#### IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA Tallahassee Division

JANE DOE et al.,

Plaintiffs,

Civil No. 4:23-cv-00114-RH-MAF

v.

JOSEPH A. LADAPO et al.,

Defendants.

#### EXPERT REPORT OF DANIEL SHUMER, M.D. ON BEHALF OF PLAINTIFFS

August 16, 2023

Prepared by Daniel Shumer, M.D.

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PL000736

Doe Pls' Trial Ex. **5** 

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# I. INTRODUCTION AND SUMMARY OF OPINIONS

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation and have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

2. In summary, prohibiting adolescent children from receiving transitionrelated health care is contrary to evidence-based best practices and standards of care for the treatment of gender dysphoria. Gender dysphoria is treatable through individualized assessment and care, which may include social transition, psychotherapy, pubertal suppression, and hormonal therapy. These treatments are supported by all major medical bodies in the field of transgender medicine and pediatrics. Banning care and access to effective treatment for gender dysphoria will not eliminate transgender youth. Rather, it will lead to an increase in mental health problems and suicidality in transgender youth and needlessly stigmatize this already vulnerable population.

3. Moreover, the informed consent forms required by the State Boards of Medicine and Osteopathic Medicine state misinformation about care provided to transgender persons, including for adults and adolescents, establish requirements for ongoing treatment of such persons that have no legitimate medical justification,

undermine rather than advance informed consent, and create unwarranted and harmful barriers to essential medical care.

## A. Qualifications

4. I am a Pediatric Endocrinologist, Associate Professor of Pediatrics, and the Clinical Director of the Child and Adolescent Gender Clinic at Mott Children's Hospital at Michigan Medicine. I am also the Medical Director of the Comprehensive Gender Services Program at Michigan Medicine, University of Michigan.

5. I am Board Certified in Pediatrics and Pediatric Endocrinology by the American Board of Pediatrics and licensed to practice medicine in the state of Michigan.

6. I received my medical degree from Northwestern University in 2008. After completing a Residency in Pediatrics at Vermont Children's Hospital, I began a Fellowship in Pediatric Endocrinology at Harvard University's Boston Children's Hospital. As a Fellow at Harvard, I trained at the Gender Management Services Clinic (GeMS) at Boston Children's Hospital where I became a clinical expert in the field of transgender medicine within Pediatric Endocrinology and began conducting research on gender identity, gender dysphoria, and the evaluation and management of gender dysphoria in children, adolescents, and young adults. Concurrent with the

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Fellowship, I completed a Master of Public Health from Harvard's T.H. Chan School of Public Health. I completed both the Fellowship and the MPH degree in 2015.

7. I have extensive experience in working with and treating children, adolescents, and young adults with endocrine conditions including differences in sex development (DSD) (also referred to as intersex conditions), gender dysphoria, type 1 diabetes, thyroid disorders, growth problems, and delayed or precocious puberty. I have been treating patients with gender dysphoria since 2015.

8. A major focus of my clinical, teaching, and research work pertains to the assessment and management of transgender adolescents and young adults.

9. I have published extensively on the topic of gender identity in pediatrics and the treatment of gender dysphoria, as well as reviewed the peer-reviewed literature concerning medical treatments for gender dysphoria, the current standards of care for the treatment of gender dysphoria, and research articles on a variety of topics with a focus on mental health in transgender adolescents and young adults.

10. I am involved in the education of medical trainees. I am the Fellowship Director in the Division of Pediatric Endocrinology, Education Lead for the Division of Pediatric Endocrinology, and Course Director for a medical student elective in Transgender Medicine. My additional academic duties as an Associate Professor include teaching several lectures, including those entitled "Puberty," "Transgender Medicine," and "Pediatric Growth and Development."

11. As a Fellow at Harvard, I was mentored by Dr. Norman Spack. Dr. Spack established the Gender Management Services Clinic (GeMS) at Boston Children's Hospital. While working and training at GeMS, I became a clinical expert in the field of transgender medicine within Pediatric Endocrinology and began conducting research on gender identity, gender dysphoria, and the evaluation and management of gender dysphoria in children and adolescents.

12. Based on my work at GeMS, I was recruited to establish a similar program assessing and treating gender diverse and transgender children and adolescents at the C.S. Mott Children's Hospital in Ann Arbor. In October 2015, I founded the hospital's Child and Adolescent Gender Services Clinic.

13. The Child and Adolescent Gender Services Clinic has treated over 600 patients since its founding. The clinic provides comprehensive assessment, and when appropriate, treatment with pubertal suppression and hormonal therapies, to patients diagnosed with gender dysphoria. I have personally evaluated and treated over 400 patients with gender dysphoria. The majority of the patients receiving care range between 10 and 24 years old. Most patients attending clinic live in Michigan or Ohio. As the Clinical Director, I oversee the clinical practice, which currently includes 4 physicians (including 1 psychiatrist), 1 nurse practitioner, 2 social workers, 1 research coordinator, as well as nursing and administrative staff. I also

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actively conduct research related to transgender medicine, gender dysphoria treatment, and mental health concerns specific to transgender youth.

I also provide care in the Differences/Disorders of Sex Development 14. (DSD) Clinic at Michigan Medicine at Mott Children's Hospital. The DSD Clinic is a multidisciplinary clinic focused on providing care to infants and children with differences in the typical path of sex development, which may be influenced by the arrangement of sex chromosomes, the functioning of our gonads (i.e. testes, ovaries), and our bodies' response to hormones. The clinic is comprised of members from Pediatric Endocrinology, Genetics, Psychology, Urology, Gynecology, Surgery, and Social Work. In this clinic I have assessed and treated over 100 patients with DSD. In my role as Medical Director of the Comprehensive Gender Services Program (CGSP), I lead Michigan Medicine's broader efforts related to transgender services. CGSP is comprised of providers from across the health system including pediatric care, adult hormone provision, gynecologic services, adult surgical services, speech/language therapy, mental health services, and primary care. I run monthly meetings with representatives from these areas to help coordinate communication between Departments. I coordinate strategic planning aimed to improve care within the health system related to our transgender population. I also serve as the medical representative for CGSP in discussions with health system administrators and outside entities.

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15. I have authored numerous peer-reviewed articles related to treatment of transgender youth. I have also co-authored chapters of medical textbooks related to medical management of transgender patients. I have been invited to speak at numerous hospitals, clinics, and conferences on topics related to clinical care and standards for treating transgender children and youth.

16. The information provided regarding my professional background, experiences, publications, and presentations is detailed in my curriculum vitae, a true and correct copy of the most up-to-date version of which is attached as **Exhibit A**.

## B. Prior Testimony

17. In the past four years, I have been retained as an expert and provided testimony at trial or by deposition in the following cases: *Loe v. Texas*, (District Court of Travis County, Texas); *Doe v. Norman*, (N.D. Georgia). Dekker v. *Weida*, No. 4:22- cv-00325 (N.D. Fla.); *K.C. v. The Individual Members of the Medical Licensing Board of Indiana*, No. 1:23-cv-00595 (S.D. Ind.);; *Roe et al v. Utah High School Activities Association et al* (Third District Court in and for Salt Lake County, UT); *Menefee v. City of Huntsville Bd. of Educ.*, No. 5:18- cv-01481 (N.D. Ala.); and *Cooper v. USA Powerlifting and Powerlifting Minnesota*, No. 62-CV-21-211 (Ramsey Cnty. Dist. Ct., Minn.). I also provided expert witness testimony on behalf of a parent in a custody dispute involving a transgender child in the following case: *In the Interest of Younger*, No. DF-15-09887 (Dallas County, Texas).

## C. Compensation

18. I am being compensated at an hourly rate for the actual time that I devote to this case, at the rate of \$325 per hour for any review of records, preparation of reports, declarations, and deposition and trial testimony. My compensation does not depend on the outcome of this litigation, the opinions that I express, or the testimony that I provide.

## **D.** Bases for Opinions

19. In preparing this report, I reviewed the text of the Standards of Practice for the Treatment of Gender Dysphoria in Minors issued by the Florida Board of Medicine and Florida Board of Osteopathic Medicine in 2023. I reviewed the text of documents adopted by the Florida Board of Medicine titled, "Puberty Suppression Treatment for Patients with Gender Dysphoria: Patient Information and Parental Consent and Assent for Minors" (DH5079-MQA, Rev. 06/23), "Masculinizing Medications for Patients with Gender Dysphoria: Patient Information and Parental Consent and Assent for Minors" (DH5081-MQA, Rev. 06/23), "Feminizing Medications for Patients with Gender Dysphoria: Patient Information and Parental Consent and Assent for Minors" (DH5081-MQA, Rev. 06/23), "Feminizing Medications for Patients with Gender Dysphoria: Patient Information and Parental Consent and Assent for Minors" (DH5080-MQA, Rev. 06/23), "Masculinizing Medications for Patients with Gender Dysphoria: Patient Information and Parental Consent and Assent for Minors" (DH5080-MQA, Rev. 06/23), "Masculinizing Medications for Patients with Gender Dysphoria: Patient Information and Parental Consent and Assent for Minors" (DH5080-MQA, Rev. 06/23), "Masculinizing Medications for Patients with Gender Dysphoria: Patient Information and Informed Consent" (DH5082-MQA, Rev. 06/23), and "Feminizing Medications for Patients

with Gender Dysphoria: Patient Information and Informed Consent" (DH5083-MQA, Rev. 06/23).

20. I have also reviewed the materials listed in the bibliography attached as **Exhibit B** to this report, as well as the materials listed within my curriculum vitae, which is attached as **Exhibit A**. The sources cited therein include authoritative, scientific peer-reviewed publications. They include the documents specifically cited as supportive examples in particular sections of this report. I may rely on these materials as additional support for my opinions.

21. In addition, I have relied on my scientific education, training, and years of clinical and research experience, and my knowledge of the scientific literature in the pertinent fields.

22. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on these subjects.

23. To the best of my knowledge, I have not met or spoken with the minor Plaintiffs or their parents, or the adult Plaintiffs. My opinions are based solely on my extensive background and experience treating transgender patients.

24. I may wish to supplement or revise these opinions or the bases for them due to new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

## **II. EXPERT OPINIONS**

# A. Medical and Scientific Background On Sex and Gender Identity

25. *Sex* is comprised of several components, including, among others, internal reproductive organs, external genitalia, chromosomes, hormones, gender identity, and secondary sex characteristics (IOM, 2011).

26. *Gender identity* is the medical term for a person's internal, innate sense of belonging to a particular sex. Everyone has a gender identity. Diversity of gender identity and incongruence between assigned sex at birth and gender identity are naturally occurring sources of human biological diversity (IOM, 2011). The term *transgender* refers to individuals whose gender identity does not align with their sex assigned at birth (Shumer, et al., 2013).

27. The terms *gender role* and *gender identity* refer to different things. *Gender roles* are behaviors, attitudes, and personality traits that a particular society considers masculine or feminine, or associates with male or female social roles. For example, the convention that girls wear pink and have longer hair, or that boys wear blue and have shorter hair, are socially constructed gender roles from a particular culture and historical period. By contrast, *gender identity* does not refer to socially contingent behaviors, attitudes, or personality traits. It is an internal and largely biological phenomenon, as reviewed below. Living consistent with one's gender

identity is critical to the health and well-being of any person, including transgender people (Hidalgo, et al., 2013; Shumer, et al., 2013; White Hughto, et al., 2015).

A person's understanding of their gender identity may evolve over time 28. in the natural course of their life, however, attempts to "cure" transgender individuals by forcing their gender identity into alignment with their birth sex has been found to be both harmful and ineffective. In one study, transgender adults who recall previous attempts from healthcare professionals to alter their gender identity reported an increase in lifetime suicide attempts and higher rates of severe psychological distress in the present (Turban, et al., 2020a). In another study, exposure to these types of attempts were found to increase the likelihood that a transgender adolescent will attempt suicide by 55% and more than double the risk for running away from home (Campbell, et al., 2002). Those practices have been denounced as unethical by all major professional associations of medical and mental health professionals, such as the American Medical Association, the American Academy of Pediatrics, the American Psychiatric Association, and the American Psychological Association, among others (Fish, et al., 2022).

29. Scientific research and medical literature across disciplines demonstrates that gender identity, like other components of sex, has a strong biological foundation. For example, there are numerous studies detailing the similarities in the brain structures of transgender and non-transgender people with

the same gender identity (Luders, et al., 2009; Rametti, et al., 2011; Berglund, et al., 2008). In one such study, the volume of the bed nucleus of the *stria terminalis* (a collection of cells in the central brain) in transgender women was equivalent to the volume found in non-transgender women (Chung, et al., 2002).

30. There are also studies highlighting the genetic components of gender identity. Twin studies are a helpful way to understand genetic influences on human diversity. Identical twins share the same DNA, while fraternal twins share roughly 50% of the same DNA, however both types of twins share the same environment. Therefore, studies comparing differences between identical and fraternal twin pairs can help isolate the genetic contribution of human characteristics. Twin studies have shown that if an identical twin is transgender, the other twin is much more likely to be transgender compared to fraternal twins, a finding which points to genetic underpinnings to gender identity development (Heylens, et al., 2012).

31. There is also ongoing research on how differences in fetal exposures to hormones may influence gender identity. This influence can be examined by studying a medical condition called congenital adrenal hyperplasia. Female fetuses affected by congenital adrenal hyperplasia produce much higher levels of testosterone compared to fetuses without the condition. While most females with congenital adrenal hyperplasia have a female gender identity in adulthood, the percentage of those with gender dysphoria is higher than that of the general

population. This suggests that fetal hormone exposures contribute to the later development of gender identity (Dessens, et al, 2005).

32. There has also been research examining specific genetic differences that appear associated with gender identity formation (Rosenthal, 2014). For example, one study examining differences in the estrogen receptor gene among transgender women and non-transgender male controls found that the transgender individuals were more likely to have a genetic difference in this gene (Henningsson, et al., 2005).

33. The above studies are representative examples of scientific research demonstrating biological influences on gender identity. Gender identity, like other complex human characteristics, is rooted in biology with important contributions from neuroanatomic, genetic and hormonal variation (Roselli, 2018).

## **B.** Rationale for Medical Treatment of Gender Dysphoria in Adolescents

34. All medical interventions, including treatment for gender dysphoria, require rigorous study and evidence base.

35. There are several studies demonstrating positive results of transitionrelated care in adolescents (de Vries, et al., 2014; de Vries, et al., 2011; Green, et al., 2022; Smith, et al., 2005; Turban, et al., 2022). These studies consistently demonstrate improvement of gender dysphoria with associated improvement of psychological functioning. A 2014 long-term follow-up study following patients

from early adolescence through young adulthood showed that gender transition treatments allowed transgender adolescents to make age-appropriate developmental transitions while living as their affirmed gender with positive outcomes as young adults (de Vries, et al., 2014). More recently, Green et al. (2022) describe that hormone therapy is correlated with reduced rates of depression and suicidality among transgender adolescents. Turban et al. (2022) documented that access to hormone therapy in adolescence is associated with favorable mental health outcomes in adulthood, when compared to individuals who desired but could not access hormonal interventions.

## C. Assessment of Gender Dysphoria in Children and Adolescents

36. Due to the incongruence between their assigned sex and gender identity, transgender people experience varying degrees of gender dysphoria, a serious medical condition defined in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5 TR) (APA, 2022). *Gender Dysphoria* is defined as an incongruence between a patient's assigned sex and their gender identity present for at least six months, which causes clinically important distress in the person's life. This distress is further defined as impairment in social, occupational, or other important areas of functioning (APA, 2022). Additional features may include a strong desire to be rid of one's primary or secondary sex characteristics, a strong desire to be treated as a member of the

identified gender, or a strong conviction that one has the typical feelings of identified gender (APA, 2022).

37. The World Health Organization's International Classification of Diseases (ICD), the diagnostic and coding compendia for mental health and medical professionals, codifies Gender Incongruence as the diagnosis resulting from the incongruity between one's gender identity and birth sex. The Gender Incongruence diagnosis is part of a new "Conditions related to sexual health" chapter in the ICD-11, which is the most recent iteration of the ICD published in 2019 (Costa, et al., 2015; WHO, 2019). This reflects evidence that transgender and gender diverse identities are not conditions of mental ill health and classifying them as such can cause enormous stigma.

38. In children and adolescents, the diagnosis of gender dysphoria is made by a health provider including but not limited to a psychiatrist, psychologist, social worker, or therapist with expertise in gender identity concerns. It is recommended that children and adolescents diagnosed with gender dysphoria engage with a multidisciplinary team of mental health and medical professionals to formulate a treatment plan, in coordination with the parent(s) or guardian(s), with a goal of reduction of gender dysphoria. The *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8* ("SOC 8"), published by the World Professional Association for Transgender Health (WPATH), provides guidance to

providers on how to provide comprehensive assessment and care to this patient population based on medical evidence. These standards recommend involving relevant disciplines, including mental health and medical professionals, to reach a decision with families about whether medical interventions are appropriate and remain indicated through the course of treatment. Multidisciplinary clinics, such as the Child and Adolescent Gender Clinic where I practice, have structured their programs around this model, as guided by the WPATH SOC.

## **D.** Evidence-Based Clinical Practice Guidelines for the Treatment of Gender Dysphoria in Children, Adolescents, and Adults

39. The goal of any intervention for gender dysphoria is to reduce dysphoria, improve functioning, and prevent the harms caused by untreated gender dysphoria.

40. Gender dysphoria is highly treatable and can be effectively managed. If left untreated, however, it can result in severe anxiety and depression, eating disorders, substance abuse, self-harm, and suicidality (Reisner, et al., 2015).

41. Based on longitudinal data, and my own clinical experience, when transgender adolescents are provided with appropriate medical treatment and have parental and social support, they are more likely to thrive and grow into healthy adults (de Vries, et al., 2014).

42. In children and adolescents, a comprehensive biopsychosocial assessment is typically the first step in evaluation, performed by a mental health

provider with experience in gender identity. The goals of this assessment are to develop a deep understanding of the young person's experience with gender identity, to consider whether the child or adolescent meets criteria for a diagnosis of gender dysphoria, and to understand what options may be desired and helpful for the adolescent (Coleman, et al., 2022; Coleman, et al., 2012; Hembree, et al., 2017; Hembree, et al., 2009).

43. For children younger than pubertal age, the only recommended treatments do not involve medications. For adolescents, additional treatments involving medications may be appropriate.

44. For pre-pubertal children with gender dysphoria, treatments may include supportive therapy, encouraging support from loved ones, and assisting the young person through elements of a social transition. Social transition may include adopting a new name and pronouns, appearance, and clothing, and correcting identity documents.

45. Options for treatment after the onset of puberty include the use of gonadotropin-releasing hormone agonists ("GnRHa") for purposes of preventing progression of pubertal development, and hormonal interventions such as testosterone and estrogen administration. These treatment options are based on robust research and clinical experience, which consistently demonstrate safety and efficacy.

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46. Clinical practice guidelines have been published by several longstanding and well-respected medical bodies: the World Professional Association for Transgender Health (WPATH) and the Endocrine Society (Coleman, et al., 2022; Coleman, et al., 2012; Hembree, et al., 2017; Hembree, et al., 2009), as well as the UCSF Center for Excellence in Transgender Health (Deutsch (ed.), 2016). The clinical practice guidelines and standards of care published by these organizations provide a framework for treatment of gender dysphoria in adolescents.

47. WPATH has been recognized as the standard-setting organization for the treatment of gender dysphoria since its founding in 1979. The most recent WPATH Standards of Care (SOC 8) were published in 2022 and represent expert consensus for clinicians related to medical care for transgender people, based on the best available science and clinical experience (Coleman, et al., 2022).

48. The purpose of the WPATH Standards of Care is to assist health providers in delivering necessary medical care to transgender people, to maximize their patients' overall health, psychological well-being, and self-fulfillment. The WPATH Standards of Care serve as one of the foundations for the care provided in my own clinic.

49. The WPATH SOC 8 is based on rigorous review of the best available science and expert professional consensus in transgender health. International professionals were selected to serve on the SOC 8 writing committee.

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Recommendation statements were developed based on data derived from independent systemic literature reviews. Grading of evidence was performed by an Evidence Review Team which determined the strength of evidence presented in each individual study relied upon in the document (Coleman, et al., 2022).

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

51. In addition, the Endocrine Society is a 100-year-old global membership organization representing professionals in the field of adult and pediatric endocrinology. In 2017, the Endocrine Society published clinical practice guidelines on treatment recommendations for the medical management of gender dysphoria, in collaboration with Pediatric Endocrine Society, the European Societies for Endocrinology and Pediatric Endocrinology, and WPATH, among others (Hembree, et al, 2017).

52. The Endocrine Society Clinical Guidelines were developed through rigorous scientific processes that "followed the approach recommended by the Grading of Recommendations, Assessment, Development, and Evaluation group, an international group with expertise in the development and implementation of evidence-based guidelines." The guidelines affirm that patients with gender

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dysphoria often must be treated with "a safe and effective hormone regimen that will (1) suppress endogenous sex hormone secretion determined by the person's genetic/gonadal sex and (2) maintain sex hormone levels within the normal range for the person's affirmed gender." (Hembree, et al., 2017).

53. The AAP is the preeminent professional body of pediatricians in the United States, with over 67,000 members. The AAP endorses a commitment to the optimal physical, mental, and social health and well-being for youth. The 2018 policy statement titled *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents* further lends support to the treatment options outlined in the WPATH Standards of Care and the Endocrine Society's Clinical Practice Guidelines (Rafferty, et al., 2018).

54. Aside from the AAP, the tenets set forth by the Endocrine Society Clinical Practice Guidelines and the WPATH Standards of Care are supported by the major professional medical and mental health associations in the United States, including the American Medical Association, the American Psychological Association, the American Psychiatric Association, and American Academy of Family Physicians, among others (e.g., AMA, 2019; American Psychological Association, 2015; Drescher, et al., 2018 (American Psychiatric Association); Hembree, et al., 2017 (Endocrine Society); Klein, et al., 2018 (AAFP); National Academies, 2020; WPATH, 2016).

55. As a board-certified pediatric endocrinologist, I follow the Endocrine Society Clinical Practice Guidelines and the WPATH Standards of Care when treating my patients.

# E. Treatment Protocols for Gender Dysphoria in Children, Adolescents, and Adults

56. Central to the guidance from WPATH, the Endocrine Society, and the AAP is the importance of familial love and support. Transgender youth who report high levels of rejection from family have lower self-esteem and higher degrees of isolation. These youth are at very high risk for health and mental health problems when they become young adults. According to the Family Acceptance Project, transgender young people who reported high levels of family rejection are significantly more likely to have attempted suicide, to report high levels of depression, to use illegal drugs, and to be at high risk for HIV and sexually transmitted diseases compared with transgender young people who report no or low levels of rejection by family due to their identity (Ryan, et al., 2010).

57. Undergoing treatment to alleviate gender dysphoria is commonly referred to as a transition. The transition process in adolescence typically includes (i) social transition and/or (ii) medications, including puberty-delaying medication and hormone therapy. The steps that make up a person's transition and their sequence will depend on that individual's medical and mental health needs and decisions made between the patient, family, and multidisciplinary care team.

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58. There are no medications considered for transition until after the onset of puberty. Puberty is a process of maturation heralded by production of sex hormones—testosterone and estrogen—leading to the development of secondary sex characteristics. Secondary sex characteristics include testosterone-induced effects such as deepening of the voice, muscular changes, facial and body hair, and estrogen-induced effects such as breast development. There is diversity in the age of pubertal onset; however, most adolescents begin puberty between ages 10 and 12 years.

59. Gender exploration in childhood is expected and healthy. The majority of prepubertal children exploring their gender do not develop gender dysphoria and are not expected to become transgender adolescents or adults. In contrast, data and personal experience shows that children whose gender dysphoria persists into adolescence are highly likely to be transgender (van der Loos, et al., 2022). Some individuals in this field misinterpret older studies showing that a large percentage of children diagnosed with gender identity disorder did not grow up to be transgender. Those studies include children who would not fulfill the current diagnostic criteria for gender dysphoria and, in any case, have no relevance to this case because no medications are prescribed to prepubertal children.

60. Puberty-delaying medication and hormone-replacement therapy—both individually and in combination—can significantly improve a transgender young

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person's mental health. These treatments allow for a physical appearance more closely aligning with gender identity and decreases the likelihood that a transgender young person will be incorrectly identified with their assigned sex, further alleviating their gender dysphoria, and bolstering the effectiveness of their social transition.

61. At the onset of puberty, adolescents begin to experience the onset of secondary sex characteristics. Adolescents with differences in gender identity may have intensification of gender dysphoria during this time due to development of secondary sex characteristics incongruent with gender identity. Persistence or intensification of gender dysphoria as puberty begins is used as a helpful diagnostic tool as it becomes more predictive of gender identity persistence into adolescence and adulthood (de Vries, et al., 2012).

## i. Treatment with puberty-delaying medications

62. Adolescents diagnosed with gender dysphoria who have entered puberty (Tanner Stage 2) may be prescribed puberty-delaying medications (GnRHa) to prevent the distress of developing permanent, unwanted physical characteristics that do not align with the adolescent's gender identity. Tanner Stage 2 refers to the stage in puberty whereby the physical effects of testosterone or estrogen production are first apparent on physical exam. Specifically, this is heralded by the onset of breast budding in an individual assigned female at birth, or the onset of testicular

enlargement in an individual assigned male at birth. For individuals assigned male at birth, Tanner Stage 2 typically occurs between age 9-14, and for those assigned female at birth between age 8-12.

63. The treatment works by pausing endogenous puberty at whatever stage it is at when the treatment begins, limiting the influence of a person's endogenous hormones on their body. For example, a transgender girl will experience no progression of physical changes caused by testosterone, including facial and body hair, an Adam's apple, or masculinized facial structures. And, in a transgender boy, those medications would prevent progression of breast development, menstruation, and widening of the hips (Coleman, et al., 2022; de Vries, et al., 2012; Deutsch (ed.), 2016; Hembree, et al., 2017; Rosenthal, 2014).

64. GnRHa have been used extensively in pediatrics for several decades. Prior to their use for gender dysphoria, they were used (and still are used) to treat precocious puberty. GnRHa work by suppressing the signal hormones from the pituitary gland (luteinizing hormone [LH] and follicle stimulating hormone [FSH]) that stimulate the testes or ovaries to produce sex hormones. Upon discontinuation of GnRHa, LH and FSH production resume and puberty will also resume.

65. GnRHa have no long-term implications on fertility. In transgender youth, it is most typical to use GnRHa from the onset of puberty (Tanner Stage 2) until mid-adolescence. While treating, the decision to continue treatment will be

continually evaluated. Should pubertal suppression no longer be desired, GnRHa would be discontinued, and puberty would re-commence.

66. Prior to initiation of GnRHa, providers counsel patients and their families extensively on potential benefits and risks. The designed benefit of the treatment is to reduce the risk of worsening gender dysphoria and mental health deterioration. Furthermore, development of secondary sex characteristics incongruent with gender identity could result in the future need for surgeries and other body alterations that would not be needed if GnRHa had been used.

67. As an experienced pediatric endocrinologist, I treat patients with these same medications for both precocious puberty and gender dysphoria and in both cases the side effects are comparable and easily managed. And for both patient populations the risks are greatly outweighed by the benefits of treatment.

68. In addition, I regularly prescribe GnRHa for patients who do not meet criteria for precocious puberty but who require pubertal suppression. Examples include patients with disabilities who are unable to tolerate puberty at the typical age due to hygienic concerns; minors with growth hormone deficiency who despite growth hormone treatment will have a very short adult height; and young women with endometriosis. As with gender dysphoria, the prescription of GnRHa to treat these conditions is "off-label," yet it is widely accepted within the field of endocrinology and not considered experimental. The same holds true for other

common medications used in pediatric endocrinology: using metformin for weight loss; growth hormone for short stature not caused by growth hormone deficiency; countless medications used to control type 2 diabetes which have an adult indication but whose manufacturers have not applied for a pediatric indication.

## ii. Treatment with hormone therapy

69. In mid-adolescence, the patient, their parents, and the patient's care team may discuss the possibility of beginning the use of testosterone or estrogen. In my practice we discuss these treatments for a patient who is currently receiving GnRHa, or patients who have already gone through their endogenous puberty and either did not have access to, desire, or elect for GnRHa treatment.

70. These hormone therapies are used to treat gender dysphoria in adolescents to facilitate development of sex-specific physical changes congruent with their gender identity. For example, a transgender boy prescribed testosterone will develop a lower voice as well as facial and body hair, while a transgender girl prescribed estrogen will experience breast growth, female fat distribution, and softer skin.

71. Under the Endocrine Society Clinical Guidelines and SOC 8, hormone therapy is an appropriate treatment for transgender adolescents with gender dysphoria when the experience of dysphoria is marked and sustained over time, the adolescent demonstrates emotional and cognitive maturity required to provide and

informed consent/assent for treatment, other mental health concerns (if any) that may interfere with diagnostic clarity and capacity to consent have been addressed, the adolescent has discussed reproductive options with their provider. SOC 8 also highlights the importance of involving parent(s)/guardian(s) in the assessment and treatment process for minors (Coleman, et al., 2022; Hembree, et al., 2017).

72. Similar to GnRHa, the risks and benefits of hormone treatment are discussed with patients (and families, if the patient is a minor) prior to initiation of testosterone or estrogen. When treated with testosterone or estrogen, the goal is to maintain the patient's hormone levels within the normal range for their gender. Laboratory testing is recommended to ensure proper dosing and hormonal levels. If starting hormonal care after completing puberty, discussion of egg or sperm preservation prior to starting treatment is recommended.

73. Regardless of the treatment plan prescribed, at every encounter with the care team there is a re-evaluation of the patient's gender identity and their transition goals. Should a patient desire to discontinue a medical intervention, the intervention is discontinued. Discontinuation of GnRHa will result in commencement of puberty. Findings from studies in which participants have undergone comprehensive evaluation prior to gender care show low levels of regret (de Vries, et al., 2011; van der Loos, et al., 2022; Wiepjes, et al., 2018).

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74. Surgical interventions, including but not limited to chest and genital surgery, are indicated in appropriately selected patients. These surgeries are not typically performed in adolescence but rather considered in adulthood. The WPATH SOC 8 outlines the current literature supporting benefits of surgical interventions for patients with gender dysphoria (Coleman, et al., 2022).

# F. Safety and Efficacy of Puberty-Delaying Medications and Hormone Therapy to Treat Gender Dysphoria

75. GnRHa, prescribed for delaying puberty in transgender adolescents, is both a safe and effective treatment. Patients under consideration for treatment are working within a multidisciplinary team of providers all dedicated to making informed and appropriate decisions with the patient and family in the best interest of the adolescent. Physicians providing this intervention are trained and qualified in gender identity concerns and childhood growth and development and are participating in this care out of a desire to improve the health and wellness of transgender youth and prevent negative outcomes such as depression and suicide.

76. GnRHa, including injectable leuprolide and implantable histrelin, have rare side effects which are discussed with patients and families prior to initiation. Mild negative effects may include pain at the injection or implantation site, sterile abscess formation, weight gain, hot flashes, abdominal pain, and headaches. These effects can be seen in patients receiving GnRHa for gender dysphoria, or for other indications such as precocious puberty. I counsel patients on maintaining a healthy

diet and promote physical activity, and regularly document height and weight during treatment. Nutritional support can be provided for patients at risk for obesity.

77. Risk of lower bone mineral density in prolonged use of GnRHa can be mitigated by screening for, and treating, vitamin D deficiency when present, and by limiting the number of years of treatment based on a patient's clinical course (Rosenthal, 2014). An exceptionally rare but significant side effect, increased intracranial pressure, has been reported in six patients (five treated for precocious puberty, one for transgender care), prompting an FDA warning in July 2022 (AAP, 2022). These cases represent an extremely small fraction of the thousands of patients who have been treated with GnRHa over decades. Symptoms of this side effect (headache, vomiting, visual changes) are reviewed with families and if they occur the medication is discontinued.

78. GnRHa do not have long-term implications on fertility. This is clearly proven from decades of use in the treatment of precocious puberty (Guaraldi, et al., 2016; Martinerie, et al, 2021). Progression through natal puberty is required for maturation of egg or sperm. If attempting fertility after previous treatment with GnRHa followed by hormone therapy is desired, an adult patient would withdraw from hormones and allow pubertal progression. Assistive reproduction could be employed if needed (T'Sjoen, et al., 2013).

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79. Patients who initiate hormones after completing puberty are offered gamete preservation prior to hormonal initiation (Coleman, et al., 2022), but even when not undertaken, withdrawal of hormones in adulthood often is successful in achieving fertility when it is desired (Light, et al., 2014; Knudson, et al., 2017).

80. Discussing the topic of fertility is important, and not specifically unique to treatment of gender dysphoria. Medications used for other medical conditions, such as chemotherapeutics used in cancer treatment, can affect fertility. For all medications with potential impacts on fertility, the potential risks and benefits of both treatment and non-treatment should be reviewed and data regarding risk for infertility clearly articulated prior to the consent or assent of the patient. Risk for fertility changes must be balanced with the risk of withholding treatment.

81. Review of relevant medical literature clearly supports the benefits of GnRHa treatment on both short-term and long-term psychological functioning and quality of life (e.g., Achille, et al., 2020; Carmichael, et al., 2021; Costa, et al., 2015; de Vries, et al., 2014; de Vries, et al., 2011; Kuper, et al., 2020; Turban, et al., 2020b; van der Miesen, et al., 2020). For example, a 2014 long-term follow-up study following patients from early adolescence through young adulthood showed that gender transition treatment allowed transgender adolescents to make age-appropriate developmental transitions while living as their affirmed gender with positive outcomes as young adults (de Vries, et al., 2014).

82. In my own practice, adolescent patients struggling with significant distress at the onset of puberty routinely have dramatic improvements in mood, school performance, and quality of life with appropriate use of GnRHa. Side effects encountered are similar to those seen in other patients treated with these medications and easily managed.

Hormone therapy (testosterone or estrogen) is prescribed to older 83. adolescents with gender dysphoria. As is the case with GnRHa, the need for hormone therapy is not unique to transgender adolescents. Patients with conditions such as delayed puberty, hypogonadism, Turner Syndrome, Klinefelter Syndrome, agonism, premature ovarian failure, and disorders of sex development all require treatment with these hormones, often starting in adolescence and continuing lifelong. Without testosterone or estrogen treatment, these patients would be unable to progress through puberty normally, which would have serious medical and social consequences. Whether used in adolescents to treat gender dysphoria, or to treat any of these other conditions, testosterone and estrogen are prescribed with a goal to raise the testosterone or estrogen level into the normal male or female range for the patient's age. Careful monitoring of blood levels and clinical progress are required. Side effects are rare, but most often related to overtreatment, which can be Additionally, side effects are considered, minimized with this monitoring.

discussed, and easily managed in all individuals needing hormone therapy regardless of the diagnosis necessitating these medications.

84. Venous thromboembolism (blood clotting) is a known side effect of estrogen therapy in all individuals placed on it including transgender women. Risk is increased in old age, in patients with cancer, and in patients who smoke nicotine. This side effect is mitigated by careful and accurate prescribing and monitoring. In my career, no patient has suffered a thromboembolism while on estrogen therapy.

85. Treatment of gender dysphoria with testosterone or estrogen is highly beneficial for both short-term and long-term psychological functioning of adolescents with gender dysphoria and withholding treatment from those who need it is harmful (e.g., Achille, et al., 2020; Allen, et al., 2019; Chen, et al., 2023; de Lara, et al., 2020; de Vries, et al., 2014; Grannis, et al., 2021; Green, et al., 2022; Kaltiala, et al., 2020; Kuper, et al., 2020). To highlight examples, Green et al. (2022) describe that hormone therapy is correlated with reduced rates of depression and suicidality among transgender adolescents. Turban et al. (2022) documented that access to hormone therapy in adolescence is associated with favorable mental health outcomes in adulthood, when compared to individuals who desired but could not access hormonal interventions.

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86. I treat many patients with gender dysphoria GnRHa, testosterone, and estrogen. Side effects related to these medications are very rare and can be treated with dose adjustment and/or lifestyle changes.

87. In sum, the use of GnRHa and hormones in adolescents for the treatment of gender dysphoria is the current standard of care and certainly not experimental. This is due to robust evidence of safety and efficacy. The sum of the data supports the conclusion that treatment of gender dysphoria with these interventions promotes wellness and helps to prevent negative mental health outcomes, including suicidality in adolescents. The data to support these interventions are so strong that withholding such interventions would be negligent and unethical.

## G. Harms Associated with Prohibiting and Discontinuing Treatment

88. Prohibition of gender transition care for adolescents is likely to have devastating consequences. I am concerned such a prohibition might lead to a staggering increase in mental health problems including suicidality for transgender children and adolescents in Florida. One study which highlights my concern is a study of over 21,000 patients who report ever desiring hormone care. When comparing those who were able to access this care to those desiring but never accessing care, those able to access care had lower odds of suicidality within the past year. In addition, those individuals where were able to access care in adolescence

had lower odds of suicidality compared to those waiting to access until adulthood (Turban, et al., 2022).

89. Even more concerning is a situation where patients currently receiving care and thriving would be forced to discontinue this care.

# H. The Boards' Informed Consent Documents Are Medically Inaccurate, Impose Medically Unwarranted and Harmful Requirements, and Undermine Rather Than Facilitate Informed Consent

90. The consent forms created by the Florida Board of Medicine are inappropriate because they provide incorrect information, mandate inappropriate restrictions on care, and create harmful barriers to minor and adult patients getting the care they need.

91. Health care professionals have both a legal and ethical obligation to ensure that patients receive accurate information about medical treatments they are prescribed. This includes a discussion of the medical condition being treated, potential treatment options, and potential risks and benefits of those treatment options. Providers must ensure that patients and the parents of minor patients have the capacity to understand these discussions and that they agree to the treatment plan. Because the forms state inaccurate information, require unnecessary restrictions on care, and falsely describe the risk/benefit ratio, these forms undermine the process of informed consent rather than facilitate it.

How health care professionals undertake the informed consent process 92. is tailored to the medical context and the individual patient-provider and, in the case of minor patients, the parent-provider relationship. Most medical decision making does not involve signing a consent form. For example, when a patient is diagnosed with diabetes, very few if any endocrinologists utilize an informed consent document prior to starting insulin even though there are significant risks associated with insulin in management of diabetes. That said, physicians may use written consent forms in a situation where they believe the form will facilitate discussion of a complex medical decision, enhance patient understanding of the intervention, or provide formal documentation that the material was reviewed with the patient. There may be, for example, providers in Florida who will decide to employ a written consent form prior to prescribing masculinizing or feminizing hormonal therapy. In so doing, they are using the consent form as a tool to improve patient care.

93. When a regulatory agency interferes with the informed consent process to require doctors to misstate information, impose medically unsupported requirements, and create unnecessary barriers to ongoing care, the process is corrupted and patient autonomy is undermined. Nowhere is this more apparent than in the consent form itself: "The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.54, F.S. This form contains information required to be

disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician." The layman's translation: the Florida legislature wants to let you know that we disagree with the decision you and your doctor are making together.

94. The consent forms are intended for use in patients with gender dysphoria considering a hormonal intervention. The goal of any intervention for gender dysphoria is to reduce dysphoria and improve functioning. Clinical practice guidelines have been published by several long-standing and well-respected medical bodies: the World Professional Association for Transgender Health (WPATH) and the Endocrine Society (Coleman, et al., 2022; Coleman, et al., 2012; Hembree, et al., 2017; Hembree, et al., 2009), as well as the UCSF Center for Excellence in Transgender Health (Deutsch (ed.), 2016). The clinical practice guidelines and standards of care published by these organizations provide a medically sound, evidence-based framework for treatment of gender dysphoria in adults. These resources provide the context for my more specific comments related to the content of the consent forms.

# I. The "Puberty Suppression Treatment" Form

95. Prior to a line-item discussion, it is important to point out that in several instances this form describes certain requirements which are medically inappropriate, have no utility, and serve only as a barrier to care. I will point these examples out alongside my discussion of other problems. In addition, because the

forms repeat a number of mistakes and misstatements, there are some redundancies in this Report that reflects that.

96. The statement in the informed consent forms that says when puberty suppression medications are prescribed for gender dysphoria they are not being "used for their intended purpose" is inaccurate, misleading, and is likely to confuse patients. Off-label use is common. The FDA itself has said that once FDA has approved medications, doctors can prescribe such medications if they judge them to be appropriate for their patients. Many medications are prescribed for off-label uses. That does not mean "they are not being used for their intended purposes."

97. The requirement for an *in person* visit before initiating puberty suppression undermines care where the individual circumstances of a minor patient and their family would be best served by a virtual visit.

98. Page 1, Paragraph 2 (Medical treatment...): This paragraph undermines the ability of parents of minor patients to make an informed decision by giving them incorrect and biased information. Describing medical treatment of gender dysphoria as being based on very limited, poor-quality research is incorrect and misleading. Medical evidence supports the treatment of gender dysphoria with puberty suppression treatment when appropriate. In addition, far from being "purely speculative," this care is well-established and based on substantial data and decades of clinical experience.

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99. Page 2, Paragraph 3 (Provera is a pill...): There is no medical reason for this document to include a discussion of Provera. Provera is a medication used for menstrual regulation and it is used in the same manner for transgender boys and non-transgender girls. Provera is not used for pubertal suppression.

100. Page 3 (The specific requirements...), Item 6 (Demonstrates knowledge...): It is unnecessary to discuss the risks and benefits associated with surgery during a conversation about puberty suppression because the decision to have surgery is completely separate from decisions about medications for minors.

101. Page 3, Item 7 (Undergoes an in-person...): While it is reasonable to schedule follow-up visits every six months during puberty suppression treatment, it is not reasonable to require those visits to be in person where, depending on the circumstances of the minor patient and their family, virtual visits may better serve their needs.

102. Page 3, Item 8 (Undergoes a suicide risk assessment...): The frequency of mental health assessments for minors being treated with puberty suppression medications must be individualized according to the needs of the minor patient. It is inappropriate to require assessments every three months for all patients.

103. Page 3, Item 9 (Undergoes relevant laboratory...): The frequency of laboratory testing should be based on the individualized needs of the minor patient.

104. Page 3, Item 10 (X-ray of the hand...): The requirement of a hand X-ray is not medically necessary. If there is no concern about a minor patient's final height, there is no need to obtain a bone age X-ray.

105. Page 3, Item 11 (Annual bone density scan...): Bone density scans (DEXA) should be served only for those individuals who are at risk for low bone density. While some minor patients experience lower bone density while being treated with puberty suppression medication, research has shown that bone density will be normal when the patient ceases puberty suppression medication, whether or not the patient continues with hormone replacement therapy. Research has helped providers to understand which patients would benefit from a DEXA assessment.

106. Page 3, Item 12 (Annual mental health assessment...): The requirement for assessments by a Board-certified Florida-licensed psychiatrist or psychologist undermines care for patients who would receive better treatment from other mental health professionals, such as therapists and social workers who are often competent and better equipped to conduct mental health assessments for transgender minors.

107. Page 4 (Effects...), Item 2 (If a minor stops...): If a minor stops treatment with puberty suppression medication, in a few months their body will restart the changes of puberty at the development stage they were before starting medication. It is false that the effects of these medications could be permanent.

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108. Page 4, Item 3 (It can take...): Puberty suppression medications work very predictably and how they arrest puberty is well understood. It is false to state that it cannot be predicted how quickly or slowly or even if a minor's body will respond to the medication.

109. Page 4, Item 6 (Puberty blockers can interfere...). Puberty suppression medications do not interfere with fertility. The contrary statement is not accurate.

110. Page 4 (Risks...), Item 1 (The adverse effects...): Puberty suppression medications are well understood to be safe and effective for treating minors with gender dysphoria. There is no evidence to support the claim that the effects are not well known.

111. Page 4, Item 2 (Treatment with puberty blockers...): There is substantial evidence that puberty suppression medications for the treatment of gender dysphoria in transgender youth are associated with improved mental health outcomes. Any statement to the contrary is false and not supported by evidence.

112. Page 4-5, Item 3 (Treatment with puberty blockers may cause...): The effects listed here, including crying, irritability, restlessness, anger, and aggression are not common or expected effects of treatment with puberty suppression medications.

113. Page 5, Item 6 (Seizures are a risk...): The association between puberty suppression medications and seizures are not well established as true.

114. Page 5, Item 13 (Puberty blockers may cause stalling...). The statement that puberty suppression medication may stall cognitive or brain development in minors is false and not supported by evidence.

#### J. The "Masculinizing Medications" Forms

115. Prior to a line-item discussion, it is important to point out that in several instances the "Masculinizing Medications" forms for minors and for adults describe certain requirements which are medically inappropriate, have no utility, and serve only as a barrier to care. I will point these examples out alongside my discussion of other problems. And as set forth above, there are redundancies in my Report as there are in the forms.

116. The forms for minors and the forms for adults include the same inaccuracies. Except where indicated, the discussion below is based on the forms for adults.

117. The statement in the informed consent forms that says when hormone therapies are prescribed for gender dysphoria they are not being "used for their intended purpose" is inaccurate, misleading and is likely to confuse patients. Offlabel use is common. The FDA itself has said that once FDA has approved medications, doctors can prescribe such medications if they judge them to be appropriate for their patients. Many medications are prescribed for off-label uses. That does not mean "they are not being used for their intended purposes."

118. Page 1, Paragraph 4 (Medical treatment...): This paragraph undermines the patient's ability to make an informed decision by giving the patient incorrect and biased information. Describing medical treatment of gender dysphoria as being based on very limited, poor-quality research is incorrect and misleading. Medical evidence supports the treatment of gender dysphoria with hormonal care when appropriate, as I have testified to extensively before this court in Dekker v. Weida. In addition, far from being "purely speculative," this care is well-established and based on substantial data and decades of clinical experience.

119. Page 3, Paragraph 2 (Before beginning...): The requirement to undergo evaluation by a Florida licensed psychiatrist or psychologist prior to starting hormone replacement therapy (HRT) and every two years after demonstrates a profound lack of understanding of gender identity and dysphoria and of how health care is provided in our country; there is no medical justification for this requirement, which serves only as an unnecessary and potentially insurmountable barrier to care. The health care professional most appropriate to assess a patient's readiness for HRT is one who has clinical expertise and experience working with gender diverse patients. As the WPATH Standards of Care recognize, this may very well be a psychiatrist or psychologist, but may also be a therapist or social worker, a primary care physician, or another health care professional fluent in these topics and

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available to meet with the patient to have detailed discussion of their experience with gender.

120. In Ann Arbor where I practice, for example, I know of no psychiatrist or psychologist that performs these types of assessments. The assessment of gender dysphoria is primarily the role of therapists and social workers. If every transgender adult in Michigan (and I would presume, in Florida) required a visit with a psychiatrist or psychologist every two years, there would be no logistical way for this to occur due to lack of access. It is also not medically necessary. Psychiatrists, since they can prescribe psychotropic medications, are critical for patients with mental health problems requiring psychotropic drugs. I would refer a transgender patient to a psychiatrist, for example, if they needed assessment and management of bipolar disorder. But there is no similar medical justification for requiring a psychiatrist to approve the use of HRT.

121. As outlined above, mandating that a transgender patient be evaluated by a psychiatrist or psychologist before starting HRT is inappropriate, but requiring the patient to undergo such an evaluation every two years, to continue treatment, compounds the harm caused by this unnecessary requirement, which serves no function that advances either patient care or patient informed consent.

122. More generally, the requirement that transgender patients undergo lifelong therapy has no medical basis. While mental health support can be helpful to

many patients, with and without gender dysphoria, the Standards of Care do not require lifelong therapy, and there is no medical justification for such a requirement. Accordingly, it is far outside the scope of informed consent to require treatment that is not necessary for care of a medical condition and doing so will keep people from getting the essential medical care they need.

123. The additional requirement that the psychiatrist or psychologist must be licensed in Florida adds another irrational, arbitrary, and harmful barrier. There is no reason that a transgender patient who was diagnosed by an appropriate healthcare provider in another state should have to be re-evaluated by a provider licensed in Florida.

124. In short, this provision of the informed consent form has no basis in medicine and does not provide patient information or promote informed consent in any sense. It is a substantive requirement not essential or even related to the informed consent process and serves only as a barrier to care.

125. The additional claim in the analogous provision on the form for minor patients indicates that a licensed mental health care professional "can work with the minor, your family and friends, and your school staff." While it may be helpful for a mental health provider to discuss a minor's case with other members of the patient's life, this form should not be considered a broad release of information. Rather, each individual collateral would require a standard release of information

form signed by the parent(s)/guardian(s) prior to HIPAA-protected discussions as in any medical context.

126. Page 3, Paragraph 1 (Testosterone is . . .): This paragraph accurately states that testosterone is not typically given as a pill. It then, however, goes on to discuss "fatal liver problems" associated with a medication that the physician is not going to prescribe. This approach of needlessly scaring patients undermines rather than enhances informed consent.

127. Page 1, Paragraph 1 (Before starting...): As outlined above, mandating the use of this form prior to starting therapy is inappropriate, but requiring it overand- over, to continue treatment, serves no function that advances either patient care or patient informed consent. The effect of having a patient sign a form multiple times that states the information creates an unnecessary barrier to the care.

128. Page 2, Paragraph 2 (Finasteride is...): Finasteride is a drug that can be used by any person with male-pattern baldness. The medical term for this is androgenic alopecia. A transgender man would only be prescribed this drug if he were having baldness and was bothered by it, just as would be true for a nontransgender man. It is not part of the course of treatment for gender dysphoria. There is no medical justification for requiring signed informed consent by a transgender man for a drug prescribed to combat baldness which he may or may not need and which could be prescribed for either transgender or non-transgender men.

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129. Page 4, Paragraph 1 (The following...). There is no medical basis for the list of items included in Page 4, Paragraph 1. Their inclusion serves only to confuse and undermine informed consent and to create unnecessary obstacles to care. Patients receiving care for gender dysphoria are diverse and have different needs. Patients doing very well may need to be seen less frequently than patients who are struggling. Patients with other medical conditions, such as diabetes or hyperlipidemia, may need lab evaluation more frequently than other patients with no medical problems. Dictating visit frequency, frequency of mental health screening, and laboratory and radiology testing is not an appropriate role for a State Medical Board. These are decisions that medical providers make while thinking critically about each individual patient.

130. Page 6, Row 3: This statement is incorrect, "[T]here is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT." In fact, there are well-established published guidelines that include timing, dosing, and type of administration of hormone therapy and that are supported by research data. (Hembree, et al., 2017; Deutsch (ed.), 2016).

131. On the form for minors, the requirement of a hand X-ray is not medically necessary. If there is no concern about a minor patient's final height, there is no need to obtain a bone age X-ray.

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132. The item in this section that stands out to me as the most egregious is annual bone scans for 5 years. Testosterone does not cause diminution in bone density; it may increase bone density slightly or have no impact. (Rothman and Iwamoto (2019). There is no medical reason to consider DEXA scans for all transmasculine patients starting testosterone. In addition, doing annual DEXA scans for any reason is illogical. DEXA scans measure bone density and the test is primarily used to assess for osteoporosis in older adults. Changes to bone density occur very slowly and therefore doing annual DEXA scans is not helpful; a year is not enough time to see meaningful change. In fact, most insurance plans that I am familiar with refuse to pay for DEXA scan in adults more frequently than every 2 years for this reason—there is no clinical reason to do this even in people with osteoporosis. The statement in the consent forms related to DEXA scans is a clear tell that the form was written by someone without familiarity with the material, that would result in millions of dollars of unnecessary health care utilization, and that creates a hindrance to transgender patients getting essential care for treatment of gender dysphoria.

133. Summary Table: This table provides a good example about why this type of document is problematic. For each patient, there may be particular risks that I want to focus on related to their situation. For example, in the case of a patient already dealing with significant acne, I would discuss a specific acne plan for them

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while starting testosterone, but I would be much less concerned about their risk for an "inflamed liver" as this is something that I have never seen occur in my clinical practice. Presenting a patient with a laundry list of risks and benefits with no information about how to assess their likelihood undermines a patient's ability to make an informed medical choice.

134. Masculinizing Effects Table, Row 4 (The following changes could be...). This row lists all the non-permanent effects of testosterone. Saying that any of these effects could be permanent is incorrect.

135. Risks of Testosterone and Estrogen Tables. As set forth above, presenting a laundry list of risks with no information about how to assess their likelihood undermines a patient's ability to make an informed medical choice.

136. In addition, I want to highlight two rows that are inaccurate. Data does not support the assertion that "treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts," and "taking testosterone causes or worsens migraines." The inclusion of these "risks" has no medical basis.

## K. The "Feminizing Medications" Forms

137. Because these forms parallel the masculinizing forms and use identical language in many sections, I will only include here items that are unique to these forms.

138. Page 2, Paragraph 2 (Cyproterone acetate...). Cyproterone acetate is not available in the United States and therefore should not be included in the consent form. Including a medication that is not available only serves to engender confusion and fear. It does not serve any legitimate purpose and deters patients from getting the care they need.

139. Page 2, Paragraphs 3 and 4. The first four paragraphs on page two include paragraphs related to medications that may or may not be prescribed to the patient. A statement in a consent form that says "various forms of progestins may also be used," provides no meaningful information and serves only to overwhelm and confuse.

140. Page 2, Paragraph 3 (The administration of finasteride ...): The form states that finasteride "is not recommended for routine use in treating populations with gender dysphoria." While finasteride is not prescribed for treating gender dysphoria in transgender men, finasteride may be prescribed to treat gender dysphoria in transgender women in certain situations when other anti-androgens not effective, and—contrary to the implications of the form's statement—there is nothing inappropriate or unsafe about such usage.

141. Page 4, related to DEXA scans in transgender women: I know of no medically supported reason to require annual DEXA scans just because a patient is a transgender woman prescribed estrogen.

142. Page 5, related to risk of breast cancer may significantly increase if a patient takes estrogen: A transgender woman receiving estrogen has a higher risk of breast cancer compared to men but not higher than other women. In fact, this risk is lower than that for non-transgender women. Therefore, transgender women are recommended to follow the same breast cancer mammogram screening guidelines as non-transgender women; they do not require stricter monitoring. (de Block et al. 2019).

## L. Other Restrictions Imposed By SB 254 Have No Medical Basis and Will Serve Only to Deter Transgender Patients from Obtaining Needed Medical Care

143. S.B. 254 arbitrarily and needlessly prohibits advanced practice registered nurses ("APRNs") from prescribing and administering hormone therapy for transgender patients. As the WPATH Standards of Care recognize, there is no medical basis for this restriction, which will serve only to make it difficult or impossible for many transgender patients to receive care.

144. Prescribing and administering hormone therapy to transgender patients to treat gender dysphoria is part of primary care. The education and training that APRNs amply qualifies them to provide this care to transgender patients.

145. S.B. 254 also arbitrarily and needlessly requires that transgender patients may not receive transition-related medical case unless a physician obtains their written consent in an in-person meeting. In addition to the many other problems

with the informed consent requirements, which I outline above, this requirement has no medical basis and serves only to erect another arbitrary and harmful barrier to care. There is nothing about discussing the risks and benefits of treatments with transgender patients and obtaining their informed consent that requires this to be done in an in-person visit, as opposed to a video or audio meeting. This requirement is not imposed for any other patients, including those receiving medications that pose far greater risks, as well as those receiving the same medications for other purposes; there is no reason to impose it only upon transgender patients.

### **III. CONCLUSION**

146. In summary, banning care for transgender adolescents runs counter to evidence-based best practices and standards of care for the treatment of gender dysphoria.

147. Gender dysphoria is a challenging condition, but it is treatable through individualized assessment and treatment, which may include social transition, psychotherapy, pubertal suppression, and hormonal therapy. These treatments are not experimental and are supported by all major medical bodies in the field of transgender medicine and pediatrics.

148. Lack of access to these treatments will result in worse outcomes for countless youth in Florida. Furthermore, banning care and access to evidence-based

treatment for gender dysphoria sends a message that transgender youth are not valid and should be stigmatized.

149. In my own clinical practice in Michigan, I have seen an influx of patients from states banning medically proven treatments for gender dysphoria who report not feeling safe living in the community that they have always called home. Parents who love and support their transgender children have described themselves as "refugees" in their own country, moving to avoid discriminatory laws which they know would clearly harm their health or the health of their child.

150. Banning care and access to effective treatment for gender dysphoria will not eliminate transgender youth, but will, unfortunately, lead to an increase in mental health problems and suicidality in an already vulnerable population.

151. Finally, the informed consent forms required by the State Boards of Medicine and Osteopathic Medicine state misinformation about care for minors and for adults, create unsupported requirements for ongoing treatment, undermine rather than advance informed consent, and create unjustified and harmful barriers to care.

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

Executed this 16<sup>th</sup> day of August 2023.

Daniel Shumer, M.D.

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# <u>Exhibit A</u> Curriculum Vitae

# **Daniel Shumer, MD MPH**

Clinical Associate Professor in Pediatrics - Endocrinology

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# EDUCATION AND TRAINING

# **Education**

08/2000-08/2003	BA, Northwestern University, Evanston, United States
08/2004-05/2008	MD, Northwestern University, Feinberg School of Medicine, Chicago, United States
07/2013-05/2015	MPH, Harvard T.H. Chan School of Public Health, Boston, United States

# **Postdoctoral Training**

06/2008-06/2011	Residency, Pediatrics, Vermont Children's Hospital at Fletcher Allen Health Care, Burlington, VT
07/2011-06/2012	Chief Resident, Chief Resident, Vermont Children's Hospital at Fletcher Allen Health Care, Burlington, VT
07/2012-06/2015	Clinical Fellow, Pediatric Endocrinology, Boston Children's Hospital, Boston, MA

# CERTIFICATION AND LICENSURE

# **Certification**

10/2011-Present American Board of Pediatrics, General

# **Licensure**

- 08/2015-Present Michigan, Medical License
- 09/2015-Present Michigan, DEA Registration

09/2015-Present Michigan, Controlled Substance

# WORK EXPERIENCE

#### Academic Appointment

10/2015-9/2022	Clinical Assistant Professor in Pediatrics - Endocrinology, University of Michigan - Ann Arbor, Ann Arbor
09/2022-Present	Clinical Associate Professor in Pediatrics - Endocrinology, University of Michigan - Ann Arbor, Ann Arbor

#### Administrative Appointment

07/2019-Present	Fellowship Director - Pediatric Endocrinology, Michigan Medicine, Department of Pediatrics, Ann Arbor
07/2020-Present	Medical Director of the University of Michigan Comprehensive Gender Services Program, Michigan Medicine, Ann Arbor
	Oversee the provision of care to transgender and gender non- conforming patients at Michigan Medicine.
07/2020-Present	Education Lead - Pediatric Endocrinology, University of Michigan - Department of Pediatrics, Ann Arbor
<b>Clinical</b> Appoint	ments

04/2022-05/2023 Medical Director in UMMG Faculty Benefits Appt., University of Michigan - Ann Arbor, Ann Arbor

# **Private Practice**

08/2013-09/2015 Staff Physician, Harvard Vanguard Medical Associates, Braintree

# **RESEARCH INTERESTS**

- Gender dysphoria
- Prader Willi Syndrome

# CLINICAL INTERESTS

- Gender dysphoria
- Disorders of Sex Development
- Prader Willi Syndrome

# GRANTS

# Past Grants

A Phase 2b/3 study to evaluate the safety, tolerability, and effects of Livoletide (AZP-531), an unacylated ghrelin analog, on food-related behaviors in patients with Prader-Willi syndrome

Millendo Therapeutics 04/2019 - 04/2021

# HONORS AND AWARDS

## <u>National</u>

2014 Annual Pediatric Endocrine Society Essay Competition: Ethical Dilemmas in Pediatric Endocrinology: competition winner - The Role of Assent in the Treatment of Transgender Adolescents

# <u>Institutional</u>

2012 - 2015 Harvard Pediatric Health Services Research Fellowship; funded my final two years of pediatric endocrine fellowship and provided tuition support for my public health degree

2016	The University of Michigan Distinguished Diversity Leaders Award, awarded by The Office of Diversity, Equity and Inclusion to the Child and Adolescent Gender Services Team under my leadership
2019	Lecturer of the Month, Department of Pediatrics, Michigan Medicine

## **TEACHING MENTORSHIP**

## **Resident**

07/2020-Present	Rebecca Warwick, Michigan Medicine (co-author on
	publication #22)

## **Clinical Fellow**

07/2017-06/2020	Adrian Araya, Michigan Medicine (co-author on publication #22, book chapter #4)
12/2020-Present	Jessica Jary, Michigan Medicine - Division of Adolescent Medicine

## **Medical Student**

09/2017-06/2020	Michael Ho, Michigan Medicine
07/2019-Present	Hadrian Kinnear, University of Michigan Medical School (co- author on book chapter #3, abstract #3)
07/2019-Present	Jourdin Batchelor, University of Michigan

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# TEACHING ACTIVITY

## <u>Regional</u>

08/2018-Present Pediatric Boards Review Course sponsored by U-M: "Thyroid Disorders and Diabetes". Ann Arbor, MI

# <u>Institutional</u>

12/2015-12/2015	Pediatric Grand Rounds: "Transgender Medicine - A Field in Transition". Michigan Medicine, Ann Arbor, MI
02/2016-02/2016	Medical Student Education: Panelist for M1 Class Session on LGBT Health, Doctoring Curriculum. Michigan Medicine, Ann Arbor, MI
02/2016-02/2016	Psychiatry Grand Rounds: "Transgender Medicine - A Field in Transition". Michigan Medicine, Ann Arbor, MI
03/2016-03/2017	Pharmacy School Education: "LGBT Health". University of Michigan School of Pharmacy, Ann Arbor, MI
04/2016-Present	Course Director: Medical Student (M4) Elective in Transgender Medicine. Michigan Medicine, Ann Arbor, MI
04/2016-04/2016	Rheumatology Grand Rounds: "Gender Identity". Michigan Medicine, Ann Arbor, MI
05/2016-05/2016	Lecture to Pediatric Rheumatology Division: "Gender Dysphoria". Michigan Medicine, Ann Arbor, MI
07/2016-07/2016	Internal Medicine Resident Education: "Gender Identity". Michigan Medicine, Ann Arbor, MI
09/2016-09/2016	Presentation to ACU Leadership: "Gender Identity Cultural Competencies". Michigan Medicine, Ann Arbor, MI
10/2016-10/2016	Presentation to Department of Dermatology: "The iPledge Program and Transgender Patients". Michigan Medicine, Ann Arbor, MI
02/2017-02/2017	Swartz Rounds Presenter. Michigan Medicine, Ann Arbor, MI
02/2017-02/2017	Lecture to Division of General Medicine: "Transgender Health". Michigan Medicine, Ann Arbor, MI

02/2017-02/2017	Presentation at Collaborative Office Rounds: "Transgender Health". Michigan Medicine, Ann Arbor, MI
10/2017-10/2017	Family Medicine Annual Conference: "Transgender Medicine". Michigan Medicine, Ann Arbor, MI
12/2017-12/2017	Presenter at Nursing Unit 12-West Annual Educational Retreat: "Gender Identity at the Children's Hospital". Michigan Medicine, Ann Arbor, MI
02/2018-Present	Pediatrics Residency Lecturer: "Puberty". Michigan Medicine, Ann Arbor, MI
02/2019-Present	Medical Student (M1) Lecturer: "Pediatric Growth and Development". Michigan Medicine, Ann Arbor, MI
02/2019-Present	Doctors of Tomorrow Preceptor: offering shadowing opportunities to students from Cass Technical High School in Detroit. Michigan Medicine, Ann Arbor, MI
03/2019-03/2019	Lecture to Division of Orthopedic Surgery: "Transgender Health". Michigan Medicine, Ann Arbor, MI

# MEMBERSHIPS IN PROFESSIONAL SOCIETIES

2012 - Present Pediatric Endocrine Society

# **COMMITTEE SERVICE**

# <u>National</u>

2014 - 2016	Pediatric Endocrine Society - Ethics Committee, Other, Member
2017 - present	Pediatric Endocrine Society - Special Interest Group on Gender Identity, Other, Member
2018 - present	Pediatric Endocrine Society - Program Directors Education Committee, Other, Member

# <u>Regional</u>

2013 - 2015	Investigational Review Board - The Fenway Institute, Boston,
	MA, Other, Voting Member

# <u>Institutional</u>

2017 - 2019	Department of Pediatrics at Michigan Medicine; Diversity, Equity, and Inclusion Committee, Other, Fellowship Lead
2017 - 2019	University of Michigan Transgender Research Group, Other, Director

# VOLUNTEER SERVICE

2014 Camp Physician, Massachusetts, Served at a camp for youth with Type 1 Diabetes

# SCHOLARLY ACTIVITIES

# PRESENTATIONS

# **Extramural Invited Presentation Speaker**

1. Grand Rounds, Shumer D, Loyola University School of Medicine, 07/2022, Chicago, Illinois

# <u>Other</u>

1. Gender Identity, Groton School, 04/2015, Groton, MA

2. Television Appearance: Gender Identity in Youth, Channel 7 WXYZ Detroit, 04/2016, Southfield, MI

3. It Gets Better: Promoting Safe and Supportive Healthcare Environments for Sexual Minority and Gender Non-Conforming Youth, Adolescent Health Initiative: Conference on Adolescent Health, 05/2016, Ypsilanti, MI

4. Gender Identity, Humanists of Southeast Michigan, 09/2016, Farmington Hills, MI

5. Gender Identity, Pine Rest Christian Mental Health Services, 10/2016, Grand Rapids, MI

6. Pediatric Grand Rounds - Hormonal Management of Transgender Youth, Beaumont Children's Hospital, 11/2016, Royal Oak, MI

7. Transgender Youth: A Field in Transition, Temple Beth Emeth, 11/2016, Ann Arbor, MI

8. Transgender Youth: A Field in Transition, Washtenaw County Medical Society, 11/2016, Ann Arbor, MI

9. Pediatric Grand Rounds: Transgender Youth - A Field in Transition, St. John Hospital, 02/2017, Detroit, MI

10. Transgender Medicine, Veterans Administration - Ann Arbor Healthcare System, 05/2017, Ann Arbor, MI

11. Gender Identity, Hegira Programs, 05/2017, Detroit, MI

12. Care of the Transgender Adolescent, Partners in Pediatric Care, 06/2017, Traverse City, MI

13. Conference planner, host, and presenter: Transgender and Gender Non-Conforming Youth: Best Practices for Mental Health Clinicians, Educators, & School Staff; 200+ attendees from fields of mental health and education from across Michigan, Michigan Medicine, 10/2017, Ypsilanti, MI

14. Endocrinology Grand Rounds: Transgender Medicine, Wayne State University, 11/2017, Detroit, MI

15. Care of the Transgender Adolescent, St. John Hospital Conference: Transgender Patients: Providing Compassionate, Affirmative and Evidence Based Care, 11/2017, Grosse Pointe Farms, MI

16. Hormonal Care in Transgender Adolescents, Michigan State University School of Osteopathic Medicine, 11/2017, East Lansing, MI

17. Working with Transgender and Gender Non-Conforming Youth, Michigan Association of Osteopathic Family Physicians, 01/2018, Bellaire, MI

18. Community Conversations, Lake Orion, 01/2018, Lake Orion, MI

19. "I Am Jazz" Reading and Discussion, St. James Episcopal Church, 03/2019, Dexter, MI

20. Gender Identity, Michigan Organization on Adolescent Sexual Health, 10/2019, Brighton, MI; Port Huron, MI

21. Ask The Expert, Stand With Trans, 05/2020, Farmington Hills, MI (Virtual due to COVID)

22. Transgender Medicine, Michigan Association of Clinical Endocrinologists Annual Symposium, 10/2020, Grand Rapids, MI (Virtual due to COVID)

23. Transgender Youth in Primary Care, Michigan Child Care Collaborative (MC3), 10/2020, Ann Arbor, MI (Virtual due to COVID)

24. Lets Talk About Hormones, Stand With Trans, 10/2020, Farmington Hills, MI (Virtual due to COVID)

25. Gender Identity, Universalist Unitarian Church of East Liberty, 04/2021, Virtual due to COVID

26. Unconscious Bias, Ascension St. John Hospital, 05/2021, Virtual due to COVID

# PUBLICATIONS/SCHOLARSHIP

## **<u>Peer-Reviewed</u>** Articles

1. Vengalil N, Shumer D, Wang F: Developing an LGBT curriculum and evaluating its impact on dermatology residents, *Int J Dermatol*.61: 99-102, 01/2022. PM34416015

## **Chapters**

1. Shumer: Coma. In Schwartz MW6, Lippincott Williams & Wilkins, Philadelphia, PA, (2012)

2. Shumer, Spack: Medical Treatment of the Adolescent Transgender Patient. In Đorđević M; Monstrey SJ; Salgado CJ Eds. CRC Press/Taylor & Francis, (2016)

3. Kinnear HA, Shumer DE: Duration of Pubertal Suppression and Initiation of Gender-Affirming Hormone Treatment in Youth. In FinlaysonElsevier, (2018)

4. Araya, Shumer DE: Endocrinology of Transgender Care – Children and Adolescents. In Poretsky; Hembree Ed. Springer, (2019)

# **Non-Peer Reviewed Articles**

1. Shumer D: The Effect of Race and Gender Labels in the Induction of Traits, *Northwestern Journal of Race and Gender Criticism*.NA01/2014

2. Shumer D: A Tribute to Medical Stereotypes, *The Pharos, Journal of the Alpha Omega Alpha Medical Society*.Summer07/2017

3. Mohnach L, Mazzola S, Shumer D, Berman DR: Prenatal diagnosis of 17hydroxylase/17,20-lyase deficiency (170HD) in a case of 46,XY sex discordance and low maternal serum estriol, *Case Reports in Perinatal Medicine*.8(1)01/2018

4. Mohnach L, Mazzola S, Shumer D, Berman DR: Prenatal Diagnosis of 17hydroxylase/17,20-lyase deficiency (170HD) in a case of 46,XY sex discordance and low maternal serum estriol, *Case Reports in Perinatal Medicine*.8(1)12/2018

5. Kim C, Harrall KK, Glueck DH, Shumer DE, Dabelea D: Childhood adiposity and adolescent sex steroids in the EPOCH (Exploring Perinatal Outcomes among Children) study, *Clin Endocrinol (Oxf)*.91(4): 525-533, 01/2019. PM31278867

6. Araya A, Shumer D, Warwick R, Selkie E: 37. "I've Been Happily Dating For 5 Years" - Romantic and Sexual Health, Experience and Expectations in Transgender Youth, *Journal of Adolescent Health*.66(2): s20, 02/2020

7. Araya A, Shumer D, Warwick R, Selkie E: 73. "I think sex is different for everybody" - Sexual Experiences and Expectations in Transgender Youth, *Journal of Pediatric and Adolescent Gynecology*.33(2): 209-210, 04/2020

8. Araya AC, Warwick R, Shumer D, Selkie E, Rath T, Ibrahim M, Srinivasan A: Romantic Health in Transgender Adolescents, *Pediatrics*.Pediatrics01/2021

9. Martin S, Sandberg ES, Shumer DE: Criminalization of Gender-Affirming Care - Interfering with Essential Treatment for Transgender Children and Adolescents, *New England Journal of Medicine*.385(7): 579-581, 08/2021. PM34010528

## **Editorial Comment**

1. Shumer DE, Harris LH, Opipari VP: The Effect of Lesbian, Gay, Bisexual, and Transgender-Related Legislation on Children, 01/2016. PM27575000

2. Shumer DE: Health Disparities Facing Transgender and Gender Nonconforming Youth Are Not Inevitable, 01/2018. PM29437859

3. Martin S, Sandberg ES, Shumer DE: Criminalization of Gender-Affirming Care - Interfering with Essential Treatment for Transgender Children and Adolescents, 01/2021

#### <u>Erratum</u>

1. Tishelman AC, Kaufman R, Edwards-Leeper L, Mandel FH, Shumer DE, Spack NP: Correction to Serving Transgender Youth: Challenges, Dilemmas, and Clinical Examples, [Professional Psychology: Research and Practice, 46(1), (2015) 37-45], *Professional Psychology: Research and Practice*.46(4): 249, 08/2015

### **Journal Articles**

1. Shumer DE, Thaker V, Taylor GA, Wassner AJ: Severe hypercalcaemia due to subcutaneous fat necrosis: Presentation, management and complications, *Archives of Disease in Childhood: Fetal and Neonatal Edition*.99(5)01/2014. PM24907163

2. Tishelman AC, Kaufman R, Edwards-Leeper L, Mandel FH, Shumer DE, Spack NP: Serving transgender youth: Challenges, dilemmas, and clinical examples, *Professional Psychology: Research and Practice*.46(1): 37-45, 02/2015. PM26807001

3. Reisner SL, Vetters R, Leclerc M, Zaslow S, Wolfrum S, Shumer DE, Mimiaga MJ: Mental health of transgender youth in care at an adolescent Urban community health center: A matched retrospective cohort study, *Journal of Adolescent Health*.56(3): 274-279, 03/2015. PM25577670

4. Shumer DE, Tishelman AC: The Role of Assent in the Treatment of Transgender Adolescents, *International Journal of Transgenderism*.16(2): 97-102, 04/2015. PM27175107

5. Shumer DE, Roberts AL, Reisner SL, Lyall K, Austin SB: Brief Report: Autistic Traits in Mothers and Children Associated with Child's Gender Nonconformity, *Journal of Autism and Developmental Disorders*.45(5): 1489-1494, 05/2015. PM25358249

6. Tishelman AC, Kaufman R, Edwards-Leeper L, Mandel FH, Shumer DE, Spack NP: Reply to comment on "serving transgender youth: Challenges, dilemmas, and clinical examples" by Tishelman et al. (2015), *Professional Psychology: Research and Practice*.46(4): 307, 08/2015. PM26858509

7. Shumer DE, Reisner SL, Edwards-Leeper L, Tishelman A: Evaluation of Asperger Syndrome in Youth Presenting to a Gender Dysphoria Clinic, *LGBT Health*.3(5): 387-390, 10/2016. PM26651183

8. Tishelman AC, Shumer DE, Nahata L: Disorders of sex development: Pediatric psychology and the genital exam, *Journal of Pediatric Psychology*.42(5): 530-543, 01/2017. PM27098964

9. Edwards-Leeper L, Shumer DE, Feldman HA, Lash BR, Tishelman AC: Psychological profile of the first sample of transgender youth presenting for medical intervention in a U.S. pediatric gender center, *Psychology of Sexual Orientation and Gender Diversity*.4(3): 374-382, 01/2017

10. Shumer DE, Abrha A, Feldman HA, Carswell J: Overrepresentation of adopted adolescents at a hospital-based gender dysphoria clinic, *Transgender Health*.2(1): 76-79, 07/2017. PM28861549

11. Strang JF, Meagher H, Kenworthy L, de Vries AL C, Menvielle E, Leibowitz S, Janssen A, Cohen-Kettenis P, Shumer DE, Edwards-Leeper L, Pleak RR, Spack N, Karasic DH, Schreier H, Balleur A, Tishelman A, Ehrensaft D, Rodnan L, Kuschner ES, Mandel F, Caretto A, Lewis HC, Anthony LG: Initial Clinical Guidelines for Co-Occurring Autism Spectrum Disorder and Gender Dysphoria or Incongruence in Adolescents, *Journal of Clinical Child and Adolescent Psychology*.47(1): 105-115, 01/2018. PM27775428

12. Selkie E, Adkins V, Masters E, Bajpai A, Shumer DE: Transgender Adolescents' Uses of Social Media for Social Support, *Journal of Adolescent Health*.66(3): 275-280, 03/2020. PM31690534

13. Warwick RM, Shumer DE: Gender-affirming multidisciplinary care for transgender and non-binary children and adolescents, *Children's Health Care*.01/2021

14. Araya AC, Warwick R, Shumer DE, Selkie E: Romantic relationships in transgender adolescents: A qualitative study, *Pediatrics*.147(2)02/2021. PM33468600

15. Warwick RM, Araya AC, Shumer DE, Selkie EM: Transgender Youths' Sexual Health and Education: A Qualitative Analysis, *Journal of Pediatric and Adolescent Gynecology*.35(2): 138-146, 04/2022. PM34619356

# **Letters**

1. Strang JF, Janssen A, Tishelman A, Leibowitz SF, Kenworthy L, McGuire JK, Edwards-Leeper L, Mazefsky CA, Rofey D, Bascom J, Caplan R, Gomez-Lobo V, Berg D, Zaks Z, Wallace GL, Wimms H, Pine-Twaddell E, Shumer DE, Register-Brown K, Sadikova E, Anthony LG: Revisiting the Link: Evidence of the Rates of Autism in Studies of Gender Diverse Individuals, *Journal of the American Academy of Child and Adolescent Psychiatry*.57(11): 885-887, 11/2018. PM30392631

# Letters to editor

1. Shumer DE: Doctor as environmental steward, 01/2009. PM19364173

# Notes

1. Shumer DE, Mehringer J, Braverman L, Dauber A: Acquired hypothyroidism in an infant related to excessive maternal iodine intake: Food for thought, *Endocrine Practice*.19(4): 729-731, 07/2013. PM23512394

# **Podcasts**

1. Gaggino L, Shumer WG D: Pediatric Meltdown: Caring for Transgender Youth with Compassion: What Pediatricians Must Know, 01/2020

# **Reviews**

1. Shumer DE, Spack NP: Current management of gender identity disorder in childhood and adolescence: Guidelines, barriers and areas of controversy, *Current Opinion in Endocrinology, Diabetes and Obesity*.20(1): 69-73, 02/2013. PM23221495

2. Guss C, Shumer DE, Katz-Wise SL: Transgender and gender nonconforming adolescent care: Psychosocial and medical considerations, *Current Opinion in Pediatrics*.27(4): 421-426, 08/2015. PM26087416

3. Shumer DE, Nokoff NJ, Spack NP: Advances in the Care of Transgender Children and Adolescents, *Advances in Pediatrics*.63(1): 79-102, 08/2016. PM27426896

# **Short Surveys**

1. Shumer DE, Spack NP: Transgender medicine-long-term outcomes from 'the Dutch model', *Nature Reviews Urology*.12(1): 12-13, 01/2015. PM25403246

# Abstracts/Posters

1. Shumer D, Kinnear H, McLain K, Morgan H: Development of a Transgender Medicine Elective for 4th Year Medical Students, National Transgender Health Summitt, Oakland, CA, 2017

2. Shumer D: Overrepresentation of Adopted Children in a Hospital Based Gender Program, World Professional Association of Transgender Health Biennial International Symposium, Amsterdam, The Netherlands, 2016

3. Shumer D: Mental Health Presentation of Transgender Youth Seeking Medical Intervention, World Professional Association of Transgender Health Biennial International Symposium, Amsterdam, The Netherlands, 2016

4. Adkins V, Masters E, Shumer D, Selkie E: Exploring Transgender Adolescents Use of Social Media for Support and Health Information Seeking (Poster Presentation), Pediatric Research Symposium, Ann Arbor, MI, 2017

# <u>Exhibit B</u> Bibliography

## **BIBLIOGRAPHY**

Achille, C., Taggart, T., Eaton, N. R., Osipoff, J., Tafuri, K., Lane, A., & Wilson, T. A. (2020). Longitudinal impact of gender-affirming endocrine intervention on the mental health and well- being of transgender youths: preliminary results. International journal of pediatric endocrinology, 2020, 8.

Allen, N. G., Krishna, K. B., & Lee, P. A. (2021). Use of gonadotropin-releasing hormone analogs in children. Current opinion in pediatrics, 33(4), 442–48.

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

American Medical Association and GLMA (2019). *Health Insurance Coverage for Gender- Affirming Care of Transgender Patients*. <u>https://www.ama-assn.org/system/files/2019-03/transgender-coverage-issue-brief.pdf</u>.

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American Psychiatric Association. (2022). *Diagnostic and statistical manual of mental disorders (5th ed., text rev.)*. Arlington, VA: American Psychiatric Publishing.

Ashley, F. (2022). *The clinical irrelevance of "desistance" research for transgender and gender creative youth*. Psychology of Sexual Orientation and Gender Diversity, 9(4), 387–97.

Bruce, Lauren, et al. (2023). Long-Term Regret and Satisfaction With Decision Following Gender-Affirming Mastectomy. JAMA Surgery. Available at: https://jamanetwork.com/journals/jamasurgery/articleabstract/2808129?utm\_campaign=articlePDF&utm\_medium=articlePDFlink& utm\_source=articlePDF&utm\_content=jamasurg.2023.3352 Campbell, Travis and Rodgers, Yana van der Meulen, *Conversion Therapy, Suicidality, and Running Away: An Analysis of Transgender Youth in the U.S.* (Nov. 15, 2022). *Available at* SSRN: <u>http://dx.doi.org/10.2139/ssrn.4180724</u>.

Carmichael, P., Butler, G., Masic, U., Cole, T. J., De Stavola, B. L., Davidson, S., Skageberg, E. M., Khadr, S., & Viner, R. M. (2021). Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. PLOS ONE, 16(2), e0243894.

Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. (2023). *Psychosocial Functioning in Transgender Youth after 2 Years of Hormones*. New England Journal of Med., 2023 Jan 19;388(3):240–50.

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*transsexual, transgender, and gender- nonconforming people, version 7.* International Journal of Transgenderism, 13(4), 165–232.

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Colizzi, M., Costa, R., Pace, V., & Todarello, O. (2013). *Hormonal treatment reduces psychobiological distress in gender identity disorder, independently of the attachment style*. The Journal of Sexual Medicine, *10*(12), 3049–58.

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de Vries, A.L., Steensma, T.D., Doreleijers, T.A., & Cohen-Kettenis, P.T. (2011). *Puberty suppression in adolescents with gender identity disorder: a prospective follow-up study. The Journal of Sexual Medicine*, 8(8), 2276–83.

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Dessens, A. B., Slijper, F. M., & Drop, S. L. (2005). Gender dysphoria and gender change in chromosomal females with congenital adrenal hyperplasia. Archives of Ssexual Behavior, 34(4), 389–97.

Deutsch, M.B. (ed.). (2016). Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People (2d ed.). San Francisco, CA: UCSF Center of Excellence for Transgender Health. <u>https://transcare.ucsf.edu/guidelines</u>.

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