# IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v.

Case No. 4:22-cv-00325-RH-MAF

JASON WEIDA, et al.,

Defendants.

# REBUTTAL EXPERT REPORT OF <u>MICHAEL K LAIDLAW, M.D.</u>

#### **DECLARATION OF MICHAEL K. LAIDLAW, M.D.**

I, Michael K. Laidlaw, M.D., hereby declare as follows:

1. This supplemental rebuttal report is an addendum to, and incorporates and includes, my entire expert report in this matter of February 17, 2023. That initial report includes a discussion of my qualifications, publications, prior expert testimony, and compensation. I have read the Expert Reports of Daniel Shumer, MD and Johanna Olson-Kennedy, MD and provide the following rebuttal to the claims in those reports.

2. The bases for my opinions expressed in this report are my review of the Shumer and Olson-Kennedy reports, my professional experience as a physician, and my knowledge of the pertinent scientific literature, including those publications cited in this report. Specifically, I have 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. 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.

#### Sex vs Gender Identity

3. 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,  $\P$  25).

4. Of note, Dr. Shumer states that the gender identity is a component of sex. This is false. 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 nonambiguous internal and external genitalia" (DSM-5 TR). Note that gender identity is not a component of biological sex as defined by the DSM 5.

5. 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 a non-physical entity, here described as a social identity. In fact, the gender identity 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. It has no correlate in the human body. In a letter to the editor from myself and colleagues critical of the Endocrine Society's Guidelines we wrote: "There are no laboratory, imaging, or other objective tests to diagnose a 'true transgender' child" on the basis of gender identity (Laidlaw et al., 2019).

6. 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. Dr. Olson-Kennedy states that gender identity "has a strong biological basis" (Olson-Kennedy decl, ¶ 18). Later she states that "multiple studies show that gender identity has a strong biological basis and cannot be changed"; yet she provides no evidence to support her claims (Olson-Kennedy decl, ¶ 25).

7. This is in contrast to all other endocrine disorders that 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, 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).

8. Dr. Olson Kennedy states that the gender-affirmative model provides "support for them to evolve into their authentic gender selves, no matter at what age" (Olson-Kennedy decl,  $\P$  18). However, she provides no definition, no evidence for existence, no objective test, nor any biological marker to identify the "authentic gender" self. She admits that it is a self-identification based on "child's self report" (Id.).

9. Dr. Shumer goes on to say in paragraph 29, "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 (Chung, et al., 2002)." The study that Dr. Shumer references involved autopsies of 50 deceased persons 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.

10. 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 (Heylens, et al., 2012)" (Shumer decl, ¶ 30). However, if gender identity is determined only by genes, then 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 in fact shows that those factors are more important than any potential genetic contribution. Furthermore, no genetic studies have ever identified a transgender gene or genes.

11. 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).

12. 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, ¶ 31). Congenital adrenal hyperplasia is a DSD. Dr. Shumer also provides no evidence that any of the plaintiffs suffered from fetal exposure to opposite sex hormones.

## Gender Dysphoria and Psychology

13. Dr. Shumer states that "transgender and gender diverse identities are not conditions of mental ill health and classifying them as such can cause enormous stigma" (Shumer decl,  $\P$  37). Ironically he refers to the Diagnostic and Statistical Manual of Mental Disorders to make his point: "gender dysphoria, a serious medical condition defined in both the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders" (Id.  $\P$  36). In fact there is an entire chapter entitled "Gender Dysphoria" which addresses the condition (DSM 5-TR).

14. Dr. Shumer attempts to use ICD-11 (which is a coding system used for medical claims) to discuss "The Gender Icongruence diagnosis" which he states "is part of a new 'conditions related to sexual health' chapter in the ICD-11" (Shumer decl, ¶ 37). Similarly, Dr. Olson-Kennedy discusses ICD-11 coding changes (Olson-

Kennedy decl,  $\P$  27). However, neither the State of Florida nor any other state in the union uses the ICD-11 medical coding system.

15. Dr. Shumer also states: "In children and adolescents, the diagnosis of gender dysphoria is made by a health provider including but not limited to a psychiatrist, psychologist, social worker, or therapist with expertise in gender identity concerns" (Shumer decl,  $\P$  38).

16. However, the 2009 Endocrine Society guidelines (ESG) specifically state that a qualified mental health professional (MHP) should make the diagnosis of gender dysphoria (at that time referred to as gender identity disorder or GID): "Because GID may be accompanied with psychological or psychiatric problems..., it is necessary that the clinician making the GID diagnosis be able 1) to make a distinction between GID and conditions that have similar features; 2) to diagnose accurately psychiatric conditions; and 3) to undertake appropriate treatment thereof. Therefore, the SOC guidelines of the WPATH recommend that the diagnosis be made by a MHP (28). For children and adolescents, the MHP should also have training in child and adolescent developmental psychopathology" (Hembree et al., 2009, p. 3136).

17. The 2017 ESG offer similar recommendations "Because of the psychological vulnerability of many individuals with GD/gender incongruence, it is important that mental health care is available before, during, and sometimes also

after transitioning. For children and adolescents, an MHP who has training/experience in child and adolescent gender development (as well as child and adolescent psychopathology) should make the diagnosis, because assessing GD/gender incongruence in children and adolescents is often extremely complex" (Hembree, 2017).

18. Dr. Shumer states, "In 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,  $\P$  43).

## Desistance

19. 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).

20. Dr. Shumer states that "data and personal experience shows that children whose gender dysphoria persists into adolescence are highly likely to be transgender" (Shumer decl,  $\P$  59). Dr. Olson-Kennedy asserts that "research to date shows that if transgender identification persists into adolescence, then desistance is

incredibly rare" (Olson-Kennedy decl,  $\P$  54). However, both of these assertions are contradicted by the evidence.

21. 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 desistence 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 nearly 13 years old.<sup>1</sup> The desistence rate varied from 61 to 88%. Since the upper age was twelve (or slightly higher), this would include children in the age range of 8-12 years old, many of whom were already adolescents going through puberty based on their age and were therefore not prepubertal<sup>2</sup>. Therefore we can infer that a high proportion of adolescents do in fact desist, contrary to what Drs. Shumer and Olson-Kennedy have stated.

<sup>1 &</sup>quot;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). "The mean age of the participating gender-referred children was 10.47 years (SD = 1.27; range, 8.11 - 12.77)" (Wallien et al., 2009). " 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 followup, 17 participants (12.2%) were judged to have persistent gender dysphoria." (Singh, 2012)

<sup>2</sup> 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.

#### **Gender Affirmative Therapy**

22. Gender affirmative therapy (GAT) 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 that are discussed in the Endocrine Society Guidelines: 1) social transition, 2) blocking normal puberty or menstruation, 3) high dose opposite sex hormones, and 4) surgery of the genitalia and breasts (Hembree et al., 2017).

# **Poor Quality Evidence for Gender Affirmative Therapy (GAT)**

23. Dr. Shumer states, "Options 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 estrogen administration. These treatment options are based on robust research and clinical experience, which consistently demonstrate safety and efficacy" (Shumer decl,  $\P$  46). However, he presents no evidence to back his claim of robust evidence.

24. In fact, with respect to the Endocrine Society's guidelines which he states he follows (Shumer decl,  $\P$  56), the quality of evidence for the treatment of adolescents is rated "very low-quality evidence" and "low quality evidence"

(Hembree, 2018). "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).

25. Further problems with the Endocrine Society's guidelines are highlighted in a recent BMJ Investigation article. It reads: "Guyatt, who codeveloped GRADE 3 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).

<sup>3 &</sup>quot;GRADE is a systematic approach to rating the certainty of evidence in systematic reviews and other evidence syntheses". GRADE is the method purportedly employed in the ESG. https://training.cochrane.org/grade-approach

26. Endocrinologists William Malone and Paul Hruz and colleagues have written that the ESG's "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; Haupt et al., 2020; "Correction", 2020).

27. In addition, the Endocrine Society's guidelines (ESG) specifically state that their "guidelines cannot guarantee any specific outcome, nor do they establish a standard of care" (Hembree at al, 2017, p. 3895).

#### WPATH

28. Dr. Olson-Kennedy states she has "been a member of the World Professional Association for Transgender Health (WPATH) since 2010" (Olson-Kennedy decl,  $\P$  9). WPATH reports that its Standard of Care 7 is a "professional consensus about the psychiatric, psychological, medical, and surgical management of gender dysphoria" (WPATH, 2022). However, the "professional consensus" exists only within the confines of its advocacy organization.

29. Dr. Olson Kennedy states that the WPATH SOC 7 "are based on the best available science and expert professional consensus" (Olson-Kennedy decl,  $\P$  29).

According to Dr. Shumer, "[t]he WPATH SOC 8 is based on rigorous review of the best available science and expert professional consensus in transgender health...Grading of evidence was performed by an Evidence Review Team which determined the strength of evidence presented in each individual study relied upon in the document (Coleman, et al., 2022)" (Shumer decl, ¶ 50).

30. With respect to the "rigorous review" of the evidence, the SOC 8 used a modification to 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). This modification meant that any recommendation of "recommend" was automatically assigned as high quality 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). Such modifications of GRADE are explicitly recommended against in the referenced GRADE document and in so doing, in my opinion, invalidates all of the SOC 8 recommendations as being evidence-based<sup>4</sup>.

<sup>4</sup> From the GRADE guidelines: "Some organizations have used modified versions of the GRADE approach. <u>We recommend against such modifications</u> 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).

## **Puberty**

31. "Puberty is a process of maturation heralded by production of sex hormones—testosterone and estrogen—leading to the development of secondary sex characteristics" (Shumer, ¶ 58). 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. Puberty is not optional. Adolescents should not be afraid to go through puberty, but need support and guidance throughout the process.

32. Puberty is a time of development of the sex organs, body, brain, and mind. There are well known changes in physical characteristics of the male such as growth of facial hair, deepening of the voice, and increasing size of the testicles and penis. Importantly the testicles will develop sperm under the influence of testosterone and become capable of ejaculation. Because of these changes, the male will become capable of fertilizing an egg. The inability to produce sperm sufficient to fertilize an egg is termed infertility.

33. For the female, pubertal development includes changes such as breast development, widening of the pelvis, and menstruation. The female will also begin the process of ovulation which is a part of the menstrual cycle and involves the release of an egg or eggs from the ovary. Once the eggs are released in a manner in which they can become fertilized by human sperm then the female is termed fertile.

The inability to release ovum that can be fertilized is infertility (Kuohong and Hornstein, 2021).

34. The Tanner staging system allows the stage of puberty to be known. 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). Awareness of the Tanner stage of the developing adolescent is also useful to assess for maturation of sex organ development leading to fertility. For girls, the first menstruation (menarche) occurs about two years after Tanner stage 2 and will typically be at Tanner stage 4 or possibly 3 (Emmanuel and Boker, 2022). The first appearance of sperm (spermarche) will typically be Tanner stages 4 (Id.). If puberty is blocked or disrupted before reaching these critical stages, the sex glands will be locked in a premature state and incapable of fertility.

## **GnRHa to Block Normal Pubertal Development and Maturation**

35. Dr. Shumer states, "In transgender youth, it is most typical to use GnRHa [puberty blockers] from the onset of puberty (Tanner Stage 2) until midadolescence" (Shumer decl,  $\P$  65). This is correct. However he also states "GnRHa have no long-term implications on fertility." That statement is incorrect. GnRHa 36. One can see that if the developing person is blocked at Tanner stage 2 as advocated by the guidelines, this is prior to becoming fertile. The gonads will remain in an immature, undeveloped state. If they remain blocked in an early pubertal stage then even the addition of opposite sex hormones will not allow for the development of fertility. In fact, high-dose opposite sex hormones may permanently damage the immature sex organs leading to sterilization. Certainly the removal of the gonads by surgery will ensure sterilization.

37. In a Dutch study by de Vries et al. that included seventy adolescents who took puberty blockers, all seventy decided to go on to hormones of the opposite sex (de Vries, et al. 2011). In a follow-up study by de Vries et al., the overwhelming majority went on to have sex reassignment surgery by either vaginoplasty for males or hysterectomy with ovariectomy for females (de Vries, et al. 2014). These surgeries resulted in sterilization. This is why puberty blockers, rather than being a "pause" to consider aspects of mental health, are instead a pathway towards future sterilizing surgeries.

38. Dr. Olson-Kennedy states that "[w]hile some argue that gender affirmation leads a child or adolescent down a path of inevitable transgender identity, no such evidence exists, either in the scientific or the clinical setting" (Olson-Kennedy decl, ¶ 36). I have not argued that gender affirmation leads to "an inevitable transgender identity". I do argue however, that it is clear from the de Vries studies

that gender affirmation therapy led to the overwhelming majority of adolescents ultimately being sterilized and suffering irreparable physical changes due to the therapy.

39. Dr. Olson-Kennedy states, "Fertility preservation is offered to all transgender patients prior to the initiation of gender affirming hormones" (Olson-Kennedy decl,  $\P$  107).

40. However, even though procedures for fertility preservation (FP) are available, studies in North America show that less than 5% of adolescents receiving GAT even attempt it (Nahata, 2017). Ovarian and testicular tissue cryopreservation would be the only FP options in children blocked prior to spermarche and menarche and are high in cost and limited to specialized centers (Laidlaw et al., 2019). Even with FP there is no guarantee of having a child.

41. 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 to stop all of these 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" (Shumer decl,  $\P$  79). However, he provides no evidence that this is even possible.

42. With respect to blocking normal puberty in gender affirmative therapy, Dr. Olson Kennedy provides contradictory information as to when it begins. On the one hand she states, "Sometimes treatment begins with puberty delaying medications (also referred to as puberty blockers), later followed by gender-affirming hormones. <u>Most</u> youth, and certainly all adults, accessing treatment <u>are already well into or</u> <u>have completed puberty</u>" (Olson-Kennedy decl, ¶ 38 (emphasis added)). On the other hand, she states that "[b]oth the Endocrine Society and the WPATH's SOC, however, <u>recommend initiation of puberty suppression at the earliest stages of</u> <u>puberty</u> (usually, Tanner 2)..., regardless of chronological age" (Olson-Kennedy decl, ¶ 40 (emphasis added)).

43. In fact we know that Dr. Olson-Kennedy has recruited children as young as age 8 into the puberty blocker arm of her study "The Impact of Early Medical Treatment in Transgender Youth," and recruited children as young as age 11 into the cross-sex hormone arm.<sup>5</sup> She also reduced the age requirement for the cross-sex hormone arm from 13 to 8 years old.<sup>6</sup>

<sup>5 &</sup>quot;Initial data from youth enrolled in the GnRHa cohort across all study sites (n=71) show that participants range in age from 8 to 14 years old, with a mean age of 11 +/- 1.4 years... Within the CSH cohort, 279 participants have been enrolled across all study sites.Participants range in age from 11 to 20 years old, with a mean age of 16 +/- 1.9 years" (Olson-Kennedy-progress-reports-so-far.pdf, p 61).

<sup>6 &</sup>quot;In addition, the minimum age for the cross-sex hormone cohort inclusion criteria was decreased from 13 to 8 to ensure that a potential participant who could be eligible for cross-sex hormones based on Tanner Staging would not be excluded due to age alone " (Olson-Kennedyprogress-reports-so-far.pdf, p 44).

## Dr. Shumer and Dr. Olson-Kennedy's Faulty Comparison of Using GnRHa for Precocious Puberty vs for Gender Dysphoria

44. Dr. Shumer states, "As an experienced pediatric endocrinologist, I treat patients with these same medications for both precocious puberty and gender dysphoria and in both cases the side effects are comparable and easily managed" (Shumer decl,  $\P$  68).

45. Dr. Olson-Kennedy states, "Puberty suppression has been used safely for decades in children with other medical conditions, including precocious puberty, and is a reversible intervention" (Olson-Kennedy decl,  $\P$  40).

46. In reality the physical effects, use case, and outcomes of using GnRHa for treating precocious puberty (which is an abnormal early puberty condition) versus stopping normal puberty in gender affirmative therapy are completely different. In the disease state of central precocious puberty, puberty begins at an abnormally young age, say age four. In order to halt this abnormally early puberty, a GnRH agonist (puberty blocker) may be administered. Here the action of the medication is to stop early sex hormone production and therefore stop abnormal pubertal development. Then, at a more normal time of pubertal development, say age 11, the medication is discontinued and normal puberty is allowed to proceed. The end result is to restore normal sex gland function and the normal timing of puberty. This is an FDA-approved, labeled use for a GnRH agonist medication. 47. What about the use of puberty blockers 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 and maturation.

48. In this case, the condition of hypogonadotropic hypogonadism (a medical disease which results in the pituitary not communicating with the sex glands to make hormones) is deliberately induced by medication. This is an iatrogenic effect of treating the psychological condition of gender dysphoria. GnRH agonist medications have not been FDA approved for this use case and are experimental with respect to blocking normal physical development and maturation.

49. We can see that in precocious puberty an abnormal condition (early puberty) is halted by medication until the patient reaches the age of normal pubertal development and then puberty is allowed to proceed normally. In the case of gender affirmative therapy (GAT), normal pubertal development is stopped medically by inducing an abnormal condition of the pituitary. This abnormal pituitary condition will continue while the patient is given GnRHa and even when they start opposite sex hormones. Therefore the use of puberty blockers in GAT imposes a disease state on healthy adolescents which will continue indefinitely while they take hormonal treatment as a part of GAT.

# GnRHa for Endometriosis is an FDA Approved Usage Contrary to Dr. Shumer's Claim

50. As Dr. Shumer also states, "I regularly prescribe GnRHa for patients who do not meet criteria for precocious puberty but who require pubertal suppression. Examples include...young women with endometriosis. As with gender dysphoria, the prescription of GnRHa to treat these conditions is 'off-label,' yet it is widely accepted within the field of endocrinology and not considered experimental." (Shumer decl,  $\P$  69).

51. Dr. Shumer erroneously states that using GnRHa for the treatment of young women with endometriosis is an off-label usage. A reading of the labeling clearly reveals otherwise. Under "Indications and Usage", it reads "LUPRON DEPOT 11.25 mg for 3-month administration is a gonadotropin-releasing hormone (GnRH) agonist indicated for: Management of endometriosis, including pain relief and reduction of endometriotic lesions." (Lupron Depot Prescibing information, 2018). The same labeling provides no such information for using GnRHa in GAT, because it doesn't exist, and because using such medications for blocking normal pubertal development is an experimental use.

#### **Puberty and Bone Health**

52. Puberty is also a time of rapid bone development. This time of development is critical in attaining what we call peak bone density or the maximum bone density that one will acquire in their lifetime (Elhakeem, 2019). 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 are 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).

53. Puberty blockers used in adolescence will inhibit the normal accrual of bone density. This can be evaluated by DEXA bone density scans. 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). 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. What this shows is that puberty blockers in adolescents is not safe for bones and in fact caused a considerable drop in bone density compared to their same age peers.

54. 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,  $\P$  63). Dr. Olson-Kennedy states, "Puberty suppression, which involves the administration of gonadotrophin-releasing hormone analogues (GnRHa), essentially pauses puberty," (Olson-Kennedy decl,  $\P$  39). In actuality, allowing a "pause" in puberty for any period of time leads to an inability to attain peak bone density and puts the patient at future risk for osteoporosis and serious fractures. GnRHa do not pause endogenous puberty, they irreversibly harm normal human development and maturation.

## **Opposite Sex Hormones**

55. 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. In spite of this, Dr. Shumer states, "When treated with testosterone or estrogen, the goal is to maintain the patient's hormone levels within the normal range for their gender" (Shumer decl,  $\P$  74). When Dr. Shumer refers to gender, he means gender identity.

56. This is because 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 which is in the normal reference range for adult men (Hembree, 2017).

However, they are of the same order of magnitude as dangerous endocrine tumors for women. A simple calculation shows this level for the adult female may be anywhere from 6 to 100 times higher than native female testosterone levels.<sup>7</sup> 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.

57. For example, with respect to testosterone and 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). Severe hyperandrogensim causes permanent physical changes that include deepening of the voice and hirsutism. Changes to the genitourinary system due to hyperandrogenism include polycystic ovaries, clitoromegaly and atrophy of the lining of the uterus and vagina. Potential cancer risks from high dose testosterone include ovarian and breast cancer (Hembree, 2017).

58. Severe hyperandrogenism also causes erythrocytosis or high red blood cell levels. Any level of erythrocytosis in young women has been shown to be an

<sup>7</sup> The normal adult female reference range for testosterone is approximately 10-50 ng/dL.

independent risk factor for cardiovascular disease, coronary heart disease and death due to both (Gagnon, 1994).

59. According to research, anabolic steroid abuse with androgens like testosterone 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).

## **Surgeries**

60. 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,  $\P$  57). However, Dr. Shumer neglects to describe surgeries as a part of the transition process. This is important to

note because although endocrinologists like he 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.

61. 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). 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). The Endocrine Society provides no grading of the quality of evidence for this surgery in adolescents.

62. 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 by Dr. Olson-Kennedy titled "Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults Comparisons of Nonsurgical and Postsurgical Cohorts" (Olson-Kennedy, 2018). This study

contained 68 natal female patients who had mastectomy surgery as a part of GAT. The age range was 13-24 years old. Of these subjects, 33 were under the age of 18 including two thirteen-year-olds and five fourteen-year-olds.

63. 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.

64. 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.

65. 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.

66. 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, 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).

67. 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).

68. The study appears to have been designed, at least in part, to justify insurance companies paying for mastectomy procedure for adolescents with gender dysphoria, 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.

### Nations Reverse Course due to Lack of Evidence for GAT

69. Dr. Shumer states "There are several studies demonstrating positive results of gender affirming care in adolescents and adults (de Vries, et al., 2014; de Vries, et al., 2011; Green, et al., 2022; Smith, et al., 2005; Turban, et al., 2022)" (Shumer decl, ¶ 35). I've already discussed the negative long-term risks in the de Vries studies as a pathway to sterilization and other damages from hormones.

70. The Smith et al. study of 2005, which Dr. Shumer references, contained initially "325 consecutive adolescent and adult applicants for sex reassignment".

However only 222 started hormone therapy and 34 dropped out of treatment altogether. The study states that "[o]nly data of the 162 adults were used to evaluate treatment" and not adolescents. So the study had a high dropout rate, and the limited remaining results were only applicable to adults.

71. With respect to the Turban et al. 2022 study, it was not a randomized controlled study nor a prospective observational study. Rather the study relied upon the 2015 U.S. Transgender Survey (USTS), which has been severely criticized for its serious limitations and weaknesses. D'Angelo et al. have written about the 2015 USTS survey as part of the criticism of another flawed study in the journal Pediatrics by Jack Turban titled "Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation" (Turban, 2020). They write in their critique of the USTS that it is "a convenience sampling, a methodology which generates low-quality, unreliable data." (Bornstein, Jager, & Putnick, 2013). Specifically, the participants were recruited through transgender advocacy organizations and subjects were asked to 'pledge' to promote the survey among friends and family. This recruiting method yielded a large but highly skewed sample...Their analysis is compromised by serious methodological flaws, including the use of a biased data sample, reliance on survey questions with poor validity, and the omission of a key control variable, namely subjects' baseline mental health status." They also state that "[s]tigmatizing non-'affirmative' psychotherapy for GD [gender dysphoria] as 'conversion' will reduce

access to treatment alternatives for patients seeking non-biomedical solutions to their distress" (D'Angelo et al., 2021).

72. In contrast with the few low-quality studies that Dr. Shumer presents, entire nations are questioning and reversing course regarding gender affirmative therapy based on reviews of the evidence. 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).

73. The case was appealed and although the medical decision making was returned to clinicians (rather than the courts), it was noted that great pains should be taken to ensure that the child and parents are properly informed before embarking on such treatments. In its conclusion the appeals court stated that "[c]linicians will inevitably take great care before recommending treatment to a child and be astute to ensure that the consent obtained from both child and parents is properly informed by the advantages and disadvantages of the proposed course of treatment and in the light of evolving research and understanding of the implications and long-term consequences of such treatment. Great care is needed to ensure that the necessary consents are properly obtained" (Bell v. Tavistock Appeal, Judgment, 2021).

74. 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).

75. 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".

76. 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).

77. 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.

## Gender Affirmative Therapy and Death by Suicide

78. Dr. Olson-Kennedy states that "The claim that treating gender dysphoria with medically supervised and recommended hormone treatment is <u>particularly risky or causes serious mental health effects is not supported by data</u>," (Olson-Kennedy decl, ¶ 103 (emphasis added)). The data from her own study show otherwise.

79. Death by suicide would be considered by most to be the most serious detrimental mental health outcome. Psychiatric hospitalizations and suicidal ideation would be other serious mental health effects.

80. The most comprehensive study of gender affirmative therapy is from Sweden in 2011. They examined data of 324 patients in Sweden over 30 years who had taken opposite sex hormones and had undergone sex reassignment surgery and compared them to matched population controls (Dhejne, 2011). The gender affirmative therapy 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.

81. The recent study published by Chen and Olson-Kennedy et al. confirms the inherent danger of gender affirmative therapy found in the Dhejne study. The New England Journal of Medicine recently published "Psychosocial Functioning in Transgender Youth after 2 Years of Hormones" in which Dr. 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<sup>8</sup>. The study was not randomized and had no control

<sup>8 &</sup>quot;[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

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. 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.

82. 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

<sup>11 – 14</sup> 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).

a much higher death rate in her experimental study. 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 (NIH FOIA 51365 April 17 2020 Production of consent forms.pdf).

83. Dr. Olson-Kennedy did not discuss these facts in her declaration. She also did not discuss the types of mental health conditions the subjects had nor the mental health care (if any) that these research subjects received. She did not discuss the dosages of opposite-sex hormones these subjects were taking, the serum levels of these hormones, nor post-mortem hormone levels. She did not discuss if these deceased subjects had autopsy reports or exactly how the cause of death was determined. She did not discuss if any other human subjects have died, been hospitalized, or have been seriously injured in the other arm of her study or any of her other studies.

84. 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.

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85. Some portion of the Olson-Kennedy study subjects did not have the legal capacity to give consent either due to age or vulnerability due to mental illness. There was an element of coercion insofar as parents and children may have been convinced that to not undergo gender affirmative therapy would lead to suicide and self-injury. Dr. Olson-Kennedy discusses this in her declaration: "The denial of gender-affirming care, on the other hand, is harmful to transgender people. It exacerbates their dysphoria and may cause anxiety, depression, and suicidality, among other harms" (Olson-Kennedy decl, ¶ 113).

86. The majority of young adolescents certainly would not have significant comprehension of the elements of the subject matter involved (particularly infertility, sexual dysfunction, and potential for sterility) to make an understanding and enlightened decision regarding these life altering effects of opposite sex hormones.

87. Further, with regard to informed consent, Dr. Olson-Kennedy's article states, "[p]articipants provided written informed consent or assent; parents provided permission for minors to participate" (Chen, Olson-Kennedy, et al., 2023). However, it is not possible for adolescents as young as age 12 to assent or consent to the permanent physical harms of gender affirmative therapy, including sterility or death. Parents cannot ethically provide "permission" for procedures that may result in either harmful outcome based on the non-objective, non-verifiable, non-biologically provable gender identity. This is very different than, for example, a parent providing

informed consent on behalf of a minor child for a potentially sterilizing or life threatening cancer treatment. Such treatment is based on an objective and verifiable physical examination, typically the biopsy of a cancerous tumor. Again, no such objective validation of an immutable gender identity exists.

88. In an article entitled "Considerations for Stopping a Clinical Trial", the first reason given is safety (Deichmann et al., 2016). The authors write, "Ethically, clinical trials must sometimes be stopped early when the results show no justification for exposing human subjects to additional potential risk by continuing the trial." (Id.). The authors discuss stopping a research trial when "[t]he risks to human subjects unexpectedly outweigh the benefits because of unexpected severe adverse events" such as "serious illness or death in human subjects" (Id.).

89. The physical harms caused by high-dose testosterone and estrogen as well as the numerous adverse reactions reportedare significant Death is one of those adverse reactionsSubjects were not offered other less risky options such as watchful waiting with psychological support to alleviate their gender dysphoria or psychological therapy to help manage comorbid mental illness. Dr. Olson-Kennedy states, however, that an "untreated control group is unethical in this context" (Olson-Kennedy decl, ¶ 73). What she means to say by "untreated" is to not be treated with hormones and surgeries. Psychotherapy, treatment of neurodevelopmental conditions like autism, cognitive behavioral therapy, trauma-based therapy, family

therapy and other alternate treatments of less risk are all possible to help these suffering adolescents<sup>9</sup>.

<sup>9 &</sup>quot;Turban et al.' s (2020) singular endorsement of 'affirmative' therapies, which their data failed to substantiate, contributes to the alarming trend to frame any non-'affirming' approaches as harmful... We believe that exploratory psychotherapy that is neither 'affirmation' nor 'conversion' should be the first-line treatment for all young people with GD, potentially reducing the need for invasive and irreversible medical procedures" (D'Angelo et al., 2021).

<sup>&</sup>quot;A psychoanalytic understanding of trauma can help clinicians develop a picture of the psychological structure of an individual' s mind, including patterns of relating, defensive structures and the capacity to reflect upon the self. When clinicians can tune into their patients' states of mind and preoccupations, they can help introduce different ways of thinking about them. This can foster a dialogue about planned actions and treatments. It is essential for healthcare professionals to explore patients' thinking, hopes and beliefs before commencing any irreversible medical intervention" (Evans, 2023).

## Conclusion

90. For the reasons set forth above and in my prior declaration, 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. These treatments have not been shown to be safe, effective, or medically necessary. The child cannot consent or assent to these procedures. The parent or guardian also cannot consent to the life-altering changes resulting from GAT. There exists insufficient evidence of benefit for adults, but serious concerns for risk of harm.

91. Finally, the June 2022 AHCA GAPMS report states: "Following a review of available literature, clinical guidelines, and coverage by other insurers and nations, Florida Medicaid has determined that the research supporting sex reassignment treatment is insufficient to demonstrate efficacy and safety" (FL Medicaid GAPMS, 2022). I strongly agree with that statement.

I declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the foregoing is true and correct.

Executed this 10th day of March 2023.

/s/ Michael K. Laidlaw

Michael K. Laidlaw, M.D.

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