Appendix Attachment

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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

SIMONE MARSTILLER, et al.,

Defendants.
_____/

Expert Declaration of Michael K. Laidlaw, MD

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 and publications are detailed in my curriculum vitae. A true and correct copy of my curriculum vitae is attached as Exhibit A.

4. In my clinical practice as an endocrinologist, I evaluate and treat patients with hormonal and/or gland disorders. Hormone and gland disorders can cause or be associated with psychiatric symptoms, such as depression, anxiety, and other psychiatric symptoms. Therefore, I frequently assess and treat patients demonstrating psychiatric symptoms and determine whether their psychiatric symptoms are being caused by a hormonal issue, gland issue, or something else.

5. I have been retained by Defendants in the above-captioned lawsuit to provide an expert opinion on the efficacy and safety of sex reassignment treatment.

6. If called to testify in this matter, I would testify truthfully and based on my expert opinion. The 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; (2) my clinical experience evaluating individuals who have or have had gender incongruence including a detransitioner; (3) my knowledge of research and studies regarding the treatment of gender dysphoria, including for minors and adults; and (4) my review of the various declarations submitted by Plaintiffs

9. I was provided with and reviewed the following case-specific materials: The Florida Medicaid's "Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria"; the expert declaration of Johanna Olson-Kennedy; the expert declaration of Loren Schechter; the expert declaration of Dan H. Karasic; the expert declaration of Armand H. Matheny Antommaria; the declaration of Brit Rothstein; the declaration of August Dekker; the declaration of Jane Doe; the declaration of Jade Ladue; files from Florida Medicaid.

10. 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.

11. The following expresses my expert opinion regarding minors and adults 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. Endocrine Disorders

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.

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.

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.

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.

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.

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.

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.

To give an example of a structural abnormality, a patient may have a lump on the thyroid gland in the neck. This may be further examined by an imaging test such as an ultrasound. A needle biopsy can be performed so that the cells can be examined under a microscope. A trained medical professional such as a pathologist can then examine the cells to determine if they are benign or cancerous. In the case of a thyroid cancer, a surgical procedure known as a thyroidectomy may be performed to remove the diseased thyroid gland in order to treat the cancer.

Noteworthy in the preceding three examples is that all three disease conditions are diagnosed by physical observations. In other words, a laboratory test of a hormone, an imaging test of an organ, an examination of cells under a microscope, or all three may be employed in the diagnosis of endocrine disease.

B. Gender Dysphoria is a Psychological Diagnosis

Gender dysphoria, on the other hand, is not an endocrine diagnosis, it is in fact a psychological diagnosis. It is diagnosed purely by psychological methods of behavioral observation and questioning.

Likewise what is termed 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, discussed above, we

wrote in our critique of the Endocrine Society Guidelines that "There are no laboratory, imaging, or other objective tests to diagnose a 'true transgender' child" (Laidlaw et al., 2019).

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.

This is in contrast to all other 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).

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.

C. Gender Dysphoria and Desistance

GD is a persistent state of distress that stems from the feeling that one's gender identity does not align with their physical sex (American Psychiatric Association, 2013). It 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.

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).

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).

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).

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).

Because there is no physical marker to diagnose gender identity, 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.

Dr. Olson-Kennedy states that "[t]he studies pertaining to desistance upon which the GAPMS Memo relies pertain to prepubertal youth, not adolescents. In fact, contrary to the GAPMS Memo's assertion, studies show that if gender dysphoria is present in adolescence, it usually persists (DeVries, et al., 2011)." (Oslon-Kennedy decl, p. 22).

Dr. Olson-Kennedy confuses prepubertal (a medical term) with preadolescence (a psychological designation). Puberty which pertains to the phsyical development of the reproductive tract, breasts and associated secondary sex characterestics can begin as early as age 8 in girls and age 9 in boys. The studies which have examined desistance involved children aged twelve and under. For example table 1 in Ristori and Steensma 2016 shows multiple studies involving children. 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.[1] The desistance 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 going through puberty based on their age and were therefore not Tanner stage 1 (pre-pubertal).[2] Therefore Dr. Olson-Kennedy's statement that "[t]he studies pertaining to desistance upon which the GAPMS Memo relies pertain to prepubertal youth" is incorrect.

D. Biological Sex in Contrast to Gender Identity

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.

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.

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[1] "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 follow-up, 17 participants (12.2%) were judged to have persistent gender dysphoria." (Singh, 2012).

[2] 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.

This is in contrast to gender identity, which does not exist in any physical sense. 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.

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.

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).

E. Human Sexual Development

1. Embryologic development

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.

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).

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.)

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.).

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

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.

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.

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.

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

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.

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.

4. Biological Sex Cannot Be Changed

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.

Furthermore, as noted earlier, several of the sex specific structures (such as the epidymis 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.

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.

In fact, as I will discuss, gender affirming therapy actually leads to infertility and potential sterilization.

F. Iatrogenic Harms

The term iatrogenic is used in medicine to describe harms or newly created medical conditions that are the result of medications, surgeries, or even psychological treatments. In this section I will discuss the iatrogenic harms of "gender affirmative treatment," for females. Each of the four interventions which I will describe (social transition, blocking normal puberty, opposite sex hormones, and surgery) lead to iatrogenic harms to the patient. 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., 2014). Thus, GAT interrupts the natural desistence process and instead places the patient on a lifetime regimen of hormonal and surgical care. A good understanding of these harms is also critical to my practice as an endocrinologist, because if I did not understand these harms, I could not advise patients of the risks associated with GAT.

G. Gender Affirmative Therapy

The approaches to gender dysphoria in minors may be divided into three main types. (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. The third option, which is the focus of that which follows, is referred to as gender affirmative therapy.

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: 1) social transition, 2) blocking normal puberty or menstruation, 3) high dose opposite sex hormones, and 4) surgery of the genitalia and breasts.

The application of this medical therapy to minors 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.

1. Social transition

The first stage of gender affirmative therapy is termed social transition. Social transition is a psychological intervention. The child may be encouraged to adopt the type of clothing and mannerisms or behaviors which are stereotypical of the opposite sex within a culture. For example, in the United States a boy might wear his hair long and wear dresses in order to socially transition. A girl may cut her hair short and wear clothes from the boys' section of a department store.

Social transition of the child has been noted by expert researcher in the field of child gender dysphoria, Ken Zucker, to itself be a form of iatrogenic harm (Zucker, 2020). This is because the social transition process may solidify the young person's belief that they are in fact the sex opposite of their biological sex.

From an endocrine point of view, it is understandable that a child having the outward appearance of the opposite sex, would believe that he or she is destined to go through puberty of the opposite sex as they have only a poor understanding of the internal structures of the body, the function of the sex glands, the role of the sex glands in fertility and so forth.

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.

In fact, it would appear that in the minds of the 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.

2. Medications which Block Pubertal Development

a. Background

A second stage of gender affirmative therapy may involve blocking normal pubertal development. This may be done with puberty blocking medications that act directly on the pituitary.

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 begin or continue their function.

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.

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.

There are conditions diagnosed by endocrinologists which involve a disruption of this normal communication between the pituitary and the sex glands. There is a medical condition called hypogonadotropic hypogonadism. The meaning of this term is that the pituitary is not sending the hormonal signals (LH and FSH) to the sex glands and therefore the sex glands are unable to make their sex hormones. The result is hormonal deficiencies of LH, FSH, and either testosterone or estrogen.

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.

Medications such as GnRH agonists 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.

b. GnRH Agonist Medication Effects Vary by Use Case

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

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.

Another labeled use of GnRH agonist medication is for the treatment of central precocious puberty. In the disease state of central precocious puberty, pituitary signaling is activated at an abnormally young age, say age four, to begin pubertal development. 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.

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.

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.

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 agonist medications have not been FDA approved for this use.

c. Adverse Health Consequences of Blocking Normal Puberty

There are a number of serious health consequences that occur as the result of blocking normal puberty. The first problem is infertility. The Endocrine Society Guidelines recommend 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. One can see that if the developing person is blocked at Tanner stage 2 or 3 as advocated by the guidelines, this is prior to becoming fertile. The gonads will remain in an immature, undeveloped state.

Dr. Antommaria writes that "The [Endocrine Society] guideline recommends that informed consent for pubertal blockers and gender-affirming hormones include a discussion of the implications for fertility and options for fertility preservation (Antommaria decl, p.23). However, even though procedures to preserve fertility are available, studies show that less than 5% of adolescents receiving GAT even attempt fertility preservation (FP) (Nahata, 2017). Moreover, "ovarian tissue cryopreservation is still considered experimental in most centers and testicular tissue cryopreservation remains entirely experimental. These experimental forms of FP would be the only options in children [with puberty] blocked prior to spermarche and menarche and are high in cost and limited to specialized centers. Even with FP there is no guarantee of having a child" (Laidlaw, Cretella, et al., 2019).

Naturally, these children are at a developmental age where they are not thinking about adult related concepts such as having children as they are children themselves. This is only natural and to be expected. The medical problem imposed on them is that 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, which will be discussed later, will ensure sterilization.

Another problem with blocking puberty 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 of the male. For the female with undeveloped genitalia potential sexual dysfunction may include painful intercourse and impairment of orgasm.

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 has 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"[3] (TLC, accessed 2022).

In addition to direct effects on the developing genitalia and fertility there are other important aspects of puberty that are negatively affected. For example, puberty is 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 would be expected to be at future risk for osteoporosis and the potential for debilitating spine and hip fractures as adults. Hip fractures for the older patient very significantly increase the risk of major morbidity and death (Bentler, 2009). Allowing a "pause" in puberty for any period of time leads to an inability to attain peak bone density.

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

Another consideration is 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.

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. This is 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.

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 discussed previously.

d. The Effect of Puberty Blockers on Desistance

As stated earlier a very high proportion of minors diagnosed with gender dysphoria will eventually desist or come to accept their physical sex. Puberty blockers have been shown to dramatically alter natural desistance.

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

being a "pause" to consider aspects of mental health, are instead a pathway towards future sterilizing surgeries. 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.).

e. Infertility as a result of Puberty Blockers in GAT

Dr. Antommaria states that "Florida Medicaid provides coverage for the use of puberty blockers to treat central precocious puberty, but now prohibits coverage for the use of puberty blockers to treat gender dysphoria, even though the use of puberty blockers to treat both conditions has comparable risks and is supported by comparable types of evidence" (Antommaria decl, p. 24). These statements fail to recognize the very different effects of PB medication in early childhood versus during adolescence.

Giving puberty blockers to a four year old with central precocious puberty will obviously not impair fertility, as the four year old has not yet become fertile. The child will at a later time have the puberty blocker discontinued and then normal pubertal development can proceed. Therefore when they are no longer taking the medication, they will gain natural fertility.

In contrast, puberty blocking medication given to minors in GAT occurs at precisely the time that the child will gain reproductive function. This will stop sperm production in the male and ovulation in the female (if these have already occurred, otherwise the functions will not even begin) which produces the infertile condition. Importantly, so long as the minor continues PB they will remain infertile. Should they continue on to opposite sex hormones as part of GAT then they will remain infertile. There is the additional possibility that cytotoxic effects of high dose opposite sex hormones will damage the immature gonads leading to permanent sterility.

3. Opposite Sex Hormones

The third stage of gender affirmative therapy involves using hormones of the opposite sex at high doses to attempt to create secondary sex characteristics in the person's body.

a. Testosterone

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.

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.

Regarding the potential for abuse, the labeling reads "Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication...Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions...Abuse and misuse of testosterone are seen in male and female adults and adolescents...There have been reports of misuse by men taking higher doses of legally obtained testosterone than prescribed and continuing testosterone despite adverse events or against medical advice." (Actavis Pharma, 2018)

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

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.

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.

"There have been postmarketing reports of venous thromboembolic events [blood clots], including deep vein thrombosis (DVT) [blood clot of the extremity such as the lef] 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).

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).

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).

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.

b. Opposite Sex Hormones - Supraphysiologic Doses of Testosterone for Females

The female person does produce some smaller amount of testosterone relative to the male. The normal reference range for adult females depending on the lab is about 10 to 50 ng/dL. However, in female disease conditions these levels can be much higher. For example, in polycystic ovarian syndrome levels may range from 50 to 150 ng/dL. PCOS has been associated with insulin resistance (Dunaif, 1989), metabolic syndrome (Apridonidze, 2005) and diabetes (Joham, 2014).

In certain endocrine tumors such as adrenal carcinoma these levels may be substantially higher in the 300 to 1000 ng/dl range. Adrenal carcinoma is a serious medical condition and may be treated by surgery and potent endocrine medications.

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[4] 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 creating a hormone imbalance known as hyperandrogenism. These extraordinarily high levels of testosterone are associated with multiple risks to the physical and mental health of the patient.

“"Studies 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). A female can also develop unhealthy, high levels of red blood cells referred to as erythrocytosis. These high red blood cell counts in young women have been shown to be an independent risk factor for cardiovascular disease, coronary heart disease and death due to both (Gagnon, 1994).

Other permanent 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. Common sense suggests that changes of voice and hair growth could be psychologically troubling should the patient attempt to reintegrate into society as a female.

Changes to the genitourinary system include polycystic ovaries and atrophy of the lining of the uterus. 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).

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[4] 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).

According to research regarding testosterone abuse, high doses of testosterone have 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. Estrogen

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.

d. Opposite Sex Hormones - Supraphysiologic Estrogen for Males

For the male, estrogen is being used at supraphysiologic doses. The high doses are used in an attempt to primarily affect an increase of male breast tissue development known as gynecomastia. Gynecomastia is the abnormal growth of breast tissue in the male. The occurrence of gynecomastia in the male is sometimes corrected by medication or more commonly by surgery if needed. Other changes of secondary sex characteristics may develop such as softening of the skin and changes in fat deposition and muscle development.

The doses of estrogen given to males for GAT are high and may vary from two to eight or more times higher than normal adult male levels. This produces the endocrine condition called hyperestrogenemia. Long-term consequences 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[5] over 5 fold" (Irwig, 2018).

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).

It is clear that supraphysiologic doses of either testosterone for the female or estrogen for the male can have detrimental health consequences. This is only now being borne out in the literature for adults. However as more children and adolescents are put on these medications one would expect these consequences to become more frequent and to occur earlier in their lives.

4. Surgeries

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.

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.

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.

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.

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

[5] 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).

that can be implanted or grown within the patient. This conceptual background is helpful when considering various gender affirming surgeries.

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

a. Mastectomy

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).

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. The future woman who later desists is left with regret about what happened to her at an age before she could provide true informed consent. Functioning breasts cannot be created by a surgeon and restored to a patient in case of regret. She is left with permanent injury and loss of function with respect to her breasts.

b. GAT Surgeries on the Male

GAT surgeries for the male include removal of the testicles alone to permanently lower testosterone levels. This is by nature a sterilizing procedure. Further surgeries may be done in an attempt to create a pseudo-vagina which is called vaginoplasty. In this procedure, the penis is surgically opened and the erectile tissue is removed. The skin is then closed and inverted into a newly created cavity in order to simulate a vagina. A dilator must be placed in the new cavity for some time so that it does not naturally close.

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).

c. GAT Surgeries of the Female Pelvis and Genitalia

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.

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.

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.

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).

H. Life Threatening Physical Medical Conditions Versus Suicidal Ideation

Any child or adolescent who has suicidal ideation or has attempted suicide should receive immediate, appropriate psychiatric care. Psychologists and psychiatrists are trained in the recognition and treatment of suicidal ideation and prevention of suicide. A child or adolescent with gender dysphoria who also has suicidal ideation should not be treated any

differently. They require compassionate care and a full psychological evaluation of comorbidities such as depression, anxiety, and self-harming behaviors.

However, suicidal ideation or attempts are categorically different than other life-threatening situations, such as a rapidly expanding brain tumor or a severe infection. In these situations, a medication or a surgery is used to stop the progression of an organic physical condition. In contrast, the danger to the self with suicidal ideation relates to a condition of the mind.

Gender affirmative therapy does not treat any life-threatening physical condition. In fact, it creates a number of new medical conditions as described above. It is also not an appropriate treatment for suicidal ideation. Neither puberty blocking medications, nor testosterone, nor estrogen have been FDA approved for suicide prevention. Moreover, as noted above, the hormone imbalances generated by the medications used in GAT actually increase psychological conditions that lead to suicidal ideation and completed suicide.

I. Informed Consent

Any person who is to take a medication, undergo a surgical procedure, or have a psychological intervention should understand the risks and benefits before proceeding. A discussion of these risks and benefits should be provided by medical professionals and then the person of sufficient intellectual capacity and maturity can consent to the treatment.

Naturally difficulties arise when a minor is involved in the process of medical decision-making. Their intellect, emotions, and judgment are not fully developed and they are not capable of fully appreciating permanent, life altering changes such as described above. Therefore, they cannot provide informed consent. They may sometimes "assent" to a procedure or medication with a parent or guardian making the final decision.

With respect to GAT, in my opinion, it is not possible for the parent or guardian to make a true informed consent decision for the child because of the poor quality of evidence of benefit, the known risks of harm, and the many unknown long-term risks of harm which could only truly be known after years and decades of gender affirmative therapy. A parent or guardian cannot consent to dubious treatments which result in irreversible changes to their child's body, infertility, sexual dysfunction, and in many cases eventual sterilization.

Because this age group is still undergoing brain development and they are immature with respect to intellect, emotion, judgment, and self-control, in my professional opinion there is a significant chance a young person may later regret the irreversible bodily changes that result from hormones or from removing an organ or organs that will no longer function and cannot be replaced.

I would also note that adolescents are more prone to high-risk behavior and less likely to fathom the risks and consequences of these decisions (Steinberg, 2008).

J. The WPATH and The Endocrine Society

According to their declarations, the experts Dr. Johanna Olson-Kennedy, Dr. Loren Schechter, and Dr. Dan H. Karasic are members of WPATH. Dr. Schechter was "co-lead author of the surgical and postoperative care chapter" for SOC 8 (Schechter decl, p 4). Dr. Karasic was a lead author of the Mental Health chapter for SOC 8 (Karasic decl, p. 3).

WPATH's Standards of Care 7 were produced over a decade ago in 2011. They were prepared within their advocacy organization and are purported to be a "professional consensus about the psychiatric, psychological, medical, and surgical management of gender dysphoria" (WPATH, 2022). However, the "professional consensus" exists only within the confines of its organization. Furthermore, their Standards of Care 7, unlike the Endocrine Society's guidelines, do not have a grading system for either the strength of their recommendations or the quality of the evidence presented.

While the Endocrine Society has issued "Endocrine Treatment of Gender-Dysphoric / Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," these are only "guidelines." 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).

With respect to the makeup of authors of the ESG, nine out of ten authors were members of WPATH or worked on WPATH's scientific committees. Seven of those nine had at some time been in WPATH leadership including the WPATH presidency and board of directors (File: WPATH - Endocrine Society 2017 guidelines.pdf).

In 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).

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.

Endocrinologists W. Malone and P. Hruz and colleagues have written critically of the Endocrine Society's (ES) guidelines: "Unlike standards of care, which should be authoritative, unbiased consensus positions designed to produce optimal outcomes, practice guidelines are suggestions or recommendations to improve care that, depending on their sponsor, may be biased. In addition, the ES claim of effectiveness of these interventions is at odds with several systematic reviews, including a recent Cochrane review of evidence (5), and a now corrected population-based study that found no evidence that hormones or surgery improve long-term psychological well-being (6). 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).

In June of 2022, the Endocrine Society published "Enhancing the Trustworthiness of the Endocrine Society's Clinical Practice Guidelines" (McCartney et al., 2022). They wrote "In an effort to enhance the trustworthiness of its clinical practice guidelines, the Endocrine Society has recently adopted new policies and more rigorous methodologies for its guideline program." (Id.) They relate that in 2019, the ECRI Guidelines Trust "asked the Society for permission to include its guidelines in the ECRI Guidelines Trust database". However, after an evaluation by ECRI, the guideline related to osteoporosis "was the only guideline for which all recommendations were based on verifiable systematic evidence review with explicit descriptions of search strategy, study selection, and evidence summaries" (Id.). Therefore we can conclude that with regard to the recommendations from the ESG 2017 on Gender Dysphoria/Gender Incongruence not all recommendations were "based on verifiable systematic 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, the ESG 2017 document was endorsed by WPATH. The "Enhancing

Trustworthiness" article recommends the opposite composition of authors for guidelines: "A majority (>50%) of non-Chair GDP members must be free of relevant C/DOI [conflict/duality of interest]" (McCartney et al., 2022).

WPATH Standards of Care 8 (SOC 8) were just published Sep. 6, 2022 (Coleman et al., 2022) . In a correction to the SOC 8, all guidelines for minimum age of surgery were removed, meaning a minor of any age could be referred for any of the GAT surgeries listed previously (Correction IJTH, 2022). All guidelines for minimum age of oppposite sex hormones were also removed.

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).

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).

Additionally, a chapter regarding eunuchs was inserted into SOC 8 that gives recommendations for how to induce hypogonadism in men who have the eunuch "gender identity"[6] by either orchiectomy [testicle removal] or chemical castration such as with GnRH analogues (Coleman et al., 2022)[7].

[6] 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).

[7] "Treatment options for eunuchs to consider include:

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).[8] 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).

Such a modification of GRADE is explicitly recommended against in the referenced GRADE document[9] and in so doing, in my opinion, invalidates all of the SOC 8 recommendations as being evidence-based.

For at least the reasons above, in my professional opinion WPATH SOC 8 represents a grave and immediate danger to minors, young adults, and adults and should not be followed by any physician, mental health care provider, or other medical professional.

K. Harms of off-label treatments in GAT

Dr. Antommaria makes a faulty comparison between migraine headaches and gender dysphoria (Antommaria decl, p. 7). First, migraine headaches are a neurological condition with a potential vascular component and not a condition of the mind, nor found as a psychological diagnosis in the DSM-5. Second the treament of migraine headaches

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• 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.)

[8] 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).

[9]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).

with a medication such as sumitriptan or similar are labled indications for the condition unlike GnRH agonists and opposite sex hormones in GAT (FDA.gov sumitriptan). Third, the side effects of medications like sumitriptan do not alter or block normal human development such as the case with puberty blocking medication, or cause permanent alterations of the body such as with sex hormones, or lead to the permanent loss of healthy functioning organs such as occurs with surgeries which alter sex as a part of GAT.

Dr. Olson-Kennedy also draws a faulty comparison when she compares the off-label use of antibiotics or anti-histamines to blocking normal puberty, administering high-dose opposite sex hormones, or the permanent removal of healthy organs as part of GAT (Olson-Kennedy decl, p. 38). The health consequences are categorically different and the lifelong potential for permanent injury are extremely high in GAT.

L. The Lack of Evidence of Effectiveness of GAT

There is much additional evidence that questions the long-term benefits of opposite sex hormones and gender reassignment surgery and in fact suggests serious harms.

1. Sweden's Long-term study of 30 years of data by Dhejne

The most comprehensive study 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.

2. The Branstrom and Pachankis Retraction

Other published studies of GAT have been shown to have serious errors. For example, a major correction was issued by the American Journal of Psychiatry. The authors and editors of a 2020 study, titled "Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study" (Bränström study, 2020) retracted their original primary conclusion. Letters to the editor by twelve authors

including myself led to a reanalysis of the data and a corrected conclusion stating that in fact the data showed no improvement in mental health for transgender identified individuals after surgical treatment nor was there improvement with opposite sex hormones ("Correction", 2020; Van Mol et al., 2020).

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).

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).

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).

In another letter, Professor Mikael Landen writes that "the authors miss the one conclusion that can be drawn: that the perioperative transition period seems to be associated with high risk for suicide attempt. Future research should use properly designed observational studies to answer the important question as to whether gender-affirming treatment affects psychiatric outcomes" (Landen, 2020).

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).

In yet another critical letter, Dr. Agnes Wold states that "[w]hether these factors involve a causal relationship (i.e., that surgery actually worsens the poor mental health in individuals with gender dysphoria) cannot be determined from such a study. Nevertheless, the data presented in the article do not support the conclusion that such surgery is beneficial to mental health in individuals with gender dysphoria" (Wold, 2020).

3. Flawed studies based on the problematic 2015 US Transgender Survey

A 2021 study by Almazan and Keurghlian attempted to address mental health outcomes in relation to surgery as a part of GAT (Almazan & Keurghlian, 2021). This was not a randomized controlled study nor a prospective observational study. Rather the study relied upon the 2015 US Transgender Survey (USTS), which has been severely criticized for its serious limitations and weaknesses.

D'Angelo et al. have written about the 2015 USTS survey as part of the criticism of another flawed study in the journal Pediatrics by Jack Turban in 2020 titled "Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation" (Turban, 2020). They write in their critique of the USTS that it is "a convenience sampling, a methodology which generates low-quality, unreliable data." (Bornstein, Jager, & Putnick, 2013). Specifically, the participants were recruited through transgender advocacy organizations and subjects were asked to 'pledge' to promote the survey among friends and family. This recruiting method yielded a large but highly skewed sample...Their analysis is compromised by serious methodological flaws, including the use of a biased data sample, reliance on survey questions with poor validity, and the omission of a key control variable, namely subjects' baseline mental health status." They also state that "[s]tigmatizing non-'affirmative' psychotherapy for GD [gender dysphoria] as 'conversion' will reduce access to treatment alternatives for patients seeking non-biomedical solutions to their distress" (D'Angelo et al., 2021).

4. Mastectomy Surgery for Minors

Any serious look at long-term effects at 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).

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.

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.

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.

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.

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).

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).

The study appears to have been designed, at least in part, to justify insurance companies paying for mastectomy procedure for minors with GD, even though they have provided no long-term statistical evidence of benefit: "These findings...underscore the importance of insurance coverage not being restricted by age" (Mehrniger, 2021). This also appears to be part of the aim of the flawed Olson-Kennedy study which stated "changes in clinical practice and in insurance plans' requirements for youth with gender dysphoria who are seeking surgery seem essential" (Olson-Kennedy, 2018). So these two studies, rather than being a thorough examination of the psychological and physical risks and benefits of mastectomy surgery over the long-term appear instead to exist, at least in part, to validate the need for insurance companies to insure the costs of these dubious procedures for minors.

5. Centers for Medicare and Medicaid Services

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."

Dr. Schecter states: "The result of CMS's review of the evidence is not applicable to other population groups" (Schecter decl, p. 39). However it does not make the converse true as

Dr. Schecter seems to imply. In other words, the CMS review does not therefore mean that there is conclusive evidence of benefit and lack of harm for the under 65 population. On the contrary, evidence of benefit is lacking and the risks and harms due to GAT are very high as I have described.

6. Nations and States Question and Reverse Course on GAT

Also noteworthy is that other nations are questioning and reversing course regarding gender affirmative therapy. For example in the *Bell v. Tavistock* Judgment in the UK, regarding puberty blockers in GAT, they concluded that "there is real uncertainty over the short and long-term consequences of the treatment with very limited evidence as to its efficacy, or indeed quite what it is seeking to achieve. This means it is, in our view, properly described as experimental treatment" (*Bell v. Tavistock* Judgment, 2020).

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).

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).

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".

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).

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).

M. Assessment of the patient with gender dysphoria

In light of the very serious medical concerns and potential harms of gender affirmative therapy, there are several criteria that I believe would be important to fulfill before applying the GAT model to a patient.

1. Minors should be evaluated to determine if they will follow the natural pattern of desistance which 50 to 98% of pediatric age children will follow[10].
2. Patients, parents and guardians should be made aware of other options for treatment of gender dysphoria including active psychosocial treatment or watching and waiting with support in order to help with natural desistance.

[10] From the DSM-5: "Rates of persistence of gender dysphoria from childhood into adolescence or adulthood vary…In natal males, persistence has ranged from 2.2% to 30%. In natal females, persistence has ranged from 12% to 50%" (American Psychiatric Association, 2013).

3. The patient should be provided an assessment by a qualified psychologist or psychiatrist who does not follow the WPATH GAT model. If underlying psychological conditions are diagnosed then these should be adequately evaluated and treated before proceeding to hormones and surgery.
4. If a medicalized approach with hormones such as testosterone or medications to stop menstruation is being considered then a clear description of the risks and benefits needs to be conveyed to the patient and if a minor also the parent or guardian. It needs to be verified that they fully understand these risks.
5. If surgical procedures such as mastectomy, hysterectomy, ovariectomy, orchiectomy, or vaginoplasty are being considered then clear descriptions of the risks and benefits need to be conveyed to the patient, and if a minor, the parent or guardian.

However, even if a minor and their parents or guardian are made fully aware of the risks and benefits of hormones and surgeries, in my opinion, the minor does not have adequate maturity and judgment to make permanent changes to their body that may result in infertility/sterility and the permanent loss of organs such as breasts whose functions will not be fully utilized (such as breastfeeding) until adulthood.

II. Medical Concerns Regarding Plaintiffs

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III. Conclusion

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.

Children and adolescents are of such immature minds that they are likely to believe that it is possible. In fact they may come to believe that their inherent, biologically necessary puberty is "terrifying" or needs to be stopped. Social transition serves to convince the child or adolescent that they can be the opposite sex. Puberty blockers sustain this state of mind by retaining a childlike state with respect to the genitalia and body habitus. High dose opposite sex hormones then cause medical conditions such as hirsutism and irreversible damage to the vocal cords in females and gynecomastia in males. These conditions serve to convince the young person that they are going through puberty of the opposite sex when in fact they are not developing sexually and are infertile.

[15] There are serious concerns regarding liver dysfunction with testosterone: "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).

There are known risks for both adults and minors, some of which I have described above, including cardiovascular disease, cancer, deficiencies in ultimate bone density, harms to sexual function, infertility, and for some permanent sterility. The child or adolescent cannot consent to these harms when they are not mature enough to fully comprehend what they mean. Long-term studies regarding the treatment effects specifically for minors with hormones and surgeries, using randomized controlled studies or even proper observational studies do not exist. The two adult plaintiffs and the two plaintiffs' children have comorbidities which make GAT particularly dangerous.

WPATH's newly released SOC 8 represents a grave and immediate danger to minors, young adults, and adults and should not be followed by any physician, mental health care provider, or other medical professional.

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. 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.

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 that the foregoing is true and correct. Executed this 2nd day of October, 2022.

//s//Michael K. Laidlaw, MD
Michael K. Laidlaw, MD

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EXHIBIT "A"

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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 2006-2022
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
2018	Publication – Laidlaw MK, Van Meter QL, Hruz PW, Van Mol A, Malone WJ. Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline." The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 3, 1 March 2019, Pages 686–687, https://doi.org/10.1210/jc.2018-01925 (first published on-line 11/2018)
2018	Publication – Laidlaw MK. "The Gender Identity Phantom". gdworkinggroup.org, 24 Oct 2018. http://gdworkinggroup.org/2018/10/24/the-gender-identity-phantom/
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

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.
2020	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