphoria and a prioritization of the affirmative care model in which the discovering pathway to gender dysphoria is far less important than the presence of the diagnosis.

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

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 surprising nor improper that—as I detailed in Section III—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 ustifies treatment for gender identity issues.

53. As outlined in Section III.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

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

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 gender 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 partner's 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 sufficient gender dysphoria 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. Dr. Shumer's mentor, Dr. Norman Spack, was singly responsible, without facts, for declaring that affirmative hormonal disruption starting with puberty blockers prevented suicide. The Plaintiffs expert was trained by America's first advocate for puberty blockers. In fact, the completed suicide rate of teens who identify as transgender is low, but the lifetime suicide rate is quite elevated. Discussions often confuse suicidal thoughts with

completed suicide. Life enhancing, on the other hand, is justified by short -term happiness with bodily changes. This concept is not based on clear systematic evidence that the mental health and function of these minors is enhanced, despite what the plaintiffs; experts report based on their clinical experience. The most recent report on a two- year prospective study of hormonal treatment of 16-year-old children showed that the changes in depression and anxiety were modestly positive statistically with great variation from subject to subject (Chen et al, 2023). A previous systematic review on the impact of these hormones on mental health failed to find evidence of clear and consistent improved mental health (Thompson et al, 2022). Based on the DSM-5-TR criterion, distress is required for the diagnosis and its subsequent hormonal and surgical interventions. Gender incongruence is often referred to as a unique form of suffering. Yet, ICD-11 the criteria for the diagnosis of Gender Incongruence 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." Thus, the emphasis on life enhancing is attenuated by providing the adolescent with what he or she wants. The diagnosis then becomes based on what the patient, however mature and emotionally healthy, wants, even if the patient does not have gender dysphoria.

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 person's asserted transgender 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 transgender 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 identified 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 individuals who identify as transgender 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 people who identify as transgender. 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

people who identify as transgender who attend meetings are committed to supporting others in their transitions. Not only have some participants who identify as transgender 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 transgender rights advocates have a worrisome track record of attacking those who have alternative views (Dreger 2015; McNamarra, et al 2022). It is apparent that the plaintiffs' experts have an uncritical belief in and trust of the scientific merits of WPATH's recommendations even though many others from other countries, mindful of the limitations of the SOC, no longer employ WPATH's guidelines. I will discuss this in more detail below.

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 person who identifies as transgender 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 transgender care facilities are staffed by MHPs who are not deeply experienced with recognizing and treating frequently associated psychiatric co-morbidities. 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, 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.

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

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 identifying with his or her biological sex. 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 medically transitioning 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 youth who identify as transgender, and the dangers of following fashion-based trends 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 an intervention for gender dysphoria is often justified by reference to the seminal work of a 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 plaintiffs’ experts acknowledge as much. The Dutch protocol only treated children with these characteristics: a stable asserted 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 United Kingdom'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 gender dysphoric 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 association 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

[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.

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. The plaintiffs' experts only reference the 2018 policy formulated by a small committee.

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 VIII 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 IDENTIT IS NOT BIOLOGICALL 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. Even twin studies which show an increased concordance in identical versus fraternal twins fail to demonstrate that the majority of identical twins are concordant for gender dysphoria. Dr. Shumer, who cites this, does not explain the influence of shared environment on gender identity and the known limitations of such studies. For instance, identical twins are not perfectly identical—just more identical than fraternal twins. Parents of identical twins can commonly tell the twins apart perfectly well. That is because identical twins are not really identical in habits, like crying, eating,

and so on. I am providing therapy to a family of identical twin in which one has juvenile diabetes, as does a parent and an older sibling, and the other twin does not. Additionally, Dr. Shumer, and the study he cites, fails to account for the social phenomena of shared adversity. Identical twins suffering a shared trauma (trauma occurring at the same time in the same manner) do not always share the same response. Instead, one may preserve an emerging gender sense of self while the other's sense of self is disrupted. One twin may react to the shared trauma in a way that propels him or her toward gender dysphoria, and the other not.

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.). Dr. Shumer's cited references relating to brain structure have now been supplanted by more rigorous reviews by Mueller et al in 2017 and Frigerio et al in 2021. (Meuller et al. American Journal of Psychiatry. Dec 2017.)

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. The plaintiffs' experts do not even mention this worldwide trend.

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

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

expansively defined.

95. I frequently read attempts to explain away the points in Section VI. They include: these problems always existed; children are now learning that there are effective treatments for their dilemma and are simply seeking them. And children have hidden their subjective discomfort with themselves throughout childhood and now that people who identify as transgender are recognized and accepted, they are presenting themselves in this new way. 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 VII.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 III.D.)

99. The vast majority of those who experience gender dysphoria, or adopt 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 gender identifications, but they provide no support for a biological basis for 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. 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.

102. 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. The Plaintiffs' experts hypothesize that, like those with recognized DSD disorders, minors with gender dysphoria must have some biological abnormality that accounts for their disorder. This is a hypothesis in search of evidence.

VI. GENDER IDENTIT IS EMPIRICALL NOT FI ED FOR MAN INDIVIDUALS.

103. There is extensive evidence that a person's self-perceived 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.

104. 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.

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

[6] See n1 *supra*.

intervention until that age.

106. 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.)

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

108. 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.

109. 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.

110. 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."

111. 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.)

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

113. 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.)

114. 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.)

115. 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 medical transitioning has become popularized, the rate of detransition appears to be accelerating.

116. A recent study from a United Kingdom 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.)

117. Another study from a United Kingdom primary care practice found that 12.2% of those who had started hormonal interventions 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 cross-sex 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 researchers 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 interventions with irreversible effects, often without the benefit of appropriate, or in some instances any, psychologic exploration.

118. While detransition has not been discussed by the plaintiffs' experts, it has been mentioned by WPATH's SOC 8th edition. What is not discussed in these standards is how to help those who have detransitioned on their own accord. The plaintiffs' experts make no mention of how they handle those whose function remains low or deteriorates with hormonal interventions. They merely emphasize how effective the medical transition is. A study has shown that 75% of those who detransition do not tell their hormone prescriber, leaving doctors and NPs believing everyone is helped (Litman, 2021).

VII. ULTIMATE GENDER IDENTIT OUTCOMES ARE IMPACTED B MEDICAL AND SOCIAL TRANSITIONING

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 medical intervention—the child will not require ongoing pharmaceutical 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 Sections IX and X 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 has a powerful psychological effect 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 encouraging social transition before or during puberty—which would include participation on athletic teams designated for the opposite sex—is a practice with potent psychological effect 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 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

[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.
[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."

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 account 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 psychological 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 Sections IX

and 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 underwent 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 E PERIMENTAL AND HAVE NOT BEEN SHOWN TO IMPROVE MENTAL OR PH SICAL HEALTH OUTCOMES B OUNG 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.E.) 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.

A. The knowledge base concerning medical transition for gender dysphoria is very low quality.

[10] *See also* Brik 2020 where Dutch researchers found nearly 97% of adolescents who received puberty blockers proceeded to cross-sex hormones.

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:

o. 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-credentialed "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;

p. A single case or series of cases (what could be called anecdotal evidence) (Levine 2016 at 239.);

q. A series of cases with a control group;

r. A cohort study;

s. A randomized double-blind clinical trial;

t. A review of multiple trials;

u. 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 of gender dysphoria 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 [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"

[11] https://cass.independent-review.uk/publications/interim-report/

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 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 X 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. outh 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 longitudinal 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 youth adopting a transgender identity 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 e youth and young adults in Chicago who identify as transgender or gender diverse 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, nor did they publish data on several parameters that they originally intended to provide. 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 problems, 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). Another

review was published in 2023 from Sweden, which likely was the basis for Sweden's policy change to limit medical intervention to approved research protocols, failed to demonstrate improved mental health (Ludviggson et al, 2023)

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 veterans who adopt a transgender identity 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 United Kingdom found a significant excess of deaths among gender dysphoric 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 transgender identified individuals than the general population. The mean age of this 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 representing 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 well-being of the child or adolescent who transitions to live in a transgender identity is not good. Gender dysphoria is not "easily managed", as the plaintiffs' experts stated, when one understands the marginalized, vulnerable physical, social, and psychological status of adult populations who identify and transgender and their premature death patterns.

I . TRANSITION AND AFFIRMATION DO NOT DECREASE, AND MA INCREASE, THE RIS 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. 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.

153. Some authors have reported rates of suicidal thoughts and behaviors among transgender 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 medical transition 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. When studies seem to demonstrate a reduction in suicidality, it is important to realize that the time period is three months after the initiation of cross sex hormones—the "honeymoon period: (Allen et al, 2019).

154. 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.

155. An important analysis of data covering patients as well as those on the waiting list (and thus untreated) at the United Kingdom 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 adolescents identifying as transgender who self-report suicidal behavior or thoughts on surveys. (Biggs 2022b.)

156. 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 youth who identify as transgender are "alarmingly high" "has no formal and systematic empirical basis." (Zucker 2019 at 3.)

157. 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.

158. 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 adolescents and young adults who identify as transgender 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.)

159. 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 medical transition 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.

160. 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.

161. There are now four long-term studies that analyze completed suicide among those

[12] Turban et al. (2020) has been described in press reports as demonstrating that administration of puberty suppressing hormones to gender dysphoric adolescents reduces suicide or suicidal ideation. The paper itself does not make that claim, nor permit that conclusion.

162. living in transgender identities into adulthood. The results vary significantly but are uniformly highly negative. Dhejne reported 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 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 patients 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. A 2021 study analyzed the case histories of a cohort of 175 gender dysphoria patients treated at one of the seven United Kingdom 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.)

167. 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.

168. 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 lifesaving measure. (Levine 2016, at 242.) In my opinion, this is an important fact that patients, parents, and even many MHPs fail to understand.

. HORMONAL INTERVENTIONS ARE E PERIMENTAL PROCEDURES THAT HAVE NOT BEEN PROVEN SAFE.

169. 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.

170. 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.

171. Because, as I have explained in Section VII, recent evidence demonstrates that pre-pubertal 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.

172. 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.)

173. 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.

174. 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 body-wide 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.

175. 14. Systematic data reviews are scientifically more reliable than individual reports with definable methodologic limitations. Without quoting extensively from the reviews done by Sweden, Finland, the United Kingdom, 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 detransition and regret, and the lack of evidence of efficacy.[13] (Swedish National Board of Health and Welfare, 2022).

176. **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.)

177. **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 available evidence remains limited and conflicting, it is not possible to conclude that the treatment is "safe."

178. **Brain development**: Important neurological growth and development in the brain

[13] https:/www.sociialstyrelsen.se/globalassets/sharepointdokument/artikelkatalog/kunskapsstod/2022- 7799.pdf

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.

179. 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.

180. 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.

181. 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.

182. Without a number of additional case studies—or preferably statistically significant clinical studies—two questions remain unanswered: Do puberty blockers cause brain anatomic or functional impairment? 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.

183. **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 transgender-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?

184. 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 transgender 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.

185. 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 will 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.

186. As with puberty blockers, all evidence concerning the safety of extended use of cross- sex hormones is of "very low quality." The United Kingdom 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.)

187. 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.)

188. **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]

189. 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. Poor families cannot afford fertility preserving procedures, nor are those procedures covered under Medicaid.

190. **Sexual response**: Puberty blockers prevent maturation of the sexual organs and response. Some, and perhaps many, individuals who did not go through puberty consistent with

[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").

their sex and are then put on cross-sex hormones face significantly diminished 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 individuals who do not identify as transgender that is ultimately applicable to those individuals who do. (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.

191. **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.

192. 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 communities of people identifying as transgender.

193. **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 individual who identifies as transgender to be in contact with those children. By adulthood, the friendships of individuals who identify as transgender tend to be confined to others who identify as transgender (often "virtual" friends known only online) and the generally limited set of others who are comfortable interacting with such 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 person adopts a transgender, every member of that person's family—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 anytime a person adopts a transgender identity. There may be too much focus on the person adopting a transgender identity as a patient and not enough as a person developing in an interpersonal, ever-changing matrix called a family.

194. **Sexual-romantic harms associated with transition**: After adolescence, individuals who identify as transgender find the pool of individuals willing to develop a romantic and intimate relationship with them to be greatly diminished. When a person who passes well reveals his or her natal sex, many potential mates lose interest. When a 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.

195. 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 IX.A. 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 gender dysphoric 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.)

196. 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 child who is adopting a transgender identity. (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.

197. 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 co-morbidities. 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 medical transition for those with previous and co- existing mental health problems have an ethical obligation to inform themselves, and to inform patients and parents, that these dramatic protocols are not a panacea.

198. 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."

I. REPL TO THE E PERT REPORTS OF DRS. SU ANNE INGER , DANIEL SHUMER, AND ARON JANSSEN

A. WPATH Endocrine Society Guidelines.

199. Dr. Janssen's report emphasizes how WPATH and The Endocrine Society guidelines require that 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. They 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 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 attempt 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).

200. 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 gender dysphoria. (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

201. None of the plaintiffs' experts question whether adolescents can provide informed consent; even more concerning, they appear unaware of the longstanding international ethical unease about youthful gender dysphoria because of seven unanswered 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.

202. The plaintiffs' experts s acknowledge that the Endocrine Society Guidelines require "informed consent" from patients but fails to mention how informed consent is obtained from minors. Similarly, Dr. Janssen mentions that the WPATH standards of care require clinicians to assess whether a patient has the requisite "capacity." Legally informed consent from those under 18 must be provided by parents or guardians. Adolescents may only assent, not consent. The Endocrine Society Guideline 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.

203. 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. Medical transition 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 social or medical transition. (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 indicates 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 the plaintiffs' experts' 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.

204. 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 clinicians who support medical transitioning, 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. 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.

206. International interest in the necessary components of informed consent can be seen from the reception that our March 2022 article has had (Levine, et al, 2022). As of June 5, 2023, the paper has been downloaded across the world over 62, 550 times. We presume that Drs. Shumer, Kingery, 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.

207. 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]

208. For years, medical transition 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.

209. Medical transition advocates have always recognized that informed consent was legally and ethically required. The issues are the following: (1) what informed 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. (Levine, et al, 2022). Contrary to Drs. Janssen's and Kingery's suggestions to the contrary, it has not been proven that youth are mature enough to provide informed consent or assent to these life altering procedures. 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 medical transition. 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 medical transition 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-

[15] Missouri Independent (2023). Missouri agencies launch investigation into health center for transgender youth. https://missouriindependent.com/2023/02/09/missouri-agencies-launch-investigation-into-health-center-for-transgender-youth/.

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 transition. 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 persons who have transitioned, and if they do not recognize the multidimensional problems described by advocates within transgender identifying communities, then they cannot help parents to consider the immediate benefits and the long terms risks involved in medical transitioning. 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

210. The plaintiffs' experts, of course, rely on the DSM-5 and DSM-5-TR (collectively "DSM") to support the assertion that gender dysphoria is a medical diagnosis. 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.

211. 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.

212. 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 transitions to better align the body with the self-perceptions formulated by 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.

213. 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.

214. The use of puberty blockers (PB) and cross sex hormones (CSH), which of course change normal anatomy 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 current transgender 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.

215. 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.

216. While patients' histories of their symptoms are 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

217. 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 medical transition 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).

218. The plaintiffs' experts assert that that "gender-affirming medical care under clinical practice guidelines, like the Endocrine Society's, is evidence based.". 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 gender dysphoric 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.

E. Low regret rates

219. WPATH and others assert that the regret rate for adult gender-diverse patients who received affirmative care is 1.1%. These authors do 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.

Adolescents who adopt a transgender identity 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 transgender person, regret eventually led to detransition. (MacKinnon, et al., 2022).

220. Low regret rates do not consider 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).

221. Regret rates less than 1% 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 transgender and then return to a sex-gender compatible state. The influence of external factors is thought to have no intrapsychic manifestations. This comes about because advocates do not recognize, or at least acknowledge, that gender dysphoric adolescents and adults are ambivalent about their transgender processes even if

they are not perceived to be so by advocates.

222. 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).

223. 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.

224. 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.

II. THE MOST RECENT S STEMATIC REVIEW PUBLISHED IN THE FIELD HIGHLIGHTS MAN OF THE POINTS MADE ABOVE

225. 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.

226. 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. (Ludvigsson 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.

227. 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.

228. 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 medically treated and medically untreated patients but had no pre- and post-transition 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. (Ludvigsson et al, 2023).

229. 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**. (Ludvigsson et al, 2023).

230. Puberty blockers arrest the puberty growth spurt and lead to increased fat mass and decreased lean body mass.

231. Obesity at age 22 was more prevalent in populations identifying as transgender.

232. 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 United Kingdom systemic review. The Swedish review concluded that the effects on psychosocial and somatic health are "unknown". (Ludvigsson et al,

2023).

233. 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.

234. 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 model clinicians and institutions that support such care also simply do not understand the limitations of science in this politicized arena.

235. When the frequently encountered psychiatric co-morbidities of youth who identify as transgender 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 8th day of June, 2023.

Stephen B. Levine, M.D.

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Zucker, K. (2019). *Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues*. ARCHIVES OF SEXUAL BEHAVIOR 48(7) 1983–1992.

Zucker, K. (2020). *Different strokes for different folks.* CHILD ADOLESC MENT HEALTH 25(1): 36–37. https://doi: 10.1111/camh.12330.

Curriculum Vita

Stephen B. Levine, M.D.

I) **Brief Introduction**

Dr. Levine is Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine. He is the solo author of five books, Sex Is Not Simple in 1989 (translated to German in 1992 and reissued in English in 1997 as Solving Common Sexual Problems); Sexual Life: A clinician's guide in 1992; Sexuality in Midlife in 1998 and Demystifying Love: Plain talk for the mental health professional in 2006; Barriers to Loving: A clinician's perspective in 2013; Psychotherapeutic Approaches to Sexual Problems: An Essential Guide for Mental Health Professionals in 2020. He is the Senior Editor of the first (2003), second (2010) and third (2016) editions of the Handbook of Clinical Sexuality for Mental Health Professionals. He has been teaching, providing clinical care, and writing since 1973 and has generated original research, invited papers, commentaries, chapters, and book reviews. He has served as a journal manuscript and book prospectus reviewer for many years. He was co-director of the Center for Marital and Sexual Health/ Levine, Risen & Associates, Inc. in Beachwood, Ohio from 1992-2017. He and two colleagues received a lifetime achievement Masters and Johnson's Award from the Society for Sex Therapy and Research in March 2005. He was given his Department of Psychiatry's Hall of Fame Award in 2021.

II) **Personal Information**

A) Date of birth 1942
B) Medical license no. Ohio 35-03-0234-L
C) Board Certification 6/76 American Board of Neurology and Psychiatry
D) Office-23425 Commerce Park, Beachwood, Ohio 44122-5402 phone 216-831-2900 x 13 fax 216-831-4306, direct dial 216-998-9905

III) **Education**

A) 1963 BA Washington and Jefferson College
B) 1967 MD Case Western Reserve University School of Medicine
C) 1967-68 internship in Internal Medicine University Hospitals of Cleveland
D) 1968-70 Research associate, National Institute of Arthritis and Metabolic Diseases, Epidemiology Field Studies Unit, Phoenix, Arizona, United States Public Health Service
E) 1970-73 Psychiatric Residency, University Hospitals of Cleveland
F) 1974-77 Robert Wood Johnson Foundation Clinical Scholar

IV) **Appointments at Case Western Reserve University School of Medicine**

A) 1973- Assistant Professor of Psychiatry
B) 1979-Associate Professor
C) 1982-Tenure
D) 1985-Full Professor
E) 1993-Clinical Professor

V) **Honors**

A) Summa Cum Laude, Washington & Jefferson
B) Teaching Excellence Award-1990 and 2010 (residency program)
C) Visiting Professorships

1) Stanford University-Pfizer Professorship program (3 days)–1995
2) St. Elizabeth's Hospital, Washington, DC –1998
3) St. Elizabeth's Hospital, Washington, DC--2002

D) Named to America's Top Doctors consecutively since 2001
E) Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research, April 2005 along with Candace Risen and Stanley Althof
F) 2006 SSTAR Book Award for The Handbook of Clinical Sexuality for Mental Health Professionals: Exceptional Merit
G) 2018—Albert Marquis Lifetime Achievement Award from Marquis Who's Who. (excelling in one's field for at least twenty years)
H) Invitations to present various Grand Rounds at Departments of Psychiatry and Continuing Education Lectures and Workshops during 2019-2022
1) March 12, 2021-The Mental Health Professionals' Role with the Transgendered: Making the Controversies Clear Grand Rounds University Hospitals of Cleveland
2) May 1, 2021 Psychotherapeutic Approaches to Sexual Problems Invited lecture to the American Psychiatric Association Annual Meeting (similar lecture in May 2020
3) Seven years of Continuing Education Courses at the American Psychiatric Association Meetings on Love and Sexuality
4) Grand Rounds at Cleveland Clinic Foundation on Sexuality Education of Psychiatric Residents June 25, 2020
5) Grand Rounds at Cleveland Clinic Foundation June 2019 Transgenderism: Beware! Repeated by invitation at Akron General Hospital and at National meeting of American Association of Partial Hospitalization in 2019
6) Three-hour workshop at Society of Sex Therapy and Research in 2020 on Therapy for Sexual Problems
7) Workshop on Teaching Sexuality to residents at the American Association of Residency Training Directors 2020 annual meeting
8) Three-hour continuing education seminar with Massachusetts Department of Corrections Gender Identity Staff Fall 2019
9) Four-hour seminar on Gender Dysphoria at Harvard Student Health Service Staff
10) Three grand rounds presentations at Henry Ford Hospital on Transgender Evaluation and Treatment of Children, Adolescents, and Adults
11) Symposium (90 minutes) at the American Psychiatric Association 2022 meeting The Management of Adolescent-Onset Transgender Identity: Should "Best Practices" Change?

VI) **Professional Societies**

A) 1971- American Psychiatric Association; fellow; #19909
B) 2005-American Psychiatric Association- **Distinguished Life Fellow**
C) 1973- Cleveland Psychiatric Society
D) 1973-Cleveland Medical Library Association
1) 1985-Life Fellow
2) 2003 Distinguished Life Fellow

E) 1974-Society for Sex Therapy and Research
1) 1987-89-President
F) 1983- International Academy of Sex Research
G) 1983- Harry Benjamin International Gender Dysphoria Association
1) 1997-8 Chairman, Standards of Care Committee
H) 1994- 1999 Society for Scientific Study of Sex

VII) **Community Boards**

A) 1999-2002Case Western Reserve University Medical Alumni Association
B) 1996-2001 Bellefaire Jewish Children's Bureau
C) 1999-2001 Physicians' Advisory Committee, The Gathering Place (cancer rehabilitation)

VIII) **Editorial Boards**

A) 1978-80 Book Review Editor Journal Sex and Marital Therapy
B) Manuscript Reviewer for
1) Archives of Sexual Behavior*
2) Annals of Internal Medicine
3) British Journal of Obstetrics and Gynecology
4) JAMA
5) Diabetes Care
6) American Journal of Psychiatry
7) Maturitas
8) Psychosomatic Medicine
9) Sexuality and Disability
10) Journal of Nervous and Mental Diseases
11) Journal of Neuropsychiatry and Clinical Neurosciences
12) Neurology
13) Journal Sex and Marital Therapy*
14) Journal Sex Education and Therapy
15) Social Behavior and Personality: an international journal (New Zealand)
16) International Journal of Psychoanalysis
17) International Journal of Transgenderism
18) Journal of Urology
19) Journal of Sexual Medicine* named Gold reviewer in 2021
20) Current Psychiatry
21) International Journal of Impotence Research
22) Postgraduate medical journal
23) Academic Psychiatry
24) Expert Opinion on Drug Safety
25) Clinical Psychology Reviews
26) Heliyon
27) Andrologia
28) Children and Youth Services Review
29) Women and Criminal Justice
30) Children
31) European Journal of Child and Adolescent Psychiatry

32) International Journal of Environmental and Public Health
33) Journal of Controversial Ideas
*frequent

C) Book Prospectus Reviewer
1) Guilford
2) Oxford University Press
3) Brunner/Routledge
4) Routledge

IX) **Administrative Responsibilities**

A) Co-director, Center for Marital and Sexual Health/ Levine, Risen & Associates, Inc. until June 30, 2017

B) Principal Investigator of approximately 70 separate studies involving pharmacological interventions for sexual dysfunction since 1989.

C) Co-leader of case conferences at DELR. LLC.com

D) **Expert Witness Appearances in Depositions or at Trial**

1) US District Court, Judge Mark L. Wolf's witness in Michelle Kosilek vs. Massachusetts Dept of Corrections et al. case (transsexual issue) in Boston 2007
2) Deposition in the Battista vs. Massachusetts Dept of Corrections case (transsexual issue) in Cleveland October 2009
3) Witness for Massachusetts Dept. of Corrections in their defense of a lawsuit brought by prisoner Katheena Soneeya. March 22, 2011 Deposition in Boston and October 2018 in Cleveland and 2019 in Boston.
4) Witness for State of Florida vs. Reyne Keohane July 2017
5) Witness for State of North Carolina in 2021 Kadel et al v. Folwell et al No.1:19-cv-00272-LCB-LPA

X) **Consultancy and Educational Contributions**

A) Massachusetts Department of Corrections—evaluation of 12 transsexual prisoners and the development of a Gender Identity Disorders Program for the state prison system. Monthly consultation with the GID treatment team since February 2009 and the GID policy committee since February 2010. Ongoing

B) California Department of Corrections and Rehabilitation; 2012-2015; education, inmate evaluation, commentary on inmate circumstances, suggestions on future policies

C) Virginia Department of Corrections –evaluation of an inmate for management purposes

D) New Jersey Department of Corrections—evaluation of an inmate for management purposes

E) Idaho Department of Corrections—workshop 2016

F) Florida Department of Corrections-workshop 2016 or 2017

G) Ohio-evaluation of a prisoner for management purposes 2015

H) Massachusetts—continuing education seminar for GID clinic staff. 2019

I) Washington State—workshop on Gender Dysphoria for mental health professionals in DOC and evaluation of two women and one male transgender inmate 2018-9
J) Evaluation of trans inmate in Boston, Massachusetts 2022
K) New Jersey Department of Corrections: Four lectures, one week apart, Jan-Feb.2023

XI) **Expert Witness Reports, Depositions, or Testimony**

A) Expert Witness report in Charlene Paige Fuller litigation against Massachusetts DOC. 2015

B) NORSWORTHY, Plaintiff,v.JEFFREYBEARD,etal, Defendants.United StatesDistrict Court,Northern Districtof California,CaseNo.C14- -00695JST. 2015

C) SHILOH QUINE (a/k/a RODNEY JAMES QUINE), Plaintiff, Vs. JEFFREY BEARD; S. PAJONG; D.)BRIGHT; J. DUNLAP; J. LEWIS;) and DOES 1-30, Defendants. California 2015

D) Pennsylvania legislative testimony. Written submission and live testimony before a committee of the Pennsylvania legislature. March 2020. (Engaged by Pennsylvania Family Institute.)

E) In the Interests of the Younger Children. Expert testimony by deposition and at trial in Dallas, TX. (Engaged by Texas counsel Odeneal & Odeneal.) (Dallas Cty. Dist. Ct. 2019). Testimony at trial

F) Doe v. Madison Metropolitan School District. Expert declaration submitted February 19, 2020, rebuttal declaration submitted August 14, 2020.

G) Hecox v. Idaho. Expert declaration submitted June 4, 2020
H) Testimony to Subcommittee on Health to Pennsylvania legislature in March 2020
I) Claire et. a. v. DMS et. Al November 16, 2020
J) Kadel et al vs. Folwell et al. North Carolina insurance case deposition Septemer 2021

K) Rhys & Lynn Crawford (Washington State). 3/30/2021

L) Tingley v. Washington State.. (W.D. Wa.) 2021

M) Queen (Quincy Bell) vs. Tavistock and Portman Clinics and NHS in High Court of London, Decision handed down on December 1, 2020.

N) IN THE HIGH COURT OF JUSTICE QUEEN'S BENCH DIVISION ADMINISTRATIVE COURT B E T W E E N: THE QUEEN (on the application of) L and Hampshire County Council-2021
O) *Hennessy-Waller v. Snyder, Case No. CV-20-00335-TUC-SHR, 2021 WL 1192842, at *5-6 & n.10 (D. Ariz. Mar. 30, 2021. Supplemental report 2022 (court prevents access because it involves a minor).*
P) Fain v. PEIA. West Virginia Medicaid Case submitted Feb.18, 2022.
Q B.P.J. v. West Virginia Board of Education, et al.; Case No. 2:21-cv-316 (United States District Court, Southern District of West Virginia **IN DEVELOPMENT March 30, 2022--deposition**

R) DYLAN BRANDT, et al., V. LESLIE RUTLEDGE, et al., LESLIE RUTLEDGE, et al., No. 4:21-CV-00450-JM Eastern Division of Arkansas , Central Division—deposition May 26, 2022; court testimony 11/28/2022
S L.E. vs. Lee MD Tenn. No.3:21-cv-00835.—deposition August 18, 2022
T Siefert v Hamilton County—deposition January 19, 2023
U AURORA REGINO v. KELLY STALEY, Chico United School District. (CASE NO: 2:23−CV−00032−JAM−DMC) expert reported provided December 27, 2022
V JESSICA KONEN and A.G., her minor child v. SPRECKELS UNION SCHOOL DISTRICT; CASE NO: 5:22-CV-05195-EJD); report not yet filed
W) Dekker et al v Marsteller et al. Case no. 4:22-ev-00325 RH-MAF expert opinion filed February 14, 2023; testimony May 17,2023
X) Greenland v Greenland testimony March 21, 2023 Third District Circuit Madison County, Illinois Case no. 15D1070
Y) Doe 1 et al. v Thornbury et al., 3:23-cv-00230-DJH (W.D.Ky) expert opinion submitted June, 2023

XII) **Grant Support/Research Studies**

A) TAP–studies of Apomorphine sublingual in treatment of erectile dysfunction
B) Pfizer–Sertraline for premature ejaculation
C) Pfizer–Viagra and depression; Viagra and female sexual dysfunction; Viagra as a treatment for SSRI-induced erectile dysfunction
D) NIH- Systemic lupus erythematosis and sexuality in women
E) Sihler Mental Health Foundation
    1) Program for Professionals
    2) Setting up of Center for Marital and Sexual Health
    3) Clomipramine and Premature ejaculation
    4) Follow-up study of clergy accused of sexual impropriety
    5) Establishment of services for women with breast cancer
F) Alza–controlled study of a novel SSRI for rapid ejaculation
G) Pfizer–Viagra and self-esteem
H) Pfizer- double-blind placebo control studies of a compound for premature ejaculation
I) Johnson & Johnson – controlled studies of Dapoxetine for rapid ejaculation
J) Proctor and Gamble: multiple studies to test testosterone patch for post menopausal sexual dysfunction for women on and off estrogen replacement
K) Lilly-Icos—study of Cialis for erectile dysfunction
L) VIVUS – study for premenopausal women with FSAD
M) Palatin Technologies- studies of bremelanotide in female sexual dysfunction—first intranasal then subcutaneous administration
N) Medtap – interview validation questionnaire studies
O) HRA- quantitative debriefing study for Female partners os men with premature ejaculation, Validation of a New Distress Measure for FSD,

P) Boehringer-Ingelheim- double blind and open label studies of a prosexual agent for hypoactive female sexual desire disorder
Q) Biosante- studies of testosterone gel administration for post menopausal women with HSDD
R) J&J a single-blind, multi-center, in home use study to evaluate sexual enhancement effects of a product in females.
S) UBC-Content validity study of an electronic FSEP-R and FSDS-DAO and usability of study PRO measures in premenopausal women with FSAD, HSDD or Mixed FSAD/HSDD
T) National registry trial for women with HSDD
U) Endoceutics—two studies of DHEA for vaginal atrophy and dryness in post menopausal women
V) Palatin—study of SQ Bremelanotide for HSDD and FSAD
W) Trimel- a double-blind, placebo controlled study for women with acquired female orgasmic disorder.
X) S1 Biopharma- a phase 1-B non-blinded study of safety, tolerability and efficacy of Lorexys in premenopausal women with HSDD
Y) HRA – qualitative and cognitive interview study for men experiencing PE

XIII) **Publications**

A) Books

1) Pariser SR, Levine SB, McDowell M (eds.), Clinical Sexuality, Marcel Dekker, New York, 1985
2) Sex Is Not Simple, Ohio Psychological Publishing Company, 1988
   (a) Translated into German as Angstfreie Sexualitat: Gluck und Erfullung in der Liebe, Wilhelm Heyne Verlag, Muchen, 1992
   (b) Reissued in paperback as: Solving Common Sexual Problems: Toward a Problem Free Sexual Life, Jason Aronson, Livingston, NJ. 1997
3) Sexual Life: A Clinician's Guide. Plenum Publishing Corporation. New York, 1992
   (a) See review in Archives of Sexual Behavior 28(4): 361-363,1999
4) Sexuality in Midlife. Plenum Publishing Corporation. New York, 1998
   (a) See review in Am Journal of Psychiatry 156((9):1468, 1999
   (b) See review in Contemporary Psychology APA Review of Books 44(4):293-295, 1999
   (c) See review J Sex Education and Therapy January, 2000
   (d) See review J Sex and Marital Therapy, Winter, 2000
5) Editor. Clinical Sexuality. Psychiatric Clinics of North America, March, 1995.
6) Editor, (Candace Risen and Stanley Althof, associate editors) Handbook of Clinical Sexuality for Mental Health Professionals. Routledge, New York, 2003
   1. see review American Journal of Psychiatry April, 2005
   2. 2006 SSTAR Book Award: Exceptional Merit
   3. see review in Archives of Sexual Behavior 35(6):757-758
   4. see two reviews in Journal of Sex and Marital Therapy 33(3):272-276

7) Demystifying Love: Plain Talk For The Mental Health Professional. Routledge, New York, 2006
   (a) See review in Psychiatric Times, August 2008 by Leonore Tiefer
   (b) See review in Journal of Sex and Marital Therapy 34(5)-459-460.
8) Senior editor, (Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals. 2nd edition Routledge, New York, 2010. See review by Pega Ren, JSex&Marital Therapy
9) Barriers to Loving: A Clinician's Perspective. Routledge, New York, 2014.
10) Senior editor Candace B. Risen and Stanley E. Althof, Associate editors), Handbook of Clinical Sexuality for Mental Health Professionals. 3rd edition Routledge, New York, 2016
11) Psychotherapeutic Approaches to Sexual Problems: An essential guide for mental health professionals, 2020
   (i) See review in J Sex and Marital Therapy

B) Research and Invited Papers When his name is not listed in a citation, Dr. Levine is either the solo or the senior author

1) Sampliner R. Parotid enlargement in Pima Indians. Annals of Internal Medicine 1970; 73:571-73
2) Confrontation and residency activism: A technique for assisting residency change: World Journal of Psychosynthesis 1974; 6: 23-26
3) Activism and confrontation: A technique to spur reform. Resident and Intern Consultant 173; 2
4) Medicine and Sexuality. Case Western Reserve Medical Alumni Bulletin 1974:37:9-11.
5) Some thoughts on the pathogenesis of premature ejaculation. J. Sex & Marital Therapy 1975; 1:326-334
6) Marital Sexual Dysfunction: Introductory Concepts. Annals of Internal Medicine 1976;84:448-453
7) Marital Sexual Dysfunction: Ejaculation Disturbances . Annals of Internal Medicine 1976; 84:575-579
8) Yost MA: Frequency of female sexual dysfunction in a gynecology clinic: An epidemiological approach. Archives of Sexual Behavior 1976;5:229-238
9) Engel IM, Resnick PJ, Levine SB: Use of programmed patients and videotape in teaching medical students to take a sexual history. Journal of Medical Education 1976;51:425-427
10) Marital Sexual Dysfunction: Erectile dysfunction. Annals of Internal Medicine 1976;85:342-350
11) Articles in Medical Aspects of Human Sexuality
   (a) Treating the single impotent male. 1976; 10:123, 137
   (b) Do men enjoy being caressed during foreplay as much as women do? 1977; 11:9
   (c) Do men like women to be sexually assertive? 1977;11:44

(d) Absence of sexual desire in women: Do some women never experience sexual desire? Is this possibility genetically determined? 1977; 11:31
(e) Barriers to the attainment of ejaculatory control. 1979; 13:32-56.
(f) Commentary on sexual revenge.1979;13:19-21
(g) Prosthesis for psychogenic impotence? 1979;13:7
(h) Habits that infuriate mates. 1980;14:8-19
(i) Greenberger-Englander, Levine SB. Is an enema an erotic equivalent?1981; 15:116
(j) Ford AB, Levine SB. Sexual Behavior and the Chronically Ill Patients. 1982; 16:138-150
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3. Humanize with Wesley Smith. May 11, 2023. https://humanize.today/podcast/stephen-b-levine-m-d-on-the-science-of-gender-affirming-care/
4. Gender a wider lens, with Ayad and O-Malley and Julia Mason, May 12, 2023

EXHIBIT 8

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISIVLLE DIVISION

Electronically filed

DOE 1, *et al.*
Plaintiffs

v.

THORNBURY, *et al.*
Defendants

and

COMMONWEALTH OF KENTUCKY, *ex rel.* ATTORNEY GENERAL DANIEL CAMERON
Intervening Defendant

Civil Action No. 3:23-CV-00230-DJH

DECLARATION GEETA NANGIA, M.D.

TABLE OF CONTENTS

I, Geeta Nangia, MD, have been retained by counsel for the Intervening defendant, Commonwealth of Kentucky, *ex rel.* Attorney General Daniel Cameron (hereinafter "the Commonwealth")in connection with the above captioned litigation.

1. I have been asked by counsel for the Commonwealth to provide my expert opinion on the diagnosis and treatment of gender dysphoria in minors as it relates to Kentucky SB 150.

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 successfully 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 standards) 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.), *Boe v. Marshall,* No. 2:22-cv-0184 (M.D. Ala.), and *L.W.et al v. Skrmetti*, No. 3:23-cv-00376 (M.D. TN).

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 desire to prevent the development of the anticipated secondary sex characteristics)
- A strong desire for the primary and/or secondary sex characteristics of the other gender
- A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
- A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)

- A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)

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 and in opposite gender activities, preferred cross-gender roles in make believe play, wanted to 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 exploration 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 "bandwagon 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 during 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 did not challenge 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 physician 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. Non-maleficence 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) decision-making 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 decision-making 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 understanding, 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 always 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 decision-making 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 development 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 pre-adolescence), 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.

GENDER DYSPHORIA AND INFORMED CONSENT IN MINORS

115. As explained above, informed consent requires that a patient have decision-making 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 (medical/surgical gender transition), 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 accompanying 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, physicians 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 co-occurring 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 identified 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 transition 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 development. (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 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) identification 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-nonconforming 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 explored 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 being 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 gender incongruent 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 thinking 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 gender 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 psychiatric medication for off-label uses, 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 de-transitioners?
- 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 consequences 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 others in this same situation, given these are low in risk and likely high in benefit.

III. Kentucky Senate Bill 150 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.

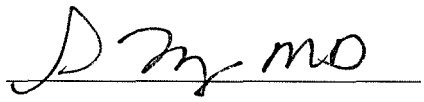
173. They deserve to have methodologically and scientifically sound research conducted on all possible pathways of treatment, so that they can make well informed decisions as adults about which pathway of treatment they'd like to choose.

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.



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June 8, 2023

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APPENDIX A. TRIADIC MODEL OF NEUROBIOLOGY

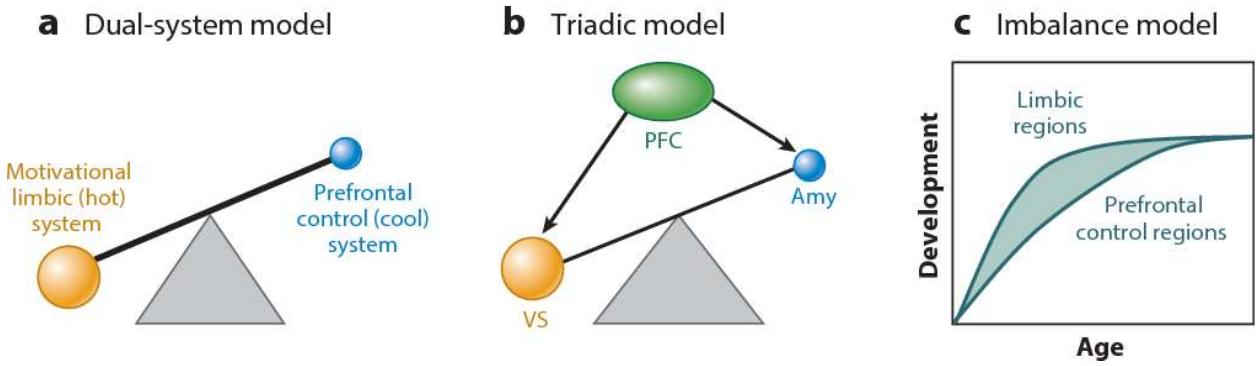

Figure 2

Published in Annual Review of Psychology 2015

Beyond simple models of self-control to circuit-based accounts of adolescent behavior.

B. Casey

APPENDIX B. ADOLESCENT FMRI STUDIES WHEN PRESENTED WITH REWARD

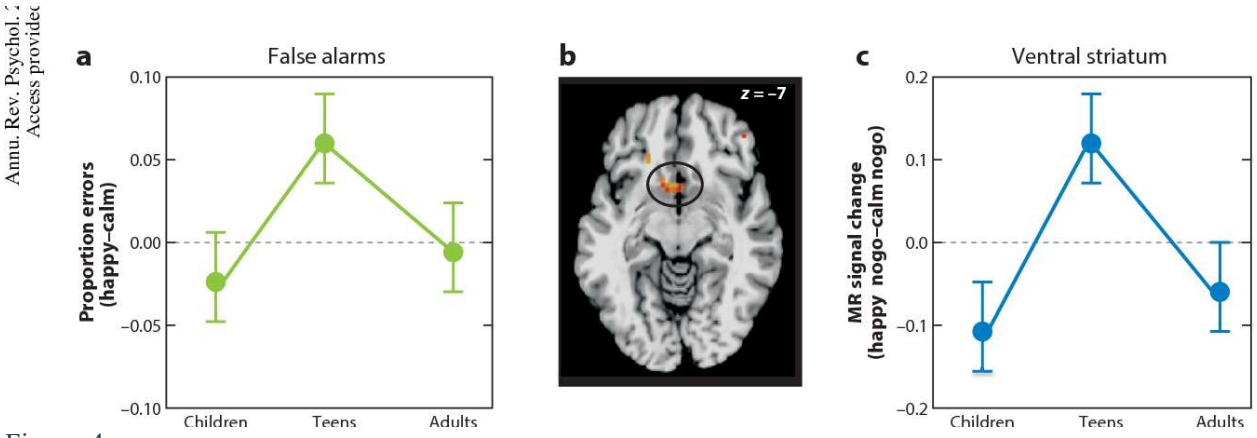

Figure 4
Published in Annual Review of Psychology 2015
Beyond simple models of self-control to circuit-based accounts of adolescent behavior.
B. Casey

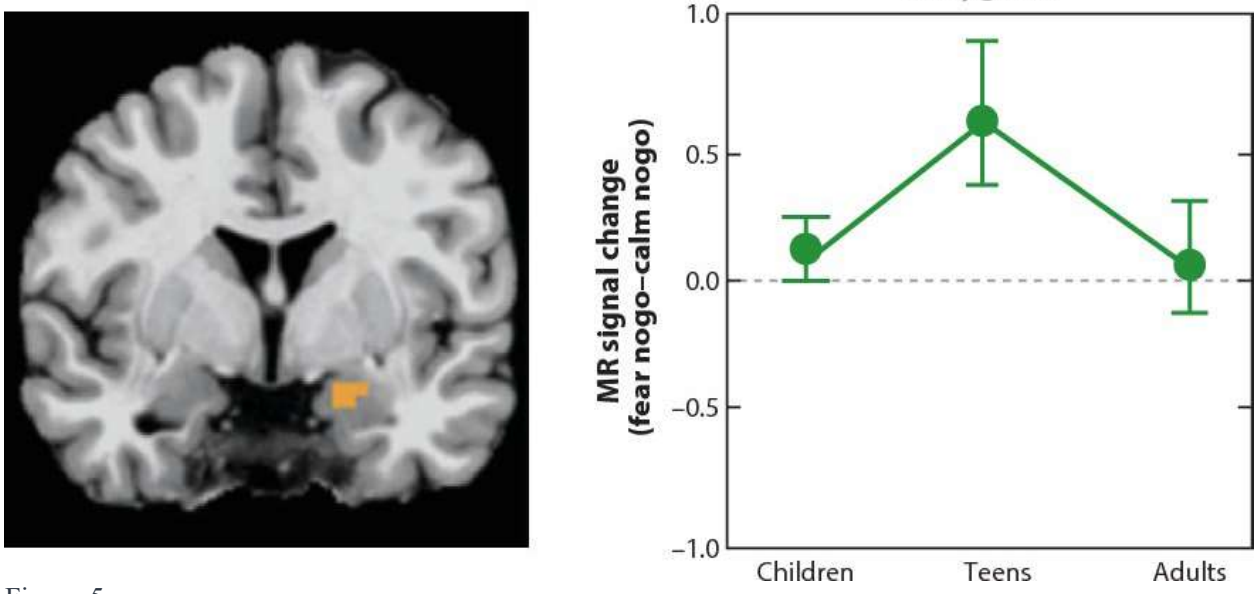

Figure 5
Published in Annual Review of Psychology 2015

Beyond simple models of self-control to circuit-based accounts of adolescent behavior.

APPENDIX C. CROSS TALK BETWEEN THE PFC AND VENTRAL STRIATUM

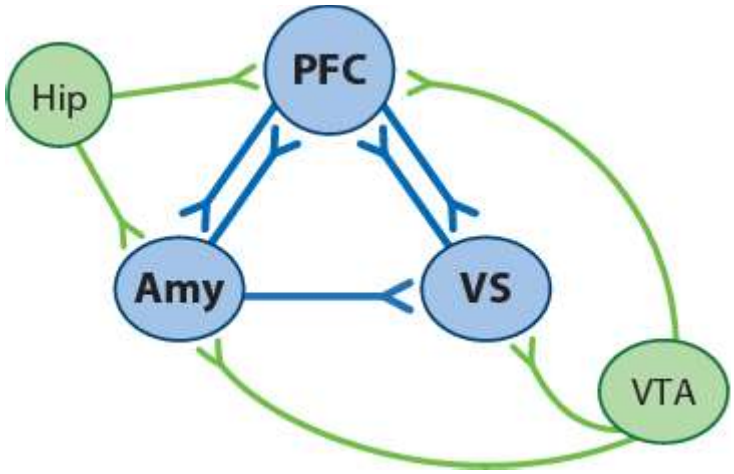

FIGURE 3

Published in Annual Review of Psychology 2015

Beyond simple models of self-control to circuit-based accounts of adolescent behavior.

B. Casey

APPENDIX D. ERIKSON'S PSYCHOSOCIAL DEVELOPMENT MODEL

Geeta Nangia, M.D.
Board Certified in Adult Psychiatry and Child & Adolescent Psychiatry
Phone (864) 318-9930 • drnangia@jothgreenville.com

EDUCATION

Boston University School of Medicine — **Boston, MA**
Doctor of Medicine — May 2002

Boston University — **Boston, MA**
Bachelor of Arts Biochemistry, Molecular Biology — May 1998

INTERNSHIP AND RESIDENCY

Medical University of South Carolina — **Charleston, SC**
Child and Adolescent Psychiatry Fellow — June 2007

Medical University of South Carolina — **Charleston, SC**
General Psychiatry Resident — June 2006

EXPERIENCE

Known and Loved — **Greenville, SC**
CEO — **2021-present**
Educating, equipping, and supporting the growth of healthy families in our region. Providing mental health education and support to parents, with a special focus on foster and adoptive families. Helping parents to establish secure and healthy attachments with children, thereby improving their long term mental health outcomes. Laying the groundwork for schools, community service organizations, first responders, medical providers, and families to become educated and informed about Trust Based Relational Intervention (TBRI) and the importance of a trauma informed approach in working with children and youth.

Journey of the Heart, LLC — **Piedmont, SC**
Child and Adolescent Psychiatrist — **2022-present**
Providing behavioral health care for children and families, specializing in complex cases and trauma.

Parkside Pediatrics Behavioral Health — **Greenville, SC**
Child & Adolescent Psychiatrist — **2019-2022**
Opened and developed Parkside Behavioral Health at Parkside Pediatrics for Upstate SC children and families. Consulted on child and adolescent mental health cases for a large pediatric group with multiple sites. Coordinated care with local schools in order to provide accommodations and support for children

and youth. Provided parent and provider education classes. Specialized in complex cases and trauma.

Carolina Family Services **Greenville, SC**
Staff Psychiatrist **2016-2018**
Provided behavioral health care for children and families.

Edward Via College of Osteopathic Medicine **Spartanburg, SC**
Community Clinical Faculty and Lecturer **2015-2020**
Taught medical students about the principles of childhood development and clinical psychiatry.

Carolina Center for Behavioral Health **Greer, SC**
Staff Psychiatrist **2015-2016**
Provided psychiatric services in an inpatient unit for children and adults of all ages who were in need of acute crisis stabilization and mental health services. Provided medication management for intensive outpatient programs and addiction programs.

The Well Planted Child, LLC **Bellefonte, PA**
Child and Adolescent Psychiatrist **2014- 2015**
Provided school based psychiatric consultation services for children with behavioral and/or academic difficulties. Assisted teachers in developing effective classroom management strategies and in creating accommodations for children with special needs. Provided care for the BLAST Intermediate Unit which serves multiple school districts in the region.

Centre County Christian Academy **Bellefonte, PA**
Kindergarten Teacher **2014-2015**
Primary teacher for morning academics at a private school for an academic year. Assessed classroom modifications and strategies typically recommended by clinical mental health professionals to assess their efficacy. Provided consulting services for children with special needs or behavioral issues.

Diversified Treatment Alternatives **Lewisburg, PA**
Child and Adolescent Psychiatrist **2012- 2015**
Provided evaluation and treatment for children in two residential care facilities. Provided care for a high risk youth population with a special focus on sexual abuse, sexual perpetration, trauma, and addiction. Supervised treatment teams who were providing trauma focused treatment for children. Provided psychiatric care for children and adolescents in a partial hospitalization program.

Sunpointe Health **State College, PA**
Child and Adolescent Outpatient Psychiatrist **2011-2012**
Adult Psychiatry Inpatient Attending Psychiatrist
Provided inpatient adult psychiatric evaluation and treatment in an acute care setting at Mount Nittany Medical Center. Taught medical students during their psychiatry rotation. Provided outpatient psychiatric care for children and adolescents.

Palmetto Christian Psychiatry **Charleston, SC**
Private Practice Psychiatrist **2010-2011**
Provided psychiatric evaluation and treatment for individuals of all ages. Provided individual and family psychotherapy.

Susquehanna Health Medical Group **Williamsport, PA**
Child and Adolescent Psychiatrist **2007-2010**
Adult Psychiatry Inpatient Attending Psychiatrist
Spearheaded The Department of Child Psychiatry at a local community hospital with a mission to serve children who otherwise did not have access to mental health care. Performed evaluations and treatment for children and adults with a broad spectrum of mental health and developmental disorders. Actively conducted family therapy, psychodynamic therapy, cognitive behavioral therapy, play therapy, as well as group therapy. Provided medication management. Worked with outlying community agencies in all arenas, consulting with and for schools, social services, court systems, pediatricians and primary care physicians, wrap around services, and partial hospitalization programs to coordinate care for children. Taught in the family medicine residency program weekly. Supervised staff therapist and psychiatric nurse. Provided courtroom testimony in custody and abuse cases. Performed on call duties on the adult inpatient unit.

Carolina Center for Behavioral Health **Greer, SC**
Staff Psychiatrist **2006-2007**
Served in a weekend moonlighting position servicing an adult inpatient population while in fellowship training. Managed crisis calls, multiple levels of acuity, and geriatric patients on weekends during my fellowship.

HONORS

Susquehanna Physician Appreciation Award, 2008
Family Medicine Residency Teaching Certificate 2008
Circle of Excellence in Teaching 2003
Ruth Hunter Johnson Prize in Psychiatry 2002

LICENSURES

Pennsylvania Medical License MD 431126 inactive
South Carolina Medical License MD 26215 active

CERTIFICATIONS

American Board of Psychiatry and Neurology, General Psychiatry
American Board of Psychiatry and Neurology, Child and Adolescent Psychiatry

EXHIBIT 9

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISIVLLE DIVISION

Electronically filed

DOE 1, *et al.*
Plaintiffs

v.

THORNBURY, *et al.*
Defendants

and

COMMONWEALTH OF KENTUCKY, *ex rel.* ATTORNEY GENERAL DANIEL CAMERON
Intervening Defendant

Civil Action No. 3:23-CV-00230-DJH

DECLARATION OF LAYLA JANE [PSEUDONYM] IN SUPPORT OF INTERVENOR DEFENDANT'S OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, Layla Jane[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 Intervenor Defendants' opposition to Plaintiffs' Motion for a Preliminary Injunction.

[1] Declarant is submitting this Declaration using a pseudonym to protect the privacy of her family.

2. Sections 4(a) and 4(b) of Kentucky's SB 150 are necessary, potentially life-saving provisions that will protect vulnerable children and their parents from the heartbreaking regret, irreversible physical changes, and emotional pain that I have experienced after undertaking medical interventions aimed at "transitioning" me from female to male before even starting high school.

3. I have always felt like I did not "fit in" with my peers, especially my female friends.

4. I felt displeasure, even hatred, about my body. This became more intense when I began puberty early, at age 9 in fourth grade.

5. I experienced trauma in elementary school through my early teen years. I was not taught how to cope with the trauma and with the difficulties of pubertal changes in my body.

6. As a result, I began struggling with depression, and had issues with suicidality in elementary school. When puberty started, I began engaging in self-harm.

7. I hated myself and saw myself as not as good as other girls. I winced at my physical features, including my fluctuating weight, my curves, my large breasts and my arms. I was bothered by wearing bras. I was so unhappy with my chest that I was wearing a chest binder all the time, to the point that I would not take a shower, would sleep in the binder and work out in it.

8. I spent a lot of time on Instagram, which exposed me to gender identity ideology. The algorithms Instagram uses showed me more of what I looked at.

9. I started to identify as a male in the sixth grade, at age 11. I had heard about transgenderism and began to wonder if I could transition. The idea of transitioning was appealing in light of all that had happened to me already.

10. I saw a therapist after I came out as trans. The therapist referred my parents and me to a gender specialist with Kaiser. The gender specialist sent me to a gynecologist who prescribed birth control to stop my periods. I had a negative reaction and stopped taking it.

11. I was then referred to a pediatric transgender clinic with Kaiser, where I saw an endocrinologist who prescribed Lupron for my gender dysphoria in late 2016. I was 12 years old.

12. In June 2017 I saw another Kaiser endocrinologist who prescribed testosterone. I remained on testosterone until I was 17 years old.

13. A month after my 13th birthday, I had a double mastectomy when I was in 8th grade. I was constantly binding my chest and was hurting myself with the binder to the point where I would get delirious, so I wanted to remove the breasts and my parents agreed.

14. Lupron caused me to put on a lot of weight. It was like going through menopause at age 13. I would get intense hot flashes. It made it hard to do homework. The Lupron negatively affected my mental health -- my depression and anger were actually worse. I was given Lupron to relieve my mental distress about getting my period. It stopped my periods, but my mental health got worse. I continued to engage in self-harm while on Lupron.

15. Testosterone caused me to lose weight. It gave me energy, but really affected my sleep. My voice deepened and I got facial and increased body hair permanently. Testosterone also gave me an Adam's apple for life.

16. Testosterone may have affected my liver. When I was 14, doctors did some lab work and asked me if I drank alcohol because my liver results were so bad. I had neither drunk alcohol nor taken illegal drugs.

17. Immediately after I began taking testosterone I felt great and my body discomfort was alleviated for a time . But the good feeling only lasted between six months and a year. Then, the elation faded. I started to have doubts. I continued to dislike my body. Even though my breasts were gone I still disliked everything else with my body. All the discomfort came back full force.

18. My mental health grew turbulent while I was on testosterone. Over time my self-harming got worse, and I started to consider and engage in methods of self-harm I had never used before. I would see my gender specialist regularly, but there was no meaningful mental health therapy throughout the time that I was taking Lupron and testosterone.

19. I was unhappy and not really functioning. I could barely bring myself to do my schoolwork and could barely go to the store without having a panic attack. The testosterone made it harder for me to process things, harder to cry, to feel things or get my emotions out.

20. I began spacing out my testosterone injections and by age 17, I stopped taking testosterone. However, I will forever have some of its effects – an Adam's apple, deep voice, facial hair, and other impacts I am still learning about.

21. At the time I received these treatments I wholeheartedly believed they were what I needed. I believed that if I received these treatments the mental health problems and issues with my body would go away. My parents were also led to believe that and so agreed to my getting the treatments. I could never actually become a male but I was in denial about that fact for a long time, and I am still in the process of reconnecting with my female body.

22. Now I realize that these treatments should not be given to minors even with parental consent. I do not blame my parents. I blame the professionals who advised me and my parents. I understand that my providers convinced my parents that I should undergo these treatments by indicating that "it is better to have a live son than a dead daughter." Changing a child's physiology or removing body parts are very heavy decisions for parents to make. Parents are trying to help their kids and depend on the professionals for advice, as my parents did, and they are not getting good advice in this area.

23. Laws such as Kentucky's SB 150 that do not allow these treatments to be given to minors should be supported in the interest of protecting children. Once a person is an adult and can make a truly informed decision that is a different issue. Minors, however, should be safeguarded.

24. I was initially called hateful and transphobic when I shared my experience, but now I know many others who have had similar experiences. It is not hateful to allow children to grow up before subjecting themselves to these life-altering treatments. I urge the Court to uphold this life-saving law.

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

Dated: June 8, 2023.

/s/ *Layla Jane*
Layla Jane

EXHIBIT 10

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISIVLLE DIVISION

Electronically filed

DOE 1, *et al.*
Plaintiffs

v.

THORNBURY, *et al.*
Defendants

and

COMMONWEALTH OF KENTUCKY, *ex rel.* ATTORNEY GENERAL DANIEL CAMERON
Intervening Defendant

Civil Action No. 3:23-CV-00230-DJH

DECLARATION OF EVELYN G. [PSEUDONYM] IN SUPPORT OF INTERVENOR DEFENDANT'S OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, Evelyn G.,[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 Intervenor Defendant's opposition to Plaintiffs' Motion for a Preliminary Injunction.

[1] Declarant is submitting this Declaration using a pseudonym to protect the privacy of her children and other family members.

2. I am resident of Kentucky, and the mother of S.C., a teenage girl, enrolled in public school in Kentucky. S.C. is currently 16 years of age.

3. When S.C. was in middle school (12 to 13 years old), she struggled with anxiety and depression. Her father and I believed these issues arouse from a known trauma she experienced at the hands of a classmate earlier in her childhood and circumstances surrounding the COVID restrictions and lockdowns.

4. As a family we sought help for S.C.'s anxiety and depression from a therapist associated with a practice then known as Beaumont Behavioral Health ("BBH"),[2] a prominent mental health provider in our area.

5. S.C.'s anxiety and depression only grew worse after beginning therapy at BBH.

6. S.C. informed me that after only a few counseling sessions the therapist at BBH introduced her to the "Gingerbread Person" resource[3] and suggested to S.C. that she may suffer from gender dysphoria. S.C. was confused and did not know why the therapist showed her the "Gingerbread Person" material. It made her more anxious, as she did not understand what it meant or why it was being shown to her.

7. S.C. had never previously indicated any confusion regarding her gender identity or shown any indication of gender dysphoria prior to her therapy at BBH. To the contrary, S.C., had always presented as a typical "girly girl."

[2] BBH is now part of LifeStance Health.
[3] *See* https://www.genderbread.org/.

8. S.C.'s father and I asked the BBH therapist to focus on S.C.'s trauma, anxiety, and depression, and to stop providing counseling actively encouraging S.C. to view herself as having a gender identity inconsistent with her actual sex.

9. In response to the intervention by S.C.'s father and myself, the BBH provider said that S.C. was suicidal and required inpatient psychiatric treatment. As a result, S.C. was admitted to The Ridge (a behavioral health facility in Kentucky) for an eight-day inpatient evaluation.

10. During S.C.'s treatment at The Ridge, she was told that she was "gender non-binary" and had "body dysmorphia."

11. After her eight days at The Ridge, S.C. was firmly convinced that she was "trans" and "identified" as a boy.

12. The mental health care providers at both BBH and The Ridge urged me and S.C.'s father to immediately facilitate S.C.'s "social transition" by using her preferred pronouns, allowing her to dress and present herself as a boy, and using a new male name when referring to S.C. They then recommended that we seek medical intervention to "transition" S.C. physically so as to fully "affirm" her identity as a boy. To that end, both provided referrals to a hospital that would provide "gender-affirming" interventions, including both hormone therapy and surgeries, to minors.

13. S.C.'s father and I declined the referral for "gender-affirming" medical intervention, and instead sought out therapy that would help S.C. address her underlying mental health issues without creating or encouraging gender dysphoria

14. Nonetheless, S.C.'s teachers at a public middle school in Kentucky "affirmed" S.C.'s new identity and called her by an alternative, male name and used male pronouns when addressing her while she was at school. The school did not inform me or S.C.'s father as S.C.'s parents of this.

15. One middle school teacher gave S.C. a chest band (to help hide her developing breasts while at school, and more effectively present as a boy), and wrote S.C. personal letters encouraging S.C. to "transition," which I later discovered. The same teacher told S.C. that she would be S.C.'s "new mom" and gave S.C. other trans themed gifts. I only discovered this after the teacher had gifts directed to S.C. delivered to our home.

16. S.C.'s depression and anxiety were only exacerbated by the care provided by BBH or The Ridge and by the encouragement to identify as a boy that she received in middle school.

17. The health providers at BBH and The Ridge and the teachers at S.C.'s middle school drove a wedge between S.C. and her family, doing further damage to her mental health rather than treating the actual sources of her anxiety and depression.

18. S.C. has now been in high school for several years and removed from the influence of the middle school teacher who actively encouraged her to adopt a "trans" identity.

19. For several years now, S.C. has also been receiving counseling that has focused on the sources of her anxiety and depression, and not on an ideologically driven agenda.

20. As she approaches her 17th birthday, S.C. is doing much better and is showing signs of moving on from the influence of trans ideology that created so much confusion for her. We are not completely "there" with healing, but her depression and anxiety have been diagnosed and are finally being treated in an effective way. As a result, she is living a happier life and reconnecting with her family.

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

Executed on June 9, 2023.

/s/ *Evelyn G.*
Evelyn G.

EXHIBIT 11

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISIVLLE DIVISION

Electronically filed

DOE 1, *et al.*
Plaintiffs

v.

THORNBURY, *et al.*
Defendants

and

COMMONWEALTH OF KENTUCKY, *ex rel.* ATTORNEY GENERAL DANIEL CAMERON
Intervening Defendant

Civil Action No. 3:23-CV-00230-DJH

DECLARATION OF ELIZABETH T. [PSEUDONYM] IN SUPPORT OF INTERVENOR DEFENDANT'S OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, Elizabeth T.,[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 Intervenor Defendant's opposition to Plaintiffs' Motion for a Preliminary Injunction.

[1] Declarant is submitting this Declaration using a pseudonym to protect the privacy of her children and other family members.

2. I am resident of Kentucky, and the mother of A, a teenage girl, enrolled in a high school in Kentucky. I am also a licensed medical care provider.

3. Prior to high school, A never expressed any concern about her gender identity or presented any indications of gender confusion or dysphoria.

4. During A's first year of high school, she became involved in a club designed to encourage students to discuss and explore issues related to "sexuality and gender" that was sponsored by her school. The school also used a curriculum that encouraged students to consider whether they might identify as a gender inconsistent with their biological sex. Though that curriculum A was introduced to the Gingerbread Person resource.[2]

5. After being exposed to these influences, A began dressing more androgynously, and eventually told her father and I that she was transgender and insisted that she should be addressed with the pronouns "they/them."

6. As she was beginning high school, A also struggled with anxiety, which her father and I believe arose largely from circumstances surrounding the COVID restrictions and lockdowns.

7. As a family we sought help for A's anxiety from a therapist associated with a state university in Kentucky.

8. That therapy did not help alleviate A's anxiety but did have the effect of increasing A's insistence that she was transgender.

[2] *See* https://www.genderbread.org/.

9. About six months into therapy, I asked A's therapist to stop providing counseling encouraging A to view herself as having a gender identity inconsistent with her actual sex. The therapist insisted that I and A's father should "affirm" A's transgender identity.

10. My husband and I consulted several other medical and mental health professionals and decided that further "affirming" care was not in A's best interests. We therefore found A a new therapist who provides supportive, exploratory therapy, that does not actively encourage A to think of herself as transgender.

11. While she initially expressed displeasure with our family's decision not to "affirm" her "transgender identity," A has come to accept that decision and now accepts her identity as a young woman, consistent with her biological sex. She has also experienced significant improvement in her overall mental health and happiness.

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

Executed on June 8, 2023.

/s/ *Elizabeth T.*
Elizabeth T. [pseudonym]