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

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

EXPERT REPORT OF KRISTOPHER KALIEBE, M.D.

Introduction

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

1. I have been asked by the defendants to discuss my membership in professional associations, and the relevant guidelines and policies concerning gender dysphoria in those associations. I have been asked to provide a review of the evidence base for treatments of gender dysphoria. I also have been asked to opine on the influence of activism and suppression of open inquiry which has distorted academic dialogue and made published research and expert recommendations untrustworthy with regard to gender dysphoria.

2. This report is entirely my own work product, and no one was consulted for this this report.

3. If called to testify in this matter, I will testify truthfully based on my personal experience and knowledge.

4. I am being compensated at an hourly rate of \$400 per hour for my time preparing this declaration. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

Here I provide a summary of my major points:

a. While historical reports of gender dysphoria exist, it has been rare until the last two decades.

b. There is no consensus in the field regarding the treatment of gender dysphoria, nor is there an evidence-base sufficient to lead to any confident recommendations.

c. Multiple reviews of the evidence base regarding treatment of gender dysphoria indicate that the evidence for affirmative treatment is low-quality.

d. Small numbers of advocate physicians within medical organizations have been able to leverage moralized claims and low quality evidence in order to promote affirmative care for gender dysphoria.

e. Significant evidence points to a spread of ideology combined with technologically induced contagion effects leading the recent increase in gender dysphoria.

f. As American medical professional organizations have already endorsed the concept of affirmative care as evidence-based and ethical, they are no longer neutral with regards to the science and have instead entered into advocacy roles.

g. Much of the slogans and assumptions associated with affirmative care for gender dysphoria are conjecture, opinion or misinformation presenting as established fact.

h. Due to the highly politicized and ideological nature of the issue of gender dysphoria, there is limited rigorous scholarly dialogue within American professional medical organizations and medical journals.

Background

6. I am an associate professor at the University of South Florida in Tampa Florida. I am Board Certified in Psychiatry, Child and Adolescent Psychiatry and Forensic Psychiatry. My clinical work has been primarily in University based clinics, Federally Qualified Health Centers and juvenile corrections.

7. I was awarded my medical degree in 1999, and subsequently completed general psychiatry, child and adolescent psychiatry and forensic psychiatry training. This training includes education in human biology, human sexuality, development, brain functioning, normal development and psychopathology. Gender dysphoria and gender dysphoria treatment were part of my professional training.

8. From 2005 to 2016 I was Assistant Professor at Louisiana State University Health Science Center – New Orleans. I was the program director of the LSU Child Psychiatry Fellowship for 2 years. Since 2016 I have been Associate Professor at the University of South Florida where my clinical roles which mainly include working with juvenile corrections, supporting primary care physicians through the Florida Medicaid Psychiatric Medication hotline and in a university child and adolescent psychiatry clinic. I cover at Tampa General Hospital and recently added an adult psychiatry resident clinic to my schedule. I also practice forensic psychiatry including child and adult cases, both within criminal and civil court.

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9. As a supervising physician at the University of South Florida's Silver Child Development Center my role is to function as a clinical supervisor and instructor. Child psychiatry residents and general psychiatry residents serve as the primary patient evaluators and clinicians. I evaluate new patients directly, and after see patients directly as needed. I oversee the resident's work products and function as the physician of record. Within this clinic I evaluate and treat patients with gender dysphoria.

10. In addition to these direct clinical experiences, part of my scope of duties within the Silver Child Development Center is training residents regarding the treatment of patients, including patients with gender dysphoria.

11. Within the juvenile justice system I also evaluate and treat patients with gender dysphoria. I further have been consulted to provide a second opinion and coordinate care regarding a patient with gender dysphoria in the Louisiana juvenile correctional system.

12. In addition to direct clinical care, I am routinely consulted by colleagues. Within my work at the Florida Medicaid Psychiatric Hotline I have collaborated in the care of patients with gender dysphoria. My colleague consultation includes providing my opinion regarding would a youth be competent to consent as requested by an endocrinologist regarding a youth considering puberty blockers on

a path toward sex hormone treatment and potential surgeries. I have been consulted regarding psychotherapeutic approaches to young adult patients who detransitioned.

13. I have extensive teaching experience including medical students, general psychiatry residents, child and adolescent psychiatry fellows and forensic psychiatry fellows. I have years of extensive positive feedback from medical students and psychiatrist residents.

14. My approach to the practice of medicine includes utilizing and appreciating the amazing progress modern medicine has made. I practice and support conventional medicine, I have strongly advocated for the expansion of Federally Qualified Health Centers, along with improved collaboration of mental health with primary care (Kaliebe 2016, Kaliebe 2017).

15. My support of, and attempts to improve conventional medicine, is balanced by a healthy degree of caution. The history of medicine is filled with examples of the harms which can come with unproven, unnecessary, aggressive or counterproductive interventions. As such, I've presented twice at the Preventing Overdiagnosis conference.

16. I am involved with Integrative Medicine, focused mainly on the role of mind-body medicine, mindfulness, nutrition and exercise, along with how modern medicine has adopted approaches which underemphasize and at times neglect the basics of health. Another academic interest of mine is the tradeoffs and stress of

moving to primarily electronics based communications, especially on young people. (Kaliebe 2002, Gerwin 2018) I have a longstanding interest in how technology and the media intersect with society and culture, including the impacts of social media, recent increases in tribalism and the spread of misinformation.

17. With Paul Weigle, I co-edited the Child and Adolescent Psychiatric Clinics of North America *Youth Internet Habits and Mental Health* edition in 2018 with 16 chapters by invited experts on digital and mental health related issues. (Kaliebe 2018)

18. I am a member of the American Academy of Psychiatry and the American Psychiatric Association. I have been most active within the American Academy of Child and Adolescent Psychiatry (AACAP). I was awarded status as a Distinguished Fellow at AACAP in 2016. I first presented regarding the media at the 2004 AACAP annual conference, and have now presented at the annual conference 25 times. I served as co-chair of the Media Committee from 2013-2021. I served as the Liaison from AACAP to the American Academy of Pediatrics from 2016-2022. I was an author on their practice guidelines for telepsychiatry. I have also served AACAP in the state affiliates, for the Louisiana Council for Child Psychiatry I was secretary / treasurer for 4 years and served as president for 2 years.

19. I have a longstanding interest in psychotherapy. I have additional training in Cognitive Behavioral Therapy and trauma-focused therapies. I have been

providing psychotherapy and teaching psychotherapy to psychiatry trainees throughout my career. I currently routinely supervise psychiatry residents regarding psychotherapy with the USF residency program. I created and taught a Cognitive Behavioral Therapy practicum for LSU residents from 2007 to 2016. I was a member of the Association for Behavioral and Cognitive Therapies from 2004 to 2016.

- 20. I have been on the Best Doctors list annually since 2007.
- 21. I also practice and teach forensic psychiatry and have testified in deposition or trial in the following cases over the past four years:
 - a. <u>Civil Testimony</u>, retained by the defense:
 - i. In the Interest of RW, LL, AP Minor Children January 28, 2020 Circuit Court of the 13th judicial circuit, Juvenile Division, Judge Lisa Campbell, Tampa FL
 - b. <u>Civil Testimony, court appointed</u>:
 - i. February 28, 2020, Jeffrey Spivey, petitioner/father and Teresa Spivey N/K/A Teresa Cartwright, respondent/mother Case No.: 2016 DR0471's, Circuit Court of the 12th judicial circuit in and for Manatee County Florida. Judge Kevin Bruning
 - c. <u>Civil Testimony, court appointed</u>:
 - i. Re: The Marriage of Robyn Cohen McCarthy and John McCarthy November 1, 2019 11th Judicial Circuit, Family Division, Dade County, Judge Jason Dimitris, Miami FL
 - d. <u>Criminal Testimony, retained by the defense</u>:

- i. The State of Florida v. Bill Paul Marquardt December 19, 2019
 5th Judicial Circuit, Sumner County, Florida, Judge William Hallman III, Bushnell Florida
- ii. The State of Florida v. Bill Paul Marquardt August 24, 2022 5th Judicial Circuit, Sumner County, Florida, Judge Mary P. Hatcher Bushnell Florida
- e. <u>Civil Depositions, retained by the defense</u>:
 - i. Z.M.L., a minor, through her parents and guardians, -vs- D.R. Horton, Inc., a foreign corporation authorized to do business in Florida, United States District Court, Middle Division of Florida, Tampa, May 6, 2021
 - ii. THE ESTATE of JEAN LINDOR, deceased minor, by and through the Personal Representative of the Estate, JAMES LACROIX and NOUSE ANDREE LACROIX, individually, Plaintiffs, v. BOS TRANSPORT, LLC, a Florida Limited Liability Company, and ORESTES ZAMORA FLEITES, individually, December 5th, 2022
- f. <u>Civil Depositions, retained by the plaintiff</u>:
 - Carlton Collins, individually, and on behalf of his minor son, Connor Samuel Collins v. David R. Wallace, Sr., M.D. Louisiana's 14th judicial district, Civil Suit: 2019 – 4128 – D, March 4th, 2022
- g. Criminal Deposition, retained by the defense:
 - i. State of Florida v. Justin Mitchell Pennell, 2020CF000159FAXWS, 6th Judicial Circuit of the State of Florida in and for Pasco County, March 11, 2022Since 2016
- 22. A list of my publications is attached to this report as Exhibit "A".

The abrupt rise in transgender and non-binary identification

23. The discussion regarding transgender care is in the context of an unexplained and remarkable rise in patients reporting gender dysphoria. During my medical school experience and 3 residencies, I never encountered a patient reporting symptoms of gender dysphoria. For eleven years, from 2005 to 2016, I had a busy psychiatry clinic with about 80% minors and 20% adult patients without a single patient expressing gender dysphoria.

24. During those eleven years, none of the hundreds of medical students or residents I supervised presented cases to me describing patients with gender dysphoria. None of my social work or psychologist colleagues ever asked for consultation or advice regarding how to clinically approach patients with gender dysphoria. Within the last year, on a single day, I have treated three adolescent patients diagnosed with gender dysphoria.

25. My experience is consistent with statistics indicating an abrupt rise in gender dysphoria and presentations to medical clinics for related services. When a new patient population emerges, it creates challenges for physicians to respond. In medicine, typically when such an abrupt change in patient populations occur, the subsequent scholarly literature would typically discuss and debate underlying causes of this phenomenon.

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26. Never before has there been large cohorts of individuals seeking medical services to alter their secondary sex characteristics. There had been decades of extremely rare treatment which was at the time acknowledged as compassionate but experimental care. Yet the current patients expressing gender dysphoria represent primarily a new and distinct patient population, not a population which has historically existed.

27. As a psychiatrist, I have encountered many patients who are uncomfortable with their bodies. This discomfort and dissatisfaction is often comingled with anxiety and depression, along with various diagnoses which involve bodily discomfort including eating disorders or Body Dysmorphic Disorder.

28. I have observed bodily discomfort more often in females, and especially as girls enter puberty, which is consistent with the epidemiological literature. Puberty introduces significant challenges and risks to females as they receive more attention from males, including adult males, along with increased competition from peers. Puberty now comes much younger than for our ancestors, creating a greater mismatch between brain and body maturity.

29. While the exact number is unknown it can be said that the incidence of gender dysphoria in youth was previously rare. The American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders published in 2013 rated in adults at 2-14 per 100000 (American Psychiatric Association p454).

Referrals at the Tavistock clinic in England increased over 50 fold in just a decade from 2009 to 2019. (Tavistock & Portman, NAHS Foundation Trust, 2020).

30. Similar increases have been reported across much of the economically advanced countries in the world, many showing over 1000% rise in gender dysphoria over the last decades (Marianowicz-Szczygiel 2022). This phenomenon requires some explanation and any complex phenomenon likely has a multifactorial line of causation. Yet multiple lines of evidence point to direct social influences and online and social media contagion as a major contributors to this increase in gender dysphoria. Biological factors causing the increase of gender dysphoria, such as endocrine disrupting chemicals, are plausible but have not been explored in the scholarly literature.

31. The involvement of social spread is supported by Lisa Littman's work (Littman 2018). It is supported by the timing of the massive increase in gender dysphoria coinciding with the rise in social media and associated "influencers". It is supported by the largest rise in gender dysphoria occurring in vulnerable adolescent females. This is precisely the same population most susceptible to online contagions such as "functional" rapid onset tics disorders, suicidal behavior, non-suicidal self-harm and increase self-reported Dissociative Identity Disorder.

32. The influence of culture, medical theories and ideology on symptom production is long-standing and well known. Shorter detailed numerous examples

of how culture intersects with psychiatric illness from the Victorian to modern era (Shorter 1993). For a discussion of how psychopathology can spread among psychiatric disorders, see Horesh et al's recent article (Horesh 2022).

33. Humans evolved as a sexually dimorphic, ultra-social and cultural species. Culture has co-mingled with our evolution, because unlike other animals, learning from others enables our very survival. Humans acquire a considerable portion of our behaviors and viewpoints "by tapping into a large body of non-genetic information that has been filtered and accumulated over generations. This process, termed cumulative cultural evolution, creates a storehouse in the form of strategies, attentional biases, motivations, tastes, and cognitive heuristics that are necessary for us to accomplish even the basics of survival". (p 210 Henrich 2021).

34. Thus humans can't explain the rationale for much of our routines, habits and customs because they have been shaped over time, some for thousands of year, some more recently. This raises the possibility there is time tested wisdom in many of our cultural adaptations. Cumulative culture constantly changes, but the recent rate of change has been exponentially faster due to the explosion of technologies. The modern world is thus experiencing perhaps the largest generation gap in history. Today's children and adolescents are exposed to so much more than out grandparents. 35. In ancient evolutionary environments, copying others aided survival via the transmission of acquired knowledge about what areas are safe, how to make shelters or weapons, what berries or mushrooms are safe to eat, and what type of social behavior is acceptable within a group. Humans' brains are particularly adapted with exceptional abilities to notice and copy the behavior of others.

36. Transmission of culture occurs in part via humans naturally mimicking what we observe in others. Yet these same instincts that develop helpful behavioral norms also enable social contagions that co-mingle with mental and behavioral disorders. Long-standing scholarly consensus exists confirming that direct social contagion not only affects health such as cardiac disease (Christakis. 2013), but interacts with technology enabled spread of mental health problems. (Haltigan 2023)

37. This can be seen in relation to suicide contagion (Yıldız,2019), nonsuicidal self-injury (Jarvi, 2013), contagion related to eating disorders such as anorexia (Allison 2014). Since the Covid 19 pandemic, there has been an explosive increase of young people displaying features of Dissociative Identity Disorder and movements similar to those seen in Tic Disorders such as Tourette's (Pringsheim 2021). A google scholar review shows a dozen articles linking rapid onset tic disorders to social media. Similar to other examples of social contagion, these sudden onset tic presentations tend to be comorbid with pre-existing mental illnesses and adolescent girls show themselves to be the most susceptible. 38. The phenomenon labeled Mass Social Media Induced Illness (Giedinghagen, 2022) shows us that at scale, users of social media can develop technology facilitated psychosomatic illness. Psychiatrists have seen an abrupt rise in patients presenting with a self-diagnosis (Rettew 2022).

39. Consistent with all this evidence, the spread of beliefs about gender identity, such that all individuals should consider and question their gender identity, appears quite plausibly capable of significantly increasing the incidence of gender dysphoria. This is especially true as traditional sources of knowledge about the world such as families, school, local culture and religion have been replaced by what children observe on electronic screens. Youth even form complex reciprocal relationships with their avatars (Szolin 2023).

40. In their February 25, 2022 press release "Medicine and gender transidentity in children and adolescents" the French National Academy of Medicine notes "Whatever the mechanisms involved in the adolescent – overuse of social networks, greater social acceptability, or example in the entourage - this epidemic-like phenomenon results in the appearance of cases or even clusters in the immediate surroundings". It continues "The vigilance of parents in response to their children's questions on transidentity or their malaise, underlining the addictive character of excessive consultation of social networks which is both harmful to the psychological development of young people and responsible, for a very important part, of the

growing sense of gender incongruence." Thus the French National Academy of Medicine has concluded that the "epidemic-like" rise in gender dysphoria is tied to social media.

41. Psychiatrists also believe social media has significantly contributed to the rise in gender dysphoria. Yet most child and adolescent psychiatrists admit to me they will not speak publicly on this subject due to how sensitive the topic is, and also fears of hostilities from activists along with condemnation and retribution from others within their universities or organizations.

42. My personal conversations align with recent polling. While I was on stage presenting at the October 2022 American Academy of Child and Adolescent Psychiatry annual conference, as part of the presentation, the audience was anonymously polled on a number of topics. When polled: *How often do you see teens who seem to be influenced by social media in regards to their sexual and/or gender identity*? 80 of 97 (82%) indicated social media was an influence somewhat often or very often. To my knowledge, this is the first data confirming that the vast majority of a group of child and adolescent psychiatrists acknowledge social contagion is a major contributor to the rise in gender dysphoria.

43. A similar poll was conducted at the January 18, 2023, meeting of the Child & Adolescent Psychiatry Society of Greater Washington, all attendees were physician members. For the question *How often do you see teens who seem to be*

influenced by social media in regards to their sexual and/or gender identity? Of the 34 respondents, 47% indicated *Occasionally* and 35% indicated *Often*. So again 82% of these child and adolescent psychiatrists reported they see their patients gender identity is influenced by social media.

44. It is plausible and probable that ideological and social factors underlie the increase in gender dysphoria. This does not rule out other factors. Concern, open discussion and scholarly exploration of this data does not constitute bias, discrimination or transphobia. This area requires thoughtful analysis and further study.

Review of the Evidence Base for Treatments of Gender Dysphoria

45. Neither Gender dysphoria (GD) itself, nor what is the best psychotherapeutic or medical approach is well understood. My review of the research concludes that the evidence base for gender dysphoria treatments is mixed and generally low quality. Below I provide detail to this assessment.

46. The administration of sex hormones and performing of surgeries are medical interventions with substantial risks, and as these interventions target otherwise healthy tissue, a high degree of evidence is expected before such a life altering intervention. Until recently cross sex hormone and surgeries for gender dysphoria have been exceedingly rare, thus there exists nominal long term data. It is especially challenging to evaluate this evidence base due to changing definitions and

epidemiology. It is my opinion that insufficient data is available to make confident proclamation regarding the risks and benefits of treatments of gender dysphoria.

47. I have reviewed Drs. Brignardello-Peterson and Wiercioch's 2022 *Effects of gender affirming therapies in people with gender dysphoria: Evaluation of the best available evidence*. This report was compiled for the Florida Agency for Health Care Administration. This report utilized GRADE: Grading of recommendations, assessment, development, and evaluations. This is the most widely used method for appraising studies to be included in systematic reviews and guidelines. (Goldet 2013). Their review revealed that the quality of evidence supporting treatments is generally low. The conclusions rendered fit the data and are logically sound.

48. Drs. Brignardello-Peterson and Wiercioch's review is consistent with the Endocrine Society's own grading in their 2017 Clinical Practice Guidelines. The Endocrine Society also utilizes the GRADE system (Hembree 2017). In fact, the Endocrine Society 2017 Clinical Practice Guidelines only grade as moderate or high quality recommendations for assessment or education. All recommendations regarding treatment are graded as supported by very low-quality or low quality evidence.

49. Similar to the state of Florida, countries across the globe have responded to concerns about medical practice for gender dysphoria by conducting

reviews. After the reviews, each country changed their approach. Many of these countries, due in part to their smaller and better organized medical systems, have offered more comprehensive and structured treatment regimens for gender dysphoria. In addition, these treatment options in Nordic countries have been in place longer than they have been typically more available in the United States.

50. In Sweden, the National Board of Health and Welfare (NBHW) was commissioned by the Swedish government to update guidelines via its *Care of Children and Adolescents with Gender Dysphoria*. After this systematic review was published in 2022 by the Swedish Agency for Health Technology Assessment and Assessment of Social Services, Sweden's NBHW recommended a move away from cross sex hormones. The authors conclude that risks currently outweighs the possible benefits and most patients will need psychotherapy and supports rather than medical care. The Swedish National Board of Health and Welfare reported the 3 main factors:

- a. A lack of reliable scientific evidence concerning the safety and efficacy of treatments.
- b. Increasing concerns about de-transition.
- c. Uncertainty brought about by the extreme rise in those seeking care, especially females.

51. They further conclude that "Evidence for non-binary gender identity is lacking." and the evidence is limited for adults. They further report "Gender dysphoria rather than gender identity should determine access to care". The authors conclude the "For adolescent with gender incongruence NBHW deems that the risks of puberty suppressing treatment with GnRH -analogues and gender affirming hormonal treatment currently outweighs the possible benefits. Treatment should be offered only in exceptional cases."

52. Sweden has made these changes within a context of longstanding access to care for gender dysphoria and much of the available data regarding longer term outcomes. A 2011 article reviewed sex-reassigned patients in Sweden from 1973 to 2003 and showed increased risk for suicide attempts and inpatient psychiatric care. (Dhejne 2011). A recent article, initially published claiming positive mental health results, after Letters to the Editors, caused a correction (Bränström 2020). This article reviewed patients diagnosed with gender incongruence between 2005 and 2015. The reanalysis and multiple Letters to the Editor in the end led even the authors to conclude that the methodological shortcomings preclude any statement on the suitability of surgery in persons seeking treatment for gender noncongruence. The peer review issues exemplified by these events will be discussed later in this report.

53. Finland is another Nordic country with an organized medical system and longstanding availability of care for gender dysphoria. Finland's recent Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland) *Medical Treatment Methods for Dysphoria Related to Gender Variance In Minors* concluded "The first-line treatment for gender dysphoria is psychosocial support and, as necessary, psychotherapy and treatment of possible comorbid psychiatric disorders." The authors further report cross sex identification "even in extreme cases, generally disappears during puberty. In some cases it persists or intensifies."

54. The authors state "A lack of recognition of comorbid psychiatric disorders common among gender-dysphoric adolescents can also be detrimental. Since reduction of psychiatric symptoms cannot be achieved with hormonal and surgical interventions, it is not a valid justification for gender reassignment. A young person's identity and personality development must be stable so that they can genuinely face and discuss their gender dysphoria, the significance of their own feelings, and the need for various treatment options." They conclude: "In light of available evidence, gender reassignment of minors is an experimental practice. Based on studies examining gender identity in minors, hormonal interventions may be considered before reaching adulthood in those with firmly established transgender identities, but it must be done with a great deal of caution, and no

irreversible treatment should be initiated. Information about the potential harms of hormone therapies is accumulating slowly and is not systematically reported."

55. In their 2021 Position statement, *Recognizing and addressing the mental health needs of people experiencing Gender Dysphoria / Gender Incongruence*, the Royal Australian and New Zealand College of Psychiatrists (RANZCP) provides an overview of Gender Dysphoria and highlights the importance of respecting an individual's gender identity.

56. This position statement indicates that "Comprehensive Assessment is critical." "Evidence and professional opinion is divided whether an affirmative approach should be taken in relation to treatment of transgender children or whether other options are more appropriate." They further reflect that "There is a paucity of quality evidence on the outcomes of those presenting with Gender Dysphoria."

57. The 2022 press release of the French National Academy of Medicine, *Medicine and gender transidentity in children and adolescents*, reporting that on the epidemic like increase and that "This primarily social problem is based, in part, on a questioning of an excessively dichotomous vision of gender identity by some young people." "Therefore, faced with a request for care for this reason, it is essential to provide, first of all, a medical and psychological support to these children or adolescents, but also to their parents, especially since there is no test to distinguish a "structural" gender dysphoria from transient dysphoria in adolescence.

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Moreover, the risk of over-diagnosis is real, as shown by the increasing number of transgender young adults wishing to "detransition". It is therefore advisable to extend as much as possible the psychological support phase."

58. They further report "However, a great medical caution must be taken in children and adolescents, given the vulnerability, particularly psychological, of this population and the many undesirable effects, and even serious complications, that some of the available therapies can cause."

59. Similarly, The National Health Service of England commissioned the Cass Review to evaluate the safety and effectiveness of gender dysphoria care. The systematic review commissioned in the UK found the evidence for puberty blockers and cross-sex hormones to be of "very low certainty."

60. "The key limitation to identifying the effectiveness and safety of gender-affirming hormones for children and adolescents with gender dysphoria is the lack of reliable comparative studies. All the studies included in the evidence review are uncontrolled observational studies, which are subject to bias and confounding and were of very low certainty using modified GRADE. A fundamental limitation of all the uncontrolled studies included in this review is that any changes in scores from baseline to follow-up could be attributed to a regression-to-the-mean. " The authors further noted that the studies have relatively short follow-up and studies with a longer follow-up are needed to determine the long-

term effect of gender-affirming hormones for children and adolescents with gender dysphoria.

61. The World Professional Association for Transgender Health (WPATH) is an international, multidisciplinary, professional association whose reports themselves to have a "mission is to promote evidence-based care, education, research, public policy, and respect in transgender health." WPATH has created their Stands of Care (SOC) documents which shares some features equivalent to what a medical organization would call a clinical practice guideline. These documents are referred to as the Standards of Care (SOC), the 2011 edition as SOC -7 and the 2022 version as SOC-8. The authors of SOC-8 state: "The overall goal of SOC-8 is to provide health care professionals (HCPs) with clinical guidance to assist TGD people in accessing safe and effective pathways to achieving lasting personal comfort with their gendered selves with the aim of optimizing their overall physical health, psychological well-being, and self-fulfillment."

62. Due to its recent release, a thorough systematic review of WPATH SOC-8 is not available. Dahlen et al provided a systematic review and quality assessment of international clinical practice guidelines for gender minority/trans people which included the review of WPATH SOC-7. They note that WPATH SOC7 "contains no list of key recommendations nor auditable quality standards." Among the principal findings was that WPATH SOC 7 cannot be considered 'gold

standard'. The WPATH review scored poorly on editorial independence, applicability, and rigor of development. The review scored better on scope, stakeholder involvement and clarity of presentation. The reviewers noted that WPATH and other international clinical practice guidelines tended to prioritize stakeholder involvement rather than methodological rigor.

63. Among the implications were that "Clinicians should be made aware that gender minority/trans health CPGs outside of HIV-related topics are linked to a weak evidence base" and that "Organizations producing guidelines and aspiring to higher-level quality could use more robust methods, handling of competing interests and quality assessment."

64. The Mayo Clinic Proceedings article, *Clinical Practice Guidelines: a Primer on Development and Dissemination*, (Murad 2017) highlights that "trustworthy clinical practice guidelines require a systematic review to select the best available evidence and should explicitly evaluate the quality of evidence". The authors' criteria for trustworthy guidelines include:

- a. "Be based on explicit and transparent process that minimizes distortions, biases and conflicts of interest"
- b. "Provide a clear explanation of the logical relationships between alternative care options and health outcomes"

c. "Provide ratings of the quality of evidence and the strength of the recommendations"

65. Despite the well-known methodological weakness to SOC 7, WPATHS created SOC 8 in a similar manner, again disregarding the conventions expected to create a trustworthy clinical practice guideline.

66. While SOC 8 is a large document and it is beyond the scope of this report to review completely, I must note 4 major concerns as a mental health professional.

- a. SOC 8 makes no analysis of privileging gender affirmation over body affirmation. For clinicians and psychotherapist these trade-offs are fundamental concerns.
- b. SOC 8 suggests consumer-driven medical and surgical interventions and deems these medically necessary without adequate supporting evidence.
- c. SOC 8 normalizes self-mutilation via inclusion of "Eunichs" as just another non-binary category without any suggestion that these individual require mental health assessment prior to any consideration of chemical or surgical procedures.
- d. SOC 8 downplays concerns related to de-transitioning.

67. Four final thoughts regarding the limited evidence for treatments for gender dysphoria. Firstly, advocates of gender affirming treatments point to short-term improvements observed in some studies. It is possible that much of these improvements are placebo effects. Placebo effects are positive changes based on expectations. Placebo effects are routinely seen in other treatments, such as pills for depression. Vulnerable youth expressing gender dysphoria may be especially susceptible to believe in remedies celebrated by online influencers or advocate physicians. The enthusiastic claims of effectiveness of gender affirming treatments in the press, by medical societies and expressed by advocates at high prestige institutions, would be expected to enhance placebo effects (Clayton 2022). This creation of false expectations has significant potential to cause harm.

68. The second concern is many proponents of early transition of youth with gender dysphoria point to what is known as the "Dutch Protocol". Yet a recent reviews display that while some call published reports regarding results of the Dutch Protocol reliable research, this "research", is in fact severely flawed (Biggs 2022). This is because the Dutch protocol selected out patients to assure only the most successful outcomes. The clinicians flipped the questionnaire, leaving it unclear if gender dysphoria was resolved. Lastly, concomitant psychotherapy confounds whether effects were from psychotherapy or the hormones and surgeries. Added to this, is that clinics in the United States do not follow the rigor of the

original studies, and as such the result are unlikely to be generalizable (Abbruzzese 2022).

The third problem regards Informed Consent. It is a concern of 69. clinicians, as I have been asked about it by colleagues. It is curious that there has been minimal dialogue exploring the unanswered questions related to informed consent in medical journals. These matters are disputed in other journals (Latham 2022, Levine 2022). Medical organizations have come out strongly for affirmative care, supporting the opinion that minors have the emotional and cognitive development to be responsible for whatever consequence their teenage selves make. Yet when the question was mandatory life in prison in Miller V. Alabama, The American Academy of Child and Adolescent Psychiatry (with the American Medical Association) Amicus Curiae (2012. P2-3) claims: "Scientists have found that adolescents as a group, even at later stages of adolescence, are more likely than adults to engage in risky, impulsive, and sensation-seeking behavior. This is, in part, because they overvalue short-term benefits and rewards, and are less capable of controlling their impulses making them susceptible to acting in a reflexive rather than a planned voluntary manner. Adolescents are also more emotionally volatile and susceptible to stress and peer influences. In short, the average adolescent cannot be expected to act with the same control or foresight as a mature adult." It is thus my opinion that The American Academy of Child and Adolescent Psychiatry is so

politicized it cannot keep track of its own claims in Amicus Briefs which contradict each other. Unless this organization is willing to backpedal on its well substantiated and well documented arguments in the Miller v Alabama case, how can it basically argue the opposite when it comes to consent for irreversible treatment within the context of low quality evidence and significant risk of harm?

70. The fourth concern is most grave. A recent article in the New England Journal of Medicine tracked 315 youths undergoing 2 years of gender affirming hormones (Chen 2023). Within 315 hormone treated youth there were 2 completed suicides. Curiously, this remarkably high suicide rate is not explored in the article. By comparison, a recent review tracked the Gender Identity Development Service in England, Wales and Northern Ireland from 2010 to 2020 (Biggs 2022). This found 4 completed suicides of 15032 transgender patients over 10 years. As Gender Identity Development Service in these locations were overwhelmed with patients, only a small fraction were receiving gender affirming hormones. If these are compared the American hormone treatment group, it would be akin to a waitlist control. Thus the most recent research shows a much higher than expected rate of suicide in the condition of affirmative hormone treatment.

Lack of consensus regarding treatment of gender dysphoria

71. With rapidly growing cohorts of patients expressing novel symptoms clusters in an new area of medicine where a limited evidence base exist, differences

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of opinion regarding clinical care for gender dysphoria are expected. It would be remarkable if there was uniformity of opinion. Furthermore, gender care is politicized, and opinions tend to cluster in a manner consistent with an influence of political ideology (Regnerus 2022).

72. Within this context of low quality evidence and divergent opinions, there are bound to be calls for reasonable clinical safeguards. There are also serious reservations regarding the effectiveness and concerns about the risks from affirmative treatment for Gender Dysphoria (Clayton 2022, Biggs 2022).

73. Much of the push for affirmative treatment for gender dysphoria treatment has come from professional organizations such as the Endocrine Society, American Academy of Pediatrics and the American Psychiatric Association and the American Academy of Child and Adolescent Psychiatry. Medical professional organizations are large bureaucracies which serve many functions. They are important components of our medical system and usually provide great services for the profession and the public.

74. Just as other parts of society, professional medical organizations are susceptible to tribal influences and politicization. Their influence and credibility can be misused in a harmful manner. I have directly observed, that over the last decade, but particularly the last 5 years these organizations have prioritized a politicized and narrow vision of social justice advocacy. While this has arisen from

good intentions, it has contributed to the creation and spread of misinformation regarding treatment of gender dysphoria. I will explain how this occurred.

75. I have directly observed that within these organizations, the members most enthusiastic about a certain type of medicine self-selected into "special interest groups" or committees. For instance, the psychopharmacology committee is filled with supporters of using psychopharmacology and the psychotherapy committee is populated by members enthusiastic about psychotherapy. Committees on gender and sexuality have been no exception. By participating in a committee, a small group of people can establish themselves as content experts within their organization.

76. Using committees as content experts usually works well, as it did during my eight years as co-chair within AACAP's media committee. ACCAP leadership utilized our input to make decisions about policy statements, clinical recommendations, public education or relevant legislation.

77. Over the recent years that gender clinics started to spread across America, gender medicine enthusiasts self-selected into these clinics and also into gender relevant committees. Most physicians are wary of the very concept that it can be beneficial to give cross sex hormones to still developing minors. Thus those who venture into medicalized gender care are already a select few who bring to this work certain viewpoints and aspirations. Just as with the psychopharmacology or

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psychotherapy committee members, gender committee members have strong personal and professional investment in the success of their favored type of treatment. This created a well-intentioned but homogenous group of gender medicine supporters.

78. Without the knowledge of most members of a professional organization, as few as the dozen members in a committee can steer these organization's leadership to advocate for treatments or policy positions. Once medical organizations have come out with policy statements, clinical practice guidelines and press releases advocating strongly for a position, they have difficulty accepting they may have misstated evidence, advocated for unwise policy or otherwise caused harm.

79. For example, the highly influential 2018 Policy Statement from the American Academy of Pediatrics (AAP) (Rafferty 2018) contained many citation errors, overstatements and unfortunately mischaracterized the longstanding and well-regarded clinical approach of watchful waiting (Cantor 2020). This policy statement has been particularly detrimental to the scholarly exchange of ideas related to gender dysphoria treatments, as it used the prestige and trustworthiness of the AAP to privilege the concept of affirmative care and denigrate other treatment. It also increased momentum to enshrine social transition and access to

medical treatments in minors, whether or not these are prudent or evidence based approaches.

80. Medical and psychiatric journals editors are surely aware of their affiliated professional organization's policy statements and political advocacy. Since the Endocrine Society, American Academy of Pediatrics, American Psychiatric Association and American Academy of Child and Adolescent Psychiatry have been all openly involved in political advocacy in support of gender affirming care, in reality their journal are no longer are scientifically neutral. This politicization is reflected in the editors' actions as medical and psychiatric journals have recently attempted to consolidate favorable opinion toward gender affirming treatments for gender dysphoria rather than promoting open scholarly debate.

81. This is not just my theory, Michael Norko, the editor of the Journal of the American Academy of Psychiatry and the Law emailed to me in June 2022: "The Journal is an instrument of AAPL, and it is my responsibility as Editor to lead it in a direction that supports the efforts and goals of the parent organization."

82. Not surprisingly, skeptical voices have been difficult to find within any of the journals of the Endocrine Society, American Academy of Pediatrics, American Psychiatric Association or American Academy of Child and Adolescent Psychiatry. In fact, I have not found a single skeptical or even ideologically balanced article in any of these journals. Journal editors have a wide discretion to

choose what topics are covered in their journals by choosing what articles are sent for review, commentaries, clinical perspective, vetting Letters to the Editor guiding what is included in the book review column and setting policies.

83. The medical journal I follow most closely, The Journal of the American Academy of Child and Adolescent Psychiatry has only published articles seeking conformity of thought with gender ideology and affirmative care, and has not allowed actual scholarly dialogue to be voiced. Please see the commentaries (Dixon 20202), clinical perspectives (Turban 2017, Turban 2018), and book reviews (Suto 2021, Chilton 2021, Kim 2021).

84. The 2017 Turban article provided the perspectives of transgender and gender nonconforming youth and reading that viewpoint can certainly be valuable for clinicians. Yet most striking was the youth's ideological assertions, misunderstanding of the evidence and pleas for their physicians to believe suppositions such as ""Sexuality and gender are two different things. TOTALLY separate." and "Puberty blockers and cross-sex hormones can save my life." It also contained a pressure to join the movement: "Let me know that you are on my team." These youth somehow have gotten the impression there is no doubt regarding the safety and efficacy of hormones and surgery. They also have the belief that changing society is the solution to their mental health challenges: "If I am depressed or anxious, it's likely not because I have issues with my gender identity,

but because everyone else does." More striking was that that authors expressed agreement with the youths' ideology. The authors conclude: "Likely due to a combination of minority stress and dysphoria related to being 'trapped in the wrong body,' these young people are disproportionately burdened by depression, anxiety, and suicide attempts." The evidence actually points to youth who are depressed, anxious and suicidal are more like express gender dysphoria (Kaltiala 2020).

The Journal of the American Academy of Child and Adolescent 85. Psychiatry even published a Commentary filled with misinformation which pressured researchers to adopt progressive gender theories to "become allies" (Dixon 2022). It is curious but revealing that the participants seemed uninterested in core unanswered questions such as why individuals experience themselves as nonbinary or transgender. Conversely, the youth and authors used the commentary to push researchers to adopt ideology and allyship. These pressures on scholars are antithetical to the scientific method and have been a corrupting force in much recent research and academic dialogue regarding sex and gender. This politicized, low quality scholarship has minimal credibility and is a prime example of how medical journals have prioritized advocacy and ideology over trustworthy science. With two child and adolescent psychiatric colleagues, in response to Dixon et al, we wrote a Letter to the Editor of the Journal of the American Academy of Child and Adolescent Psychiatry. The journal editor refused to even send this letter out for review.

86. Not only are the articles one sided, the peer review process regarding gender medicine within medical journals has become dysfunctional. Many recent examples show how prominent medical journals ignore significant weakness in methods, allow erroneous conclusions and overstatement of the strength of the evidence when articles support affirmative care or related concepts (Bigg 2020, Deangelo 2021, Kalin 2020, Giovanelli R. 2022). As mentioned earlier, the Journal of the American Psychiatric Association published a study with an erroneous positive conclusion regarding gender surgeries in Sweden, prompting a flurry of letters to the editors and later revision (Bränström 2020).

87. In 2018 Lisa Littman published an article which revealed aspects of the rapid spread of gender dysphoria in adolescents. After this research was peer reviewed and published, the journal PLOS ONE had a re-editing of the publication with a commentary added. This showed a disregard for the typical rules of scientific discourse, and should be noted was not a corrections, as there was no finding of error, misconduct or faulty methods. As confirmed by the PLOS ONE re-review, Dr. Littman's research methods were unremarkable and comparable to other mental health research, and this was not a correction as claimed by activists. Various journals also published articles deriding Dr. Littman's work and she was personally
harassed by activists. Brown University also did not make any effort to defend her Dr. Littman from attacks on her freedom to pursue science. This antagonism of Dr. Littman was not about her methods, but rather that her data indicated that Gender Dysphoria was spreading in a pattern consistent with social influence. Dr. Littman's other heresy was revealing how many parents perceive the gender affirming approach is dysfunctional. (Littman 2018)

88. Similar dynamics are in place even in newsletters. A colleague related a difficult experience with editors of the American Academy of Psychiatry and the Law Newsletter. The editors would not permit him to describe in his article the actual problematic behaviors of youth who declared themselves to be transgender on his inpatient unit. This silencing of actual clinical situations undermine the exchange of ideas on how to best provide clinical care.

89. Thankfully, journals outside of medicine have not allied themselves to one viewpoint and are willing to embrace open scholarly dialogue (Abbruzzesse 2023, D' Angelo 2021).

The breakdown of scholarly dialogue

90. Open inquiry is the ability to ask questions and share ideas without risk of censure. It is fundamental to medical research and scientific progress. Within medicine the ability for constructive disagreement and the expression of divergent

opinions has withered with regards to questions of biological sex, gender and gender medicine.

91. Political and social pressures are not new to this line of research and clinical care and do not come from only one political pole or fraction of society. Yet especially within the last decade, academia, including academic medicine has become more tribal, moralizing and more likely to attempt to silence divergent opinions (Bindewald 2021).

92. I witnessed these dynamics personally at the American Psychiatric Association 2022 annual conference. At the Clinical Perspective The Management of Adolescent Onset Transgender Identity: Should "Best Practices" Change on May 24th 2022, the was a preamble. In a procedure I've never before seen at a conference, the representatives from American Psychiatric Association who were monitoring the event were asked by leadership to read a statement prior to presentation indicating the content of the presentation clashed with official proclamations of the organization. During this Clinical Perspectives four speakers presented convincing data and opined that they questioned the evidence based and logic supporting current affirmative psychotherapy and medicalized practice regarding the treatment of transgender youth. Most of the audience respectfully sat while enjoying the thoughtful presentation. Yet a small crowd in the audience was disruptive. There were many interruptions of the presentation by a member of the

crowd who repeatedly provided his input. During the question-and-answer session, a series "questions" were rather hostile ad-hominem statements towards the presenters. Only a tiny fraction of the questions actually responded to any of the evidence or viewpoints presented. I have never previously observed any comparable unprofessional behavior or hostility toward presenters in any medical or psychiatric conference.

93. Similarly, in 2018 Lisa Littman, MD presented her research data at American Academy of Child and Adolescent Psychiatry conference and received personal enmity which caused a colleague to remark he has never seen a presenter at a conference treated with such hostility. I did not attend live but later watched the presentation online and also heard the many demeaning and unprofessional comments directed toward Dr. Littman.

94. Members of APA and AACAP who attend meetings and observe scholars being condemned will certainly think twice before voicing their concerns. This polarization and moralization can create a "spiral of silence": an appearance of agreement because a small moralizing group dominates the discussion (Noelle-Neumann 1974). This is consistent with my experience as I have been told by a range of child psychiatrists, from very senior AACAP "life members" to residents in training that they are unwilling to openly express their viewpoint, but they do not see data or logic supporting gender affirming treatments.

95. The 2022 American Academy of Child and Adolescent Psychiatry conference featured at least 6 presentations related to gender dysphoria or transgender patients, none presenting new research. Yet a research Symposium was rejected which was to include a prominent international researcher, Dr. Littman, a clinician experienced in treating gender dysphoria and was to feature detransitioners. The AACAP program committee co-chair James McGough later indicated via a May 28th 2022 email this highly unusual rejection was in part due to "concerns" about the methods employed in several of the presentations and that detransitioners would be involved. It defies logic that the only time methods are an issue is when the results of the research raises questions about affirmative care. Furthermore, I am aware of a number of presentations which have been accepted with the condition of making a small adjustment. The detransitioners as discussants could have easily been replaced as their only role would be to ask questions after the research is presented.

96. Dr. McGough indicates he took these concerns seriously. He referred concerned parties to "Aron Janssen co-chair the AACAP committee charged with taking the lead on trans issues." Dr. McGough also noted that "Aron is also on the program committee". A program committee member "taking the lead on trans issues" would give Dr. Janssen significant power to support or suppress presentations. I have seen Dr. Janssen present twice and spoken with him. Though

we disagree, he is a thoughtful person and means well. Yet those concerned with free exchange of scholarly ideas should notice the words he chose in his 2021 "Perspectives" article (Janssen 2021) whereas he characterized legislative and political endeavors to limit medical care as "malicious changes" that "provide fodder to perpetuate discrimination, fear and exclusion." He specifically states: "It is our ethical responsibility to respond to this assault".

97. Dr. Janssen characterizes those arguing against gender affirmative care as making "an effort to oppress". This all makes clear he does not want open rigorous scholarly exchange that would raise substantial questions about the ethics and efficacy of gender affirming care. It is further my assessment that across medical organizations and medical journals those who are "taking the lead on trans issues" share Dr. Janssen perspective.

98. For those not familiar with the proceedings of medical conferences, research symposiums are eagerly sought out by the medical societies. The same program chair has commented to me personally that research symposiums are by far the easiest type of presentation to be accepted. For this same conference I also submitted, with two other physicians, for a Special Interest Group presentation which was to feature data on de-transitioning. This proposal obviously provided data which raised questions about affirmative care, it was also not accepted.

99. Despite unclear evidence and significant disagreement among psychiatrists regarding the treatment of gender dysphoria, medical professional organizations have enthusiastically conducted a public campaign to portray these treatments as evidence based. The organizations' political activism has important ramifications and creates a false impression that gender affirming treatment rests on strong and settled science. Two recent press releases provide examples. The September 28th 2022 American Academy of Pediatrics (AAP) press release regarding the State of Oklahoma condemnation of any limits on gender affirming health care. Defending scope of practice is typical for medical associations. Yet the press release frames these limits as discrimination based on gender identity, a moralized characterization of restrictions on care.

100. American Academy of Pediatrics' opposition to Oklahoma's limits on moral grounds (discrimination) fails to acknowledge ethical concerns regarding treatment of children with gender dysphoria including large scale potentially irreversible damage to minors. This is an example of two competing moral frameworks which both express valid concerns. As such, a more appropriate perspective from a medical organization would be a call for reasoned dialogue to evaluate the moral claims on each side, examine the logic and data behind these moral frameworks and treatments. It is not immoral to seek to find more cautious ways to care for and support those with gender dysphoria, or to seek a higher level of evidence before allowing minors to make permanent decisions regarding altering their bodies.

101. Curiously, the AAP statement invokes parental rights, but without clarifying if the AAP supports the very likely majority, who do not want hormonal or surgical treatment for their child's gender dysphoria. This AAP statement misses an opportunity to show respect for those who disagree, which is an indication of how politicized the AAP organization has become.

The American Academy of Child and Adolescent Psychiatry (AACAP) 102. made a number of similar statements regarding limits on care such as the March 1, 2022 statement which characterized actions in Texas as "attacks" which endanger young people. The statement curiously claims "Gender affirming care is informed by long-standing standards of care and by evidence-based clinical studies". How longstanding are we talking about, because gender dysphoria was previously so rare I went over 20 years from medical school through over the first decade of my career without a single patient reporting gender dysphoria. The first gender clinic in the United States just opened in 2007. It is reasonable for AACAP to defend scope of practice, oppose criminalization of physicians and call out inappropriate use of child protective services. Yet a medical professional organization overstating evidence and using divisive rhetoric reveals serious ideological and political influence which undermines it's own legitimacy.

103. Even more revealing is the American Academy of Child and Adolescent Psychiatry's (AACAP) March 18th, 2022 press release reveals their leadership's strident position by remarking on an education bill, outside psychiatrists' area of expertise. AACAP's statement used politicized derogatory phrasing by calling Florida's legislation the "Don't Say Gay or Trans" bill. The press release quotes the current president of AACAP who demonizes supporters of the bill as unconscionable and implies these supporters "target and harm" LGBTQ+ youth". The American Academy of Child and Adolescent Psychiatry's leadership moralizes the debate, uses polarizing language and does not engage in forthright discussion which must include skepticism, not just affirmation.

104. It should be noted the national organization offered my regional AACAP branch (in the Tampa area) the opportunity to sign on to "BRIEF OF CURIAE ACADEMY OF AMICI AMERICAN PEDIATRICS AND ADDITIONAL NATIONAL AND STATE MEDICAL AND MENTAL HEALTH **ORGANIZATIONS** PLAINTIFFS' IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION". The Tampa regional organization refused to sign on.

105. While I have little direct experience with the Endocrine Society, my assessment is that many endocrinologists, and perhaps most, also believe their professional organization is also too strongly influenced by activist physicians.

Similar to AACAP and AAP, they take a polarized position and misstate the strength of the evidence regarding gender affirming care. In particular, the April 20th 2022 press release "Endocrine Society Opposes Florida Department of Health Policy on Gender Dysphoria Treatment for Children and Adolescents" reveals overstatements of the strength of evidence and the false appearance of consensus in the medical community. This statement mischaracterizes puberty delaying medication as a "safe, reversible and conservative approach." This statement claims that attempts to restrict care are based on politics, rather than acknowledging legitimate concerns. It is interesting that they cite the Endocrine Society's own clinical practice guidelines. As noted previously, the Endocrine Society's own guidelines themselves graded the supporting evidence as low or very low quality for their clinical recommendations.

106. These organizations portrayal of affirmative treatments for gender dysphoria as both effective and virtuous has had a chilling effect on scholarly dialogue regarding gender dysphoria in the medical community. This framework brands those who disagree regarding the evidence base as morally inferior and biased. Through mechanisms I will describe below, moralization has been counterproductive to developing trustworthy science and has contributed to the spread of misinformation regarding treatment approaches to gender dysphoria. 107. Prudent physicians generally avoid being part of a partisan and moralized debate, and do not want to be harassed by gender activists (Evans 2021). When anonymously polled, as cited above, physicians are free to provide their actual opinion and show their skepticism. Supporters of affirmative care could survey physicians to specifically test their hypothesis of broad based support. Why have they not conducted such a survey?

108. As mentioned earlier, the highly politicized dialogue regarding the issue of transgender care (Evans 2021) mirrors a larger phenomenon within the academic community. On many complex and divisive issues within academia, there has been a push from the progressive left demanding conformity of opinion with a narrow, highly moralized viewpoints (Bindewald 2021). The example of gender dysphoria shows that academic medicine has not been immune to this same phenomenon.

109. Pressures to make affirmative therapies the only treatment for gender dysphoria essentially push all parties involved to adopt a simple clear framework for gender dysphoria treatment. Yet simple and clear does not represent the reality or the evidence base. All- or-nothing rhetoric can be an effective technique to rally support around a cause. Yet the treatment of gender dysphoria has complex ethical, legal, social and clinical trade-offs. 110. This moralized framing of affirmative treatments for gender dysphoria encourages a cognitive shortcut known as attribution substitution. Attribution substitution is the process whereby a simple, related moral judgement is substituted for various conceptually complex decisions. This common cognitive bias causes humans to intuitively believe viewpoints which appear virtuous, especially ideas which seem widely held within their social group. Affirmative care does sound compassionate and supportive, and these minor semantic can have a surprising influence.

111. For comparison, the Covid-19 pandemic provided a clear parallel of how moralizing medical issues can lead to misinformation and poor decision making. Individuals' tribal associations were shown to often influence their viewpoint of lockdowns, masks and vaccines more than data. (Kerr 2021, Jiang 2021). Call for conformity meant that dissenting physicians, even academic titans like John Ioannidis, Jay Bhattacharya, and Scott Atlas were treated badly both online and within the medical community. These pressures against voicing skepticism distorted the professional dialogue. Respectful conflict of opinion and impersonal rigorous exchange would have likely reduced harms, such as education loss and mental health deterioration associated with prolonged American school closures during the pandemic (Dooley 2022). 112. Ideological homogeneity and group identity are risk factors for developing irrational beliefs and spreading misinformation. (Su 2022, Sun 2022, Macy 2018). This directly relates to attitudes about transgenderism and gender dysphoria treatments where ideological dogma has distorted scientific exploration. Those who dare to question the dogma are treated as heretics.

113. These dynamics are understandable. Many times within psychiatry and medicine we as practitioners face enormous suffering. Gender non-conforming patients do at times face harassment and discrimination. Patients expressing gender dysphoria have high rates of depression, anxiety and self-harm. All physicians and mental health professionals want to help. Those who started gender clinics hoped to relieve suffering. Yet in medicine false hope can cause suffering.

114. All humans, including physicians, tend to find arguments in favor of conclusions we want to believe, and this bias in known as motivated reasoning (Peters 2020). Supporters of gender affirming treatment want to believe they have found an ethical and evidence based solution. This motivated reasoning explains the strong divergence between the enthusiastic support for gender affirming treatments and the relatively weak evidence base.

115. Once a group, such as a gender committee, endorses a statement of belief, such as "gender affirmative care is life-saving", the other psychiatrists in their professional organization who have not reviewed the facts tend not to question

it. Psychiatrists face a rapidly expanding evidence base across disorders, and we depend on specialization to lead us toward progress in our varied patient populations.

116. Especially if the "experts" assert a strong moral claim regarding a clinical approach, other members would assume it is based on strong evidence. This creates a group process whereas the leadership responds to show support and loyalty, and others tend to follow. Support of this moral claim becomes a marker of virtue and raises status within the group. Those who are skeptical tend to self-censor (a Spiral of Silence) rather than taking a risk of being called unethical. These dynamics, especially leaderships' endorsement, make opinions appear like facts within the group. Members of this group they never hear counter arguments or disconfirming data and become ever more confident.

117. Within such moralized environments education and intelligence offer limited protection from irrational beliefs. In fact, sophisticated language skills enable virtuosity in creating and promoting false narratives. These dynamics have happened many times before in medicine and it is my assessment this has occurred again with regards to affirmative treatments of gender dysphoria.

118. Contrary to popular belief, humans' emotional programing drives much of our cognitive processes. That is, we tend to create beliefs that go along with what we feel, rather than the other way around. This usually works well, but also causes

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serious problems. In cognitive therapy it is known as "emotional reasoning". Emotional reasoning helps explain opinion cascades, partisanship and group-think.

119. Our highly social nature and limited rationality demand that, in medicine and science, we create conditions which foster trustworthy data and minimize the creation and spread of misinformation. Recently, as shown, medical organizations and journals have prioritized advocacy, putting them at risk for producing and officially sanctifying misinformation.

120. A prescription for open exchange and deliberate consideration regarding gender dysphoria treatments should aspire to:

- a. Solicit a diversity of perspectives.
- b. Discuss the argument, rather than the person making the argument.
- c. Clarify the methods, source of data and its limitations.
- d. Use precise language rather than broad ideologies.
- e. Discuss potential sources of bias, including those related to group affiliation.
- f. Quickly acknowledge and correct mistakes.

121. This framework would depersonalize the search for truth and esteem empirical dialogue. Yet conflict is required to help us create a trustworthy scholarly dialogue regarding gender dysphoria. This has not occurred and as such claim that there is an evidence base supporting gender affirming treatments is not credible. 122. Complex ethical issues regarding treatment of gender dysphoria deserve attention. Yet pressures to accept affirmation treatment as being the most virtuous and only effective approach discourages good faith scholarly dialogue. Furthermore, the characterization of those who oppose gender affirming care as transphobic or hateful has been used to justify silencing scholars whose data or logic does not support the gender affirming approach. This occurred with Lisa Littman. Former sex researchers have left the field due to the harassment and intellectual bullying they had received (Soh 2021).

123. Thus we are in the curious situation where in private, but not in public, most psychiatrists will acknowledge their doubts regarding affirmative care. My personal interactions with many thoughtful well regarded psychiatrists display a full range of views. Most child and adolescent psychiatrists consider automatic affirmation inappropriate, even though many are willing to use affirmative approaches selectively. (Evans 2021). Most psychiatrists are willing to admit we don't have enough research to really know how to proceed.

124. Within medicine and academia we need to create space to allow input from those who hold the opinion that logic and the evidence base do not support medical interventions for gender dysphoria. We require a frank discussion of the moral issues involved, including moral hazards associated with medical treatments

for gender dysphoria. Currently, I see no evidence any of this scholarly dialogue happening.

125. Beyond hormones and surgeries, thus the costs and benefits of gender self-identification have not gone through academic inquiry with open rigorous academic review. Social affirmation can be considered a psychosocial treatment, and the recent push for adoption of social affirmation is an attempt at a grand social experiment. This is most concerning as it pertains to children. Statements of physician advocates and medical organizations are used to justify social affirmation, yet social affirmation of children seems more driven by ideology than thoughtful reflection. Throughout human history societies have grouped children by biological sex rather than gender identity. In fact, children naturally group themselves by biological sex (Maccoby 1998). Grouping children by biological sex requires tradeoffs but works well. As it has been standard practice throughout the world there has never been the need for literature to defend this practice. Yet abandoning this convention for the experiment of childhood gender selfidentification appears imprudent on many grounds, not least of which is that it will likely be psychologically destabilizing for children and adolescents.

126. Social affirmation for children is portrayed as ethical, but to what degree it is ethical depends on how it will affect children's lives. No substantial evidence guides this movement to rewire a basic element of society. There is a

longstanding forensic psychiatric literature showing that children are suggestible (Ceci 2000). It is easy to see the widespread suggestions of the existence of multiple genders and each child should declare their gender will increase confusion and cross sex identification. This should be expected to increase the incidence of, and persistence of, gender dysphoria. It is thus reasonable to expect social affirmation can cause harm, especially for emotionally vulnerable and neurocognitively impaired youth.

127. Social affirmation of children's and adolescents' self-declared gender requires more research and discussion before the risks and benefits are fully explored(Zucker 2020). Until more is known, and more rigorous scholarly dialogue takes place, society and academic medicine should avoid pushing such a large scale social experiment.

Psychotherapy

128. Patients presenting with gender dysphoria have real symptoms, typically with other comorbid mental health disorders. These patients require validation and support. I recommend their mental health treatment start with psychosocial supports and psychotherapy (Schwartz 2021). In psychiatry, we typically refer to other providers such as social workers, psychologists and licensed clinical therapists who tend to provide the bulk of psychotherapy. Despite this, as

noted in my background, I have extensive experience with psychotherapy, and additional training beyond the majority of psychiatrists.

129. Quality psychotherapy includes the process of exploring patient life history, emotions, coping style and thought patterns. This includes validating how patients feel, but it also includes teaching patients to not be guided solely by their feelings. Psychotherapy involves getting patients to recognize their own thought patterns, disturbed emotions, and, when appropriate, includes challenging irrational, self-defeating and harmful beliefs.

130. There is not an evidence base to support strictly "affirmative" psychotherapy for gender dysphoria, where therapists actively agree with a patient's self-assessment. Automatically agreeing with patient viewpoints is a radical departure from traditional mental health treatments and psychotherapy. Psychiatrists do not "affirm" hopelessness in depression, delusions in schizophrenia or distorted body image in anorexia or body dysmorphic disorder. The similarities between body dysmorphic disorder and gender dysphoria, and the contrast in how they are approached, provide significant evidence of how ideological and political forces have influenced medical practice (Kohls 2022).

131. Is it, for example, sensible, compassionate or good medical practice to, for instance, soon after a sexual assault, to automatically agree with a teen's new

self-assigned gender label? What about when a 9 year old girl spontaneously says "I feel like I am a boy", do we immediately ask what boy name to call her(him)?

132. In psychotherapy with a patient with gender dysphoria, the therapist would not advise a patient to change a gender identity, but also should not "agree" that a patient is the opposite sex. It is surely reasonable and compassionate for a psychotherapist to prefer a patient no longer to suffer with gender dysphoria. It would be inappropriate for a mental health professional to prefer gender dysphoria to continue. Yet the false binary of affirmative psychotherapy versus conversion therapy for gender dysphoria is being used to push therapists from any consideration that acceptance of one's biological sex or resolution of gender dysphoria is a positive event.

133. This categorizing of quality psychotherapy as conversion therapy is a serious misunderstanding of the complexities of ethical and effective psychotherapy (Schwartz 2021, D' Angelo 2021). The term "conversion therapy" is often misused by the supporters of affirmative care as an attempt to devalue and pathologize approaches other than purely affirming a patient's gender self-identification (Griffin 2021, Evans 2020). The only conversation therapy which has ever been researched is the attempt to change, or convert, sexual orientation.

134. Sexual orientation, with rare exception, appears to arise from in utero or early life biological factors. Thus conversion therapy for sexual orientation is ineffective, hostile and pathologizing to same sex attracted individuals. Decades ago conversation therapy was rejected by modern medicine and mental health. Conversion therapy is a historical reality within the United States, but accusations of conversation therapy have been used as a technique to change the discussion from a question of nuanced mental health care to all-or-nothing thinking regarding affirmation. During my entire career I have never once encountered a single mental health professional that has practiced conversion therapy for sexual orientation. Nor has a single patient ever described to me that they endured conversion therapy.

135. Gender identity is distinct from sexual orientation. Gender identity is often described as fluid, and as this implies, often changes over time, particularly in young people. This gender fluidity is also why it is inappropriate to affirm a declared gender identity in a child. Psychotherapists need space to ask questions about gender identity. Exploring gender identity is not conversion therapy.

136. Time-tested and widely effective psychotherapy approaches include supportive therapy or cognitive behavioral therapy. Cognitive behavioral therapy has proven effective for virtually every mental health condition it has been researched for, including the full range of anxiety disorders, depressive and mood disorders, disturbed anger, sleep disturbance and trauma reactions including Post Traumatic Stress Disorder. Due to the high levels of comorbidity of psychiatric disorders in patients with gender dysphoria, cognitive behavioral therapy could be extremely helpful as the same approach and techniques have proven effective with so many problems including anxiety, depression and in reducing self-harm.

137. Any psychotherapy should aim to help individuals gain a deeper understanding of themselves, develop coping skills and provide a neutral, unbiased process. Beyond standard psychotherapies, more specific and nuanced approaches for gender dysphoria exist, such as Exploratory Therapy (https://genderexploratory.com/). This "talking therapy" allows time for exploration of mental health concerns without pushing an ideological or political agenda.

138. Advocates of affirmative treatment dismissal of other approaches can be especially harmful in the cases of gender dysphoria presenting in the context of severe pre-existing psychiatric illness. Psychotherapy could led to the resolution of these comorbid illnesses. I can provide three examples.

139. Trauma: There is longstanding psychiatric literature showing that exposure to sexual trauma can lead to changes in gender expression (Cosentino 1993), and this has also been revealed by recent research on detransitioners. (Littman 2021). A recent review on Dissociative Identity Disorder and cooccurring Gender Dysphoria showed frequent childhood sexual abuse (Soldati 2022).

140. A core feature of Post-Traumatic Stress Disorder (PTSD) is avoidance. Repeatedly patients have described to me their physical and emotional distress when they are exposed to trauma reminders. Thus, they frequently have difficulty engaging in psychotherapy for PTSD. Even if they participate, they often actively avoid discussing their trauma. This is unfortunate as trauma focused therapies such as Trauma Focused Cognitive Behavioral Therapy have an excellent evidence base.

141. The massive rise in expressions of gender dysphoria has been most pronounced in adolescent females. This is a population where assessment for, and treatment of trauma, should be a top priority. Furthermore, based on the link between sexual abuse and gender dysphoria seen in detransitioners, assessment and treatment of trauma symptoms should be prioritized. It is possible that for many patients the delivery of trauma based psychotherapy may cause the desistence of gender dysphoria, which in some cases could be considered a co-occurring disorder related to the trauma.

142. Another feature which links gender dysphoria to trauma is the wellknown phenomenon of traumatized individuals feeling "cut off" or disconnected from their bodies (Van der Kolk, 1994). Van der Kolk and other prominent PTSD experts recommend mind-body techniques and experiential moving meditations such as yoga to help the body process trauma. These techniques help ground people in the physical world, mindfully experience their bodies and increase positive physical sensations. While only small studies exist, yoga is being used with success in many settings including prisons and substance abuse facilities. Yoga and other somatic therapies should be studied as a component of comprehensive treatment for gender dysphoria.

<u>Autism</u>

143. Autism Spectrum Disorders are neurodevelopment disorders. People with Autism Spectrum Disorder by definition have problems with social communication and interaction along with restricted or repetitive behaviors or interests. People with Autism Spectrum Disorders are consistently shown to be at increased risk for developing gender dysphoria (Cooper 2022). One review found gender dysphoria to be over 4 times as likely in patients with Autism Spectrum Disorders (Hisle-Gorman et al., 2019). Another review found compared to typically developing control, autistic adults who endorsed the wish to be the opposite sex were found to have more mental health challenges, bullying, suicidal ideation and worse quality of life. They also had worse autism symptoms and more co-morbid disorders than autistic adults who did not report the wish to be the opposite sex.

144. Autistic people experiencing gender dysphoria are a complex patient cohort. There is limited evidence of how best to help and support this specific populations. Due to the neurocognitive limitations in patients with Autism Spectrum Disorders they may be more suggestible. Autistic patients struggle socially and often spend large amounts of time online. Due to their rigid and obsessive thought patterns, if they develop gender dysphoria they can become fixated and preoccupied with receiving hormonal or surgical procedures, whether or not they understand the risks. Patients with Autism Spectrum Disorder can be incredibly insistent, single minded and determined. They also may have limited insight and minimal ability to anticipate the negative consequences of obtaining the object of their obsessions. Until more is known about the specific outcome related to this vulnerable population, caution with any clinical approach is warranted. Again, special psychotherapy approaches would likely be helpful in this population, but as of yet none have been studied.

Borderline Personality Disorder

145. Personality Disorders are enduring patterns of inner experience and behavior which deviates from expected and causes distress and impairment in functioning. The epidemiology of personality disorders in individuals with gender dysphoria is unknown and estimates vary (Furlong 2022). Many estimates have the population extremely increased, such as 50% of adults, but others show smaller increases. One review of emergency room visits of transgender patients diagnosed personality disorders at 4%, versus matched community sample of 1%. The hospitalized sample was at 5% versus 2% in controls (Lam 2021). Little scholarly guidance exists regarding specific approaches related to the various personality disorders with comorbid gender dysphoria.

146. In Borderline Personality Disorder there is, by definition, an unstable sense of self, and this leads to frequent personality changes. This typically means sudden shifts in employment, relationship, sexual identity, frequent moves and changes in types of friends. Patients with Borderline Personality Disorder often have early life trauma and find many social environments invalidating. Patients with Borderline Personality Disorder have high levels of emotional dysregulation, selfharm and substance use. This population is extremely difficult to treat.

147. With an unstable sense of self being a feature of the disorder, this patient population seems an especially poor candidate for affirming treatments, especially irreversible treatments. There are two psychotherapeutic approaches which have shown significant success, the most established is Dialectical Behavioral Therapy (Gillespie 2022), but Mentalization Base Therapy (Vogt 2019) also has significant evidence as a successful approach.

148. Especially for a young person developing signs of Borderline Personality Disorder, starting these proven approaches as early as possible is their best chance of avoiding a life course which is full of emptiness, struggle and suffering. Again, in this patient population, a focus on gender affirming treatments as the solution to this constellation of serious mental health problems is extremely

problematic, and appears likely to cause harm if it delays access to evidenced based treatments.

Conclusion

149. It is scientific and medical consensus that patients with gender dysphoria typically also have a mix of anxiety, depression, self-harm, personality disorders, neurodevelopmental disorders and trauma related symptoms. Yet these mental health problems generally pre-date or co-occur with the development of gender dysphoria.

150. There is not a scientific or medical consensus that comorbid mental health disorders are due to "untreated" gender dysphoria. This claim does not match the data. These co-occurring mental health problems pre-date and are, for the most part, not caused by the gender dysphoria.

151. As reported in the Finnish review (PALKO / COHERE Finland 2020): "A lack of recognition of comorbid psychiatric disorders common among genderdysphoric adolescents can also be detrimental. Since reduction of psychiatric symptoms cannot be achieved with hormonal and surgical interventions, it is not a valid justification for gender reassignment." The Finnish experience shows that "treating" the gender dysphoria with affirmative medications and surgeries does not resolve the patients' mental health disorders (Kaltiala 2020). 152. Claims of medical necessity for hormones and surgeries for minors can be refuted by the fact that all cohorts of previous children and adolescent throughout human history have never "needed" these procedures. The burden of proof is on those who proposed hormones and surgeries for minors to conduct long term studies and show these practices to be safe and effective. These are currently experimental approaches which seem highly intertwined with ideology. As detransitioners become more visible and relate their stories, it is clear that this ideology has distorted the practice of medicine, leading to harm.

153. The medical system has a long history of spurts of overdiagnosis and overtreatment. Many of our interventions such as frontal lobotomies were celebrated at the time. Eventually society sees the harm, pushes back and the medical profession eventually reforms.

154. Harmful and unnecessary interventions are especially likely to occur when patient desires are combined with financial incentives and the best of intentions. The American opiate epidemic was ushered in by "expert" physicians who proposed physicians need more compassion because "pain is the 5th vital sign" (Mandell 2016, Adams 2016). Too much compassion can cause harm.

155. Psychiatrist Anna Lembke, in her 2016 Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop discusses how susceptible to manipulations physicians can be. "Doctors are by and large pleasers. They make it through the complex maze of schooling all the way to medical school by figuring out early what people want and providing it." (Lembke 2016 P 104) In this way, physicians tend to go along with patient narratives and over-treat.

156. Conditions resting on entirely subjective assessments like level of pain or gender identity have the most potential for harmful overtreatment. In both cases, patients can easily find out what symptoms to report to obtain the treatment they desire. In the current political climate, physicians feel the pressure to not be assailed as a "gatekeepers", even when logic and data tell them outside social pressures should not distort medical care.

157. Dr. Lembke discusses the modern phenomenon of illness as identity: "Illness identities offer a chance for community." "The adoption of illness identities is driven by the breakdown of traditional social roles. Illness provides a way to define the self in a rapidly changing and increasingly fragmented world. Furthermore, ill persons today are lionized as heroes because they fight a battle against overwhelming physical forces. In a world where the struggle for basic survival (food, clothing, shelter) has become largely irrelevant for most Americans, the ill person is among the last great warriors." (Lemke 2016 P 98)

158. What Lembke points out is critical to the debate regarding gender dysphoria treatments. Community is so important for all of us, but especially

adolescents. There is significant evidence that a lack of socialization, and social struggles are factors which put adolescents at risk for gender dysphoria.

159. Depression and anxiety in adolescents often relate to social struggles and these generally predate the emergence of gender dysphoria. Autism is primarily a social disorder. Many child psychiatrists have expressed to me their experience that patients expressing a transgender or non-binary orientation have tended to struggle socially prior to declaring this orientation.

160. Sweden, England and Finland have all reviewed the evidence and pressed pause. These are countries with medical systems that have better tracking, more organized care and compassionate attitudes toward gender non-conforming persons. As the Finish review stated (PALKO / COHERE Finland 2020): "The first-line treatment for gender dysphoria is psychosocial support and, as necessary, psychotherapy and treatment of possible comorbid psychiatric disorders."

161. After reviews, all countries concluded that restricting care and emphasizing psychotherapy rather than hormones and surgery is the compassionate course. Affirmative treatments are not, in fact, medically necessary. This is true when it comes to the most grave concern of all, suicide. Based on long term data in Sweden, Gender Affirming treatment have not been shown to be life-saving. We do not have convening data that affirmative treatments reduce suicidality, and based on recent data, we should be especially concerned that it could increase it(Chen 2023).

162. When claims are made that there exists a scientific and medical consensus supporting gender affirming care for gender dysphoria, this rests on the assertions of a small group of physicians who are already personally invested in this type of care. Those already providing hormones and surgeries have extremely powerful reasons to want to believe affirmative care is effective, and thus they are biased. I know psychiatrists involved in this type of care and they are smart, compassionate physicians. I have no doubt they have received significant positive feedback from patients and families. This is consistent with multiple studies showing short term benefit in mood and social dysphoria from affirming treatment.

163. Yet when the enthusiasm for affirming procedures is this celebratory, it is also clear that the detransitioners and other patients with less optimal outcomes will not return to these affirmative providers. We need controlled studies because gender clinics staff's personal experience is thus potentially biased toward the good responders they continue to see, without clear tracking of the rest. Short term positives responses can also be explained by placebo effects, especially under the current conditions where most gender clinics offer multidisciplinary teams providing support and therapy along with hormones and medical procedures. 164. For these many reasons the "gender experts" are not neutral observers. This is why long term controlled studies are needed. Just over two decades ago a previous group of "experts" minimized the risks of opiates when they proposed pain as the 5th vital sign. This turned out to be a large scale social disaster instigated in large part by the medical community. When aligned with economic and ideological forces, a small group of physicians can wield disproportionate influence. The modern medical system does make serious mistakes at scale. We should be taking a cautious approach and encouraging rigorous open scholarly dialogue where physicians who doubt the merits of affirmative gender care can speak freely without being attacked as immoral.

165. Gender roles will always exist, as humans are a sexually dimorphic species. Gender roles are not problems to be solved, but we do need to acknowledge the trade-offs. Much of the ideological and political activism is a reaction against a perception that gender roles are too rigid or stifling. Many young people want more ability to express themselves as they please, and it is agreed that we need to create space for all in our society. Yet the recent overall rise in depression, anxiety and self-harm supports that we are not meeting the needs of our youth. Yet in the debate regarding treatments for gender dysphoria, the medical system should still apply rules of evidence and proceed with caution.

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I declare, pursuant to 28 U.S.C. s. 1746, under penalty of perjury that the foregoing is true and correct. Executed this 17th day of February, 2023.

Knitgh E Kaluh MO

Kristopher E. Kaliebe, M.D.

Attachment "A"

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https://www.aacap.org/AACAP/zLatest_News/Floridas_Dont_Say_Gay_or_Trans _Law_Stigmatizes_LGBTQ_Youth_Families.aspx

https://www.aacap.org/AACAP/zLatest_News/AACAP_Statement_Opposing_Act ions_in_Texas.aspx

https://www.aap.org/en/news-room/news-releases/aap/2022/statement-from-theamerican-academy-of-pediatrics-and-the-oklahoma-chapter-of-the-americanacademy-of-pediatrics-on-gender-affirming-care/

https://www.endocrine.org/news-and-advocacy/news-room/2022/endocrinesociety-opposes-florida-department-of-health-policy-on-gender-dysphoriatreatment

Kristopher Kaliebe, M.D.

Publications

Kaliebe, Kristopher and Adrian Sondheimer. "The media: Relationships to psychiatry and children." *Academic Psychiatry* 26.3 (2002): 205-215.

Kaliebe, Kristopher "Rules of thumb: three simple ideas for overcoming the complex problem of childhood obesity." *Journal of the American Academy of Child* & *Adolescent Psychiatry* 53.4 (2014): 385-387.

Kaliebe, Kristopher. "Dr Kaliebe Replies", Journal of the American Academy of Child & Adolescent Psychiatry, (2014) 53:10 1134.

Kaliebe, Kristopher "The Future of Psychiatric Collaboration in Federally Qualified Health Centers." *Psychiatric Services* (2016): appi-ps.

Kaliebe, Kristopher, and Josh Sanderson. "A Proposal for Postmodern Stress Disorder." The American journal of medicine 129.7 (2016): e79.

Osofsky, Howard J., Anthony Speier, Tonya Cross Hansel, John H. Wells II, **Kristopher E. Kaliebe**, and Nicole J. Savage. "Collaborative Health Care and Emerging Trends in a Community-Based Psychiatry Residency Model." *Academic Psychiatry* (2016): 1-8.

Yeh, Y. Y. and **K. Kaliebe**. "Impact of Nutrition on Neurocognition." *Southern medical journal* 109.8 (2016): 454.

K. Kaliebe Expanding Our Reach: Integrating Child and Adolescent Psychiatry Into Primary Care at Federally Qualified Health Centers. J Am Acad Child Adolesc Psychiatry. 56.11 (2017)

Kiss, R. and **Kaliebe, K**., Stress and Inflammation: New Perspectives on Major Depressive Disorder. JAACAP Connect, p.22. Winter 2020

Tamburello, A., Penn, J., Negron-Muñoz, R., & Kaliebe, K. (2023). Prescribing Psychotropic Medications for Justice-Involved Juveniles. Journal of Correctional Health Care.

Books, Textbook Chapters:

Weigle, P., **Kaliebe, K**., Dalope, K., Asamoah, T., & Shafi, R. M. A. (2021). 18 Digital Media Use in Transitional-Age Youth: Challenges and Opportunities. Transition-Age Youth Mental Health Care: Bridging the Gap Between Pediatric and Adult Psychiatric Care, 357.

Invited Publications

"Telepsychiatry in Juvenile Justice Settings", **K Kaliebe**, J Heneghan, T Kim, Child and Adolescent Clinics of North America, 20 (2011) 113-123

American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Telepsychiatry and AACAP Committee on Quality Issues. Clinical Update: Telepsychiatry With Children and Adolescents. J Am Acad Child Adolesc Psychiatry. 2017 Oct; 56(10):875-893. Epub 2017 Jul 25. PMID: 28942810.

Kaliebe, Kristopher and Paul Weigle. "Child Psychiatry in the Age of the Internet." (2017). Child and Adolescent Psychiatric Clinics of North America, April 2018Volume 27, Issue 2, Pages xiii–xv

Gerwin, Roslyn L., **Kristopher Kaliebe**, and Monica Daigle. "The Interplay Between Digital Media Use and Development." Child and Adolescent Psychiatric Clinics 27.2 (2018): 345-355.

CURRICULUM VITAE

Kristopher Edward Kaliebe, MD

Associate Professor University of South Florida, Morsani College of Medicine, Tampa Florida

Address

Psychiatry and Behavioral Neurosciences 3515 E. Fletcher Avenue, MDC 14 Tampa FL 33613 Office: 813974-5460 Cellular: 504782-9070 kkaliebe@usf.edu

Citizenship

United States

Education

Graduate/Medical: St. George's University School of Medicine, Grenada, West Indies	
Medical Doctor	January 1995- June 1999
Undergraduate: Columbia College, Columbia University New York, NY, Bachelor of Arts, Biochemistry	September 1988-May 1992
Postgraduate Training	
Clinical Fellowships: Fellow, Forensic Psychiatry (PGY6) Louisiana State University Medical Center 1542 Tulane Ave., New Orleans, LA 70112	July 2004 to June 2005
Fellow, Child and Adolescent Psychiatry (PGY 4-5) Louisiana State University Medical Center 1542 Tulane Ave., New Orleans, LA 70112	July 2002 to June 2004
Chief Resident in Child and Adolescent PsychiatryActed as liaison between Child Psychiatry Fellows	and Administration

• Coordinated with Program Director lecture and rotation schedules

July 2003 to June 2004

Residency:

Resident, Psychiatry (PGY 2-3) University of Medicine and Dentistry-New Jersey Medical School 185 S Orange Ave, Newark, NJ 07103

July 2000- June 2002

Internship: (PGY 1) University of Medicine and Dentistry-New Jersey Medical School 185 S Orange Ave, Newark, NJ 07103

July 1999- June 2000

Diplomate, American Board of Psychiatry and Neurology:

- Board Certification in General Psychiatry, awarded 2004, active
- Specialty Board Certification Child and Adolescent Psychiatry, awarded 2005, active
- Specialty Board Certification Forensic Psychiatry, awarded 2007, active

Awards, Honors, Honorary Society Memberships:

Department of Veterans Affairs Special Contribution Award for Clinical Service in Psychiatry

February 22, 2002

Outstanding Resident Award, Presented at the American Academy of Child and Adolescent Psychiatry, Miami, Florida,

October 17, 2003

Inducted into Berkeley Preparatory School Athletic Hall of Fame, Tampa, Florida, November 7, 2003

Fellow, Louisiana State University Academy for the Advancement of Educational scholarship

October 2007 - 2016

Best Doctors, Louisiana in the subspecialty of Child and Adolescent Psychiatry Awarded 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015 and 2016

Best Doctors, in Tampa Florida

2017, 2018, 2019, 2020, 2021, 2022

Awarded status as a Distinguished Fellow of the American Academy of Child and Adolescent Psychiatry

July 6, 2016

Appointments:

Associate Professor, University of South Florida Medical School, Department of Psychiatry. September 2016 to present

• Supervise one afternoon weekly of outpatient Child and Adolescent Psychiatry Silver Center Resident Clinic with USF General Psychiatry Residents and Child and Adolescent Psychiatry fellows who performed assessment, consultation, and treatment.

Tampa General Hospital Psychiatrist on DutySeptember 2016 to presentManage the night, weekend and holiday clinical responsibilities of TampaGeneral Hospital including the over 1000 bed hospital and a 24-hour emergency room.Usually done in partnership with a psychiatric resident from the University of SouthFlorida.

Facility Psychiatrist. Tampa Residential Facility September 2016 to present

• Performed psychiatric evaluations and treatment in Florida's juvenile correctional system. Tampa Residential Facility is the most intensive level of mental health and substance abuse treatment, subcontracted to Truecore Solutions.

Facility Psychiatrist. Les Peters Academy Residential Facility

May 2017 to present

• Performed psychiatric evaluations and treatment in Florida's juvenile correctional system, subcontracted to Truecore Solutions.

Staff Psychiatrist, Orleans Parish Justice System March 2018 to July 2018

• Performed telepsychiatric evaluations and treatment in Orleans Parish Prison correctional system, subcontracted to Correct Care Solutions.

Facility Psychiatrist. Charles Britt Academy Residential Facility

November 2019 to July 2022 •Performed psychiatric evaluations and treatment in Florida's juvenile correctional system, subcontracted by Sequel.

Facility Psychiatrist. Columbus Youth Academy Residential Facility

June 2020 to present •Performed psychiatric evaluations and treatment in Florida's juvenile correctional system, subcontracted by Sequel.

Louisiana State University Health Science Center Assistant Professor of Clinical Psychiatry July 2005 to June 2017 Louisiana State University Health Science Center Associate Professor of Clinical Psychiatry July 2016 - 2017

Mental Health Medical Director, St. Charles Community Health Center, Luling, Louisiana July 2005 to 2016

• Evaluated and treated a primarily Medicaid and underserved population of adult, child and adolescent patients in a Federally Qualified Health Care Center.

Coordinator for Child and Adolescent Integrated Mental and Behavioral Health Services, Louisiana Mental and Behavioral Health Capacity Project

September 2012 to July 2017

- Performed assessment, consultation, training, prevention, and education services to Federally Qualified Health Centers and community clinics in Coastal Louisiana.
- Evaluated and treat both on site and using remote video conferencing equipment (telehealth).

Staff Psychiatrist, Back-up coverage, Louisiana Juvenile Justice System July 2016 to September 2022

- Performed psychiatric evaluations and treatment in Louisiana's juvenile correctional system, subcontracted to Wellpath (formerly Correct Care Solutions).
- Back up on call coverage for on-site psychiatrists
- As needed evaluated and treated remote video conferencing equipment (telehealth).

Staff Psychiatrist, Louisiana Juvenile Justice System July 2010 to July 2016

- Performed psychiatric evaluations and treatment in Louisiana's juvenile correctional system, subcontracted to Correct Care Solutions.
- Evaluated and treated both on site and using remote video conferencing equipment (telehealth).

Staff Psychiatrist on Duty

October 2011 to July 2016

Children Hospital, Calhoun Campus. New Orleans, Louisiana

- Facilitated development of protocols and supervision regarding the training of Medical Students, General Psychiatry Residents and Child and Adolescent Psychiatric Fellows who utilize the Calhoun unit as primary training site for Child Psychiatry.
- Manage night and weekend clinical responsibilities for Children's Hospital emergency room and Inpatient Psychiatric Unit, including individually assessing all inpatients each weekend.

Staff Psychiatrist, Louisiana State University Juvenile Justice Program July 2005 to August 2010

- Performed psychiatric evaluations and treatment in Louisiana's juvenile correctional system at Bridge City Center for Youth and Jetson Center for Youth.
- Evaluated and treated both on site and using remote video conferencing equipment (telehealth).

Staff Psychiatrist, Florida Parish Juvenile Detention Center,

July 2007 to August 2010

• Performed psychiatric evaluations and treatment using remote video conferencing equipment (telehealth).

Medical Officer on Duty

New Orleans Adolescent Hospital. New Orleans, Louisiana

• Managed clinical responsibilities of Crisis Intervention Services, a 24-hour emergency mental health response team serving families, children and adolescents from the Southeast Louisiana region.

• Managed two psychiatric inpatient units including a twenty bed adolescent and ten bed children's unit after hours on call.

• On call physician for Crisis Respite, a short term residential facility for children and adolescents located on hospital grounds.

Psychiatrist on Duty

New Orleans Veterans Administration Medical Center, New Orleans, Louisiana

- Managed clinical psychiatric responsibilities of a 450 bed hospital
- Managed clinical psychiatric responsibilities of a 27 bed inpatient psychiatric unit
- Managed clinical psychiatric responsibilities of 24-hour emergency room

Psychiatrist on Duty

New Jersey Medical Center Veterans Administration

• East Orange Medical Center, East Orange, NJ

Managed clinical psychiatric responsibilities of 24 hour emergency room along with a 295 bed hospital, 30 Nursing Home and 30 Domiciliary beds.

• Lyons Hospital, Lyons, NJ

Managed clinical psychiatric responsibilities of 356 bed hospital.

Teaching, Lecture

Undergraduate Medical Student

BMS6920.002, BMS6920.001 University of South Florida: Created five session elective: "Mind Body Medicine" Developed as part of University of South Florida medical school elective curriculum from 2017-current. Offered for up to 12 students as a credited elective including study guide, organizing readings, and experiential class learning. 2017 to present

At Louisiana State University Health Science Center New Orleans:

July 2002 to July 2005

September 2003 to July 2005

September 2001 to June 2002

4 one-hour lectures instructing all Medical Students (MS2) in Child and Adolescent mental health during Psychiatry Basic Science block

February 2004 to February 2016

LSU Physical therapy Annual 2 two-hour lectures on a range of mental health topics annually 2012 to 2016

LSU Public Health Annual 2 hour lecture on psychopharmacology to incoming Masters Level students in Public Health

2012 to 2016

Graduate Medical Teaching

MEL 8602 C65 M: Child and Adolescent Psychiatry

Child and Adolescent Psychiatry Resident Teaching:

Arranged and co-instructed Forensics Lecture Series, bi-annually 10 lecture hours and 4 hours of individual lectures.

2016 to present.

Teach various topics within residency training. 1 lecture per year.

2016 to present.

University of South Florida General Psychiatry Residency:

Co-Produced elective track for 2 residents per year within University of South Florida Psychiatry Residency. Supervision of Integrative Psychiatry residents within the University of South Florida's Integrative Psychiatry Track, biweekly sessions utilizing curriculum from the Andrew Weil Center for Integrative Medicine.

July 2020- present

Forensic Psychiatry Resident Teaching:

Teach child and corrections related forensic topics within residency training. 4 lectures per year.

2018 to present.

LSUHSC New Orleans, General Psychiatry Resident Teaching

• Created and taught one hour weekly (44 weeks per year) Cognitive Behavioral Therapy practicum for PGY 3 residents

2007 to 2016

• One hour lecture on evolution and mood disorder each year for PGY3 residents 2010 to 2016

LSUHSC New Orleans Child and Adolescent Psychiatry Resident Teaching

• One-hour didactic lectures on psychopharmacology for 8 weeks and cognitive behavior therapy for 4 weeks bi-annually

2008-2016

• Organized and taught majority of the year-long bi-weekly one hour didactic program entitled Special Topics including a wide range of topics including development, forensic psychiatry, evolution, anthropology, nutrition, effects of technology, electronic media, sleep, exercise and physical activity, wellness and systems of care.

2008 to 2016

LSU- Kenner Family Practice Residency: Once yearly didactic lectures for 1 to 2 hours for Kenner Family Practice Residents 2009 to 2016

Created one session Mini-Course: "Optimizing Neurocognition through Nutrition." Developed and co-facilitated a module as part of Goldring Center for Culinary Medicine curriculum for medical students and other trainees with Annie Yeh, MD). Offered as a 1 credit elective for Tulane medical students including study guide, organizing readings, online webinar to be viewed prior to class, case studies during class and test. 2014

At Louisiana State University Health Science Center New Orleans: Core Clinical Psychiatry Rotation Lecture, 1 hour lecture presented to MS3 students every six weeks to 3rd year medical students covering Child Psychiatry Basics.

October 2003 to June 2005

At University of Medicine and Dentistry- New Jersey Medical School, Department of Psychiatry

• Lecture: "The Media and Psychiatry" for General Psychiatry Residents, created as part of the Culture and Psychiatry Seminar

August 2001 and 2002

Teaching, Supervisory

At University of South Florida, Tampa Florida:

Medical Student supervision

University of South Florida -MEL 8109 L69 M 2017 to present

BCC 7154 002 M Psychiatry / Neurology Clerkship. Medical Students rotation through clinic one afternoon weekly of outpatient Child and Adolescent Psychiatry Silver Center Resident Clinic

Psychiatry Elective, 2 to 4 week Medical Student rotation through Child and Adolescent Psychiatry Silver Center Resident Clinic

Graduate Medical Education Supervision

Child and Adolescent Psychiatry Residency

Supervise one afternoon weekly of outpatient Child and Adolescent Psychiatry Silver Center Resident Clinic with USF Child and Adolescent Psychiatry residents who performed assessment, consultation, and treatment.

September 2016 to June 2021

Supervise one afternoon weekly of outpatient Child and Adolescent Psychiatry correctional psychiatry with USF Child and Adolescent Psychiatry residents who observe clinical care in juvenile correctional facilities.

September 2016 to present

General Psychiatry Residency:

Supervise one afternoon weekly of outpatient Child and Adolescent Psychiatry Silver Center Resident Clinic with USF General Psychiatry Residents who performed assessment, consultation, and treatment.

September 2016 to present

Forensic Psychiatry Resident Teaching

Supervision of forensic psychiatry trainees within the University of South Florida forensic psychiatry training program. This includes review of resident competency evaluations along with co-evaluation of criminal defendants as individual cases arise. 2018 to present

At Louisiana State University Health Science Center New Orleans

LSU- Kenner Family Practice Residency:

• One month, once weekly half day mental health rotation at St Charles Community Health Center for all Kenner Family Practice Residents

2008 to 2016

Clerkship/Residency Directorship:

Child and Adolescent Psychiatry Fellowship Training Director, Louisiana State University Medical Center. Oversaw and supervised resident physician training Managed administrative, evaluation and scheduling issues within the training program Collaborated with Louisiana State University psychiatric faculty to develop policies and procedures at various clinical site.

July 2010 to September 2012

Teaching Awards:

Association for Academic Psychiatry Honorary Fellow

October 2001- October 2002

Louisiana State University Child and Adolescent Psychiatry Department Outstanding Teacher Award for the 2006-2007 academic year

Louisiana State University Child and Adolescent Psychiatry Department Outstanding Teacher Award for the 2015-2016 academic year

Peer to Peer: Institutional Grand Rounds

"The Minds, They are a Changin' – An Overview and Update on MDMA and Psilocybin Grand Rounds University of South Florida Psychiatry Department, Tampa Florida January 28 2022

"3 Simple Rules for Overcoming Obesity" University of South Florida Endocrinology Department, Tampa Florida

November 9, 2021

"A hard pill to swallow: psychotropic medications in foster care", University of South Florida, Department of Public Health, Tampa Florida

November 3, 2017

"Rules of Thumb: The importance of heuristic and cognitive biases in pediatric physical and mental health" Grand Rounds Children's Hospital, New Orleans July 30, 2014,

Grand Rounds, Louisiana State University Department of Psychiatry, "Rules of Thumb, lifestyle interventions for mental health professionals." New Orleans, Louisiana January 23, 2014

"Just say No, the Case against Stimulant Medication" Grand Rounds Children's Hospital, New Orleans, Louisiana

May 19th, 2010

"Violence: Neurobiology, Risk Assessment and Beyond", Grand Rounds Louisiana State University Department of Psychiatry, New Orleans, Louisiana

August 9, 2012

"Is ADHD a Nutritional Disorder", Grand Rounds Louisiana State University Department of Psychiatry, New Orleans, Louisiana

July 28, 2011

"Just say No, the Case Against Stimulant Medication", Grand Rounds Louisiana State University Department of Psychiatry, New Orleans, Louisiana July 29th, 2010

Grand Rounds Department of Psychiatry, Louisiana State University School of Medicine, New Orleans, Louisiana "The Application of Darwinian Principles to Child Custody Evaluations", New Orleans, Louisiana

May 26th, 2005

"Attention Deficit Hyperactivity Disorder" Grand Rounds Department of Pediatrics, Louisiana State University School of Medicine, New Orleans, Louisiana May 25th, 2005

"The Media, Our New Social World, How Should Pediatricians Respond?" Grand Rounds, Louisiana State University School of Medicine, Children's Hospital, New Orleans, Louisiana

June 2nd, 2004

"Attention Deficit Disorder" for Louisiana State University Health Science Center Juvenile Corrections Program Continuing Medical Education Presentation via telemedicine New Orleans, Louisiana

March 16th, 2004

"The Media, Relationships to Children and Psychiatry", Grand Rounds, Department of Psychiatry, Louisiana State University School of Medicine, New Orleans, Louisiana June 4th, 2003

"The Media, Relationships to Children and Psychiatry", Grand Rounds, New Orleans Adolescent Hospital, New Orleans, Louisiana

March 28th 2003

Lectures by Invitation

"The Media, Relationships to Children and Psychiatry" Grand Rounds, University of West Virginia, Charleston, West Virginia, Department of Psychiatry and Behavioral Science

April 10th 2003

"The Media and Child and Adolescent Psychiatry –An Evolving Relationship" Chair and Presenter, Media Theatre, Annual Conference of the American Academy of Child and Adolescent Psychiatry

October 21st, 2004

"The Media, Our New Social World, How Should Health Care Professionals Respond?" Continuing Medical Education Presentation Snowshoe Mountain Retreat, Snowshoe Mountain, West Virginia

September 19th, 2004

"The Application of Darwinian Principles to Child Custody Evaluations" Grand Rounds Department of Psychiatry, University of South Florida, Tampa, Florida October 31st, 2005

"The Evaluation and Treatment of Traumatized Children and Adolescents with ADHD" Web Cast Presentation and Grand Rounds sponsored by the National Center for Child Traumatic Stress Network's Rural Consortium, New Orleans, Louisiana January 25th, 2007

"Behavioral Disorder or Traumatized Child?" Louisiana Federation of Families for Children's Mental Health, Children's Mental Health Conference, Houma Louisiana May 9th, 2008

"Behavioral Disorder or Traumatized Child?" Grand Rounds Tulane University Department of Child Psychiatry, New Orleans, Louisiana

March 13th, 2009

"Brother's Little Helper: The Simpsons Satirizes Stimulant Medication as a Response to Childhood Behavior Problems" Media Theatre, Annual meeting of the American Academy of Child and Adolescent Psychiatry, New York, New York Kristopher Kaliebe MD, K. Dalope, MD

October 30, 2010

"Violence Risk Assessment" Louisiana Psychiatric Medical Association Annual Meeting, New Orleans, LA

March 2, 2013,

"Telepsychiatry in Juvenile Justice Settings" part of "Telepsychiatry: Challenges and Successes Across Settings." Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Orlando FL October 22, 2013

"What are they Missing, When Electronic Media Displaces Sleep, Academics and Exercise" part of "Identifying and Treating Internet-Related Mental Health Problems: An Evidence-Based Approach" Clinical Perspectives. Annual meeting of the American Academy of Child and Adolescent Psychiatry, Toronto, Canada

October 24, 2014

"The Implications of the Pharmacological Treatment of Children" Michigan Drug Court Annual Conference, Lansing, Michigan

March 12, 2014

"Three rules to prevent and treat ADHD symptoms" as part of the Louisiana ADHD Symposium, organized by the Louisiana Department of Health and Hospitals ADHD Task Force, Baton Rouge, Louisiana

December 9, 2014

"Non-Pharmaceutical Interventions for ADHD", Invited Professorship: St George's University School of Medicine Complementary and Alternative Medicine Selective, St George's, Grenada, West Indies

August 28 – Sept. 3rd, 2014

"Screen Time and Childhood Behavior: Disruptive Influence or Easy Scapegoat" as part of "Caught in the Net, How Electronics effects Mental Illness" Chair and Presenter, Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, San Diego, California

October 30, 2014

"The Management of Childhood Obesity" and "Disordered Eating in Children and Adolescents" Oregon Psychiatric Medical Association Conference, Portland, Oregon February 27 and 28, 2015

"Rules of Thumb: 3 Simple Rules to Optimize Physical and Mental Health" National Alliance for the Mentally III Louisiana Annual Conference, New Orleans, Louisiana April 17, 2015

"ADHD overdiagnosis in Louisiana, a child and adolescent psychiatrist's perspective" Preventing Overdiagnosis Conference, National Institutes of Health (NIH), Bethesda Maryland

September 2, 2015

"An alternative to diagnosis-based practice in pediatric mental health" Preventing Overdiagnosis Conference: National Institutes of Health NIH Bethesda Maryland September 2, 2015

"Shell Shocked: Growing up in the Murder Capital of America". Discussant for Media Theatre, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Holly Peek, MD, Kristopher Kaliebe, MD San Antonio, Texas

October 29, 2015

"Screen Time and Childhood Behavior: Disruptive Influence or Easy Scapegoat" as part of "Caught in the Net, How Electronics effects Mental Illness" Chair and Presenter, Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, San Antonio, Texas

October 31, 2015

"What are they (we) Missing? When Electronic Media Displaces Sleep, Academics, and Exercise" Grand Rounds University of South Florida Psychiatry Department, Tampa Florida

November 12th, 2015

ADHD overdiagnosis in Louisiana, a child and adolescent psychiatrist's perspective, Louisiana Psychological Association, New Orleans, LA

May 20, 2016

"Rules of Thumb: 3 Simple Rules to Optimize Physical and Mental Health" Crohns and Colitis Association of America Regional Conference, New Orleans, LA, June 12, 2016

"Evaluating and Assuring the Effective and Safe Use of Psychotropic Medications in Children" Webinar: National Council of Juvenile and Family Court Judges, with Judge Constance Cohen; Janie Huddleston and Dr. Joy Osofsky, Ph.D.

June 24, 2016,

"Psychotropic Medications 101: What Judges Need to Know for Effective Decision Making" Florida Child Protection Summit, with Melinda Sczepanski, Orlando FL September 9, 2016

"Communicating With the Media and the Public as Child and Adolescent Psychiatrists Around Disaster and Highly Traumatic Events." Workshop, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Media Training Workshop, New York, New York

October 27, 2016

"Evolutionary Biology is a Basic Science for Child and Adolescent Psychiatry" Special Interest Group, Annual meeting of the American Academy of Child and Adolescent Psychiatry, New York, New York

October 28, 2016

"Is War Ever Really Over? War-Affected Youth From Home to Host ountry", Discussant, Clinical Perspectives. Annual meeting of the American Academy of Child and Adolescent Psychiatry, New York, New York

October 28, 2016

"Psychotropic Medications 101: The pertinent essentials for all involved in the child welfare system" Florida Child Protection Summit, with Melinda Sczepanski, Orlando, Florida

August 30, 2017

"Safe Use of Psychotropic Medications in Children." 2017 Safe Babies Court Teams Cross Sites Meeting, Fort Lauderdale, Florida

August 17, 2017

"Health Promotion in Pediatric Mental Health" Discussant, Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Washington, DC October 23, 2017

"New Technologies, New Laws, New Childhood" as part of "Clinical Guidelines for Navigating Media Use" Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Washington, DC

October 24, 2017

"Screen Time and Childhood Behavior: Disruptive Influence or Easy Scapegoat" as part of "Caught in the Net, How Electronics effects Mental Illness" Chair and Presenter, Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Washington, DC

October 26, 2017

"The Business of News, the Role of Child and Adolescent Psychiatrists in the Media, and Risk Communication." Member Services Forum, Annual meeting of the American Academy of Child and Adolescent Psychiatry: Washington, DC

October 27, 2017

"Caught in the net: a child psychiatrist's guide for navigating the internet age.", Workshop, International Association for Child and Adolescent Psychiatry and Allied Professions, Prague, Czechoslovakia

July 27, 2018

Chair, Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, "Caught in the Net: How Digital Media Shapes Mental Illnesses in Youth and How Psychiatrists Should Respond." Seattle, Washington October 24, 2018

"Self-Care in the Child Welfare System" YMCA/Safe Children Coalition Conference, with Catarlyn Glenn, Sarasota Florida

April 18, 2019

"Psychotropic Medications 101: The pertinent essentials for all involved in the child welfare system" Florida Child Protection Summit, with Catarlyn Glenn, Orlando Florida December 17, 2019

"Caught in the Net: How Digital Media Interacts with Mental Illness in Children and Adolescents", Annual Conference of the Florida Psychiatric Society, Tampa, Florida September 21, 2019 "Effective Strategies for Higher Education and Beyond" Clinical Perspectives, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Mastering Information Flow for Transitional-Age Youth (TAY): as part of "Promoting Digital Citizenship in Transitional-Aged Youth (TAY) and College Students", Chicago, IL October 19, 2019

"Caught in the Net: How Digital Media Interacts with Mental Illness", virtually presented at the Andrew Weil Center for Integrative Medicine, Tucson, Arizona April 1, 2020

"A deeper dive into child and adolescent psychopharmacology for families and professionals involved in the child welfare system" Florida Child Protection Summit, with Catarlyn Glenn. Orlando, FL

September 3, 2020

"Screenagers: Next Chapter – How Online Behaviors Affect Depression and Anxiety Disorders in Adolescents", Media Theater (virtual) Annual meeting of the American Academy of Child and Adolescent Psychiatry

October 19, 2020.

"Helping Child Psychiatrists Navigate the Internet Age", "Career Focus: Setup Your Own Telepsychiatry Practice", "COVID-19 Related Psychiatric Issues" Oasis Child and Adolescent Psychiatry Conference, Charleston, SC May 17, 2021

"Conversation about health information, COVID, news, and related topics", discussant and breakout group leader, Digital Media and Mental Health Research Virtual Retreat May 24th 2021

"The Social Dilemma: Helping Families Navigate the Pull, Pulse, and Power of Social Media", Media Theater, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Virtual

October 29, 2021

"Appealing Applications for Adolescent Mental Health: Social Media's Transformation During the COVID-19 Pandemic", Discussant, Clinical Perspective, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Virtual October 25, 2021

"Angry Young Men, Common Threads in Different Types of Extremist Groups" as part of Political Extremism & Hate Group Recruitment of Adolescents", Clinical Perspective, Annual meeting of the American Academy of Child and Adolescent Psychiatry, Virtual October 26, 2021 "Angry Young Men: Boys and Adolescent Males with Disruptive and Aggressive Behavior", "Nutritional Child Psychiatry" Oasis Child and Adolescent Psychiatry Conference, Charleston, SC

May 1^{st /} 2nd, 2022

"Sexts, Lies & Videogames: Adolescent Boys, the Internet, & Mental Health" Chair and presenter on violence and young men: Clinical Perspective, Annual Meeting of the American Academy of Psychiatry Annual Meeting, New Orleans, LA May 25, 2022

Clinical Activities or Innovation

Licensure:

Louisiana State Medical License, expires December 31st, 2022 Florida Medical License, expires January 31st, 2024

Federal DEA Controlled Substances License12/31/2023Louisiana license for Controlled Dangerous Substances expires 10/1/2022Certification: ECFMG Certificate 0-573-532-9

Forensic Training:

Florida Forensic Examiner Training completed through the University of South Florida Department of Mental Health Law and Policy

August 15-17, 2019

Certifications in Psychotherapy:

Basic Practicum in Rational Emotive Behavior Therapy completed at the Albert Ellis Institute in New York, NY

July 13, 2003 Advanced Practicum in Rational Emotive Behavior Therapy completed at the Albert Ellis Institute in New York, NY

July 20, 2003

Associate Fellowship in Rational Emotive Behavior Therapy completed at the Albert Ellis Institute in New York, NY,

July 15, 2005

Accelerated Resolution Therapy, Basic Training

April 1-3, 2017

Accelerated Resolution Therapy, Enhanced Training

Sept 31, October 1, 2018

Accelerated Resolution Therapy, Advanced Training

October 2,3, 2018

American Association of Medical Colleges Medical Education Research Certificate October 13th, 2010

Scholarly Activity

Funded block grants

Co-investigator on the Mental and Behavioral Health Capacity Project from September 2012 to June 2017

Unfunded research

Supervisor mentoring Medical Students:

University of South Florida IRB: Faculty Advisor Co Investigator May 2021

What is the impact of coronavirus confinement on Japanese college students' mental health? Ivana Radosavljevic STUDY002335

University of South Florida IRB: Faculty Advisor Co Investigator May 2021 Changes in college aged students' metabolic health due to Covid-19 confinement Matthew Udine, STUDY002341

PI as student supervisor, STUDY004118, IRB approved as Exempt Status, Palliative Care Patients' Attitudes & Openness to Psilocybin assisted Psychotherapy for Treatment of Existential Distress, Julia Wang

Journal Publications:

Peer Reviewed

Kaliebe, Kristopher and Adrian Sondheimer. "The media: Relationships to psychiatry and children." *Academic Psychiatry* 26.3 (2002): 205-215.

Kaliebe, Kristopher "Rules of thumb: three simple ideas for overcoming the complex problem of childhood obesity." *Journal of the American Academy of Child & Adolescent Psychiatry* 53.4 (2014): 385-387.

Kaliebe, Kristopher. "Dr Kaliebe Replies", Journal of the American Academy of Child & Adolescent Psychiatry, (2014) 53:10 1134.

Kaliebe, Kristopher "The Future of Psychiatric Collaboration in Federally Qualified Health Centers." *Psychiatric Services* (2016): appi-ps.

Kaliebe, Kristopher, and Josh Sanderson. "A Proposal for Postmodern Stress Disorder." The American journal of medicine 129.7 (2016): e79.

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Case Reports, Technical Notes, Letters

Books, Textbook Chapters:

Weigle, P., Kaliebe, K., Dalope, K., Asamoah, T., & Shafi, R. M. A. (2021). 18 Digital Media Use in Transitional-Age Youth: Challenges and Opportunities. Transition-Age Youth Mental Health Care: Bridging the Gap Between Pediatric and Adult Psychiatric Care, 357.

Papers in Press:

Accepted for publication: Prescribing Psychotropic Medications for Justice-Involved Juveniles, Journal of Correctional Health Care, A Tamburello, J Penn, R Negron-Muñoz, **K Kaliebe**

Invited Publications

"Telepsychiatry in Juvenile Justice Settings", **K Kaliebe**, J Heneghan, T Kim, Child and Adolescent Clinics of North America, 20 (2011) 113-123

American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Telepsychiatry and AACAP Committee on Quality Issues. Clinical Update: Telepsychiatry With Children and Adolescents. J Am Acad Child Adolesc Psychiatry. 2017 Oct; 56(10):875-893. Epub 2017 Jul 25. PMID: 28942810.

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Gerwin, Roslyn L., **Kristopher Kaliebe**, and Monica Daigle. "The Interplay Between Digital Media Use and Development." Child and Adolescent Psychiatric Clinics 27.2 (2018): 345-355.

Other Research and Creative Achievements:

Poster Presentations:

"Collaborative Child and Adolescent Psychiatry within Primary Care Clinics in Coastal Louisiana" Poster, Annual meeting of the American Academy of Child and Adolescent Psychiatry, **Kristopher Kaliebe MD**, Joy Osofsky, PhD; Howard Osofsky, MD, PhD; Lucy King, BA; Tonya Hansel, PhD, San Antonio, TX

October 29, 2015

"Benefits of Integrating Young Child Psychiatric Services Into Primary Care Clinics in Underserved Communities" Poster, Annual meeting of the American Academy of Child and Adolescent Psychiatry, New York, NY Joy Osofsky, PhD; Howard Osofsky, MD, PhD; Lucy King, BA; Tonya Hansel, PhD, **Kristopher Kaliebe MD** October 28, 2016

"Integrating child and adolescent psychiatry into community based primary care networks", Poster, International Association for Child and Adolescent Psychiatry and Allied Professions, Prague, Czechoslovakia **Kristopher Kaliebe MD** July 25, 2018

"The Prevalence of the Adverse Childhood Experiences (ACE) in Florida Youth Referred to the Department of Juvenile Justice" Poster, Annual meeting of the American Academy of Psychiatry and the Law, Greg Iannuzzi, MD, Mark Greenwald, PhD, **Kristopher Kaliebe MD**

October 25, 2018

Other articles:

"LSU's *Breakfast Club* emphasizes education and recruitment into Child and Adolescent Psychiatry", American Academy of Child and Adolescent Psychiatry News,

January 2004

"Trix are for Kids!", American Academy of Child and Adolescent Psychiatry News, May, 2013

Expanded Psychiatric Care Can Transform Federally Qualified Health Centers, American Psychiatric Association News,

..... Published online June 17, 2016 News Stories on Suicide, Fictional Content may Increase Risk for Contagion, Hansa Bhargava and **Kristopher Kaliebe**, American Academy of Pediatrics News, *Mastering the Media Column*,

Published online July 10, 2019

Webinars and creation of enduring materials:

 Rules for Optimal Health, Webinar, University of South Florida Quality Parenting

 Initiative, Florida's Center for Child Welfare Information and Training Resources for

 Child Welfare Professionals, released

 December 11, 2017

 Florida's Center for Child Welfare Information and Training Resources, webinars series

 on pediatric mental health for child welfare professionals and caregivers, Kristopher

 Kaliebe with Catarolyn Johnson;

 June 1, 8, 15, 22 and 29, 2020

 "Don't just sit there- Adapt and Optimize in a post Covid world" University of South

 Florida Global Health Conversation Series, presented virtually

 September 22, 2020

Service

Membership in Professional Organizations:

Member, American Academy of Child and Adolescent Psychiatry (AACAP), 2000 to present

AACAP Media Committee member

2003 - 2021

C0-Chair, AACAP Media Committee

2013-2021

Media Committee Liaison to the Complementary and Integrative Medicine Committee of the AACAP

2012 to 2019

Liaison to the Committee on Communications and Media of the American Academy of Pediatrics, from American Academy of Child and Adolescent Psychiatry (AACAP) 2015 to present

Member Association for Behavioral and Cognitive Therapies 2004 – 2016

Member American Academy of Psychiatry and the Law 2004 to present

Member Zero to Three

	2017 to 2021	
Member Louisiana Council for Child Psychiatry (Lo	CCP) 2003 to 2016	
Louisiana Council for Child Psychiatry (LCCP)		
Secretary-Treasurer	March 2010-March 2014	
President	March 2014- June 2016	
Member, American Psychiatric Association	2000 - 2012, 2021 to present	
LSUHSC Psychiatry Interest Group Faculty advisor	2008 to 2012	
University of South Florida Medical School Integra faculty advisor	tive Medicine Student Interest Group January 2020 to present	
University of South Florida Medical School Mindfulness and Meditation in Medicine Group faculty advisor		
University of South Florida Interdisciplinary (university wide) Psychedelics Interest Group faculty advisor March 2022 to present		
Editorial Posts and Activities: Journal editorships, Reviewer	1	
LSUHSC Institutional Review Board alternate revie	ewer 2008-2012	
Safety Committee Member, Accelerated Resolution Therapy for Treatment of Complicated Grief in Senior Adults, University of South Florida		
Expert reviewer for <i>Adolescent Psychiatry</i> Thematic Online: Challenges of Treating the Internet Generat	2017-19 c Special Issue: Coming of Age ion: (2), 4, 2014	
Expert reviewer for Academic Psychiatry Media Co	lumn June 2018	

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Expert Reviewer for Pediatrics	January 2021
Expert reviewer for Academic Psychiatry Media Column	March 2022
Expert Reviewer for Harvard Review of Psychiatry	May 2021

Co-editor: Kaliebe, Kristopher, and Paul Weigle. <u>Youth Internet Habits and Mental</u> <u>Health</u>, An Issue of Child and Adolescent Psychiatric Clinics of North America, E-Book. Vol. 27. No. 2. Elsevier Health Sciences. 2018

Member, Planning Committee for the Digital Media and Mental Health Research Retreat hosted by the nonprofit Children and Screens.

May 24th, 25th 2021.

Revised: October 2022

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

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

REBUTTAL EXPERT REPORT OF QUENTIN VAN METER, M.D.

I, Quentin Van Meter, M.D., declare that the facts contained herein are true and correct to the best of my knowledge and belief, and that the opinions expressed herein represent my own.

Introduction

1. I have been asked by counsel for the Defendants to respond to the expert report of Dr. Johanna Olson-Kennedy.

2. I received my B.A. in Science from the College of William and Mary and my M.D. from the Medical College of Virginia, Virginia Commonwealth University. I am currently a pediatric endocrinologist in private practice in Atlanta, Georgia. I am the President of Van Meter Pediatric Endocrinology, P.C. I am on the clinical faculties of Emory University School of Medicine and Morehouse College of Medicine, in the role of adjunct Associate Professor of Pediatrics. I am board certified in Pediatrics and Pediatric Endocrinology. I have been licensed to practice medicine in Georgia since 1991. I have been previously licensed to practice medicine in California, Louisiana, and Maryland.

3. I did my Pediatric Endocrine fellowship at Johns Hopkins Hospital from 1978-1980. The faculty present at that time had carried on the tradition of excellence established by Lawson Wilkins, M.D. Because of the reputation of the endocrine program as a center for exceptional care for children with disorders of sexual differentiation, I had well-above average exposure to such patients. As a Pediatric Fellow, I was also exposed to adults with Gender Identity Disorder, then called Trans-Sexuality, and received training from John Money, Ph.D., in his Psycho-hormonal Division. Over the past 44 years, I have closely followed the topic of incongruent gender in children, adolescents, and adults, but I am focusing this report on working with children and adolescents.

4. The bases for my opinions expressed in this report are my review of Dr. Olson-Kennedy's report dated February 16, 2023, my professional experience as a pediatric endocrinologist, and my knowledge of the pertinent scientific literature, including those publications listed in the attached bibliography.

5. A list of my publications is included in my curriculum vitae, which is attached as Exhibit "A" hereto.

6. Over the past four years, I have testified at trial and/or deposition in the following cases:

- 2019: Multiple Plaintiffs v. State of Ohio Bureau of Records, Columbus, Ohio, deposed.
- 2020: Loughman v. Loughman, Harris County, Texas, deposed, court testimony.
- 2021: Spahr v. Spahr, St Louis County, Missouri, court testimony.
- 2021: Laura Cauthen v. James Cauthen, Cobb County, Georgia, court testimony.

7. I am being compensated at an hourly rate for actual time devoted, at the rate of \$350 per hour including report drafting, travel, testimony, and consultation. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

Response to Dr. Olson-Kennedy

8. In paragraph 1 on page 8 of her report, Dr. Olson-Kennedy wrongly states that gender identity "has a strong biological basis." To the contrary, there is no biologic basis for gender identity.¹ Genetic markers have been evaluated but there is no statistical significance between genomic sequences in transidentified individuals compared to the sequences of non-trans humans of the same sex.^{2,3} MRI studies on human adults do not show an identifiable female or male brain.⁴ A study purporting to show a female configuration of the brain in trans female patients was marred by the small sample size and inability to reproduce the findings⁵ and the differences reported can be explained by neuroplasticity.⁶

9. The term gender has crept into the vernacular as a replacement for the word sex. Gender originally was a linguistic term describing nouns as either masculine or feminine in a number of languages. It was actually John Money who introduced the term gender identity as the internal sexed self in 1955.⁶ This contradicts this statement in paragraph 1 of Dr. Olson-Kennedy's opinion, suggesting that it was coined by Robert J. Stoller some 9 years later. Dr. Olson-Kennedy states that gender identity and gender are the same, when that is not the case if sex and gender are used interchangeably.

10. Contrary to the suggestion in paragraph 8 of the report, there is absolutely no spectrum to biologic sex. Sex is binary. Individuals with disorders of sexual differentiation are not a third sex.⁸ Mosaicism can occur in varying degrees, but the patient remains either male or female, not both. In my clinical

experience over 42 years of practice, none of my hundreds of DSD patients have experienced any gender identity confusion. The same Endocrine Society whose guidelines say "biologic sex" is a term that should not be used subsequently published a statement that biologic sex is a necessary determinant of human propensity for disease, and that it is necessary to understand the response to therapeutic interventions.⁹

11. In paragraph 10 on page 12 of her report, Dr. Olson-Kennedy refers to the World Professional Association of Transgender Health's (WPATH's) Standards of Care version 8 (SOC 8). However, "SOC 8" are not indeed standards of care, by definition, since there is clearly no consensus of opinion For example, Drs. Kenneth Zucker and Paul McHugh are internationally recognized experts in the field of human sexuality and yet their contrary viewpoints were not discussed or included in "SOC 8".

12. As Dr. Olson-Kennedy notes in paragraphs 11 and 12, the WPATH "SOC 7" served as the template for the recommendations of the Endocrine Society, the Pediatric Endocrine Society, the UCSF guidelines and the position statement of the American Academy of Pediatrics. However, she fails to note that all of the recommendations were essentially the product of authors in leadshipe positions within WPATH. The recommendations are not uniformly supported by members of those other organizations. The American Academy of Pediatrics' 67,000 members were not consulted. The Endocrine Society sent their standards out for comment to membership before approval, but they did not acknowledge the input or make any changes based on our objections. The Pediatric Endocrine Society requested input from membership with a warning that suggestions like those we made to the Endocrine Society would not be considered. The leadership of the American Academy of Pediatrics called to question the wisdom of that organization's 2018 policy statement.¹⁰

13. The vast amount of publications which exist, including the DSM-V¹ and the Handbook of Human Sexuality published by the American Psychological Association indicate gender identity is fluid and can change.¹¹ There are over 11 published studies which clearly prove that desistance occurs in children who have been allowed to proceed uninterrupted through natural puberty ranging 50-98 percent of the time.^{1,12,13,14,15,16,17,18,19,20,21} In-depth mental health evaluation of the patient, the family, and those in close contact with the patient and subsequent counseling to resolve pathology is truly beneficial and most often effective.²²

14. In paragraph 14 on pages 13-14 of her report, Dr. Olson-Kennedy incorrectly suggests that my report attached to the GAPMS determination somehow endorsed what she calls "conversion," "redirection," and "corrective" therapy. Nowhere in my report do I state that I endorse conversion or redirection therapy. Those are her terms, not mine. Instead, I outline the use of extensive in-depth evaluation of the mental health of the patient, parents, and siblings and assessment of the adverse childhood events to which the patient was exposed. The term conversion therapy is used pejoratively to suggest that allowing the patient to examine their underlying mental health issues is somehow converting
a male or female patient, when recommended counseling is indeed just addressing the mental health morbidities to facilitate healing the patient.

15. In paragraph 16 of her report, Dr. Olson-Kennedy expands on a topic never mentioned by me and refers to "people like me" who advocate "redirection" therapy. But my report never mentions "redirection" therapy. She refers to my statement on the recommended use of counseling as unethical and ineffective. In doing so, she refuses to acknowledge the consequential body of literature in peer-reviewed journals which shows the beneficial outcomes that result from counseling.^{22,23,24,25,26} She also stands against her own referenced documents (Endocrine Society Guidelines and WPATH SOC 7) which state that first and foremost, mental health evaluations and counseling must be done before any social, medical, or surgical interventions are considered. The American Academy of Pediatrics' policy statement does clearly state that any kind of counseling is unethical, but it came under fire for that.^{27,28}

16. In paragraph 17 on pages 15-16 of her report, Dr. Olson-Kennedy's version of wait-and-see suggests that once puberty starts, medical intervention follows immediately, whereas wait-and-see has been used by others to describe waiting until *completion* of puberty at the age of consent, since by that time the vast majority of patients have desisted.

17. In paragraphs 18, 19, and 20 on pages 16-18 of her report, Dr. Olson-Kennedyattempts to make her treatment plans sound compassionate and other treatment plans sound barbaric. She is wrong in stating that there is no goal to

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affirm any specific outcome. Why would anyone socially transition a child if their goal were not to follow on with medical, and then surgical transition. The director of the transgender clinic in Columbus, Ohio stated, under oath, that she was unaware of any patients who dropped out from that pathway.²⁹ Dr. Olson-Kennedy's statement that there is no data to support the automaticity of the intervention cascade is true because there is no transparency of full data from any of the transgender care centers. Her theory that social affirmation in pre-pubertal patients does not lead to medical and surgical interventions during puberty is false.¹³

18. Dr. Olson-Kennedy's claim in paragraph 21 on page 18 of her report that treatment is individualized is not substantiated by data from each transgender center, again with a complete lack of transparency.

19. Dr. Olson-Kennedy refuses to recognize that patients with gender dysphoria have undercurrent mental health issues. Patients referred to me with the diagnosis of gender dysphoria have undercurrent depression and/or anxiety that historically preceded the gender dysphoria. The published literature suggests that a conservative estimate for undercurrent mental health issues is 70%. Data are hard to extract because there is no uniformity or transparency to the protocols used in the transgender clinics in the United States. The recent published data from the NIH study clearly point that out. Each of the four study centers had different consent forms and the study design was an observation of the response to interventions at four independent sites.³⁰ This was the explanation used to

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explain why there was no central uniform design or accountability to an Institutional Review Board (IRB).

20. GnRH super-agonists (puberty blockers) interrupt signaling to the gonads and thereby suppress the innate gonadal steroid production. The "Dutch protocol" (cited in paragraph 24 on page 20 of Dr. Olson-Kennedy's report) started pubertal suppression in Tanner stage III (average age 14 years), but never before age 12 (which is the average age of onset of menstruation in females). This intervention is suggested to be used as a "pause" at the very onset of puberty (stage II) by the Endocrine Society Guidelines.¹³ However, the pause in U.S. transgender clinics is often for as little as a month.³¹ Delayed puberty is a reason why adolescents seek endocrine consultation because of the social consequences that surround delay. It is the most common reason we see adolescent boys for evaluation of short stature.

21. In paragraph 24 on page 20 of her report, Dr. Olson-Kennedy refers to the use of GnRH super-agonist therapy in the FDA-approved indication for precocious puberty and cites the safety data and the reversible nature of such treatment. That is comparing apples to oranges. Stopping puberty in the range and then overlapping adolescent age cross-sex hormones in supraphysiologic dosing is a completely different circumstance. It is an openended experiment involving minors with no competent oversight or control. The release of data from Australian and European centers has shown no diminution of gender dysphoria and worsening of mental health, causing their governments

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to intervene and stop such therapy^{32,33,34,35,36,37,38}. As for using age as a criteria for any intervention, the most recent version of guidelines from WPATH ("SOC 8") eliminates use of age as a determinant of when to intervene socially, medically or surgically.³⁹

22. As to paragraphs 25-32 on pages 21-24 of Dr. Olson-Kennedy's report, the "growing body of evidence" of purported benefits of pubertal suppression in regard to the mental health of the adolescents comes from studies of what is called convenience sampling. This describes using survey data obtained by advertising through advocacy sites such as the Trevor Project or the U.S. Transgender Survey to anyone with an interest in the survey subject matter. This inherently biases the nature of the survey participants. People who experienced significant regret or who died as a result of their efforts to transition are not likely to respond. Those who do respond provide answers that cannot be verified. These data bases show potential correlation at best, but prove no direct causation.⁴⁰ Unlike blocking precocious puberty, blocking puberty during the adolescent time frame causes irreversible loss of calcium accretion to the skeleton and affects the development of the brain and the gonads.⁴¹ Without knowing if these latter two issues are reversible if the patient chooses to cease suppression of puberty later on, continued use is, once again, an uncontrolled experiment involving minors who cannot ethically consent. The "dark places of despair" she describes are just buried deeper as a result of the false sense of security. The frontal lobe of the teen brain is unable to see the folly of short term gains that result in long-term losses.³⁸ Blocking puberty does indeed change the landscape: it leads the patients to cross-sex hormones 100% of the time in the Dutch transgender clinics.⁴³ The N.I.C.E. review highlighted a clear lack of scientific proof of any benefit from suppressing natural puberty during adolescence, and the UK banned the general use of puberty blockers due to documented worsening of mental health.⁴⁴

23. Beginning with paragraph 32 on page 24 of her report, Dr. Olson-Kennedy discusses cross-sex hormones. Cross-sex hormones are indeed used to transform the appearance of the body to look like the opposite sex. Again, the fact that 100% of children who have puberty blocked also go on the cross-sex hormones points out clearly that the "case-by-case" assessment is really not that at all. The adolescent cannot really consent to a process that induces life-long medical morbidity, including sterilization. The only full population study that has been published indicated that medical intervention did not reduce mental health morbidity after extended periods of time.⁴⁵ It is clearly not surprising that there is initial euphoria in females treated with testosterone. There is an increase in physical and emotional energy and a sense of reaching a goal as the physical changes begin to occur. But those who detransition are left with these subsequently unwanted and irreversible physical changes. What starts out as euphoric energy can easily turn into extreme anxiety. The clear risk of cancers, strokes, and heart disease among other pathologies, not to mention infertility, is

widely known. An adolescent minor cannot fully understand or consent to the long-term problems caused by seeking short term "gains."

24. The study referenced in paragraph 39 of Dr. Olson-Kennedy's report included two years of data and is flawed by the death of three patients by suicide.³⁰ Any independent review board would have halted the study in its tracks with such serious adverse events as death of study participants, especially with a study population already suffering from depression and anxiety. It is also flawed because regret and detransition is known to occur much later than two years after interventions begin. The only truly valid data from long-term studies comes from the two population studies which showed no improvement in mental health over the long run.^{45,46}

25. Dr. Olson-Kennedy's opinions about surgical intervention in paragraphs 44 to 46 on pages 28-29 of her report are belied the Branstrom and Djheine studies, which clearly demonstrated that when followed for long-enough periods of time, surgical intervention did not improve mental health.^{45,46,47}

26. The "SOC 8" referenced in paragraph 47 on page 30 of her report clearly states that its recommendations are merely guidelines. They are not true standards of care in the legal sense.

27. In paragraph 48 on page 32 of her report, Dr. Olson-Kennedy states that gender-affirming medical interventions are recognized as "medically necessary" by many major medical organizations. However, the guidelines were written by special interest groups within medical organizations, mostly members of WPATH (8 of the 9 authors of the 2017 revision), reflecting the opinion of WPATH and not the whole of the membership of those organizations. Contrary opinions are suppressed or ignored.¹¹ Good science involves evolution of thought which considers all data, not just selected, affirming data.

28. In paragraph 40 on page 27 of her report, Dr. Olson-Kennedy simply dismisses the influence of social media. In my experience, patients were convinced they had gender dysphoria because of the online influence to which they were exposed. A Google search that I performed identified 482,000,000 entries on the subject. Troubled adolescents, struggling for acceptance by peers or for some sense of celebrity have existed forever, but social media now presents them with a one-size-fits-all solution which offers acceptance and celebrity instantly. Before the advent of social media, transgender teens turned to parental support and counseling, which resolved their gender identity confusion 60-98% of the time.²²

29. At least half of my patients were recruited by transgender or nonbinary individuals. There is no published data because, once again, there is no transparency about data collection protocols in the transgender centers in the U.S. The studies Dr. Olson-Kennedy cites to "prove" a biologic basis are limited by small numbers and no ability to prove causation.

30. In paragraph 52 on page 32 of Dr. Olson-Kennedy's report, the actual data reported by Zucker, collected before any exposure to medical or social

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interventions, showed desistance if the patients were followed through completion of puberty.²²

31. In paragraph 54 on pages 33-34 of her report, Dr. Olson-Kennedy attempts to draw a distinction between Gender Identity Disorder and Gender Dysphoria to discredit certain studies cited in the GAPMS report. Like Gender Dysphoria, Gender Identity Disorder was based on mental health morbidity as a key part of the diagnostic criteria. Failing to recognize this, Dr. Olson-Kennedy wrongly suggests that these patients did not suffer from gender dysphoria. The name change was just that—a name change.

32. In paragraphs 57 on pages 34-35 and paragraph 64 on page 38 of Dr. Olson-Kennedy's report, she mentions a subset of patients who do not present until adolescence, but then turns around in paragraph 58 and denies that Dr. Lisa Littman's cohort of studied patients could possibly exist and be called, instead, adolescent-onset patients. In fact, upwards of 80% of children presenting with gender incongruence are female (compared to 30% ten years ago) and that of those, the majority are teenagers with no history of gender incongruence in young childhood. Although she dismisses Littman's 2019 study^{48,49}, the data that Littman collected was not retracted in the accepted revision of her article—the conclusions were the same, but the terminology was revised.

33. In paragraph 65 on page 39 of her report, Dr. Olson-Kennedy explains that the increased incidence of gender incongruence is due to the increased social acceptance from reduction of social stigma. The overwhelming

increase in the number of patients presenting to Tavistock is what caused the NHS to take a deeper look at what caused the rise, and lessening social stigma was clearly shown not to be the cause.⁵⁰ What makes data collection nearly impossible in the U.S. is the utter lack of transparency about what goes on behind closed doors. The magnitude of increase in incidence can only be truly ascertained by opening the files of the transgender treatment centers at which time data can be obtained by independent monitors.

In paragraph 70 on page 42 of her report, Dr. Olson-Kennedy 34. recognizes the need for longitudinal studies, which have been called for by the original and revised version of the Endocrine Society Guidelines.¹³ More importantly, such studies should be rigorous and have a control group. She incorrectly assumes that any random controlled trial is blinded, which clearly is not possible or necessary. She expresses dismay about the probable dropout potential, but does not mention the high dropout rates in the Dutch protocol study which is the foundation upon which transgender clinic protocols are ostensibly built.⁵¹ There has been recent criticism by one of the authors or the Dutch protocol that what he gleaned from having a glimpse inside the U.S. clinics was that his protocol was not actually being followed.⁵² Dismissing the need for a randomized control group based on the theory that patients in the control arm will die from suicide is insupportable, since there is published evidence that counseling alone is highly effective in resolving gender dysphoria.²² It is also obvious that no IRB would even consider allowing a treatment arm in a study that would include reported complications such as sterility and decreased sexual function, let alone increased risk of heart disease, stroke, and cancer.⁵³

35. In response to paragraphs 87-89 on pages 49-50 of Dr. Olson-Kennedy's report, evidence-based medicine is practiced when all sides of a medical issue are researched, and the results graded independently. Evidence-based medicine supports standards of care. It is abused when only some evidence is used, and especially when that evidence is indirect opposition to existing evidence and subsequently published evidence. The GRADE system interprets data to determine the degree to which the recommendations are evidence-based medical practices. The Endocrine Society Guidelines in both iterations failed miserably. SOC7 failed the evidence-based test entirely.⁵⁴

36. Dr. Olson-Kennedy's discussion in paragraphs 91 to 93 on pages 50-51 of her report regarding off-label use of medication compares apples to oranges. There are medications which are used off label because of published studies showing benefit and clear lack of harm, but there is no desire for the manufacturer to apply for FDA approval due to the complexity and cost of doing so, especially when there is no future compensatory return on investment. Puberty blockers were studied for safety and efficacy and their ability to prevent progression of secondary sex characteristics and stall bone maturation in patients with precocious puberty. The drugs passed muster in their ability to do such and were therefore approved by the FDA, with a proviso that the study patients be followed longitudinally indefinitely to monitor for any signals of harm. One such signal was announced recently and has been added to the product insert of puberty blocking medications used for treatment of precocious puberty.⁵⁵ The manufacturers of puberty blockers have not engaged in clinical research studies about the safety and efficacy of puberty blockers in gender incongruent children and adolescents despite the fact that they would profit if these drugs were FDA-approved for such.

37. In response to paragraph 96 on pages 53-54 of Dr. Olson-Kennedy's report, it is a bit self-serving that WPATH recommends multidisciplinary staffing for transgender clinics, all of whom follow its recommended guidelines. It is clear from the history of the Tavistock Clinic that if you do not follow the WPATH protocol or if you call out the harm the WPATH protocol generates, you are not considered to be a part of "the team."⁵⁶

38. In response to paragraphs 99 to 100 on pages 54-55 of Dr. Olson-Kennedy's report, the "growing body of evidence" of purported benefits of pubertal suppression in regard to the mental health of the adolescents comes from studies of convenience sampling involving the retrospective memories of those who chose to answer the surveys. These data bases have been used repeatedly by the authors who cherry pick the recalled memories of participants in an attempt to prove a point. The surveys failed to verify the mental health status of the participants at any point in time by independent examination. They show no direct causation.^{57,58,59,60,61} Heretofore, no reputable editor would accept such studies for publication in peer-reviewed journals. 39. Paragraphs 104 to 105 on pages 56-57 of Dr. Olson-Kennedy's report provide another case of apples vs. oranges: the studies of young people with precocious puberty show full recovery of function after two years off therapy. Dr. Olson-Kennedy mentions not using the puberty blockers for longer than two years, thereby admitting the relentless continuum of puberty blockers followed by cross-sex hormones in the U.S. gender clinics—once again proving the pause theory to be mythical. The precocious puberty patients are not in adolescence, which is when calcium accretion is critical.

40. In response to paragraph 108 on page 59 of Dr. Olson-Kennedy's report, supraphysiologic levels of hormones are always prone to cause severe side effects, regardless of whether the patient is experiencing gender dysphoria or not. That proves that they are never appropriate.

41. In response to paragraph 112 on page 60 of her report, Dr. Olson-Kennedy completely ignores the phenomenal published experience of Kenneth Zucker's behavioral interventions because they do not fit the narrative reflected in her report. In fact, desistance has been documented with behavioral health interventions in Canada and Europe since the 1980s. ^{1,12,13,14,15,16,17,18,19,20,21}

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

Executed this 10th day of March 2023.

/s/ Quentin Van Meter Quentin Van Meter, M.D.

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- 5. Gooren, L. (2021). Interview. In A. Bakker (Ed.), The Dutch approach: Fifty years of transgender health care at the VU Amsterdam gender clinic. Los Angeles, CA: Boom.
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Exhibit A

QUENTIN L. VAN METER, M.D.	
1800 Howell Mill Road NW, Suite 475	
Atlanta, Georgia 30318	

updated 5 March, 2023

Atlanta, Georgia 30318	(678) 961-2100	
PERSONAL		
Home Address:	26 Paces West Drive NW, Atlanta GA 30327	
Home Phone:	(404) 963-5618	
Date of Birth:	September 13, 1947	
Place of Birth:	Laramie, Wyoming	
Citizenship:	USA	
EDUCATION.		
EDUCATION:		
Undergraduate:	College of William & Mary, 1969 B.S. – 1969	
Medical School:	Medical College of Virginia, 1973 M.D. – 1973	
CLINICAL TRAINING:		
Institution: Hospital: Position:	The University of California, San Francisco Naval Regional Medical Center, Oakland Pediatric Intern – 1973 – 1974 Pediatric Resident – 1974 – 1976	
Institution: Hospital: Position:	Johns Hopkins University Johns Hopkins Hospital Fellow, Pediatric Endocrinology 1978 – 1980 Fellowship Program Director: Claude Migeon, M.D.	
Current Position:	Pediatric Endocrinologist Van Meter Pediatric Endocrinology, P.C. 1800 Howell Mill Road, Suite 475 Atlanta, Georgia 30318	

PROFESSIONAL CERTIFICATION & SOCIETIES:

Diplomate, National Board of Medical Examiners, 1974

American Board of Pediatrics, certified in general pediatrics, 1978, sub-board certified in Pediatric Endocrinology, 1983

Fellow:	American Academy of Pediatrics, Georgia Chapter 1975 -present President, Uniformed Services West Chapter, 1987 – 1990 District VIII member, AAP Committee on Awards for Excellence in Research, 1990-1994 Editor, <u>The Georgia Pediatrician</u> , 1994 – 1998
	Chairman, Georgia Chapter Legislative Committee, 1996 – 2006
Fellow:	The American College of Pediatricians, 2007 – present Member of the Board of Directors, 2008- present Immediate Past President
Member:	Pediatric Endocrine Society, 1989 – present
Member:	American Diabetes Association Professional Section, 1988 – present
Member:	Endocrine Society, 1994-present
Member:	Southern Pediatric Endocrine Society, 1992 - Present
Member:	American Association of Clinical Endocrinologists, 2005 – 2022
Licensure:	Georgia, #34734

FACULTY POSITIONS:

Institution:	Morehouse School of Medicine
Position:	Associate Clinical Professor, Pediatrics, 2004 – present
Institution:	Emory University School of Medicine
Position:	Adjunct Associate Professor, Pediatrics, 1991 – 2020
Institution:	University of California, San Francisco
Position:	Associate Clinical Professor, Pediatrics, 1989 – 1991
Institution:	University of California, San Diego, School of Medicine
Position:	Assistant Clinical Professor, Pediatrics, 1980 – 1986
Institution:	LSU School of Medicine, Clinical Instructor, Pediatrics, 1977 – 1978

MILITARY SERVICE:

Commission: Rank: Duty Stations:	Medical Corps, United States Navy, August 1971 Captain, retired Health Professional Scholarship Student, 1971 – 1974
	Intern and Resident, Pediatrics, Naval Regional Medical Center, Oakland, 1973 – 1976
	Staff Pediatrician, Naval Regional Medical Center, Oakland, 1976

Quentin L. Van Meter, M.D.

Staff Pediatrician, Naval Regional Medical Center, New Orleans, 1976 – 1978

Full time out-service fellow in Pediatric Endocrinology, Johns Hopkins Hospital, 1978 - 1980

Staff Pediatric Endocrinologist, Naval Hospital San Diego, 1980 - 1986

Chairman and Director, Residency Training, Department of Pediatrics Naval Hospital Oakland, 1986 – 1991

OTHER PROFESSIONAL ACTIVITIES:

Consultant, Pediatric Endocrinology, Nellis Air Force Base Hospital, Las Vegas, Nevada 1981 - 1991

Consultant, Pediatric Endocrinology, Naval Hospital Lemoore, CA 1986 – 1991

Consultant, Pediatric Endocrinology, Letterman Army Medical Center, Presidio of San Francisco, CA 1990 - 1991

Consulting Endocrinologist, Columbus Regional Medical Center, Columbus, GA 1991 - 1994

Pediatrician and Pediatric Endocrinologist, partner Fayette Medical Clinic Peachtree City, Georgia 30269 September 1991 – October 2003

Speaker's Bureau Novo Nordisk **Eton Pharamceuticals** AAP Eqipp course on Growth- development committee- 2012

PUBLICATIONS: (Articles in Peer Reviewed Journals)

Riddick, JR, Flora R., Van Meter, QL: "Computerized Preparation of Two-Way Analysis of Variance Control Charts for Clinical Chemistry," <u>Clinical Chemistry</u>, 18:250, March 1972.

Van Meter, QL, Gareis FJ, Hayes, JW, Wilson, CB: "Galactorrhea in a 12 Year Old Boy with Chromophobe Adenoma," J. Pediatrics 90:756, May 1977.

Plotnick, LP, Van Meter, QL, Kowarski, AA, "Human Growth Hormone Treatment of Children with Growth Failure and Normal Growth Hormone Levels by Immunoassay: Lack of Correlation with Somatomedin Generation: <u>Pediatrics</u> 71:324, March 1983.

Brawley, RW, Van Meter, QL, "Mebendazole Ascaris Migration," <u>W.J.</u> <u>Med</u>, 145:514015, October 1986.

Van Meter, QL, "The Role of the Primary Care Physician in Caring for Patients with Type-1 Diabetes," <u>Comp Ther</u> 1998; 24(2):93–101

Midyett LK, Rogol AD, Van Meter QL, Frane J, and Bright GM, "Recombinant Insulin-Like Growth factor (IGF)-I Treatment in Short Children with Low IGF-I Levels: First-Year Results from a Randomized Clinical Trial," <u>J Clin Endocrinol Metab</u>, 2010;95:611–619.

Laidlaw MK, Van Meter QL, Hruz PW, Von Mol A, and Malone WJ, Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," J CLin Endo Metab 2019;104: 1-2.

Van Meter QL, Bringing Transparency to the Treatment of Transgender Persons, Issues in Law and Medicine 2019:34;147-152.

Laidlaw, MK Von Mol A,Van Meter Q, and Hansen JE, Letter to the Editor from Laidlaw et al: "erythrocytoisis in a large cohort of thansgender Men using testosterone: a long-term follow-up study on prevalence, determinants, and exposure years" J Clin Endocrinol Metab, 2021 December 2021, e5275-35276 <u>Https://doi/10.1210/clinem/dg</u> ab514

ABSTRACTS/LETTERS:

Van Meter, Q L, & Lee, PA: "Evaluation of Puberty in Male and Female Patients with Noonan Syndrome," <u>Pediatric Research</u> 14:485, 1980.

Van Meter, QL, et al: "Characterization of Pituitary Function in Double Bolus GnRH Infusion as a Diagnostic Tool," <u>Pediatric Research</u> 32:111, 1984.

Van Meter, QL, Felix, SD, Lin, FL: "Evaluation of the Pituitary-Adrenal Axis in Patients Treated with nasal Beclomethasone," (Presented at the 1991 Annual Meeting of the Endocrine Society and the 6th Annual Naval Academic Research Competition, Bethesda, MD, 17 May, 1991).

Rogol AD Midyett LK Van Meter Q, Frane J, Baily J, and Bright GM, Recombinant Human IGF-1 for Children with Primary IGF-1 Deficiency (IGFD): Safety Data from Ongoing Clinical Trials (presented at the PAS 2007, Toronto).

Van Meter Q, Midyett LK, Deeb L et al, Prevalence of primary IGFD among untreated children with short stature in a prospective, multicenter study (Poster POO715) ICE Rio de Janeiro, Brazil 2008.

G.M. Bright¹, W.V.Moore², J.Nguyen³, G. Kletter⁴, B. S. Miller⁵, Q. L. Van Meter⁶, E. Humphriss¹, J.A. Moore⁷ and J.L. Cleland¹ Results of a Phase 1b Study of a new long-acting human growth hormone (VRS-317) in pediatric growth hormone deficiency (PGHD). PAS 2014 May 2014

Van Meter Q, Welstead B and Low J, Characteristics of a Population of Obese Children and Adolescents: Suggesting a New Paradigm, presented at ESPE meeting, Dublin 2014.

Wayne V. Moore¹, Patricia Y. Fechner², Huong Jil Nguyen³, Quentin L. Van Meter⁴, John S. Fuqua⁵, Bradley S. Miller⁶, David Ng⁷, Eric Humphriss⁸, R. W. Charlton⁸, George M. Bright⁸, Safety and Efficacy of Somavaratan (VRS-317), a Long-Acting rhGH, in Children with Growth Hormone Deficiency (GHD): 3-Year Update of the VERTICAL & VISTA Trials, presented at the 2017 Endocrine Society meeting in Orlando FL

Bradley S. Miller¹, Wayne V. Moore², Patricia Y. Fechner³, Huong Jil Nguyen⁴, Quentin L. Van Meter⁵, John S. Fuqua⁶, David Ng⁷, Eric Humphriss⁸, R. W. Charlton⁸, George M. Bright⁸, 3-Year Update of the Phase 2a and Long-term Safety Studies (VERTICAL and VISTA) of Somavaratan (VRS-317), a Long-acting rhGH for the Treatment of Pediatric Growth Hormone Deficiency, presented at the 2017 IMPE meeting in Washington D.C.

ADDITIONAL PRESENTATIONS/LECTURES:

Pediatrics Update, CME Associates, San Diego – Orlando Annual Conferences: Lectures on Pediatric Endocrine Subjects – 1986 – 2001. Course Moderator, 1997, 1998, 1999, 2000, 2001

Endocrine and Gastroenterology Update, CME Associates, Maui HI Nov 2001, Lecturer and Course Moderator

Lecture on Panhypopitutarism, Pharmacia Conference, Nashville TN April 2002.

Family Medicine Review Course, Orlando, FL, 1992 - 2001

Pediatric Grand Rounds, Tanner Medical Center, October 1997

Pediatric Grand Rounds, Hughes Spaulding Children's Hospital, September, 2003

Pediatrics in the Park, Fall CME meeting for the Georgia Chapter of the American Academy of Pediatrics, November 2003

Pediatric Grand Rounds, Columbus Regional Medical Center, January 2004

Frontiers in Pediatrics CME Course, sponsored by the Atlanta Children's Health Network, Atlanta, March 2004.

Pediatric Grand Rounds, Eggleston Children's Hospital, May 2004.

Sue Schley Matthews Pediatric Conference, Columbus Regional Medical Center, September 2004

56th Annual Scientific Assembly and Exhibition of the Georgia Academy of Family Physicians, Nov 2004

Program Co-Chairman: Southern Pediatric Endocrine Society Annual meeting, Nov 2004, November 2014

Presentations on Diabetes, Growth Failure, and Thyroid Disease to the Postgraduate Pediatric Nurse Practitioner Program, Georgia State University, Nov 2005, June 2006, May 2007

Issues in Medicine, US Medical Congress Conference and Exhibition, Las Vegas, meeting planner and speaker, June, 2006

CME Presentations for the Georgia Chapter of the American Academy of Pediatrics Spring and Fall Meetings 2004-present

Pediatric Grand Rounds, Columbus Regional Medical Center, Columbus, GA, 2011-present

Human Growth Foundation Regional CME Conference, Atlanta GA March 2013, February 2014 Columbus Georgia

International Federation of Therapeutic Counseling Choice: Transgender Medicine, IFTCC Launch, October 15, 2018 London, Third International Congress, October 25 2018 Budapest.

Southern Pediatric Endocrine Society, Orlando FL, Feb 2019

Matthew Bulfin Conference, Indianapolis IN April 2019

CMDA annual conference, Ridgecrest NC, May 2019

Support 4 Family conference, London, UK June 2019

Audio Digest Pediatrics - ① v. 41, no. 4; ② v. 41, no. 20; ③ v. 43, no. 17

Audio Digest Family Practice - ① v. 42, no. 5; ② v. 44, no. 11; ③ v. 44, no. 44; ④ v. 45, no 15

Audio Digest Otolaryngology - ① v. 32, no. 14

CURRENT HOSPITAL APPOINTMENTS:

Eggleston/Scottish Rite Children's Hospitals, active staff, Pediatric Endocrinology

PAST AND CURRENT CLINICAL RESEARCH:

2006	Sanofi-Aventis	
	HMR1964D/3001	study completed 2007
2006	Tercica MS301-	study completed 2008
2007	Tercica MS310-	study completed 2008
2007	Tercica MS306-	study completed 2010
2007	Tercica MS316-	study completed 2012
2008	EMD Serono 28358	study completed 2009
2012	Versartis 12VR2	study completed 2014
2012	Debiopharm 8206-CPP-301	study started July 2012
2013	Versartis 13 VR3	study started Dec 2013
2014	Novo-Nordisk Elipse	study started 2014
2015	Versartis 14 VR4	study completed 2017
2017	Mannkind MKC-TI-155	study completed 2019
2018	Abbvie M16-904	study started 2018
2019	Novo-Nordisk Real-4	study started 2019
2019	Lilly 18B-MC-ITSB	study started 2019
2021	Pfizer PROGRES	study started 2021

2021	Lumos OragrowtH210	study started July 2021
2022	Novo-Nordisk Real-8	study started July 2022

LEGAL EXPERT WITNESS:

- 2017 North Carolina Legislature- transgender bathroom bill
- 2018 Jessica Siefert transgender case, Cincinnati, OH
- 2018 Alberta, Canada school system transgender case
- 2018 Decatur GA School Board transgender case
- 2019 British Columbia transgender case
- 2019 Gavin Grimm transgender case, Gloucester County, VA
- 2019 Rowe vs Isle of Wight School Board, UK
- 2019 Younger transgender case, Dallas, TX
- 2020 Alabama State House and Senate committee hearings
- 2020 Pennsylvania State House Health Subcommittee hearings
- 2020 Iowa State House committee hearing
- 2020 California State House committee hearing
- 2020 Harris County TX custody case
- 2021 Missouri State House committee hearing
- 2021 NAACP *v* State of Arkansas
- 2022 Seifert Civil Suit affidavit
- 2022 development of Florida GAPMS
- 2022 testimony before Florida State Medical Board
- 2023 testimony before Idaho legislative hearing
- 2023 testimony prepared for Kansas state legislative hearing

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF FLORIDA TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

/

EXPERT REPORT OF SOPHIE SCOTT, PH.D.

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

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

2. I have testified as an expert witness in the following cases, at trial or in deposition in the last four years: Bell v Mrs A vs Tavistock and Portman Trust, Case No: CO/60/2020, December 2020.

3. I am being compensated at an hourly rate for actual time devoted, at the rate of \$400 per hour including report drafting, testimony, and consultation. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

4. The opinions expressed in this report are based on my training and experience as a neuroscientist, my reading and my assessment of the relevant neuroscientific literature on brain development, and the potential effects of gonadotropin-releasing hormone (GnRH) agonists (the most common form of what are often called puberty blockers) on the developing brain.

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

2

Introduction

6. I am the Director of University College London's (UCL's) Institute of Cognitive Neuroscience. I have published over 130 peer reviewed scientific papers, including papers in Nature, Science, and the Proceedings of the Academy of Natural Sciences. I am a fellow of the Academy of Medical Sciences, and of the British Academy. Since my PhD was awarded in 1994, I have been working in cognitive neuroscience, a scientific field that examines the relationships between human behaviour to the human brain, and how these can be affected by age, disease and individual differences. *See* Attached Curriculum Vitae.

7. As a neuroscientist I am very familiar with the existence of variations of sexual preference, and the existence of variations in gender identity. I think that the anecdotal evidence we have suggests that transition may, for some younger people, be an effective treatment for gender dysphoria, and that the medical approaches taken to achieve this may therefore be appropriate. Thus is it entirely possible that the use of puberty blockers is appropriate in some exceptional cases of gender dysphoria in prepubescent and adolescent individuals. My concern is that we do not yet have enough evidence about the best ways to identify the individuals for whom they are appropriate: we have not identified any biological markers or other characteristics to identify individuals for whom GnRH antagonists might provide effective; we do not have any reliable studies that show which young gender dysphoric individuals will remain gender dysphoric after adolescence; and we thus do not yet know who might benefit from

this highly medicalised and largely non-reversible treatment. I am also very concerned that the implications of the effects of puberty blockers on the developing brain and body are not well understood. In both of these areas much more research is needed.

8. All cultures recognise the onset of adolescence as the start of the entry into the adult world: it is a journey into that world, and a journey that takes place over several years. In 2005 the US supreme court, influenced partly by this emerging neuroscience research, increased the minimum age for capital punishment to be the same as that for voting and serving on juries. Around the world, many such limitations on the responsibility for teenagers for their own actions are in place - alongside laws which mean that teenagers could not engaging in risky behaviours that could place them or others at risk or having to live with long terms consequences (e.g. ages for driving, drinking alcohol, age of consent, getting a tattoo). Much of this reflects a lay understanding of what neuroscience is now confirming - there is variation from child to child, but teenage brains on the whole are structurally and functionally different from adult brains, and this affects both their engaging with risky behaviour, and their understanding of the implications of risky behaviour.

9. The human brain is formed of approximately 89 billion brain cells, or neurones, most of which are grown during gestation (Bayer et al. 1993; Rakic 1995). Following birth, there is a further period of extended brain development. Directly after birth, the brain grows rapidly, quadrupling in size

4

between birth and age 6, when it is roughly 90% the size of an adult brain. However the pattern of growth is underpinned by some complex changes that are occurring. These are:

- Synaptic pruning
- Myelination of different brain networks
- Differential growth of specific functional and anatomical areas.

Before I go into this in detail it's important to note that brain cells, 10. or neurones, are formed of a cell body, with a long projection (an axon) and branch-like shorter projections (dendrites) from the cell body or from the far end of the axon. The axons can be thought of as ways the neurone can connect to more distant neurones, while the dendrites connect to nearby neurones. These connections are called synapses. Changes in the brain – associated with learning and development - occur largely through the connections between neurones, which can be through the strengthening of existing connections, or through the development of new dendritic connections. The axons are coated in a slim fatty sheath, called myelin: this enables the electrical discharges that enable transfer of information in the brain to be propagated rapidly along the length of the axon. Myelination is a process that increases the speed and efficiently of neural function. Neurones are highly organised in the brain, with the cell bodies forming structure layers on the surface of the brain (the cortex), as well as in sub cortical nuclei of cell bodies: the axons form tracts of connections between cortical areas, to and from sub cortical areas, and between the two hemispheres of the brain.

These tracts look white, due to the fatty myelin sheaths: this leads to the name 'white matter' for these tracts or connective networks. In contrast, the unmyelinated neuronal cell bodies look grey, hence the term 'grey matter'.

11. At birth and in early infancy, many dendritic connections exist and are created between neurones: this is known as *synaptic exuberance*. In the early years of life these are rapidly pruned, at first quickly, then more slowly. During adolescence a more adult profile of synaptic connections starts to appear: this appears most slowly in prefrontal fields compared to sensory and is still not established fully at age 18yrs (Huttenlocher and Dabholkar, 1997). The relationship between synaptic exuberance and pruning and their implications for the developing brain and experience are still being explored, but in terms of brain connectivity, the adult pattern is not yet established at 18: development continues into the early 20s.

12. Myelination in the human brain begins in visual brain areas a couple of months before birth and continues in other sensory brain areas over the first year. This process continues in other cortical and subcortical systems into the middle of the third decade. This has been expressly linked to the development of cognitive skills in children and adolescents, as myelination greatly improves the speed of condition of neurones, and hence their efficiency. Myelination proceeds in a roughly caudal to rostral direction in the brain, which means form back to front. This means that it is frontal and prefrontal fields that are those continuing to be myelinated into the mid 20s: this has been confirmed by more recent studies

looking at fractional anisotopy in the brain (Lebel et al., 2008). At 18yrs old, the connections to the frontal lobes are not myelinated like a mature adult brain, and this is likely to affect frontal lobe functions.

13. Throughout childhood, the brain grows and changes: this involves a non-linear pattern of change in the proportion of white and grey matter, which may partly involve changes in myelination (see above) and also the loss of cells through cell death (Sowell et al. 2004). A recent study looking at this pattern into adolescence found that "First, we found evidence for continued development of both intracranial volume (ICV) and whole brain volume (WBV) through adolescence, albeit following distinct trajectories. Second, our results indicate that CGMV is at its highest in childhood, decreasing steadily through the second decade with deceleration in the third decade, while CWMV increases until midto-late adolescence before decelerating" (Mills et al, 2016). This indicates that considerable changes are still happening in the structure of the adolescent brain. In terms of specific brain areas, while the cortex continues to thin through adolescence, the decreases are most marked in the parietal lobes and least marked (or growth is seen) in temporal and prefrontal fields (Tamnes et al, 2017).

Implications

14. The pattern of maturation of the brain in adolescence suggests a particular issue with frontal lobe functions – the frontal and temporal lobes are showing a different pattern of change (in terms of movement towards adult profiles) compared to more caudal fields, and the frontal lobes are the last to be

fully myelinated. The frontal lobes are associated with complex cognitive control processes, so called 'meta-cognitive processes' that enable us to plan our behaviour, control our responses, to be able to adapt our behaviour to different contexts and requirements, and to anticipate the implications and consequences of behaviour. The absence of mature frontal lobe connectivity and functions has been linked to increased impulsivity and risk-taking in adolescence, and to their greater susceptibility to peer opinions and behaviour (Blakemore and Robbins, Nature Neuroscience, 2012). Functional imaging studies – addressing how brains function under different task requirement – have shown that while adults recruit frontal lobe networks during decision making tasks, teenagers are more likely to recruit 'limbic networks" i.e. sub cortical networks linked more to emotional processing and reward processing: the implication is that the differential integrity of frontal lobe connectivity leads to teenagers making different, more risky decisions than adults, and relying on different brain networks to do so. This is backed up by behavioural studies showing that when decision making is 'hot' (i.e. more emotional), under 18yr olds make less rational decisions than when the responses are being made in a colder, less emotional context.

15. Puberty blockers (specifically, gonadotrophin-releasing hormone agonists) work by preventing the release of gonadotrophin-releasing hormone from the hypothalamus. Gonadotrophin releasing hormones have many effects, including stimulating the gonads (testes and ovaries) to produce testosterone and oestrogen. In childhood, the level of Gonadotrophin releasing hormones is very

low, but an increase in this prompts the onset of puberty, with the release of testosterone and oestrogen; these in turn have masculinising or feminising effects on the bodies and the brain. As puberty is associated with very marked changes in the structure of the brain (as outlined above) the use of puberty blockers may have serious consequences for the development of the human brain. We know from studies on sheep (Nuruddin et al, 2013) that treatment around the onset of puberty with gonadotrophin-releasing hormone agonists is associated with significant differences in the size of the amygdala (found to be larger in treated animals) and this was linked to some differences in emotional reactions. The male treated sheep showed greater approach responses and more risk taking behaviours, while the treated female sheep showed higher levels of anxiety and greater avoidance behaviour (Wojniusz et al, 2011). A behavioural study of natal girls who were treated for precocious (early) puberty with Gonadotrophin releasing hormone agonists (Wojniusz 2016) found that they also showed significant greater emotional reactivity on one of the tests used, relative to the control group. The treated girls also showed significantly lower heart rates than the untreated control group. In a commentary on this article (Hayes, 2017) it was pointed out that there were also notably lower scores on IQ measures and sub scales in the group of girls who were treated with Gonadotrophin releasing hormone agonists. He points out that "their reassuring statement in the abstract that girls undergoing GnRHa treatment for CPP and controls "showed very similar scores with regard to cognitive performance" and their conclusion that
"GnRHa treated girls do not differ in their cognitive functioning ... from the same age peers" (Wojniusz et al., 2016) may be overly optimistic. These statements minimize the fairly substantial difference found in IQ scores" (Hayes, 2017). Hayes also points to an older study that found a significant drop in IQ associated with taking triptorelin acetate to treat precocious puberty (Mul et al, 2001). Note that in all of these cases, in humans and other mammals, we cannot say if the results are due to direct effects of the Gonadotrophin releasing hormones on the brain, heart and behaviour, or if they are secondary to this (e.g. due to the altered levels of testosterone or oestrogen, or changes in the heart rate itself). All the papers I can find suggest that we need much more data on the long-term brain effects of Gonadotrophin releasing hormones when administered around puberty, the effects this can have on behaviour, and the extent to which any of this is altered if the treatment with Gonadotrophin releasing hormones is stopped.

16. I am very concerned that the current treatment regime is exposing young people to significant risk of harm. The greater susceptibility to peer pressure in those under 18 may make them especially vulnerable to risk taking, and this may well be enhanced by social media, where actions can be encouraged without any responsibility for outcomes. We need more research to be able to determine the potential for puberty blockers to be effective in alleviating some aspects of gender dysphoria, and to be able to differentiate those who might be helped by this treatment from those who will not. Furthermore, given the risks of puberty blocking treatment, and the fact that these will have irreversible, lifelong effects, it is very possible for an adolescent to be unable to fully grasp the implications of puberty-blocking treatment, even if the risks are well explained. All the evidence we have suggests that the complex, emotionally charged decisions required to engage with this treatment are not yet acquired as a skill at this age, both in terms of brain maturation and in terms of behaviour.

I declare, pursuant to 28 USC § 1746, under penalty of perjury that the foregoing is true and correct. Executed on February 16th, 2023.

/s/ Sophie Scott Sophie Scott, Ph.D. Exhibit "A"

PROF SOPHIE KERTTU SCOTT CBE, FMEDSCI, FBA

Date of Birth: 16-11-1966

Address: Institute of Cognitive Neuroscience, UCL, 17 Queen Square, London, WC1N 3AR

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CURRENT POSITION

2019 – Director, Institute of Cognitive Neuroscience, University College London

EDUCATION/QUALIFICATIONS

1994 University College London, PhD in Cognitive Science 1990 Polytechnic of Central London, BSc (Hons) 2:1, Psychology

PROFESSIONAL HISTORY

1993-1998 MRC Applied Psychology Unit, Cambridge, Senior Scientific Officer

1998-2001 Research Fellow, Institute of Cognitive Neuroscience, UCL.
2001-2005 Wellcome Career Development Fellow, Dept. Psychology, UCL
2004 - Group Leader, Speech Communication Lab
2006- Professor of Cognitive Neuroscience, UCL
2005-2016 Wellcome Trust Senior Fellow, Institute of Cognitive

Neuroscience

2013-2019Deputy Director, Institute of Cognitive Neuroscience, UCL 2019 – Director, Institute of Cognitive Neuroscience, University College London

I took maternity leave between June 2006-June 2007.

PRIZES AND RECOGNITION

2022 Awarded an Honorary degree by the University of Westminster

2021 awarded the Michael Faraday prize by the Royal Society

2020 appointed Commander of the Most Excellent Order of the British Empire for services to Neuroscience

2019 Royal Literature Society "Reading Matters" prize, for "The Neuromantics", my podcast with poet and writer Dr Will Eaves

2017 presented the Royal Institution Christmas Lectures

2017 Royal Society Summer Science Exhibition, "What's in a Voice?"

2016 elected as a Fellow of the British Academy

2016-2018 UCL TEDx License holder

2015 spoke at the annual TED conference, Vancouver (talk has been viewed over 4.4 million times on TED.com).

2015 gave Prize Lecture at the Physiology Society meeting, Cardiff.

2014 included in Who's Who

2013 won UCL Provosts' Award for Public Engagement (grade 8 and above category).

2012 Royal Society Summer Science Exhibition, "LOL: Science and Art of Laughter"

2012 Elected as Fellow of the Academy of Medical Sciences

2003 Royal Society Summer Science Exhibition, "Science of Speaking"

SUPERVISION OF GRADUATE STUDENTS

Since 2002, 14 PhD students supervised at UCL, and 35 MSc students at UCL, 2 at City University and one at the University of Reading

EDITORIAL WORK

2015 – associate editor for *The Psychologist* (British Psychological Society monthly journal).

2009 – 2014 Editorial Board of Cognitive Neuroscience

2010 – 2013 Section Editor, Language, Neuropsychologia

2008 – 2015 Associate Editor of Brain and Language

2004 –2009 Associate Editor of the *Quarterly Journal of Experimental Psychology*

MANAGEMENT AND FACILITATION

2020 - PALS Director for EDI

2015 - member, PALS Academic Careers and Diversity Committee

2015-2019- chair of ICN Public Activities Committee

2014 – 2019 deputizing for Prof Neil Burgess (ICN Director) at Faculty of Brain Sciences' Faculty Executive Committee meetings

2004 – representing the Speech Communication Group at the ICN Group Leader's committee

JUDGING AND COMMITTEES

2022 - member of ILCB advisory board

2019- Chair of Board of Trustees, Told By An Idiot theatre company (https://www.toldbyanidiot.org/about/)

2017- 2022 member of the Royal Society Dorothy Hodgkin Fellowship Committee

2015- associate Editor of the Psychologist and Digest Policy Advisory Committee, British Psychological Society

2015 Judge, Comment Awards

2015, 2018 Judge, Philip Leverhulme Prize

2014 Judge, Wellcome science writing prize

2013- Trustee, Jericho House theatre company (registered charity number 1131984)

EXTERNAL EXAMINING

2009-2012 External Examiner, BSc Psychology, University of Sussex 2009-2013 External Examiner, MSc Cognitive Neuroscience, University of York

2015-2019 External Examiner, BSc Psychology, University of Reading

TEACHING

2011-2014 Course convener, "Theories and Paradigms in Cognitive Neuroscience" UCL MSc in Cognitive Neuroscience.

2015- Module Convener, "Science Communication for Cognitive Neuroscientists" UCL MSc/MRes in Cognitive Neuroscience.

2023- Module Convener, "Power, Inclusion, Exclusion and Working with local communities".

GRANTS

Wellcome Trust Hub award development funding, for 'Talking Funny', £13000 over 18 months

Wellcome Trust Public engagement award, for "What's in a Voice" exhibit at the Royal Society Summer Science Exhibition, £20,000 over 12 months. Wellcome Trust People Award for public engagement activities: for LOL event at the Royal Society, awarded 2012, amount £19,000 over 12 months. Wellcome Trust Senior Fellowship, awarded April 2010 "Neurobiology of speech communication - cognition, plasticity, and social interactions" total amount awarded £1,184, 506, over 60 months.

Wellcome Trust Senior Fellowship, awarded May 2004 'the Neurobiology of Speech Perception – Cognitive and Clinical Links'. Total amount awarded £800,270, over 60 months.

Wellcome Trust RCDF grant, from April 2001-April 2005, 'the Neurobiology of speech perception'. Total amount awarded £358,376, over 48 months.

Marie Curie Incoming Scientist Fellowship, awarded November 2004, sponsoring Narly Golestani, £100,914 over 24 months.

ESRC grant awarded for new post doctoral researchers, sponsoring Charlotte Jacquemot, awarded May 2004, £30,919 awarded over 12 months.

ESRC grant awarded for new post doctoral researchers, sponsoring Patti Adank, awarded May 2005, £31,591 awarded over 12 months

ESRC +3 studentship award, awarded May 2004 (supervising Carolyn McGettigan)

British Academy meetings award, for the John Morton Festschrift, £2000 Experimental Psychology Society research seminar award, for the John Morton Festschrift, £3000

British Association for the Advancement of Science award for Key events in National Science and Engineering Week, 2008, £1000

ACADEMIC SUPERVISION

2001 -2004 Supervised Charvy Narain, the research assistant on my Wellcome RCDF award. Charvy was awarded a PhD in 2003 and took a job as an editor at Nature Neuroscience: she is now a Scientific Outreach Manager at the University of Oxford.

2002 -2006 supervised Disa Sauter, a research student in the Dept. Psychology at UCL. Disa passed her PhD viva without corrections in December 2006, and currently holds her a lecturer position at the University of Amsterdam..

2004 -2005 Supervised Dr. Charlotte Jacquemot, a post-doctoral fellow. Charlotte has been awarded a permanent CNRS position in France, which she began in 2006

2004 - 2012 supervised Carolyn McGettigan, a research student in the Dept of Human Communication Sciences. Carolyn passed her PhD viva without corrections in March 2008, was employed as a post-doctoral fellow on my Wellcome SRF grant until 2012 when she left to take up a lectureship at RHUL. She is now a Professor at UCL.

2005 -2006 supervised Dr. Patti Adank, a post-doctoral fellow. Patti is now a Professor at UCL.

2005 -2008 Supervised Dr Frank Eisner as a post-doctoral fellow on my Wellcome SRF award. Since January 2009, Frank held post-doc position at the Max-Planck-Institute for Psycholinguistics in Nijmegen, and is now a researcher at the Centre for Cognition of the Donders Institute for Brain, Cognition and Behaviour.

2005 -2007 Supervised Dr. Jonas Obleser as a post-doctoral fellow on my Wellcome SRF award. Since April 2007, Jonas has held a Junior Staff Scientist position at the Max Planck Institute for Human Cognitive and Brain Sciences, Leipzig, Germany, where ran his own research group: he is now a Professor at the Department of Psychology, University of Lübeck. 2005-2007 supervised Dr. Narly Golestani, a post-doctoral fellow, who now heads the Brain and Language Lab at the Cognitive Science Hub of the University of Vienna, Austria, and at the Department of Psychology at the University of Geneva, Switzerland.2008 -2009 – supervised Nicholas Abreu, who has a Fulbright Scholarship to work in the UK for a year. Nicholas started medical school at Harvard in September 2009.

2009 - 2013 Dr Zarinah Agnew appointed as a post-doctoral fellow on my Wellcome SRF grant. Zarinah now works at UCSF as a post-doc in John Houde's lab.

2010 -2015 supervised Pradheep Shanmugalingam as an ESRC funded PhD student. Pradheep is now training in simultaneous translation.

2012 - 2015 supervising Kyle Jasmin as a PhD student on the UCL/NIH program (NIH supervisor Alex Martin). Kyle joined my lab as a post-doctoral fellow and then was awarded a a Leverhulme research fellowship at Birkbeck: he is now a lecturer at Royal Holloway UL.

2012 -2013 Nadine Lavan joined my lab as an RA for 12 months. Nadine left to take up a PhD place at RHUL: she now holds a Wellcome Fellowship at QMUL.

2013 - Supervising Sophie Meekings as an ESRC funded PhD student.
Sophie was awarded a BA fellowship at Newcastle University, and was awarded a Dorothy Hodgkin fellowship in 2021, held at University of York.
2013 - Supervising Sinead Chen as a PhD student funded by a grant from the Taiwanese Government. Sinead now works for a policy think tank in Taiwan.

2013 -2015 Samuel Evans joined my lab as a post-doc on my Wellcome SRF grant. Now a lecturer at the University of Westminster

2013 – 2014 Dana Boebinger joined my lab as an RA. Dana left in August 2014 to start a PhD at Harvard, she is now a post do at the University of Rochester.

2015 – 2016 César Lima joined my lab as a senior post-doctoral fellow on my Wellcome SRF grant. César Lima is Assistant Professor of Psychology at Iscte - University Institute of Lisbon since 2017.

2017- Qing Cai joined my lab as a PhD student with funding from the Chinese government from 2018.

2017- Alexis Deighton McIntyre joined my lab as a PhD student with a UCL Graduate School studentship. In October 2021 she joined the MRC CBU as a postdoctoral researcher.

2018-Addison Billings joined my lab as a PhD student

2019 - Efe Caswell Niven joined my lab as a PhD student

SCIENTIFIC PUBLICATIONS-REFEREED ARTICLES

- 1. Scott, SK, Jasmin, K (2022) Rostro-caudal networks for sound processing in the primate brain, Frontiers in Neuroscience, 16, 1076374, 10.3389/fnins.2022.1076374
- Scott, SK, Cai, CQ, Billing, A (2022) Robert Provine: the critical human importance of laughter, connections and contagion. Philosophical Transactions of the Royal Society B-Biological Sciences, 377(1863) 20210178 10.1098/rstb.2021.0178
- 3. Scott, SK (2022) Why public engagement is important for neuroscientists. Nature Reviews Neuroscience, 23(8):453-4.
- 4. MacIntyre, AD, Scott, SK (2022) Listeners are sensitive to the speech breathing time series: Evidence from a gap detection task. Cognition, 225, 105171 10.1016/j.cognition.2022.105171
- 5. Conde, T, Correia, AI, Roberto, MS, Scott, SK, Lima, CF, Pinheiro, AP (2022) The time course of emotional authenticity detection in nonverbal vocalizations, Cortex, 151:116-132.
- 6.
- 7. Billing, ADN, Scott, SK (2022) Possible limitations of perceptual studies for informing production networks-The case of laughter. Cortex, 148: : 218-221.
- 8. MacIntyre, AD, Cai, CQ, Scott, SK (2022) Pushing the envelope: Evaluating speech rhythm with different envelope extraction techniques, Journal of the Acoustical Society of America. 151(3):2002:2026.
- Alderson-Day B, Moffatt, J, Lima, CF, Krishnan, S, Fernyhough, C, Scott, SK, Denton, S, Leong, IYT, Oncel, AD, Wu, YL, Gurbuz, Z, Evans, S (2022) Susceptibility to auditory hallucinations is associated with spontaneous but not directed modulation of top-down expectations for speech. Neuroscience of Consciousness, 2022(1) <u>https://doi.org/10.1093/nc/niac002</u>
- 10.Kamiloglu, RG, Tanaka, A, Scott, SK, Sauter, DA (2022) Perception of group membership from spontaneous and volitional laughter. Philosophical Transactions of the Royal Society B-Biological Sciences, 377: 20200404.
- 11.Pinheiro, AP, Anikin, A, Conde, T, Sarzedas, J, Chen, S, Scott, SK, Lima, CF (2021) Emotional authenticity modulates affective and social trait inferences from voices. Philosophical Transactions of the Royal Society B-Biological Sciences 376: 20200402.
- 12.Billing ADN, Cooper RJ, Scott SK (2021) Pre-SMA activation and the perception of contagiousness and authenticity in laughter sounds, Cortex, 143: 57-68.
- 13.Scott SK (2021) The neural control of volitional vocal production-from speech to identity, from social meaning to song. Philos Trans R Soc Lond B Biol Sci, 377(1841):20200395.

- 14.Lavan N, Scott SK, McGettigan C (2017) Impaired generalization of speaker identity in the perception of familiar and unfamiliar voices. J Exp Psychol Gen., 145(12):1604-1614
- 15.Cosme G, Rosa PJ, Lima CF, Tavares V, Scott S, Chen S, Wilcockson TDW, Crawford TJ, Prata D (2021). Pupil dilation reflects the authenticity of received nonverbal vocalizations. Scientific Reports. 11:3733.
- 16.Meekings S, Scott SK. (in press) Error in the Superior Temporal Gyrus? A Systematic Review and Activation Likelihood Estimation Meta-Analysis of Speech Production Studies. Journal of Cognitive Neuroscience.
- 17.Cai Q, Chen S, White SJ, Scott SK (2019). Modulation of humor ratings of bad jokes by other people's laughter. Current Biology. 29(14):R677-R678
- 18.Scott SK (2019) From speech and talkers to the social world: The neural processing of human spoken language. *Science*. Oct 4;366(6461):58-62.
- 19.Jasmin K, Lima CF, Scott SK (2019) Understanding rostral-caudal auditory cortex contributions to auditory perception. Nature Reviews Neuroscience, 20(7):425-434
- 20.Lima CF, Anikin A, Monteiro AC, Scott SK, Castro SL (2018) Automaticity in the recognition of nonverbal emotional vocalizations. Emotion. 2018 May 24. doi: 10.1037/emo0000429.
- 21.Neves L, Cordeiro C, Scott SK, Castro SL, Lima CF (2018) High emotional contagion and empathy are associated with enhanced detection of emotional authenticity in laughter, Q J Exp Psychol (Hove). Nov;71(11):2355-2363.
- 22.Krishnan S, Lima CF, Evans S, Chen S, Guldner S, Yeff H, Manly T, Scott SK (2018) Beatboxers and Guitarists Engage Sensorimotor Regions Selectively When Listening to the Instruments They can Play. Cereb Cortex. 2018 Nov 1;28(11):4063-4079.
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- 24. Lavan N, Burton AM, Scott SK, McGettigan C. (2018) Flexible voices: Identity perception from variable vocal signals. Psychon Bull Rev. 2018 Jun 25. doi: 10.3758/s13423-018-1497-7.
- 25.Agnew ZK, Banissy MJ, McGettigan C, Walsh V, Scott SK (2018) Investigating the Neural Basis of Theta Burst Stimulation to Premotor Cortex on Emotional Vocalization Perception: A Combined TMS-fMRI Study. FRONTIERS IN HUMAN NEUROSCIENCE Volume: 12 Article Number: 150 Published: MAY 15 2018
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- 31.Lima CF, Brancatisano O, Fancourt A, Müllensiefen D, Scott SK, Warren JD, Stewart L (2016) Impaired socio-emotional processing in a developmental music disorder. Sci Rep. 2016 Oct 11;6:34911.
- 32.Lima Č, Krishnan S, Scott SK (2016) Roles of Supplementary Motor Areas in Auditory Processing and Auditory Imagery. Trends in Neurosciences, 39(8):527-42.
- 33. Wilkes J, Scott SK (2016) Poetry and Neuroscience: An Interdisciplinary Conversation. *Configuration*, ;24(3):331-350
- 34.Meekings S, Evans S, Lavan N, Boebinger D, Krieger-Redwood K, Cooke M, Scott SK (2016) Distinct neural systems recruited when speech production is modulated by different masking sounds. *Journal of the Acoustical Society of America*. 140(1): 8-19
- 35. Jasmin KM, McGettigan C, Agnew ZK, Lavan N, Josephs O, Cummins F, Scott SK (2016) Cohesion and joint speech – right hemisphere contributions to synchronized vocal production. *Journal of Neuroscience*, 36(17):4669-80
- 36.Evans, S, McGettigan, C, Agnew, ZK, Rosen, S & Scott, SK (2016) Getting the cocktail party started: Phasic and sustained neural responses in the perception of masked speech. *Journal of Cognitive Neuroscience*, 28(3):483-500.
- 37.Rezlescu, C; Penton, T; Walsh, V; Tsujimura, H; Scott, SK; Banissy, MJ (2015) Dominant Voices and Attractive Faces: The Contribution of Visual and Auditory Information to Integrated Person Impressions. *Journal of Nonverbal Behavior*, 39(4): 355-370.

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- 40.Lavan N, Lima CF, Harvey H, Scott SK, McGettigan C (2015) I thought that I heard you laughing: Contextual facial expressions modulate the perception of authentic laughter and crying. *Cognition and Emotion*, 29(5): 935-944.
- 41.Bareham CA, Bekinschtein TA, Scott SK, Manly T. (2015) Does lefthandedness confer resistance to spatial bias? *Scientific Reports*, 5:9162. doi: 10.1038/srep09162.
- 42.Agustus JL, Mahoney CJ, Downey LE, Omar R, Cohen M, White MJ, Scott SK, Mancini L, Warren JD. (2015) Functional MRI of music emotion processing in frontotemporal dementia. *Annals of the New York Academy of Sciences*, 1337:232-40. doi: 10.1111/nyas.12620.
- 43.Boebinger D, Evans S, Rosen S, Lima CF, Manly T, Scott SK. (2015) Musicians and non-musicians are equally adept at perceiving masked speech. *Journal of the Acoustical Society of America*, 137(1):378-87. doi: 10.1121/1.4904537.
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- 46.Evans S, Meekings S, Nuttall HE, Jasmin KM, Boebinger D, Adank P, Scott SK. (2014) Does musical enrichment enhance the neural coding of syllables? Neuroscientific interventions and the importance of behavioral data. *Frontiers in Human Neuroscience*, 8:964. doi: 10.3389/fnhum.2014.00964.
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- 49.Bareham CA, Manly T, Pustovaya OV, Scott SK, Bekinschtein TA. (2014) Losing the left side of the world: rightward shift in human spatial attention with sleep onset. *Scientific Reports*, 4:5092. doi: 10.1038/srep05092.
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- 51.McGettigan C, Rosen S, Scott SK (2014) Lexico-semantic and acousticphonetic processes in the perception of noise-vocoded speech: implications for cochlear implantation. *Front Syst Neurosci*. 2014 Feb 25;8:18. doi: 10.3389/fnsys.2014.00018. eCollection 2014.
- 52.Kyong JS, Scott SK, Rosen S, Howe TB, Agnew ZK, McGettigan C. (2014) Exploring the Roles of Spectral Detail and Intonation Contour in Speech Intelligibility: An fMRI Study. *J Cogn Neurosci*. 26(8):1748-63
- 53.Boets B, Op de Beeck HP, Vandermosten M, Scott SK, Gillebert CR, Mantini D, Bulthé J, Sunaert S, Wouters J, Ghesquière P. (2013) Intact but less accessible phonetic representations in adults with dyslexia. *Science*. 2013 Dec 6;342(6163):1251-4. doi: 10.1126/science.1244333.
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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

EXPERT DECLARATION OF PATRICK W. LAPPERT, M.D.

I, Patrick Lappert, M.D., pursuant to 28 USC 1746, declare as follows:

1. I am over the age of eighteen and submit this expert declaration based on my personal knowledge.

2. I have been retained by counsel for the defendants in the above captioned lawsuit to provide an expert opinion concerning the nature of gender surgery. That opinion will be based primarily in my own experience as a physician and surgeon. It will also be based in an evaluation of the scientific publications that Plaintiffs have provided to the court in support of their complaint. It will additionally include an examination the world literature on the subject, as well as an examination of the massive public controversies that have led to near complete reversal of public health policy in multiple European states who have turned away from the social, medical, and surgical transitioning of minors.

3. I am a retired plastic surgeon, as well as a retired senior medical officer in the United States Navy. I have been a physician for 40 years. I completed my undergraduate education at the University of California, Santa Barbara. While there I had significant experience in university level research having been invited to be an undergraduate research assistant, working in the laboratory of Dr. Philip C. Laris. It gave me experience in the evaluation of research publications. We were involved in the collaborative work of elucidating the electrodynamic and stoichiometric quantification of the sodium and potassium pump, located in every living cell. I

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completed my undergraduate degree in four years, and went directly to medical school.

4. I completed my preliminary medical training while on active duty in the US Navy. I attended the Uniformed Services University of the Health Sciences,F. Edward Hebert School of Medicine, graduating as Doctor of Medicine in 1983.

5. I completed a surgical internship at the Oakland Naval Hospital, followed by Aerospace Medicine/ Flight Surgeon Training at the Naval Aerospace Medical Institute, Naval Air Station Pensacola.

6. I then served for 2 1/2 years with a deploying, front-line Marine Corps fighter squadron, serving in the dual functions of medical department head, and squadron Radar Intercept Officer flying in the F-4 Phantom. I was deployed to Asia and the Western Pacific. I provided medical care to squadron personnel while deployed in Japan, Korea, and the Philippines.

7. I completed my General Surgery residency at the Oakland Naval Hospital- University of California, Davis/ East Bay Consortium. Following residency, I was retained there as a staff surgeon, and was responsible for the training of surgical residents. I was awarded the inaugural "Resident's Choice" award given to the attending surgeon deemed most effective by the residents in training, and presented by Claude Organ, MD, past President, American College of Surgeons.

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8. I trained in Plastic and Reconstructive Surgery at the University of Tennessee, Memphis, graduating in 1994. During that training I traveled to Peru and provided craniofacial surgical care for indigent Peruvian children. This included the publication of a case report of surgical management of a very late post traumatic ectopic frontal sinus mucocele.

9. I received Board Certification in General Surgery from the American Board of Surgery in 1992. I received Board Certification in Plastic and Reconstructive Surgery in 1997 from the American Board of Plastic Surgery. I recertified in Plastic and Reconstructive Surgery in 2008.

10. I served as a staff plastic surgeon at Naval Hospital Portsmouth, Virginia. 1994-2002. I became Department Chairman in 1998, and served in that office until my retirement. We had 5 staff plastic surgeons, and 10 Enlisted and civilian members. I established the Wound Care Center, providing specialized wound care services to a global catchment area. For example, our department was responsible for the limb and pelvic reconstruction of some of the sailors wounded when the USS Cole was attacked while at anchor at Aden in Yemen. I also established and chaired the multi-disciplinary Cleft Palate, Craniofacial Board. We provided comprehensive services for congenital pediatric deformities to a global catchment area.

11. Following selection to the rank of Captain, USN, I was selected to serve as Specialty Leader, Plastic and Reconstructive Surgery for the office of the Surgeon General, USN. In addition to being responsible for the selection and training of surgical residents, I was also responsible for Navy Medical Department policy concerning coverage for services, and medical evaluation and evacuation policy. I was responsible for the resolution of issues concerning what conditions constitute a requirement for immediate care in military hospitals, what may be purchased from civilian medical organizations and provided to eligible members on a delayed (elective) basis, and what is to be considered cosmetic surgery and therefore not an obligation of the government. I served in that position until my retirement. While serving as Department Chairman, I co-authored a textbook chapter on the management of combat injuries with the Chairman of Plastic Surgery at Harvard University, Dr. Eloff Ericksson. During that time I also published the first case report in the world literature detailing the use of endoscopic technique for reduction and plate fixation of a fronto-facial fracture.

12. I retired from the Navy after 24 years of continuous active duty. I was invited to join a surgical group in Scottsbluff Nebraska, primarily to provide comprehensive reconstructive surgery for women suffering breast cancer. I also provided reconstructive services to a very large regional catchment served by the Level II trauma center at Regional West Medical Center (RWMC). I established and chaired the Cleft Palate/ Craniofacial multi-specialty clinic at RWMC. I also established comprehensive wound care services for the many rural community hospitals in the western prairie including Nebraska, Eastern Wyoming, southwest South Dakota and northeast Colorado.

13. For reasons pertaining to the education of our six children, I moved my practice to Northern Alabama in 2005. I have been a solo practitioner here for the last 17 years. I was brought here by a local hospital that wanted to offer comprehensive breast reconstruction to women affected by breast cancer. I also started a comprehensive wound care center. I have also had a very active practice in aesthetic/ cosmetic surgery. I maintained my own surgical suite for in-office facial rejuvenation procedures as well as minimally invasive body contouring procedures. I was an early adopter of advanced techniques in autologous fat grafting for facial re-contouring as well as for the resolution of radiation burn wounds of the skin. I continued to serve in the training of medical students in my office practice.

14. Although I maintain a practice in wound consultation, skin care, and laser services, I retired from my surgical practice in 2020, after having practiced as a plastic and reconstructive surgeon for 30 years. I was an Active Member in good standing of the American Society of Plastic Surgery for all but the last two years in practice. With only two years remaining in my practice, I elected to forgo a third certification by the American Board of Plastic Surgery. The certification was no

longer necessary for maintaining my hospital credentials, and I saw it as an unjustifiable expense for a solo practitioner planning retirement. When my board certification lapsed, my membership in the American Society of Plastic Surgery lapsed as a result.

15. As can be gleaned from this summary, I have a meaningful breadth of experience, not only in the advanced surgical care of trauma, cancer, head/ neck disease, as well as cranial and facial birth defects. Many of those procedures require the use of the most advanced sensate, microvascular flaps, including composite and pre-fabricated flaps. These are all the same techniques employed by today's gender surgeons. As regards surgery of the breast, I co-authored a ground-breaking article regarding pre-operative plastic surgical planning in the care of women suffering from breast cancer. It is among the most frequently cited papers in the field of breast reconstruction.¹

16. Since 2014 I have made a concerted effort to examine the medical literature as it pertains to the care of self-identified transgender persons including children and adults. I have had an eight year long running discussion on these issues with Family Practitioners, Pediatricians, Pediatric and Adult Psychologists and

¹ Toth, B.A. and Lappert, P. (1991) Modified Skin Incisions for Mastectomy: The Need for Plastic Surgical Input in Pre-Operative Planning. Plastic and Reconstructive Surgery, 87, 1048-1053. <u>http://dx.doi.org/10.1097/00006534-199106000-00006</u>

Psychiatrists, Pediatric Endocrinologists, as well as PhDs who specialize in the evaluation of the validity of scientific publications. During that time I have made many public presentations to teachers, counselors, pastors, and administrators on the subject of transgender, and the medical-scientific evidence that informs that care.

17. I have offered testimony, both written and in person on this issue to state legislators, state health benefits management agencies, as well as to State Attorneys General.

18. I have also had experience in making judgments concerning distinctions between reconstructive surgery and cosmetic surgery. I gained this experience while serving in senior leadership for a government medical care system in which I had no financial stake. I have no financial interests in the matter in question, and the professional opinion that I offer is not influenced by my sources of income nor by my position in any organization that financially benefits from medical services that are discussed in this opinion.

19. My peer-reviewed publications include: Lappert PW. Peritoneal Fluid in Human Acute Pancreatitis. Surgery. 1987 Sep; 102(3):553-4; Toth B, Lappert P. Modified Skin Incisions for Mastectomy: The Need for Plastic Surgical Input in Preoperative Planning. J Plastic and Reconstructive Surgery. 1991; 87 (6): 1048-53; Lappert P. Patch Esophagoplasty. J Plastic and Reconstructive Surgery. 1993; 91 (5): 967-8; Smoot E C III, Bowen D G, Lappert P, Ruiz J A. Delayed development of an ectopic frontal sinus mucocele after pediatric cranial trauma. J Craniofacial Surg. 1995;6(4):327–331; Lappert PW. Scarless Fetal Skin Repair: "Unborn Patients" and "Fetal Material". J Plastic and Reconstructive Surgery. 1996 Nov; 98(6): 1125; Lappert PW, Lee JW. Treatment of an isolated outer table frontal sinus fracture using endoscopic reduction and fixation. Plastic and Reconstructive Surgery 1998; 102(5): 1642-5. I have also published the following medical textbooks: Wound Management in the Military. Lappert PW, Weiss DD, Eriksson E. Plastic Surgery: Indications, Operations, and Outcomes, Vol. 1; 53-63. Mosby. St. Louis, MO 2000.

20. Over the past four years, I have testified at trial and/or deposition in the following cases: *Brandt v. Rutlege*, Case No. 4:21-CV-00450-JM (E.D. Ark.) and *Kadel v. Folwell*, Case No. 1:19CV272 (M.D.N.C.). I have also submitted an expert report in *Siefert v. Hamilton County Job and Family Services*, Case No. 1:17-CV-511 (S.D.Ohio).

21. For my services as an expert witness, I am being compensated at an hourly rate of \$400 for preparation of my written testimony as well for deposition and hearing. Additionally my travel expenses will be reimbursed. My compensation is not dependent upon the substance of my opinion nor upon the outcome of the litigation.

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22. If called to testify in this matter I will do so truthfully, and to the best of my ability.

23. The Plaintiffs make the claim that "gender affirmation care" including "gender affirming (or confirming) surgery" should be paid for by the State of Florida because such care has scientifically proven efficacy, and safety. Furthermore they claim that there is such an abundance of scientific support for these treatments that they must be understood to be the standard of care, and that there is no controversy in the matter. As shall be seen in this report, the claims made by the plaintiffs are not supported in the science. This will be seen in the examination of those scientific documents which they cite in support of what will be seen to be experimental treatments on children.

24. In recent years professional medical societies have been making a concerted effort to strengthen the scientific basis upon which their particular specialties stand. This effort is commonly given the name "evidence based medicine". It is a systematic effort to categorize the quality of prognostic and therapeutic studies so that physicians reading these publications can distinguish what is vague and speculative from what is a matter of high likelihood, or grave certainty. Tools for making such distinctions have been developed that categorize clinical or experimental findings on the basis of how that data was obtained, the reliability of the test instruments used, the variability of the results, the sample size, and the

likelihood of bias among other factors. For the purposes of this response, I will use the tool developed by the American Society of Plastic Surgery². For prognostic studies, the categorization of evidence is divided into Levels I- V, with Level I being the most rigorous and having the highest likelihood of scientific certainty, and Level V having the least rigor, and having very little certainty. Here are the definitions of those levels according to the American Society of Plastic Surgery:

<u>Level I</u>: High quality prospective cohorts study with adequate power or systematic review of these studies.

<u>Level II</u>: Lesser quality prospective cohort, retrospective cohort study, untreated controls from an RCT (randomized control study), or systematic review of these studies.

Level III: Case- control study or systematic review of these studies.

Level IV: Case series

Level V: Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles".

25. For therapeutic studies, the ASPS categorization is similar, but with a few helpful distinctions:

² The Levels of Evidence and their role in Evidence-Based Medicine <u>Patricia B. Burns</u>, MPH,1 <u>Rod J. Rohrich</u>, MD,2 and <u>Kevin C. Chung</u>, MD, MS3 Plast Reconstr Surg. 2011 Jul; 128(1): 305–310.

http://www.plasticsurgery.org/Medical_Professionals/Health_Policy_and_Advocac y/Health_Policy_Resources/Evidence-

<u>based_GuidelinesPractice_Parameters/Description_and_Development_of_Evidence</u> <u>e-based_Practice_Guidelines/ASPS_Evidence_Rating_Scales.html</u>.

Level	Type of Evidence
1A	Systematic review (with homogeneity) of RCTs
1B	Individual RCT (with narrow confidence intervals)
1C	All or none study
2A	Systematic review (with homogeneity) of cohort studies
2B	Individual Cohort study (including low quality RCT, e.g. <80% follow- up)
2C	"Outcomes" research; Ecological studies
3A	Systematic review (with homogeneity) of case-control studies
3B	Individual Case-control study
4	Case series (and poor quality cohort and case-control study
5	Expert opinion without explicit critical appraisal or based on physiology bench research or "first principles"

26. These distinctions are very important to physicians who seek to understand the weight of the evidence presented in support of a change in therapeutic care. Sometimes such scientific findings can be so compelling regarding an issue, that professional societies will publish clinical guidelines that strongly suggest conformity to a new treatment plan based in that evidence. Occasionally the evidence will be of such certainty, on a matter that is so grave, that professional

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societies and even public law will assert that there exists a standard of care based in this evidence that if ignored has a high probability of injury or harm to the patient. That is what is implied when the phrase "standard of care" is used.

27. To that end, the ASPS document provides a grading system for Practice Recommendations that helps in the decision making. It is a synthesis of the breadth of scientific data that addresses the issue in question. In the case of Grade A there is an accompanying "Strong recommendation", versus Grade D where the evidence is so lacking in empirical value that the proposed treatment can only be offered as an option if at all, depending upon the strength of existing or alternative treatments, and the particular issues of a particular patient.

28. To summarize, it can be said that Level-V evidence is anecdotal, and in the world of surgery it is typified by the phrase "expert opinion". Such evidence is not to be dismissed since it is the known starting point for much meaningful research and discovery. A surgeon with great experience and unassailable credentials will observe something peculiar. He will form a hypothesis about its cause or treatment. Hopefully he will publish his single case report, and share his thoughts with the wider surgical community. Perhaps one of his residents will start a hunt for other cases. Perhaps surgeons who read his paper will report similar cases. Eventually it might lead the surgeon to apply his new principal to a series of cases, that would constitute an improvement to Level-IV evidence. Even then, it would be considered "poor" evidence because it suffers from the fact that it is a small collection of cases, from a single surgeon, and perhaps no one has yet replicated his observations. Additionally it may suffer from "selection bias" (as when the patient decides if he will receive long term follow up), lack of proper controls (which help us to separate out what is the result of our treatment, and what is within the range of normal variation in the population), inadequate study duration (if you claim a long term improvement in survival, you have to follow the patients long-term).

29. An example from the history of surgery will serve to illustrate how Level-IV and V evidence, when widely encouraged and applied through expert opinion, can result in grave missteps. For over 100 years, ulcer disease of the stomach was considered a surgical problem. This very debilitating disease did not appear to be manageable through medical means. Laboratory study of the stomach had already demonstrated that acid production in the stomach is regulated by particular nerves. That finding suggested that if those nerves are cut, acid production will decline, and the ulcer will heal. It was also determined that the surgery must include some form of "drainage procedure" because cutting the nerves would also impair the muscular contracture of the stomach. Through the course of the decades many of the greatest surgeons gave their names to the elegant techniques for selectively cutting the nerves, or draining the stomach in ways that hopefully would

not result in a "gastric cripple" (an all too common outcome). Long hospitalizations, and many months spent accommodating to the reordering of their digestive tract was expected. There is a syndrome of bad effects from these surgeries that most people adapt to but some never do. Nonetheless, untreated peptic ulcer disease was often deadly, either from peritoneal sepsis, or bleeding to death. Because of the gravity of ulcer disease, it was ethically sound to risk "post gastrectomy syndrome" if it meant saving a life.³ By the 1980s, level II and I studies had demonstrated that peptic ulcer disease is actually a bacterial infection that can be treated with antibiotics and an acid-reducing medication. This had been very seriously suspected for at least 30 years. However, poorly designed studies published by the greatest academic surgeons of the day had utterly suppressed the bacterial explanation in favor of the surgical solution. A very well-reasoned 2014 paper by Seselja and Strasser⁴ shows the heuristic pitfalls that can result in unintended harms to patients when surgical decision making is driven by expert opinions that aren't well supported by quality scientific evidence.

30. Generations of surgeons will follow what is taught to them by the academic surgeons. These are esteemed mentors who are responsible for training the

³ History and evolution of peptic ulcer surgery; John B.BlalockJr.MD1; <u>The</u> <u>American Journal of Surgery</u> Volume 141, Issue 3, March 1981, Pages 317-322 ⁴ Dunja Šešelja 1, <u>Christian Straßer</u>; Heuristic reevaluation of the bacterial hypothesis of peptic ulcer disease in the 1950s; Acta Biotheor 2014 Dec;62(4):429-54.

next generation of surgeons. That is how it has always been. However today, medical science has advanced in crucial ways through the application of the "science of science". We understand better now how to examine the evidence. We are less likely to make needless errors of judgement because we are better able to analyze the data particularly with regard to its reliability. This is indispensable when studying biological systems that, in every measurable trait, demonstrate great variability. It is particularly essential when examining and caring for the human person, because you have the added dimension of their subjective interior life.

31. In the professional literature that supports gender-affirmation care, the word "transgender" is defined on the basis of a subjective conflict within the patient's internal sense of themselves. It affirms this interior subjective division on the basis of an idea that sex is somehow "assigned" at birth, rather than scientifically discovered through tissue sampling, in utero ultrasound, or simple inspection at birth. In 99.98% of cases, simple inspection correctly detects the sex of the subject. Furthermore, this test can be administered by untrained personnel. His use of the term "assigned" implies that there can be errors of "assignment". Such an assertion demands not only that we examine the result, but we must also look at the consistency of the data. It is well understood that consistency of the data is one of the hallmarks of good evidence. Any test that can be correct 99.98% of the time regardless of who administers the test is perhaps unequaled in scientific medicine.
32. Gender, on the other hand, as it relates to sex, is a very different matter. While there are some aspects of gender that are more fixedly related to the sex, there are large areas of gender that are learned within the milieu of the local culture, and find their origins in family life. There is no objective, repeatable test, with known error rates, that can be used to detect "gender". Gender, as the term is used in the world of medicine and surgery is not objectively measurable. Such traits as hair length, occupation, preference for violent sport, clothing selection, among others, may have vague gender associations, but are so variable from culture to culture as to be useless for our purposes. This is because "gender" is one of the many expressions of the interior life of the person. It is a mercurial thing because it is not entirely fixed to that part of the patient that is a reliable object for examination and treatment. That difficulty with diagnosis and prognosis is further complicated by the fact that variability in gender presentation doesn't just occur within any particular human grouping, it is also known to vary within the span of the life of a single patient.((Zucker, K. J. (2018). The myth of persistence: response to "A critical commentary on follow-up studies and 'desistance 'theories about transgender and gender nonconforming children" by Temple Newhook et al. International Journal of Transgenderism, 19(2), online May 29. 2018. 231–245. Published http://doi.org/10.1080/15532739.2018.1468293)

33. The claim is made that hormone therapy and gender confirmation surgeries can help alleviate gender dysphoria, and that these treatments have been shown to be an effective treatment for gender dysphoria. In support of this claim, a further claim will be made that there is a prevailing consensus of the medical community that these treatments are medically necessary, and are safe and effective treatments for gender dysphoria. We will examine the efficacy, and safety by examining the papers offered in support of these claims. We will examine the world literature more broadly in order to evaluate the claim of a "prevailing consensus". The claim of consensus insists on an absence of important controversy surrounding the use of social, medical, and surgical gender affirmation, particularly with regard to the young. That examination will show that there are startling and permanent differences in outcomes between "affirmation-care" as proposed by the plaintiffs, and the historically proven approach that begins in proven psychological care, and results in resolution nearly 90% of the time.

34. In virtually every instant when the claim of the efficacy and safety of gender-affirmation is made, the WPATH "Standards of Care" will be cited in support. This document is the product of the World Professional Association of Transgender Health. It has had 8 iterations. This document has been, and continues to be produced through a process of consensus-seeking within working committees of experts. As we have seen in our discussion about the grading of scientific

evidence, expert opinion is the most rudimentary level of evidence. It is the starting point of scientific investigation, not the end. As any medical subject is investigated over time, the expert opinion becomes better supported by well developed and monitored scientific processes. In short, expert consensus is only as valuable as the scientific evidence that can be reviewed and evaluated which supports the opinion. If the evidence hasn't progressed very far beyond the category of expert opinion, then we are speaking about evidence that is neither sufficiently developed so as to drive either clinical decision making, nor fiduciary decision making when public or invested resources are involved.

35. It will be recalled that the use of the words "standards of care" imply that a particular treatment or clinical principle, if not employed, would have an unacceptable probability of harm to the patient. The term "standard of care" addresses issues of duty, negligence, harm, and causation. It is a legal term that is applied when evaluating the malpractice of medicine. In its Introduction to the WPATH standards, the authors acknowledge that their document is meant to be a guideline only, and subject to individual and local adaptation, and that it is not binding in any way. On page 2 of v.7 in bold face it states "The Standards of Care are flexible clinical guidelines". This calls into question the motivation for the use of the phrase "standards of care" in all of its publications and statements.

36. If the WPATH document is actually a collection of clinical guidelines, then we must examine how such guidelines are developed. In the International Journal of Quality in Healthcare (2016) Kredo et al.⁵ offer a helpful examination of that process. They point out that in the past they were just consensus statements offered by experts in the field. They were "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." With the push toward evidence based medicine, it was realized that guidelines required more scientific rigor, so in 2011 the definition was changed to, "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options". In order to have real value, clinical practice guidelines must therefore do two things: Use high quality scientific data to evaluate risks, and beneficial results while presenting alternative approaches for the practitioner and patient to consider.

37. With respect to the particular questions at issue in this case, "high quality scientific data to evaluate risks, and results while presenting alternative approaches for the practitioner and patient to consider", should be evidenced in the complaint, and its supporting documents.

⁵ Guide to clinical practice guidelines: the current state of play; Kredo et al. <u>Int J</u> <u>Qual Health Care.</u> 2016 Feb; 28(1): 122–128.Published online 2016 Jan 21. doi: <u>10.1093/intqhc/mzv115</u>

Among the scientific publications frequently cited in support of the 38. efficacy and safety of hormonal treatment of transgender persons is a paper by Hembree et al.⁶ which is itself a clinical practice guideline promulgated by the Endocrine Society (hereafter ES). Since this paper is a product of the Endocrine Society, it must be understood by reconstructive surgeons given that the referral path of children into the surgical treatment arm is universally through the prior evaluation by an endocrinologist. This guideline was produced in order to update an earlier guideline from 2009. It was produced using GRADE consensus methodology, and is the product of 9 experts who formed the committee. The GRADE methodology cautions its users that "inconsistency of result across multiple studies", "indirectness of evidence", "imprecision in measurement", and "publication bias" are to be watched for in its application; essentially that doctors must watch out for sloppy measurement, and bias in the working group. The scientific evidence used to support the Endocrine Society's special treatment guidelines for gender dysphoric/ gender incongruent persons appears to be of low to very low quality, since the clinical recommendations were so equivocal. It was published in 2017 and includes the statement:

⁶ Wylie C Hembree, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1 November 2017, Pages 3869–3903, <u>https://doi.org/10.1210/jc.2017-01658</u>

"guidelines cannot guarantee any specific outcome, nor do they establish a standard of care": "The guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others. The guidelines cannot guarantee any specific outcome, nor do they establish a standard of care. The guidelines are not intended to dictate the treatment of a particular patient." P. 3895.

39. As was discussed earlier, this language of uncertainty when included in a clinical practice guideline is what we would expect with low quality evidence. This is what the ASPS would call a Grade D result that rests on level IV-V evidence, and is therefore not useful in directing clinical decision making. This consensus process described by Hembree et al. would likely appear very similar to the decision making that drove peptic ulcer surgery in opposition to evidence that it is a bacterial disease. Academic physicians of the highest calibre were making recommendations to their fellow practitioners, as they are now, based upon anecdotal experience and low level evidence.

40. Just 2 years later, in 2019, the ES, along with an international panel of endocrinology societies, concluded "the only evidence-based indication for testosterone therapy for women is for the treatment of HSDD [Hypoactive sexual desire disorder]," and that "There are insufficient data to support the use of testosterone for the treatment of any other symptom or clinical condition, or for disease prevention." Also, "The safety of long-term testosterone therapy has not been established."⁷

41. It is somewhat alarming to note that these findings are entirely consistent with a consensus statement from 5 years earlier in 2014 (8). In the span of just 5 years, the Endocrine Society consensus has swung from "no other indication for androgen in women" to something akin to, "it is crucial that androgens be given to women who are gender dysphoric", and then back to "no other indication for androgen". This kind of consensus oscillation is what you would expect when there is such scant scientific basis for the decision making.

42. Leading experts in the nascent field of "gender-affirmation surgery" will cite the ES guidelines as the "criteria for initiation of surgical treatment", and that such surgery is "often necessary and effective". Additional citation of other specialty consensus statements, developed by similar methodology, includes the American Pediatric Society, and the American Psychiatric Association. These

⁷ Endocrine SocietySusan R Davis, et al, Global Consensus Position Statement on the Use of Testosterone Therapy for Women, *The Journal of Clinical Endocrinology & Metabolism*, Volume 104, Issue 10, October 2019, Pages 4660– 4666, <u>https://doi.org/10.1210/jc.2019-01603</u>.

⁽⁸⁾⁻ Margaret E. Wierman, et al. Androgen Therapy in Women: A Reappraisal: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 99, Issue 10, 1 October 2014, Pages 3489– 3510, <u>https://doi.org/10.1210/jc.2014-2260</u>

consensus statements are also important for reconstructive surgeons to be familiar with since it is in these areas of practice that the initial diagnosis of gender dysphoria is made, a diagnosis which constitutes the foundation for referral to surgery. The surgeon must understand the strength of the scientific support of the diagnosis given that in some instances breast surgery, and in all instances genital surgery is an irreversible mutilation of the child resulting in permanent losses to essential human functions.

43. Surgeries that are used in gender-affirmation care are described by plaintiffs experts as being "reconstructive". They include surgeries of the face, the chest, and the genitals. It is crucial to understand the meaning of the term reconstructive surgery, and contrast it with the term "aesthetic surgery". It is precisely this distinction that distinguishes medical necessity, which in turn is the basis for evaluating claims of obligation on the part of the State or any other 3rd party payor, to pay for these procedures. This is an area where I have some experience, having served the office of the Surgeon General, USN as specialty leader for reconstructive surgery. Making determinations of coverage for any agency is essentially about rightly answering this as the first question: "Is this reconstructive, or is this cosmetic?"

44. Reconstructive surgery is the restoration of form and function for a person who has suffered a loss through genetic, in utero developmental accident,

trauma, infection, or surgery for infectious events or cancer. It begins with the most comprehensive knowledge available concerning the nature and function of the injured part, and seeks to optimize function as the primary goal, while seeking to restore the natural form. Both form and function are understood objectively, and both have subjective effects. Restoration of form and function in a combat injured leg has measurable effects on mobility, range of motion, strength, and capacity for work. Subjectively, the impact is profound as well, but it is not the central purpose of the operation.

45. In contrast, aesthetic surgery begins in the subjective life of the patient. The patient presents seeking an opinion concerning the aesthetics of a particular feature, such as the nose. They will express a dislike of the feature. Their hope is that by modifying its appearance, they will improve their interior subjective life. What the patient is seeking is a normal human objective: to improve the aesthetics of things, for ourselves and for the people around us. When the surgeon is planning and performing the operation on the nose, there is great objective precision; however, all of it is placed in the service of the subjective life of the patient. It is of no use for the surgeon to impress himself with a technically perfect result if the patient loathes it. The surgeon additionally has the grave duty of managing the risk for the patient and weighing it against the potential benefit. The patient must not be submitted for a surgery which entails a significant risk of loss if the surgery is being performed only to achieve an aesthetic outcome. If there is a certainty of loss, then there is a certainty of error. To give a young woman a perfect nose, and in the process destroy her ability to breath through it would be a terrible error of surgical decision making. It is axiomatic in plastic surgery that we are to avoid a predictable sacrificing of function in the pursuit of cosmetic improvement.

46. All of the world's literature in the area of gender affirmation medicine and surgery begins in the subjective life of the patient. In the past the associated diagnostic terms directed us to consider the subtle processes at work in the mind of the patient that cause obsessive thinking, and compulsive behaviors that center on how the world views their sexed appearance. More recently the condition has been "de-pathologised" and now the preferred term of "gender dysphoria" has come into use. This new language has hidden away virtually all of the issues of the interior emotional life of the patient, and left us only with the vaguest descriptions of the patient's condition: "dysphoria", "unhappy". Simple though the term is, it is still entirely in the subjective life of the patient. There is nothing found in the term "gender dysphoria" that points to a lost or otherwise damaged body structure in need of reconstruction. No functional or physical loss is described or even suggested by the term "gender dysphoria". It is a fundamental characteristic of a cosmetic surgery patient that the presenting complaints are only subjective, and in the course of the complete evaluation of the patient, no functional or structural defect is found.

47. A further reason for the crucial importance of clarity in separating what is reconstructive from what is cosmetic is the part that this distinction plays in surgical planning, and informed consent processes. Planning for a reconstructive operation includes an assessment of the size and severity of the wound, or the dimensions and tissue types of the missing part. This determination guides the selection of tissue from other body areas that can be employed in the reconstruction. At the same time the surgeon must understand the scope of the harm that will be caused by harvesting that tissue to complete the reconstruction. That harm is given the name "donor defect", and it forms an important part in the risk/ benefit calculation. For example if I were to reconstruct a man's jaw that was shot away in combat, one of my first options would be to use a portion of bone from the leg. I can transpose that bone to the face, attach the blood supply, then cut and form the bone segment to replace what was lost. One of the important considerations is to prevent loss of function of the leg (donor defect). The operation is in part designed around that consideration because we seek to limit (entirely if possible) the magnitude of the functional loss caused by the donor defect. The only reason that we accept any loss at all is because of the grave nature of the original wound. We accept some small degree of loss if by doing the operation we restore the functions lost in the wounding event. Furthermore, whatever function is lost because of the donor defect is considered a complication had there been any way to avoid it.

48. In contrast cosmetic surgeries, because they begin with an otherwise fully intact person, they do not begin with any assessment of any loss from any of the wounding processes described above. The only measurable findings in cosmetic surgery are those of aesthetic proportion, and which being aesthetic find their importance in the subjective life of the observer. In the case of the cosmetic operation, any functional loss caused by surgery is considered an avoidable complication since the surgery neither anticipates nor yields any functional improvement except in the subjective life of the patient. This is why measures of success in cosmetic surgery are always made using subjective "quality of life" questionnaires.

49. As we examine the particular surgeries used in gender affirmation we will see that there is a very troubling abandonment of these first principles of reconstructive surgery. The first troubling example is "chest masculinization" surgery in female to male presentation patients. This surgery actually begins with the known expectation that the surgery will produce a loss of two essential human functions, namely: sexual arousal, and breast feeding. Both functions are permanently and irretrievably lost, and that loss is one of the expected results or the surgery. This step is then followed by the cosmetic shaping of the chest through the use of liposuctioning in an effort to further masculinize the appearance of the chest. This surgery is now being routinely performed on minor girls, and version 8 of the

WPATH "standards of care", which is presented as authoritative by proponents of gender affirmation, actually recommends mastectomy in girls as young as 15 years of age. This surgery does not involve the restoration of form and function, and is therefore not reconstructive. It is an operation that begins in the subjective life of the patient and aims at a result that also resides entirely within the subjective life of the patient. It is thus by definition an aesthetic (cosmetic) surgery. Because it includes the 100% likelihood of a massive functional loss, it must be considered unsupportable as a matter of policy.

genital surgery procedures 50. Similarly. cannot be considered reconstructive because they do not meet the definition of reconstructive surgery. They begin with an obsessive concern or anxiety in the subjective life of an otherwise normal, healthy person. They involve the planned destruction of an essential human function, and they are not restoring a form that is missing due to trauma, genetic accident, in utero event, or disease. The surgery seeks to create counterfeit structures that never could have existed in the patient, except as an artifact of surgery. I have done many reconstructive surgeries involving the entire genital area in patients with military injuries and infectious illnesses. If the injury is so devastating as to require a counterfeit structure, and that is all that can be offered, then there is no question as to how the surgeon must proceed. In contrast, gender affirmation surgery only produces counterfeit structures that are created to serve the

subjective life of the patient. Because these surgeries are cosmetic, and because they are 100% certain to produce grave functional losses, they must not be supported as a matter of public policy, and never be paid for using public funds.

In spite of these clear distinctions between reconstructive and cosmetic 51. surgery, proponents of gender affirmation surgery will claim that such procedures are medically necessary. This language of medical necessity is found in the WPATH "standards of care". It should be remembered that the WPATH standard of medical necessity is not supported in reliable scientific evidence, but only on rudimentary, low level, expert opinion/ consensus statement data, which is no support at all. The use of the term "medical necessity" is language that is used by medical insurance programs, both private and public to establish insurance coverage in the case of particular procedures. Benefits of insurance programs can vary from policy to policy, but when the term "medically necessary" is used, it implies that failure to cover the care is likely to cause harm to the beneficiary. For this reason, insurance programs, including state Medicaid programs routinely examine the efficacy of treatments in the management of medical conditions, and develop policies of coverage or exclusion if benefit has not been demonstrated, or if a less hazardous or less expensive process of care can be offered to the beneficiary.

52. There are circumstances in which the exact same surgery may be considered reconstructive in one patient, but cosmetic in another. It is important to

be familiar with this problem since advocates of gender affirmation surgery will use the similarity as the basis for claiming that it should be a covered benefit, and that failure to include surgery in the insurance coverage is evidence of legal prejudice against a particular class of patients. For example, the claim will be made that removal of breast tissue from a female seeking to present as a male is the same as removing breast tissue from a male who suffers from the condition of gynecomastia (female breast tissue on a male chest). Or they will offer the analogy that mastectomy (complete removal of the breast) in a healthy female who seeks to present as male is the same as prophylactic mastectomy in a female who has inherited a high lifetime risk of breast cancer. Both females are at present healthy, both females get mastectomy. Gender affirmation advocates will ask, why one is a covered benefit, and the other excluded?

53. One of the essential mechanisms that third-party payors (including state Medicaid agencies) have for distinguishing reconstructive surgery from cosmetic surgery is found in the laboratory examination of tissue removed during surgery. This tissue examination by the pathology department is required by insurance programs in order to confirm that the operation performed was reconstructive (covered benefit) and not cosmetic (excluded from coverage). Two operations may be outwardly identical even while one is reconstructive and the other cosmetic. An excellent example is breast reduction surgery. This surgery may be reconstructive

if it is performed on patients who suffer from chronic neck, back, and shoulder pain caused by the orthopedic effects of their heavy breasts. The same, technically identical operation, might be done for purely cosmetic reasons. In the case of reconstruction, the patient has an objectively diagnosable condition that causes lost time from work, frequent covered visits to physical therapy, or to pain clinics, chiropractors and radiologists. There is abundant actuarial data, based upon the highest levels of scientific support, that a breast reduction of sufficient weight (based upon the anthropometric measurement of the patient) has a very high probability of resolving the chronic pain. High quality medical literature that addresses this issue, and its importance to insurance plans, is typically very precise in its data gathering and actuarial interpretation.⁸ However, pain cannot really be measured. Pain is reported by the patient. Nonetheless, health insurance plans are able to distinguish cosmetic breast lift from reconstructive breast reduction based upon the measured and reported weights of the breast tissue that is submitted to pathology during surgery. An objective, repeatable medical test, with known error rates is used to confirm the diagnosis, ensure correct care for the patient, and separate cosmetic

⁸ Accuracy of Predicted Resection Weights in Breast Reduction Surgery: Kung, Theodore A. MD;

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surgery from reconstructive surgery in the interest of preserving medical resources and preventing fraud.

54. No such process exists in the case of mastectomy for chest masculinization of self-identified transgender females seeking to present as males. There is no physical, biochemical, hormonal or tissue pathology, that can be demonstrated to localize the patient's condition in her healthy breasts. It is the young woman's subjective sense of revulsion when she looks at herself that has caused her to believe that mastectomy might make her feel better.

55. In spite of this glaring lack of objective, scientifically validated methodologies for making the diagnosis, or for proving benefit of care, advocates for gender affirmation care will cite many papers, published in peer reviewed professional journals, that claim sufficient improvement in the subjective life of the patient that lifelong morbidity and suicide are avoided. Close examination of this literature will show the very low quality of evidence that is offered, even after many years of affirmation care. Before reviewing the literature supporting gender affirmation, we must understand what it means when an article is reported as "peer reviewed".

56. Peer review is the very important process by which highly educated and trained experts review scientific medical papers for publication. They are examined in order to ensure that the corpus of medical literature is protected from imprecise,

substantively erroneous, or conceptually flawed publications. It is an essential part of the historic, magisterial process in medicine. In fact, it is so much a part of the life-long learning process of doctors that any reputable training program will have a robust "journal club" in which doctors at every level of training take turns at publicly "peer reviewing" an article and leading a lively discussion of its value. A good doctor is constantly peer reviewing. It is an essential element of good medical care because it keeps the doctor in contact with the finest practitioner in their particular field, and thus improving care.

57. Establishing that an article is peer-reviewed is a basic and essential practice. You might read a medical paper with level-III evidence of high quality, or a paper that is level-V evidence of low or questionable quality, both of which undergo peer review, and are published. The level-III will likely drive decision making, and possibly a recommendation as high as "standard of care", while the poor-evidence paper suggests research, or perhaps the consideration of an alternative approach, if that approach does not put the patient in any significant risk. Papers that have very low-quality evidence, such as single case reports, or case collections by a single practitioner, or collected from several practitioners at a single medical center, will be published by peer reviewed medical journals. These papers are not offered to guide clinical decision making. They are offered in the service of advancing the understand of complex problems, and suggesting areas of research

that might lead to higher quality evidence, and thus to future improvements in the quality of care. So, the label "peer reviewed" says absolutely nothing about the value of the evidence for either clinical decision making, or larger issues of practice guidelines, and policies of medical coverage or exclusion by healthcare agencies like state Medicaid programs.

A 2019 publication by Miller et al.⁹ is typical of a single-surgeon, case 58. collection paper published in a peer reviewed medical journal. It reports a collection of cases that claims to show complete satisfaction on the part of the patients (that 100% would do it again). Upon examination of Dr. Miller's paper we see that it is a report of a single surgeon, and is a retrospective review of his cases. It begins with a chart review of only 34 patients, only 12 of whom responded to the quality-of-life questionnaire. This means 74% of the study patients dropped out (patient selfselection bias, with dropout rate greater than 20% being unacceptably high for publication in most journals). All of the data is based in subjective reporting by the patients, rather than objective findings such as substance abuse rates, psychiatric hospitalization rates, suicide attempt etc.. Published reports which use purely subjective evaluations such as satisfaction surveys, or quality of life surveys etc. are characteristic of the cosmetic surgery literature, not the reconstructive surgery

⁹ Miller, TJ, et al. Breast Augmentation in Male-to-Female Transgender Patients: Technical Considerations and Outcomes, 21 JPRAS Open 63-74 (2019)

literature. He reports that "every patient surveyed at 1 year" reported that "their life had changed for the better". This statement is again reporting only subjective data, this time following a meaninglessly short follow-up of a very small group that has been biased by self-selection. The overall study is little better from the standpoint of the duration of the study because the final follow-up was only 4 to 7 years. This paper presents level-IV and level-V (low to very low quality) evidence, and is possibly useful in suggesting further research, particularly since the author is a subject matter expert. It is not useful for clinical decision making. Neither can it be presented as evidence for anything more than a cautiously worded practice guideline (as in the ES guideline concerning the use of cross-sex hormones presented above), and certainly can never be used in support of a "standard of care".

59. A 2006 paper by Newfield et al.¹⁰ is an example of a paper that was published in a peer reviewed journal, and perhaps ought not to have been. This paper asserts that mastectomy and chest masculinization in transgender biological females "increases self-esteem and improves body image" while providing the patient with "some security and safety for those who remove their shirts in public areas such as gyms or beaches". This assertion is made by the authors in the paper's preamble, and is an assertion frequently quoted when the paper is cited in evidence to support

¹⁰ Newfield, N, et al., Female to-Male Transgender Quality of Life, 15 Quality of Life Research 1447- 1457 (2006)

gender affirmation surgery. In reading the entirety of the paper one finds that it does not demonstrate this claim at all. The assertion is a personal editorial opinion expressed by the authors in support of transgender surgery. The assertion is never verified in the objective data on post-surgical patients.

The paper is a report of an anonymous survey. It claims to provide 60. meaningful information about the effect of female to male transitioning medicine and surgery without even verifying that the subjects who responded to the survey have in fact undergone medical and surgical gender transition. Subjects were recruited "via online promotion and printed materials, including flyers and postcards that were distributed to San Francisco Bay Area community centers, cafes, stores, and health clinics that serve the transgender community." In terms of self-selection bias (patient determines who is followed by the study) it is hard to imagine a more problematic patient selection process. The researchers even admit that they were unable to determine how many surveys may have been submitted multiple times by the same study respondent. They write: "Although this procedure *helped* (italics mine) prevent duplicate submissions by the same participant, we could not employ more sophisticated computerized systems due to administrative and financial constraints".

61. All of the demographic information contained in the study was selfreported but not verified, including age, sex, health status, history of hormonal therapy, and history of gender surgery. The study uses a quality-of-life survey with 36 questions in 8 areas of interest, producing only self-reported subjective information. Even the claim of simple benefit is poorly support, as is reflected in the conclusion to the paper. The authors write, "The 376 US FTM transgender participants analyzed in this sample had diminished mental-health related QOL compared with the general US population, as measured by the SF36v2. These findings are consistent when compared against specific age and sex norms." This statement demonstrates the lack of value in the study. The study participants demonstrated a quality of life that is statistically significantly lower than the age/ sex comparison cohort, and the authors can only speculate as to the cause. There is no way to tell if treatment helped, had no effect, or harmed the patients because there was no information available about the anonymous subjects. This is because the anonymous test subjects hadn't received pre-treatment evaluation using the same or comparable test instrument. This study which is frequently offered in support of the claim of efficacy is of the lowest evidentiary value, may be useful for suggesting future research, but is of no value in directing clinical decision making, or meaningful allocation of public resources in the service of public health.

62. Another peer reviewed article, presently cited in filings by advocates in cases pending before federal courts, is from 2013 by Weigert et al.¹¹ which makes the claim that there is a statistically significant improvement in "psychosocial wellbeing" following cosmetic breast augmentation in biological males who are presenting as women. This paper is very simple to analyze and classify as not helpful in clinical-therapeutic decision making, or for establishing coverage/ exclusion criteria for public health agencies. At the bottom of the published article is written, "Clinical question/level of evidence: Therapeutic, IV." As was discussed above, this paper is at the same alarmingly low level, because it is a single-center sampling of a small cohort of patients, and relies on subjective, self-reporting through questionnaire, over a short study duration. Patient collection was made between 2008-2012. The paper was published in 2013. If the peer review process followed the usual timeline, it is likely that there are a significant number of patients in the study who were followed for less than a year. The authors, in the abstract are only able to report the pre-surgery, and the 4th month post-surgery as assured time points. This is remarkably short follow up even for a cosmetic breast augmentation study group. The article is perhaps useful in suggesting inquiry into why their cohort

¹¹ Weiger, R, Frison,E., Sessiecq, Q., et al.; Patient Satisfaction with Breasts and Psychosocial, Sexual, and Physical Well-Being after Breast Augmentation in Male to Female Transexuals. Plastic and Reoncstructive Surgery, 132(6), 1421-1429. doi:10.1097/01.prs.0000434415.70711.49 (2013)

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reported no improvement in physical well-being, given the known association between emotional health and physical health. There is nothing in the article to support even a guardedly worded clinical guideline suggestion.

63. Another citation in legal claims presently before federal courts and offered in support of gender surgery is another peer-reviewed study by Horbach et al. published in 2015.¹² This is a review of transgender surgical literature published between 1995 and encompassing nearly 20 years. It yielded 26 papers that satisfied the search criteria, and includes 1,461 patients. The paper claims that "transgender women (biological males presenting as women) who had vaginoplasty found that study participants' mean improvement in quality of life after surgery was 7.9 on a scale of one to ten". In the conclusion of the paper the authors write, "

"Sexual function and patient satisfaction were overall acceptable, but many different outcome measures were used. QoL was only reported in one study. Comparison between techniques was difficult due to the lack of standardization."

64. Of the merely 26 studies out of a sampling that spanned 20 years, only one paper was found to have used a standardized metric, one that only measures subjective, patient reported information, and the rest could not even be compared to each other. The authors write,

¹² Horbach, SER, Bouman, M, Smit, JM et al.Outcome of Vaginoplasty in Male-to-Female Transgenders: A Systematic Review of Surgical Techniques ; J Sex Med2015 Jun;12(6):1499-512. doi: 10.1111/jsm.12868.55.

"The available literature is heterogeneous in patient groups, surgical procedure, outcome measurement tools, and follow-up. Standardized protocols and prospective study designs are mandatory for correct interpretation and comparability of data."

65. This result is startlingly reminiscent of a paper offered by Tolstrup et al. published in 2020 (&&). It is a comprehensive literature review on the subject of breast surgery in transgender patients, including both male to female, and female to male presentation. It is a scoping review that yielded 849 papers of which 47 papers met the inclusion criteria based upon title, abstract, and full text. In the study results, the authors report that,

"The summary of outcome domains and classifications showed that there are large variations in outcome evaluation between studies. Although several studies reported on similar outcome categories, there was a high level of heterogeneity of domains and classifications of outcomes." The authors then conclude by explaining that "Evaluation of outcomes in gender-confirming chest surgery showed large variations in reporting, and further streamlining of reporting is therefore required to be able to compare surgical outcomes between studies."

66. Tolstrup's review of the literature¹³ show us that the general level of evidence for the efficacy of gender affirmation breast surgery is in the category of "early experimental" evidence. None of the articles examined rates of psychiatric hospitalization, substance abuse, self-harm behaviors, or suicide. This tells us that the most compelling reason offered for performing these surgeries

¹³ Tolstrup A¹, Zetner D¹, Rosenberg J¹ Measures in Gender-Confirming Chest Surgery: A Systematic Scoping Review. **Aesthetic Plastic Surgery**, 29 Oct 2019, 44(1):219-228 DOI: 10.1007/s00266-019-01523-1

(psychological distress and suicide risk) isn't even evaluated by the researchers, and can support no claims of efficacy in the world transgender surgery literature.

67. Professionally speaking, these are very disappointing findings from the comprehensive examination of the transgender surgery literature. To have a surgical sub-specialty working diligently, and guided by professionals at the highest levels of academic expertise, that has only produced case-series reports, retrospective case collections, and fruitless 20 year literature reviews, and still only have level-IV and V evidence to show for its work is alarming. It shows that the sub-specialty has not developed uniform descriptive language, standardized reporting nor test instruments that might raise the value of expert opinion to a level that could make reliable recommendations that might help in surgical decision making, rightly inform the consent process, or guide decision making by officials entrusted with the care of public and private medical resources. It would cause me to make a sober review of the medical and surgical principles that are guiding this work.

The Question of Consent in Gender-Affirmation

68. It is firmly established in high quality research¹⁴ (that persons with gender dysphoria have a greater than 30% likelihood of being on the autism

¹⁴ Kaltiala-Heino R, Sumia M, Työläjärvi M, Lindberg N. Two Years of Gender identity service for Minors: overrepresentation of natal girls with severe problems in adolescent development.

spectrum, and a nearly 40% probability of a diagnosis of depression or major anxiety disorder. The proponents of gender surgery will rightly point to the high probability of self-harming behavior, including suicide attempts and completed suicide among self-identified transgender persons.

69. However, as is known by all surgeons, it is considered imprudent to obtain consent from patients suffering from psychological conditions that provoke the patient to acts of self-harm, or to suicidal ideation. These psychological disturbances are known to impair the patient's capacity for understanding the information they are hearing from the surgeon, interpreting that information, and reasoning from that information. If those capacities are impaired by psychological disturbances sufficient to consider suicide, then meaningful consent is not actually possible. Certainly in the case of conditions that constitute a threat to life and limb in a patient with decreased competence, consent may be obtained with the assistance of family, guardian, or in particularly urgent cases a group of professionals who agree on the grave necessity to proceed with surgery.

70. The problem however is that none of the surgeries, on the list of commonly performed gender affirmation surgeries, can be described as emergency operations performed to save the life of the patient. They are all elective because

Child and Adolescent Psychiatry and Mental Health (2015) 9:9.)

they are scheduled when convenient and after the patient is deemed fully ready. Furthermore, an ever-growing percentage of patients submitted for gender surgeries are minors who by definition are not competent to consent. The claim is made that these surgeries are in fact "lifesaving". This is a claim that is not supported in high quality scientific evidence. In fact, high quality evidence, which I will present below, shows that while self-harm and suicide rates are improved in the very short term for some sub-groupings of patients, in the long-term these problems remain if not worsen.

71. Documents like the WPATH v.8 speak of the need to have these psychological disturbances "well-controlled" prior to surgery. This must be taken to mean that self-harming or suicidal thoughts must be well controlled before one can proceed with surgery. If that is the case, then the main reason for the consenting the child for surgery has been successfully treated medically, and the patient no longer requires the surgery. That would be very felicitous news to the child's parents.

72. What is more troubling is that the co-morbid conditions of autism spectrum disorder, clinical depression, and major anxiety disorder are never examined as the possible causes of the gender identity disturbance. These are conditions that, if treated, might improve or even resolve the gender problem. To the contrary, these serious problems are viewed as mere impediments to gender surgery that must be "reasonably well-controlled" so that surgery may proceed. This is

consistent with the regnant WPATH model that there is a single explanation that the child's condition is caused by a disconnection between biological reality and subjective identity which has an as-yet undiscovered cause, and has only a single solution: the social, medical, and surgical affirmation of the child's gender discordance.

73. Such a single cause/ single solution assumption would seem to be unlikely, given the massive range and the recent complete reversal in the demographics of transgenderism. What used to be a condition that was nearly exclusively found in little boys, and resolved nearly 90% of the time¹⁵, is now predominantly a condition affecting young women, and at a rate that has risen between 4000 and 5000% in the course of the last decade.

74. The claim is often made that gender affirmation surgery is not cosmetic, because it is based in a "medical diagnosis" that can be found listed in the Diagnostic and Statistical Manual. This is a document produced by the American Psychiatric Association. It is essentially a dictionary of terminologies recommended in descriptions of psychiatric conditions. This publication used to include the terms "body dysmorphic disorder", and "gender identity disorder" among others used to describe self-identified transgender person. Changes to the language found in the

¹⁵ Irreversible Damage: The Transgender Craze Seducing Our Daughters; Abigail Shreier, (2020)

DSM are based upon expert consensus methodologies described above, which are the lowest form of scientific evidence. The consensus in not obtained by polling the membership of the Society, but within a small group of provider- advocates. Conditions that were once in the category of paraphillias are now considered normal and not listed. It is in this committee that the decision was made to "depathologize" gender discordance. The difficulty is that without a medical diagnosis, you cannot generate billing for medical services. This is why the term "gender dysphoria" was chosen. No high quality scientific evidence was presented and reviewed by the committee in making the changes.

75. This methodology by the DSM committee has made the document essentially useless in making either a diagnosis, establishing principles of care, or estimating likely resolution of psychiatric medical problems. This appears to be why the National Institute of Mental Health, which has been the original source of funding for the DSM publicly its support for the DSM project just weeks before the present iteration was published in 2013. The fact that gender affirmation physicians and surgeons cite the DSM as a source document for diagnostic criteria is further proof that the condition exists in the subjective life of the patient, and therefore surgery performed to address the subjective condition is by definition cosmetic surgery.

76. Diagnostic and pre-operative selection for of patients for surgery is through a process that begins in psychology, continues with psychological support, and concludes with certification by psychological services that the patient is ready for surgical modification. At no point is there described any medical diagnostic process of history-taking, physical examination, laboratory evaluation, or radiographic examination that is used to confirm a surgical diagnosis. The entire process is in psychological services which is operating on the premise that the anxious child has made a correct diagnosis. The indication for surgery begins in the subjective life of the patient. Surgery is offered to the patient with the assurance that it is likely to improve the subjective life of the patient, and is therefore by definition cosmetic surgery.

On the Safety of Gender Affirmation Surgery

77. A discussion of surgical safety must include anticipated losses which are either expected, or even remotely possible. In order to examine the comparable issues in transgender versus reconstructive surgery our effort is simplified by comparing identical operations. I will describe two operations which use the identical techniques, and even the same tissue source so that we can better compare gender affirmation surgery, with actual reconstructive surgery.

78. On several occasions I have performed the reconstructive operation called "Sensate radial-forearm microvascular free flap hypopharyngeal

reconstruction". I performed this surgery in order to reconstruct the tongue and throat of patients who had suffered a grievous wound of the mouth and throat when he underwent removal of an aggressive cancer. The defects caused by that wounding needed to be replaced with thin, pliant, abrasion and fluid resistant tissue. It needed to provide the patient with sensation in the reconstructed area so that they can feel the food and liquids in their mouth, and manipulate the food so as to swallow it. We selected an area of skin on the inside of the forearm that has regular and robust blood flow, is thin and durable, and has an easily dissected sensory nerve that can be attached to the nerves in the wound. The forearm flap satisfied all the requirements. An operation of this complexity, duration, and technical requirements has many issues, big and small, that can diminish or destroy the result.

79. The throat reconstruction operation is in almost every way identical to the second most commonly performed female to male (FtM) gender affirmation surgery of the genital. It is called the "Sensate radial forearm microvascular free flap phalloplasty". In that operation, the identical flap is raised and transferred. It too must be resistant to abrasion, be water tight, pliant, sensate, and of correct volume. Through a process of incision, plication and suturing, a tubular phallus is constructed within which is a skin lined tube which will serve as the urethra. The suture closures in both flaps is where most things go wrong because the skin edges that define the suture line can lose their blood supply to varying degrees. In the phalloplasty, when this happens, the patient suffers from delayed healing, urine leakage, varying degrees tissue death, and scarring. All of those problems can happen with either the throat flap, or the phallus flap. When the phallus flap fails, the patient suffers due to varying degrees of tissue loss, chronic urinary leakage, or urinary obstruction due to scarring that can cause kidney injury if left un-treated. When the throat flap fails, bacteria laden saliva will leak into the neck where it can cause fulminant infections, or erode into a major artery and cause the patient to bleed to death in a matter of moments. A singularly terrible event.

80. In the case of the throat operation, if the removal of the cancer had not been performed, there was a known and significant probability that the cancer would have eroded into the tissues of the neck and caused a fulminant infection, or eroded into a large blood vessel, as described above. In contrast, if the phallus flap operation, had not been performed, the patient would have remained fully functional in every human capacity, though suffering from an inner subjective disturbance called gender dysphoria, which has not yet been adequately treated.

81. Both operations involve the use of a highly complex surgical techniques to remedy a wound. In the case of the cancer operation the wound was the result of a cancer that would have ended in a terrible death. In the case of the phallus operation the surgeon is creating multiple physical wounds in a healthy child (castration, loss of pelvic organs of reproduction, de-gloving injury of the forearm, skin graft donor site injury), with their associated risks of complications. The surgery is performed in attempt to remedy a subjective, patient-reported sense of their identity.

Clearly the pre-operative condition of the cancer patient is far more 82. grievous than the condition of the young person who is suffering from gender dysphoria. The cancer patient would likely be more than willing to endure significant loss, such as voice, or teeth, or the sense of smell. And yet, if I were discussing surgical risk pre-operatively with my patient who has the throat cancer, and told him that there was a certainty that in the course of the operation he would lose all of his reproductive organs, he would be justified in asking why he was being subjected to such an unsafe operation. The patient wouldn't be even slightly interested in any further discussion of operative risks. The question of safety addresses itself to the question of potential losses caused by surgery. Transgender surgery of the genital apparatus predictably causes grievous loss that dwarfs such complications as infection, local tissue loss, urinary leakage or scarring. Such surgery can justly be considered universally unsafe in all cases, and particularly grievous when visited upon the young.

83. One of the peer reviewed article presented in support of masculinizing chest surgery, and found in numerous expert opinions submitted in pending federal

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cases. It is a 2017 paper, published in the peer reviewed journal JAMA Pediatrics¹⁶. it claims to support the conclusion that "surgical intervention (mastectomy, or chest masculinization) positively affected both minors and adults". This paper is perhaps the most alarming of all the citations presently offered and deserves a detailed examination.

84. The principle author, Dr. Olson-Kennedy is also an academic expert in her capacity as Associate Professor of Clinical Pediatrics, Keck School of Medicine of USC, and Medical Director of The Center for Transyouth Health and Development in Los Angeles. She holds professional membership in The Society for Pediatric Research, the World Professional Association for Transgender Health(WPATH), and the Society for Adolescent Health and Medicine. If any gender affirmation expert would be in a position to offer high quality, evidencebased publications, it would certainly be Dr. Olson -Kennedy.

85. In their summary of findings, the authors report that "chest dysphoria" is common among "trans males" (natal females seeking to present as males), and that the dysphoria is decreased by surgery. They claim that regret for surgery is "rare". It is a retrospective review of children treated at a single center. The article

¹⁶ Olson-Kennedy, J., Warus, . et al. Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts; JAMA Pediatr2018 May 1;172(5):431-436. doi: 10.1001/jamapediatrics.2017.5440.

reports breast removal surgery on at least one girl aged 13 years. The average age was 19. Children were entered into the study through recruitment from among patients visiting the clinic, and by telephone over a six-month period. The authors found that patients recruited from among visitors to the clinic (convenience sampling) yielded an abundance of non-operated patients, so they were forced to reach out to all the known post-surgical patients by phone. 26% of the clinic's postsurgical patients could not be reached for various reasons including no working phone, or failure to respond to multiple messages. A 26% drop-out rate is never questioned by the authors. Were they lost to follow up because of dissatisfaction, psychiatric hospitalization, or suicide? This problem is called "self-selection bias", and is evidence of careless study design. Of the remaining 74% of patients, only 72% of them (only 53% of the study patients) completed the survey. This is a second example of self-selection bias. Why would some post-surgical patients who had been successfully contacted, not complete the survey? The authors do not ask the question.

86. In the study, dysphoria was measured using "a novel measure" (an unproven test instrument) which was a series of subjective questions about happiness. Among the designers of this novel test instrument were some of the adolescent patients themselves. Their flawed methodology included the use of an entirely unvalidated test instrument, with no known error rates, or proven predictive
power, **that was in part designed by the minors and young adults who were the subject of the study.** Furthermore, the post-surgical patients were given the survey at varying time intervals post-surgery. The longest interval between surgery and the satisfaction survey was 5 years, but children less than a year post surgery were included in their flawed sample, and yet the authors claim evidence of "negligible regret." This is a remarkable claim given that long term, longitudinal population studies show that there is a dramatic rise in post-surgical problems such as depression, hospitalization, substance abuse, and suicide beginning at around year 7 post surgery (Dhejne cited below). Surely Dr. Olson-Kennedy is familiar with the international literature on transgender outcomes?

87. Having promised in the introduction to her paper that "chest dysphoria" is reduced by surgery, at the conclusion they confess the fact that the study design and execution produced very low-quality data that is not useful for patient selection, or prediction of outcomes. They even confess that the study does not address the efficacy of surgery in improving outcomes regarding the single most compelling reason for performing the operation: mitigation of depression and suicide. The authors write:

"An additional limitation of the study was the small sample size. The nonsurgical cohort was a convenience sample, recruited from those with appointments during the data collection period. There could be unknown imbalances between the nonsurgical and postsurgical cohorts that could have confounded the study findings.

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Finally, the Chest Dysphoria Scale is not yet validated, and may not represent distress or correlate with validated measures of quality of life, depression, anxiety, or functioning."

88. This paper is a typical example of a publications which are used to support transgender medicine and surgery, written by board certified transgender expert physicians who practice in our nation's largest pediatric gender clinics, and was published in peer-reviewed medical journals. The article is essentially useless in making any clinical decisions regarding who should be offered surgery, what the likelihood is that they will benefit from it, or the likelihood that they will regret their decision. Most importantly, it cannot even vaguely estimate if the risk of hospitalization, incarceration, or suicide will be reduced. For the same reason that the paper is not useful in clinical decision making, it is likewise not meaningful in decision-making by persons responsible the just management of public and private medical resources.

On the Experimental Nature of Transgender Surgery

89. One of the important usages of the term "experimental" in the world of medical care is in the domain of insurance services, both public and private. Leadership in these agencies is charged with the responsibility of managing medical resources in a way that both preserves resources, while at the same time applying those resources to the patient as correctly as medical science and their own actuarial information will allow. Whenever a novel therapy is proposed for a given condition,

insurance services will examine the medical and actuarial data to see if the proposed therapy is likely to yield a result that serves those two purposes (health of the patient, and financial soundness of the insurance process). Typically, in the early years of a new treatment there is resistance on the part of the payors because early on (as discussed in detail above) all that the proponents are able to present is low-level scientific papers that present anecdotal case collections without controls, or multiple studies that can not be compared due to methodological variation or are methodologically questionable due to unvalidated test instruments. History has shown, and the fact remains, that good surgery demands good evidence, particularly when permanent damage to the client is a possible result.

90. Nonetheless, if the insurance agency reviewer see evidence that a new approach may be helpful, they prudently insist that therapies of known value be tried to their reasonable limit first, and that they be found to have failed in solving the patient's condition. Only the will consideration be given to the new treatment.

91. This dynamic process between the patient, the physicians, and the insurance industry has many problems, but good, well validated scientific evidence is not one of those problems. In fact well validated science is typically the best remedy for those problems. Sometime the good science is from the doctors, and sometimes the good science comes from the actuaries. In both cases the patient benefits.

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92. From the perspective of the case in question, this sense of the term "experimental surgery" may be the most important. How did the affirmation care scientific model and its associated social, medical and surgical treatments enter into the mainstream of the medical community? Did it follow this same process of gradual acceptance in both the medical and insurance communities through a process of steadily improving evidence levels? Was it used on a careful trial basis after having exhausted treatment by established methods? The answer is that it did so, but only in part.

93. The historically validated treatment model for what is today called gender dysphoria is what is called "watchful waiting". On hearing the name one is tempted to think of this as a resignation to inaction. It is not. It is a psychotherapeutic process that is rooted first in an examination of the cognitive processes of the child, and seeing how the child has responded to the reality of their life. For this reason, in order to be effective, it must include family therapy. The goal is to keep the anxious and confused child in loving contact with reality, while seeking to understand and remedy the subjective dynamic that is provoking the condition of distress. It is essentially the same process used in helping persons who suffer other obsessive-compulsive issues, like eating disorders. Psychological research, having high level evidence, has shown that over the course of time this approach results in over 80%

resolution of the cross-sex self-identification during adolescence, and nearly 92% by young adulthood.(Zucker et al.).

94. This watchful-waiting approach is likely the reason why gender discordance used to be a rare diagnosis. The vast majority of people with the condition resolved the issues, and went on to live their lives without the need for life-long medications, without destructive surgeries, without the loss of their sexual faculties, and without the loss of fertility. What has happened, however, is that the dynamic between patient, physician, and insurance services has been severely disrupted.

95. The science based medical and actuarial management of this condition has been separated from the evidence, and now rests entirely on the opinions of academic experts who have managed to influence the decision makers in their favor. In large part, they have accomplished this by never speaking about watchful waiting except to dismiss it as folly. This process of silence and dismissal is exactly what ulcer surgeons did to the proponents of the scientifically correct infection model of ulcer disease.

96. Silence and dismissal about watchful waiting is not the only reason for the 5,000% increase in the diagnosis of transgender over the past decade. Surgeons who were seeking to achieve the best results for their transgender patients came to realize that most of the difficulty with good cosmetic results was that young men seeking to present as women tend to appear too masculine, and young women seeking to present as men tend to appear too feminine. They reasoned that if their masculine or feminine development had been arrested early, they would achieve better results. It was reasonable, in light of their treatment model, to think that a better cosmetic result would mean a better resolution of the gender incongruence. Thus the idea was born that the earlier the child was transitioned, the better the cosmetic surgical result, and thus the better psychological result, which is the goal.

97. This theoretical improvement in outcomes for transgender persons through early transition was certainly an idea worth investigating. Because the lifelong effects of the approach might include some really bad outcomes for the children, and because the actual outcomes were unknown at the time, it would have been prudent, and scientifically consistent to categorize this from the above described insurance industry perspective, as experimental. It would have required that the patients exhaust the fully established and proven treatment model of watchful waiting. If that treatment failed to resolve the issue, then on a trial basis, and supervised under very strenuous human experimentation oversight, the affirmation model could be tried.

98. In order for any highly supervised experimental approach to pass ethical standards in human experimentation there would have to have been a previously established diagnostic and patient selection process of very high specificity. If the proven and established method of watchful waiting is yielding 92% resolution, then what the ethically minded surgeon is really supposed to be doing is trying to find that 8% of children who would have failed watchful waiting, and select them out for surgery earlier in their life. Then studying the result on a very long-term and comprehensive basis, he would have been able to provide high-value evidence that his hypothesis about the successful early management of transgenderism is a safe and valid option for his patient. This was not done. Instead, the routine social and medical transitioning of children began, which includes puberty blockade, and cross-sex hormones in children and youth.

99. Instead of seeking the historically small cohort of children who would have carried the condition into adulthood and treating them, physicians and surgeons are treating all of those children now. Instead of seeking the scientific methodology with which to make a correct diagnosis so as to increase the likelihood that you are operating on the right person, the transgender treatment model is essentially turning all affected children into "the right person". By the time the youth or young adult person arrives in the surgeon's office the process has been locked into place.

100. It would seem that the best course of action for those who serve the insurance industry, including state Medicaid, is to return this process to the time tested dynamic model of patient, physician, and insurance plan discussed above.

Because the affirmation model rests upon such low-quality evidence, it seems justifiable to suspend financial support until such time as testing and patient selection processes are improved to acceptable levels of reliability. Given the serious, lifelong consequences of mis-diagnosis, and the misapplication of surgery, levels of patient selection reliability would have to be quite high.

101. A review of the European literature on this topic is instructful. The American literature used in support of the claim of benefit is of low reliability. We make this assertion based on the fact that to date all scientific citations offered in support of gender affirmation medicine and surgery is that they report studies of short duration. Follow up durations of less than 3 years are common. Some, as we have seen are as short as 4 months. This fact helps us to understand why proponents of the affirmation model are enthusiastic. Medical services in a number of European countries utilize centralized medical databases which employ uniform language, and report care over the life of the citizen.

102. The Swedish medical establishment maintains an excellent and centralized data base of all episodes of care for beneficiaries. It uses uniform language, and captures treatment events at all levels, from school clinics, to psychiatric hospitals, to prison infirmaries, to public clinics. The database can be analyzed for such things as emergency room visits, drug addiction treatment, hospitalization for suicide, psychiatric admissions for self-harming event etc.

In 2011, Dhejne et al.¹⁷ published a population based, longitudinal 103. cohort study of that database that sought to examine the lifetime hazard ratio of such things as substance abuse, incarceration for violent behavior, psychiatric hospitalization, and completed suicide. This is level-III evidence of high order given the methodology employed and the proven reliability of the database. It examined persons who have fully completed the gender affirmation process and compares them to age and sex matched controls in the Swedish population. It did not use anonymous surveys, or other faulty convenience sampling. It found the posttransition patients by finding the associated episodes of care, such as when hormone therapy prescriptions began, or admission for gender surgery occurred. The data set spans 30 years. What it shows is that fully transitioned subjects showed a relative risk of suicide roughly equal to the age/ sex matched controls, but the effect appears to last for just a few years. The trend line for death from any cause begins a sharp drop at approximately 10 years and continues to drop massively over the subsequent 15 years. When the researchers looked at the aggregate life-time relative risk of suicide, persons who fully transitioned were over 19 times more likely to have killed themselves when compared to age and sex matched controls. If you only look at the subgroup of biological females who transitioned to male-presentation, the risk of

¹⁷ Dhejne,C., Lichtenstein, P., et al. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden; PLoS One2011 Feb 22;6(2):e16885. doi: 10.1371/journal.pone.0016885.

suicide is 40 times higher than the control group. Results such as these, because they are obtained using tested and reliable methodology, are able to help meaningfully in clinical and administrative decision making, and in several European countries it has.

104. Over the past several years, the medical systems in Great Britain, Sweden, Finland, and France¹⁸¹⁹²⁰ have stepped away from early medical and surgical transitioning of the young. The Tavistock-Portman Institute in London, which was the sole provider of these services to children in Great Britain was closed

 ¹⁸ NHS Amendments to service specifications for Gender Identity Development Service (GIDS) for children and adolescents, effective 01 Dec 2020. https://www.england.nhs.uk/wp-content/uploads/2020/12/Amendment-to-Gender-Identity-Development-Service-Specification-for-Children-and-Adolescents.pdf
 ¹⁹ Sweden's Karolinska Hospital (affectingAstrid Lindgren Children's Hospital's pediatric gender services) issues a policy change effective April 1, 2021:

- "For patients between ages 16 and 18, it is hereby decided that treatment may only occur within the clinical trial settings approved by the EPM (*Ethical Review Agency/Swedish Institutional Review Board*)."
- "These changes shall not affect the continued psychological and psychiatric care within BUP (*Public Child and Adolescent Psychiatry*) for patients under 18 years of age." "The patient must receive comprehensive information about potential risks of the treatment..."
- Cited UK High Court Decision, NHS policy change in light of it, and that in "2019, the SBU (*Swedish Agency for Health Technology Assessment and Assessment of Social Services*) published an overview of the knowledge base which showed a lack of evidence for both the long-term consequences of the treatments, and the reasons for the large influx of patients in recent years."¹⁹
- "These treatments are potentially fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis."

Karolinska Policyförändring K2021-3343 March 2021 (Swedish).pdf Karolinska Policy Change K2021-3343 March 2021 (English, unofficial translation).pdf

²⁰ Finland rejects routine "affirmation" pathway for minors with GD. From Finnish Health Authority, *Council for Choices in Health Care in Finland (COHERE Finland)* 2020:

^{• &}quot;...hormonal treatments (*i.e., puberty blocking and cross-sex hormones, see above*) will not be initiated in gender dysphoric patients under the age of 16."

recently following the public declaration by a review committee that the Institute was "unsafe for children". Similarly, the Karolinska Institute in Stockholm reversed its policy by suspending the medical and surgical transitioning of the young in favor or psychological support and treatment. Similar changes in treatment guidelines for self-identified transgender youth have been published in Finland, and are currently being developed in Italy.

105. Based upon these developments in Europe, it is very troubling to read assessments or declarations by leaders in the field of transgender surgery which assert that these treatments are mainstream and beyond controversy, or that they are part of a core curriculum of surgical training, or that an oral board examiner might fail a candidate surgeon if their answers reveal a reticence to join the mainstream as defined by gender affirmation advocates. The world literature demonstrates emphatically that early medical and surgical transitioning is in fact so controversial that medical leadership in multiple countries has put a stop to it.

106. In summary, transgender surgery is based in a treatment model of affirmation that lacks scientific support based in quality evidence. The scientific support offered by the leaders in the field is entirely composed of small studies, single provider /single center studies that are lacking in control cohorts, and are often rendered uninterpretable due to haphazard case-collections such as the solicitation of study participants without methodology to confirm that the patient is a treatment

subject. All of the studies cited in expert filings by gender affirmation practitioners have short follow-up, and most studies suffer from massive self-selection bias and high drop-out rates. The studies often employ untested assessment methodologies, and all of the literature cited by experts report only subjective data, which is typical of papers that address outcomes in cosmetic surgery.

107. Transgender surgery is, by definition, cosmetic surgery. The move towards surgery begins in the subjective life of the patient, is conducted with the aim of improving the subjective life of the patient, and outcomes are measured in subjective terms based in satisfaction surveys. Transgender surgery violates fundamental principle of cosmetic surgery, because it predictably destroys essential functions of the human person. It is not reconstructive surgery because the patient is physically healthy before the surgery, and has no definable deficit that can be objectively characterized to be the cause of the presenting complaint. There is no objective test to confirm the diagnosis of transgender, and no way to correctly select patients for surgery from among the young. The enterprise of gender affirmation medicine and surgery is based entirely in a consensus of expert opinion of low reliability because it is supported by unreliable scientific evidence. I declare, pursuant to 28 USC § 1746, under penalty of perjury that the

foregoing is true and correct. Executed this 16th day of February, 2023.

<u>/s/ Patrick W. Lappert</u> Dr. Patrick W. Lappert, M.D.

Curriculum Vitae- Patrick W. Lappert, MD

Education and Training :

— Bachelor of Arts in Biological Sciences at the University of California, Santa Barbara, 1979. Research in cell membrane physiology with Dr. Philip C. Laris, studying stoichiometry of the sodium: potassium ATPase pump.

- M.D., Doctor of Medicine degree at the Uniformed Services University of the Health Sciences, 1983 at Bethesda, Md.

- General Surgery Residency at the Naval Hospital Oakland/ UC Davis East Bay Consortium, 1987-1991
- Chief Resident, Department of Surgery, Naval Hospital Oakland, 1990-1991.
- Plastic Surgery Residency at the University of Tennessee- Memphis, 1992-1994.

Board Certifications in Medicine :

- Board Certified in Surgery American Board of Surgery, 1992-2002
- Board Certified in Plastic Surgery American Board of Plastic Surgery, 1997-2018

Medical Staff Appointments :

- Staff General Surgeon at the Naval Hospital Oakland, CA 1991-1992
- Associate Professor of Surgery, UC Davis-East Bay, 1991-1992.
- Plastic and Reconstructive Surgeon, Naval Medical Center, Portsmouth, VA 1994-2002
- Chairman, Department of Plastic and Reconstructive Surgery, Naval Hospital Portsmouth, VA 1996-2002.
- Clinical Assistant Professor, Department of Surgery, Uniformed Services University of the Health Sciences, 1995-2002

- Founding Director, Pediatric Cleft Palate and Craniofacial Deformities Clinic, Naval Hospital Portsmouth, VA 1996-20002

- Founding Director, Wound Care Center, Naval Hospital Portsmouth, VA 1995-2002.

— Staff Plastic Surgeon in Nebraska, and Alabama.

U.S.N. Surgeon General Service:

- Specialty Leader, Plastic and Reconstructive Surgery, Office of the Surgeon General-USN, 1997-2002

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- Teaching Faculty at Eastern Virginia Medical School, Division of Plastic Surgery, 1995-2002

Military Service :

- Aviation Officer Candidate, Naval Aviation Schools Command, NAS Pensacola, 1978
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- Designated Naval Flight Surgeon, Naval Aerospace Medical Institute, 1985
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- Radar Intercept Officer in the Marine F-4S Phantom, accumulating 235 flight hours, and trained for qualification as an Air Combat Tactics Instructor.

- Deployed to the Western Pacific as UDP forward deployed fighter squadron in Korea, Japan, and the Philippines.

- Service in the US Navy for 24 years
- Service in the US Marine Corp. for 3 years.
- Retired with the rank of Captain, USN in 2002

Military Awards:

- Navy Commendation Medal For service with Marine Fighter/Attack Squadron 451
- Meritorious Unit Citation- 3rd award
- Humanitarian Service Medal For service in the aftermath of the Loma Prieta earthquake.

Publications - Peer Reviewed Medical Journals :

- Lappert PW. Peritoneal Fluid in Human Acute Pancreatitis. Surgery. 1987 Sep;102(3):553-4

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Publications - Medical Textbooks:

— Wound Management in the Military. Lappert PW, Weiss DD, Eriksson E. Plastic Surgery: Indications, Operations, and Outcomes, Vol. 1; 53-63. Mosby. St. Louis, MO 2000

Operations and Clinical Experience - Consultations and Discussions : As a physician and surgeon, I have treated many thousands of patients in 7 states and 4 foreign nations. My practice has included Primary Care, Family Medicine, Aerospace Medicine, General Surgery, Reconstructive Surgery for combat injured, cancer reconstructive surgeries including extensive experience with microvascular surgery, Pediatric Congenital Deformity, and the care of chronic wounds. I have practiced in rural medicine, urban trauma centers, military field hospitals, university teaching hospitals, and as a solo private practitioner. In my private practice I have had occasion to treat many self-identified transgender patients for skin pathologies related to their use of high dose sex steroids, laser therapies for management of facial hair both in transitioners and detransitioners. I have performed breast reversal surgeries for detransitioning patients. My practice is rated as "LGBTQ friendly" on social media. I have consulted with families with children who are experiencing gender discordance. I have given many presentations to professional meetings of educators and counselors on the subject of transgender, and the present state of the science and treatment. I have discussed the scientific issues relevant to the case with many physicians and experts over a number of years and also discussed related issues with parents and others.

Endocrine Treatment of Gender-Dysphoric Gender-Incongruent Persons: An Endocrine Society* **Clinical Practice Guideline**

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> *Cosponsoring Associations: American Association of Clinical Endocrinologists, American Society of Andrology, European Society for Pediatric Endocrinology, European Society of Endocrinology, Pediatric Endocrine Society, and World Professional Association for Transgender Health.

Objective: To update the "Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline," published by the Endocrine Society in 2009.

Participants: The participants include an Endocrine Society-appointed task force of nine experts, a methodologist, and a medical writer.

Evidence: This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation approach to describe the strength of recommendations and the quality of evidence. The task force commissioned two systematic reviews and used the best available evidence from other published systematic reviews and individual studies.

Consensus Process: Group meetings, conference calls, and e-mail communications enabled consensus. Endocrine Society committees, members and cosponsoring organizations reviewed and commented on preliminary drafts of the guidelines.

Conclusion: Gender affirmation is multidisciplinary treatment in which endocrinologists play an important role. Gender-dysphoric/gender-incongruent persons seek and/or are referred to endocrinologists to develop the physical characteristics of the affirmed gender. They require 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. Hormone treatment is not recommended for prepubertal gender-dysphoric/gender-incongruent persons. Those clinicians who recommend gender-affirming endocrine treatments-appropriately trained diagnosing clinicians (required), a mental health provider for adolescents (required) and mental health

ISSN Print 0021-972X ISSN Online 1945-7197 Printed in USA Copyright © 2017 Endocrine Society Received 24 July 2017. Accepted 24 August 2017. First Published Online 13 September 2017

doi: 10.1210/jc.2017-01658

J Clin Endocrinol Metab, November 2017, 102(11):3869–3903 https://academic.oup.com/jcem

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Abbreviations: BMD, bone mineral density; DSD, disorder/difference of sex development; DSM, Diagnostic and Statistical Manual of Mental Disorders; GD, gender dysphoria; GnRH, gonadotropin-releasing hormone; ICD, International Statistical Classification of Diseases and Related Health Problems; MHP, mental health professional; VTE, venous thromboembolism.

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professional for adults (recommended)—should be knowledgeable about the diagnostic criteria and criteria for gender-affirming treatment, have sufficient training and experience in assessing psychopathology, and be willing to participate in the ongoing care throughout the endocrine transition. We recommend treating gender-dysphoric/gender-incongruent adolescents who have entered puberty at Tanner Stage G2/B2 by suppression with gonadotropin-releasing hormone agonists. Clinicians may add gender-affirming hormones after a multidisciplinary team has confirmed the persistence of gender dysphoria/gender incongruence and sufficient mental capacity to give informed consent to this partially irreversible treatment. Most adolescents have this capacity by age 16 years old. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to age 16 years, although there is minimal published experience treating prior to 13.5 to 14 years of age. For the care of peripubertal youths and older adolescents, we recommend that an expert multidisciplinary team comprised of medical professionals and mental health professionals manage this treatment. The treating physician must confirm the criteria for treatment used by the referring mental health practitioner and collaborate with them in decisions about gender-affirming surgery in older adolescents. For adult gender-dysphoric/gender-incongruent persons, the treating clinicians (collectively) should have expertise in transgender-specific diagnostic criteria, mental health, primary care, hormone treatment, and surgery, as needed by the patient. We suggest maintaining physiologic levels of gender-appropriate hormones and monitoring for known risks and complications. When high doses of sex steroids are required to suppress endogenous sex steroids and/or in advanced age, clinicians may consider surgically removing natal gonads along with reducing sex steroid treatment. Clinicians should monitor both transgender males (female to male) and transgender females (male to female) for reproductive organ cancer risk when surgical removal is incomplete. Additionally, clinicians should persistently monitor adverse effects of sex steroids. For gender-affirming surgeries in adults, the treating physician must collaborate with and confirm the criteria for treatment used by the referring physician. Clinicians should avoid harming individuals (via hormone treatment) who have conditions other than gender dysphoria/gender incongruence and who may not benefit from the physical changes associated with this treatment. (J Clin Endocrinol Metab 102: 3869-3903, 2017)

Summary of Recommendations

1.0 Evaluation of youth and adults

- 1.1. We advise that only trained mental health professionals (MHPs) who meet the following criteria should diagnose gender dysphoria (GD)/ gender incongruence in adults: (1) competence in using the Diagnostic and Statistical Manual of Mental Disorders (DSM) and/or the International Statistical Classification of Diseases and Related Health Problems (ICD) for diagnostic purposes, (2) the ability to diagnose GD/ gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)
- 1.2. We advise that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or the ICD for diagnostic purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents. (Ungraded Good Practice Statement)
- 1.3. We advise that decisions regarding the social transition of prepubertal youths with GD/gender incongruence are made with the assistance of an MHP or another experienced professional. (Ungraded Good Practice Statement).

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- 1.4. We recommend against puberty blocking and gender-affirming hormone treatment in pre-pubertal children with GD/gender incongruence. (1 |⊕⊕○○)
- 1.5. We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. (1 l⊕⊕⊕○)

2.0 Treatment of adolescents

- 2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment, and are requesting treatment should initially undergo treatment to suppress pubertal development. (2 I⊕⊕○○)
- We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty. (2 I⊕⊕○○)
- 2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones. (1 I⊕⊕○○)
- 2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years. (1 |⊕⊕○○).
- 2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/ gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 |⊕000)
- 2.6. We suggest monitoring clinical pubertal development every 3 to 6 months and laboratory parameters every 6 to 12 months during sex hormone treatment, (2 |⊕⊕○○)

3.0 Hormonal therapy for transgender adults

3.1. We recommend that clinicians confirm the diagnostic criteria of GD/gender incongruence and the criteria for the endocrine phase of gender transition before beginning treatment. $(1 \mid \oplus \oplus \oplus \bigcirc)$

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- 3.2. We recommend that clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment. (1 1⊕⊕⊕○)
- 3.3. We suggest that clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex steroids are maintained in the normal physiologic range for the affirmed gender. (2 I⊕⊕○○)
- 3.4. We suggest that endocrinologists provide education to transgender individuals undergoing treatment about the onset and time course of physical changes induced by sex hormone treatment. (2 I⊕○○○)

4.0 Adverse outcome prevention and long-term care

- 4.1. We suggest regular clinical evaluation for physical changes and potential adverse changes in response to sex steroid hormones and laboratory monitoring of sex steroid hormone levels every 3 months during the first year of hormone therapy for transgender males and females and then once or twice yearly. (2 |⊕⊕○○)
- 4.2. We suggest periodically monitoring prolactin levels in transgender females treated with estrogens. (2 |⊕⊕○○)
- 4.3. We suggest that clinicians evaluate transgender persons treated with hormones for cardiovas-cular risk factors using fasting lipid profiles, diabetes screening, and/or other diagnostic tools. (2 l⊕⊕○○)
- 4.4. We recommend that clinicians obtain bone mineral density (BMD) measurements when risk factors for osteoporosis exist, specifically in those who stop sex hormone therapy after gonadectomy. (1 |⊕⊕○○)
- 4.5. We suggest that transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for non-transgender females. (2 I⊕⊕○○)
- 4.6. We suggest that transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer. (2 I⊕○○○)
- 4.7. We advise that clinicians determine the medical necessity of including a total hysterectomy and oophorectomy as part of gender-affirming surgery. (Ungraded Good Practice Statement)

5.0 Surgery for sex reassignment and gender confirmation

- 5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being. (1 |⊕⊕○○)
- 5.2. We advise that clinicians approve genital genderaffirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)
- 5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)
- 5.4. We recommend that clinicians refer hormonetreated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 I⊕OOO)
- 5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. (2 I⊕⊕○○).
- 5.6. We suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement. (2 I⊕OOO)

Changes Since the Previous Guideline

Both the current guideline and the one published in 2009 contain similar sections. Listed here are the sections contained in the current guideline and the corresponding number of recommendations: Introduction, Evaluation of Youth and Adults (5), Treatment of Adolescents (6), Hormonal Therapy for Transgender Adults (4), Adverse Outcomes Prevention and Long-term Care (7), and Surgery for Sex Reassignment and Gender Confirmation (6). The current introduction updates the diagnostic classification of "gender dysphoria/gender incongruence." It also reviews the development of "gender identity" and summarizes its natural development. The section on clinical evaluation of both youth and adults, defines in detail the professional qualifications required of those who diagnose and treat both adolescents and adults. We advise that decisions regarding the social transition of prepubertal youth are made with the assistance of a mental health professional or similarly experienced professional. We recommend against puberty blocking followed by gender-affirming hormone treatment of prepubertal children. Clinicians should inform pubertal children, adolescents, and adults seeking genderconfirming treatment of their options for fertility preservation. Prior to treatment, clinicians should evaluate the presence of medical conditions that may be worsened by hormone depletion and/or treatment. A multidisciplinary team, preferably composed of medical and mental health professionals, should monitor treatments. Clinicians evaluating transgender adults for endocrine treatment should confirm the diagnosis of persistent gender dysphoria/gender incongruence. Physicians should educate transgender persons regarding the time course of steroid-induced physical changes. Treatment should include periodic monitoring of hormone levels and metabolic parameters, as well as assessments of bone density and the impact upon prostate, gonads, and uterus. We also make recommendations for transgender persons who plan genital gender-affirming surgery.

Method of Development of Evidence-Based Clinical Practice Guidelines

The Clinical Guidelines Subcommittee (CGS) of the Endocrine Society deemed the diagnosis and treatment of individuals with GD/gender incongruence a priority area for revision and appointed a task force to formulate evidence-based recommendations. The task force 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 (1). A detailed description of the grading scheme has been published elsewhere (2). The task force used the best available research evidence to develop the recommendations. The task force also used consistent language and graphical descriptions of both the strength of a recommendation and the quality of evidence. In terms of the strength of the recommendation, strong recommendations use the phrase "we recommend" and the number 1, and weak recommendations use the phrase "we suggest" and the number 2. Cross-filled circles indicate the quality of the evidence, such that $\oplus 000$ denotes very low-quality evidence; $\oplus \oplus \bigcirc \bigcirc$, low quality; $\oplus \oplus \oplus \odot$, moderate quality; and $\oplus \oplus \oplus \oplus$, high quality. The task force has confidence that persons who receive care according to the strong recommendations will derive, on average, more benefit than harm. Weak recommendations require more careful consideration of the person's circumstances, values, and preferences to determine the best course of action. Linked to each recommendation is a description of the evidence and the

values that the task force considered in making the recommendation. In some instances, there are remarks in which the task force offers technical suggestions for testing conditions, dosing, and monitoring. These technical comments reflect the best available evidence applied to a typical person being treated. Often this evidence comes from the unsystematic observations of the task force and their preferences; therefore, one should consider these remarks as suggestions.

In this guideline, the task force made several statements to emphasize the importance of shared decision-making, general preventive care measures, and basic principles of the treatment of transgender persons. They labeled these "Ungraded Good Practice Statement." Direct evidence for these statements was either unavailable or not systematically appraised and considered out of the scope of this guideline. The intention of these statements is to draw attention to these principles.

The Endocrine Society maintains a rigorous conflict-ofinterest review process for developing clinical practice guidelines. All task force members must declare any potential conflicts of interest by completing a conflict-of-interest form. The CGS reviews all conflicts of interest before the Society's Council approves the members to participate on the task force and periodically during the development of the guideline. All others participating in the guideline's development must also disclose any conflicts of interest in the matter under study, and most of these participants must be without any conflicts of interest. The CGS and the task force have reviewed all disclosures for this guideline and resolved or managed all identified conflicts of interest.

Conflicts of interest are defined as remuneration in any amount from commercial interests; grants; research support; consulting fees; salary; ownership interests [*e.g.*, stocks and stock options (excluding diversified mutual funds)]; honoraria and other payments for participation in speakers' bureaus, advisory boards, or boards of directors; and all other financial benefits. Completed forms are available through the Endocrine Society office.

The Endocrine Society provided the funding for this guideline; the task force received no funding or remuneration from commercial or other entities.

Commissioned Systematic Review

The task force commissioned two systematic reviews to support this guideline. The first one aimed to summarize the available evidence on the effect of sex steroid use in transgender individuals on lipids and cardiovascular outcomes. The review identified 29 eligible studies at moderate risk of bias. In transgender males (female to male), sex steroid therapy was associated with a statistically significant increase in serum triglycerides and low-density lipoprotein cholesterol levels. High-density lipoprotein cholesterol levels decreased significantly across all follow-up time periods. In transgender females (male to female), serum triglycerides were significantly higher without any changes in other parameters. Few myocardial infarction, stroke, venous thromboembolism (VTE), and death events were reported. These events were more frequent in transgender females. However, the quality of the evidence was low. The second review summarized the available evidence regarding the effect of sex steroids on bone health in transgender individuals and identified 13 studies. In transgender males, there was no statistically significant difference in the lumbar spine, femoral neck, or total hip BMD at 12 and 24 months compared with baseline values before initiating masculinizing hormone therapy. In transgender females, there was a statistically significant increase in lumbar spine BMD at 12 months and 24 months compared with baseline values before initiation of feminizing hormone therapy. There was minimal information on fracture rates. The quality of evidence was also low.

Introduction

Throughout recorded history (in the absence of an endocrine disorder) some men and women have experienced confusion and anguish resulting from rigid, forced conformity to sexual dimorphism. In modern history, there have been numerous ongoing biological, psychological, cultural, political, and sociological debates over various aspects of gender variance. The 20th century marked the emergence of a social awakening for men and women with the belief that they are "trapped" in the wrong body (3). Magnus Hirschfeld and Harry Benjamin, among others, pioneered the medical responses to those who sought relief from and a resolution to their profound discomfort. Although the term transsexual became widely known after Benjamin wrote "The Transsexual Phenomenon" (4), it was Hirschfeld who coined the term "transsexual" in 1923 to describe people who want to live a life that corresponds with their experienced gender vs their designated gender (5). Magnus Hirschfeld (6) and others (4, 7) have described other types of trans phenomena besides transsexualism. These early researchers proposed that the gender identity of these people was located somewhere along a unidimensional continuum. This continuum ranged from all male through "something in between" to all female. Yet such a classification does not take into account that people may have gender identities outside this continuum. For instance, some experience themselves as having both a male and female gender identity, whereas others completely renounce any gender classification (8, 9). There are also reports of individuals experiencing a continuous and rapid involuntary alternation between a male and female identity (10) or men who do not experience themselves as men but do not want to live as women (11, 12). In some countries, (e.g., Nepal, Bangladesh, and Australia), these nonmale or nonfemale genders are officially recognized (13). Specific treatment protocols, however, have not yet been developed for these groups.

Instead of the term transsexualism, the current classification system of the American Psychiatric Association uses the term gender dysphoria in its diagnosis of persons who are not satisfied with their designated gender (14). The current version of the World Health Organization's ICD-10 still uses the term transsexualism when diagnosing adolescents and adults. However, for the ICD-11, the World Health Organization has proposed using the term "gender incongruence" (15).

Treating persons with GD/gender incongruence (15) was previously limited to relatively ineffective elixirs or creams. However, more effective endocrinology-based treatments became possible with the availability of testosterone in 1935 and diethylstilbestrol in 1938. Reports of individuals with GD/gender incongruence who were treated with hormones and gender-affirming surgery appeared in the press during the second half of the 20th century. The Harry Benjamin International Gender Dysphoria Association was founded in September 1979 and is now called the World Professional Association for Transgender Health (WPATH). WPATH published its first Standards of Care in 1979. These standards have since been regularly updated, providing guidance for treating persons with GD/gender incongruence (16).

Prior to 1975, few peer-reviewed articles were published concerning endocrine treatment of transgender persons. Since then, more than two thousand articles about various aspects of transgender care have appeared.

It is the purpose of this guideline to make detailed recommendations and suggestions, based on existing medical literature and clinical experience, that will enable treating physicians to maximize benefit and minimize risk when caring for individuals diagnosed with GD/gender incongruence.

In the future, we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols. Specifically, endocrine treatment protocols for GD/gender incongruence should include the careful assessment of the following: (1) the effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain (including effects on cognitive, emotional, social, and sexual development); (2) the effects of treatment in adults on sex hormone levels; (3) the requirement for and the effects of progestins and other agents used to suppress endogenous sex steroids during treatment; and (4) the risks and benefits of gender-affirming hormone treatment in older transgender people.

To successfully establish and enact these protocols, a commitment of mental health and endocrine investigators is required to collaborate in long-term, large-scale studies across countries that use the same diagnostic and inclusion criteria, medications, assay methods, and response assessment tools (*e.g.*, the European Network for the Investigation of Gender Incongruence) (17, 18).

Terminology and its use vary and continue to evolve. Table 1 contains the definitions of terms as they are used throughout this guideline.

Biological Determinants of Gender Identity Development

One's self-awareness as male or female changes gradually during infant life and childhood. This process of cognitive and affective learning evolves with interactions with parents, peers, and environment. A fairly accurate timetable exists outlining the steps in this process (19). Normative psychological literature, however, does not address if and when gender identity becomes crystallized and what factors contribute to the development of a gender identity that is not congruent with the gender of rearing. Results of studies from a variety of biomedical disciplines—genetic, endocrine, and neuroanatomic—support the concept that gender identity and/or gender expression (20) likely reflect a complex interplay of biological, environmental, and cultural factors (21, 22).

With respect to endocrine considerations, studies have failed to find differences in circulating levels of sex steroids between transgender and nontransgender individuals (23). However, studies in individuals with a disorder/difference of sex development (DSD) have informed our understanding of the role that hormones may play in gender identity outcome, even though most persons with GD/gender incongruence do not have a DSD. For example, although most 46,XX adult individuals with virilizing congenital adrenal hyperplasia caused by mutations in CYP21A2 reported a female gender identity, the prevalence of GD/gender incongruence was much greater in this group than in the general population without a DSD. This supports the concept that there is a role for prenatal/postnatal androgens in gender development (24-26), although some studies indicate that prenatal androgens are more likely to affect gender behavior and sexual orientation rather than gender identity per se (27, 28).

Researchers have made similar observations regarding the potential role of androgens in the development of gender identity in other individuals with DSD. For example, a review of two groups of 46,XY persons, each with androgen synthesis deficiencies and female raised, reported transgender male (female-to-male) gender role changes in 56% to 63% and 39% to 64% of patients, respectively (29). Also, in 46,XY female-raised individuals with cloacal

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Table 1. Definitions of Terms Used in This Guideline

- Biological sex, biological male or female: These terms refer to physical aspects of maleness and femaleness. As these may not be in line with each other (e.g., a person with XY chromosomes may have female-appearing genitalia), the terms biological sex and biological male or female are imprecise and should be avoided.
- Cisgender: This means not transgender. An alternative way to describe individuals who are not transgender is "non-transgender people."

Gender-affirming (hormone) treatment: See "gender reassignment"

- Gender dysphoria: This is the distress and unease experienced if gender identity and designated gender are not completely congruent (see Table 2). In 2013, the American Psychiatric Association released the fifth edition of the DSM-5, which replaced "gender identity disorder" with "gender dysphoria" and changed the criteria for diagnosis.
- Gender expression: This refers to external manifestations of gender, expressed through one's name, pronouns, clothing, haircut, behavior, voice, or body characteristics. Typically, transgender people seek to make their gender expression align with their gender identity, rather than their designated gender.
- Gender identity/experienced gender: This refers to one's internal, deeply held sense of gender. For transgender people, their gender identity does not match their sex designated at birth. Most people have a gender identity of man or woman (or boy or girl). For some people, their gender identity does not fit neatly into one of those two choices. Unlike gender expression (see below), gender identity is not visible to others.
- Gender identity disorder: This is the term used for GD/gender incongruence in previous versions of DSM (see "gender dysphoria"). The ICD-10 still uses the term for diagnosing child diagnoses, but the upcoming ICD-11 has proposed using "gender incongruence of childhood."
- Gender incongruence: This is an umbrella term used when the gender identity and/or gender expression differs from what is typically associated with the designated gender. Gender incongruence is also the proposed name of the gender identity–related diagnoses in ICD-11. Not all individuals with gender incongruence have gender dysphoria or seek treatment. Gender variance: See "gender incongruence"
- Gender reassignment: This refers to the treatment procedure for those who want to adapt their bodies to the experienced gender by means of hormones and/or surgery. This is also called gender-confirming or gender-affirming treatment.
- Gender-reassignment surgery (gender-confirming/gender-affirming surgery): These terms refer only to the surgical part of genderconfirming/gender-affirming treatment.
- Gender role: This refers to behaviors, attitudes, and personality traits that a society (in a given culture and historical period) designates as masculine or feminine and/or that society associates with or considers typical of the social role of men or women.
- Sex designated at birth: This refers to sex assigned at birth, usually based on genital anatomy.
- Sex: This refers to attributes that characterize biological maleness or femaleness. The best known attributes include the sex-determining genes, the sex chromosomes, the H-Y antigen, the gonads, sex hormones, internal and external genitalia, and secondary sex characteristics.
- Sexual orientation: This term describes an individual's enduring physical and emotional attraction to another person. Gender identity and sexual orientation are not the same. Irrespective of their gender identity, transgender people may be attracted to women (gynephilic), attracted to men (androphilic), bisexual, asexual, or queer.
- Transgender: This is an umbrella term for people whose gender identity and/or gender expression differs from what is typically associated with their sex designated at birth. Not all transgender individuals seek treatment.
- Transgender male (also: trans man, female-to-male, transgender male): This refers to individuals assigned female at birth but who identify and live as men.
- Transgender woman (also: trans woman, male-to female, transgender female): This refers to individuals assigned male at birth but who identify and live as women.
- Transition: This refers to the process during which transgender persons change their physical, social, and/or legal characteristics consistent with the affirmed gender identity. Prepubertal children may choose to transition socially.
- Transsexual: This is an older term that originated in the medical and psychological communities to refer to individuals who have permanently transitioned through medical interventions or desired to do so.

exstrophy and penile agenesis, the occurrence of transgender male changes was significantly more prevalent than in the general population (30, 31). However, the fact that a high percentage of individuals with the same conditions did not change gender suggests that cultural factors may play a role as well.

With respect to genetics and gender identity, several studies have suggested heritability of GD/gender incongruence (32, 33). In particular, a study by Heylens *et al.* (33) demonstrated a 39.1% concordance rate for gender identity disorder (based on the DSM-IV criteria) in 23 monozygotic twin pairs but no concordance in 21 same-sex dizygotic or seven opposite-sex twin pairs. Although numerous investigators have sought to identify

specific genes associated with GD/gender incongruence, such studies have been inconsistent and without strong statistical significance (34–38).

Studies focusing on brain structure suggest that the brain phenotypes of people with GD/gender incongruence differ in various ways from control males and females, but that there is not a complete sex reversal in brain structures (39).

In summary, although there is much that is still unknown with respect to gender identity and its expression, compelling studies support the concept that biologic factors, in addition to environmental factors, contribute to this fundamental aspect of human development. 3876 Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869–3903

Natural History of Children With GD/Gender Incongruence

With current knowledge, we cannot predict the psychosexual outcome for any specific child. Prospective follow-up studies show that childhood GD/gender incongruence does not invariably persist into adolescence and adulthood (so-called "desisters"). Combining all outcome studies to date, the GD/gender incongruence of a minority of prepubertal children appears to persist in adolescence (20, 40). In adolescence, a significant number of these desisters identify as homosexual or bisexual. It may be that children who only showed some gender nonconforming characteristics have been included in the follow-up studies, because the DSM-IV text revision criteria for a diagnosis were rather broad. However, the persistence of GD/gender incongruence into adolescence is more likely if it had been extreme in childhood (41, 42). With the newer, stricter criteria of the DSM-5 (Table 2), persistence rates may well be different in future studies.

1.0 Evaluation of Youth and Adults

Gender-affirming treatment is a multidisciplinary effort. After evaluation, education, and diagnosis, treatment may include mental health care, hormone therapy, and/or surgical therapy. Together with an MHP, hormoneprescribing clinicians should examine the psychosocial impact of the potential changes on people's lives, including mental health, friends, family, jobs, and their role in society. Transgender individuals should be encouraged to experience living in the new gender role and assess whether this improves their quality of life. Although the focus of this guideline is gender-affirming hormone therapy, collaboration with appropriate professionals responsible for each aspect of treatment maximizes a successful outcome.

Diagnostic assessment and mental health care

GD/gender incongruence may be accompanied with psychological or psychiatric problems (43-51). It is therefore necessary that clinicians who prescribe hormones and are involved in diagnosis and psychosocial assessment meet the following criteria: (1) are competent in using the DSM and/or the ICD for diagnostic purposes, (2) are able to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) are trained in diagnosing psychiatric conditions, (4) undertake or refer for appropriate treatment, (5) are able to do a psychosocial assessment of the patient's understanding, mental health, and social conditions that can impact genderaffirming hormone therapy, and (6) regularly attend relevant professional meetings.

Because of the psychological vulnerability of many individuals with GD/gender incongruence, it is important that mental health care is available before, during, and sometimes also after transitioning. For children and adolescents, an MHP who has training/experience in child and adolescent gender development (as well as child and adolescent psychopathology) should make the diagnosis, because assessing GD/gender incongruence in children and adolescents is often extremely complex.

During assessment, the clinician obtains information from the individual seeking gender-affirming treatment. In the case

Table 2. DSM-5 Criteria for Gender Dysphoria in Adolescents and Adults

A. A marked incongruence between one's experienced/expressed gender and natal gender of at least 6 mo in duration, as manifested by at least two of the following:

- 1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
- A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
- 3. A strong desire for the primary and/or secondary sex characteristics of the other gender
- 4. A strong desire to be of the other gender (or some alternative gender different from one's designated gender)
- 5. A strong desire to be treated as the other gender (or some alternative gender different from one's designated gender)
- 6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's designated gender)
- B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Specify if:

- 1. The condition exists with a disorder of sex development.
- 2. The condition is posttransitional, in that the individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one sex-related medical procedure or treatment regimen—namely, regular sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in natal males; mastectomy or phalloplasty in natal females).

Reference: American Psychiatric Association (14).

of adolescents, the clinician also obtains information from the parents or guardians regarding various aspects of the child's general and psychosexual development and current functioning. On the basis of this information, the clinician:

- decides whether the individual fulfills criteria for treatment (see Tables 2 and 3) for GD/gender incongruence (DSM-5) or transsexualism (DSM-5 and/or ICD-10);
- informs the individual about the possibilities and limitations of various kinds of treatment (hormonal/ surgical and nonhormonal), and if medical treatment is desired, provides correct information to prevent unrealistically high expectations;
- assesses whether medical interventions may result in unfavorable psychological and social outcomes.

In cases in which severe psychopathology, circumstances, or both seriously interfere with the diagnostic work or make satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues. Literature on postoperative regret suggests that besides poor quality of surgery, severe psychiatric comorbidity and lack of support may interfere with positive outcomes (52–56).

For adolescents, the diagnostic procedure usually includes a complete psychodiagnostic assessment (57) and an assessment of the decision-making capability of the youth. An evaluation to assess the family's ability to endure stress, give support, and deal with the complexities of the adolescent's situation should be part of the diagnostic phase (58).

Social transitioning

A change in gender expression and role (which may involve living part time or full time in another gender role that is consistent with one's gender identity) may test the person's resolve, the capacity to function in the affirmed gender, and the adequacy of social, economic, and psychological supports. It assists both the individual and the clinician in their judgments about how to proceed (16). During social transitioning, the person's feelings about the social transformation (including coping with the responses of others) is a major focus of the counseling. The optimal timing for social transitioning may differ between individuals. Sometimes people wait until they start gender-affirming hormone treatment to make social transitioning easier, but individuals increasingly start social transitioning long before they receive medically supervised, gender-affirming hormone treatment.

Criteria

Adolescents and adults seeking gender-affirming hormone treatment and surgery should satisfy certain criteria before proceeding (16). Criteria for genderaffirming hormone therapy for adults are in Table 4, and criteria for gender-affirming hormone therapy for adolescents are in Table 5. Follow-up studies in adults meeting these criteria indicate a high satisfaction rate with treatment (59). However, the quality of evidence is usually low. A few follow-up studies on adolescents who fulfilled these criteria also indicated good treatment results (60–63).

Recommendations for Those Involved in the Gender-Affirming Hormone Treatment of Individuals With GD/Gender Incongruence

- 1.1. We advise that only trained MHPs who meet the following criteria should diagnose GD/gender incongruence in adults: (1) competence in using the DSM and/or the ICD for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)
- 1.2. We advise that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or ICD for diagnostic

Table 3. ICD-10 Criteria for Transsexualism

Transsexualism (F64.0) has three criteria:

- The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatments.
- 2. The transsexual identity has been present persistently for at least 2 y.
- 3. The disorder is not a symptom of another mental disorder or a genetic, DSD, or chromosomal abnormality.

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Table 4. Criteria for Gender-Affirming Hormone Therapy for Adults

- 1. Persistent, well-documented gender dysphoria/gender incongruence
- 2. The capacity to make a fully informed decision and to consent for treatment
- 3. The age of majority in a given country (if younger, follow the criteria for adolescents)
- 4. Mental health concerns, if present, must be reasonably well controlled

Reproduced from World Professional Association for Transgender Health (16).

purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents. (Ungraded Good Practice Statement)

Evidence

Individuals with gender identity issues may have psychological or psychiatric problems (43–48, 50, 51, 64, 65). It is therefore necessary that clinicians making the diagnosis are able to make a distinction between GD/ gender incongruence and conditions that have similar features. Examples of conditions with similar features are body dysmorphic disorder, body identity integrity disorder (a condition in which individuals have a sense that their anatomical configuration as an able-bodied person is somehow wrong or inappropriate) (66), or certain forms of eunuchism (in which a person is preoccupied with or engages in castration and/or penectomy for

Table 5. Criteria for Gender-Affirming Hormone Therapy for Adolescents

Adolescents are eligible for GnRH agonist treatment if:

- 1. A qualified MHP has confirmed that:
- the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed),
- gender dysphoria worsened with the onset of puberty,
- any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment,
 the adolescent has sufficient mental capacity to give informed consent to this (reversible) treatment,
- 2. And the adolescent:
- has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility,
- has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on
 applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting
 the adolescent throughout the treatment process,
- 3. And a pediatric endocrinologist or other clinician experienced in pubertal assessment
- •agrees with the indication for GnRH agonist treatment,
- has confirmed that puberty has started in the adolescent (Tanner stage ≥G2/B2),
- •has confirmed that there are no medical contraindications to GnRH agonist treatment.

Adolescents are eligible for subsequent sex hormone treatment if:

1. A gualified MHP has confirmed:

- the persistence of gender dysphoria,
- any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start sex hormone treatment,
- the adolescent has sufficient mental capacity (which most adolescents have by age 16 years) to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to this (partly) irreversible treatment,
- 2. And the adolescent:
- has been informed of the (irreversible) effects and side effects of treatment (including potential loss of fertility and options to preserve fertility),
- has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,
- 3. And a pediatric endocrinologist or other clinician experienced in pubertal induction:
- agrees with the indication for sex hormone treatment,
- has confirmed that there are no medical contraindications to sex hormone treatment.

Reproduced from World Professional Association for Transgender Health (16).

reasons that are not gender identity related) (11). Clinicians should also be able to diagnose psychiatric conditions accurately and ensure that these conditions are treated appropriately, particularly when the conditions may complicate treatment, affect the outcome of genderaffirming treatment, or be affected by hormone use.

Values and preferences

The task force placed a very high value on avoiding harm from hormone treatment in individuals who have conditions other than GD/gender incongruence and who may not benefit from the physical changes associated with this treatment and placed a low value on any potential benefit these persons believe they may derive from hormone treatment. This justifies the good practice statement.

- 1.3. We advise that decisions regarding the social transition of prepubertal youths with GD/gender incongruence are made with the assistance of an MHP or another experienced professional. (Ungraded Good Practice Statement).
- 1.4. We recommend against puberty blocking and gender-affirming hormone treatment in pre-pubertal children with GD/gender incongruence. (1 |⊕⊕○○)

Evidence

In most children diagnosed with GD/gender incongruence, it did not persist into adolescence. The percentages differed among studies, probably dependent on which version of the DSM clinicians used, the patient's age, the recruitment criteria, and perhaps cultural factors. However, the large majority (about 85%) of prepubertal children with a childhood diagnosis did not remain GD/ gender incongruent in adolescence (20). If children have completely socially transitioned, they may have great difficulty in returning to the original gender role upon entering puberty (40). Social transition is associated with the persistence of GD/gender incongruence as a child progresses into adolescence. It may be that the presence of GD/gender incongruence in prepubertal children is the earliest sign that a child is destined to be transgender as an adolescent/adult (20). However, social transition (in addition to GD/gender incongruence) has been found to contribute to the likelihood of persistence.

This recommendation, however, does not imply that children should be discouraged from showing gendervariant behaviors or should be punished for exhibiting such behaviors. In individual cases, an early complete social transition may result in a more favorable outcome, but there are currently no criteria to identify the GD/gender-incongruent children to whom this applies. At the present time, clinical experience suggests that persistence of GD/gender incongruence can only be reliably assessed after the first signs of puberty.

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Values and preferences

The task force placed a high value on avoiding harm with gender-affirming hormone therapy in prepubertal children with GD/gender incongruence. This justifies the strong recommendation in the face of low-quality evidence.

1.5. We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. (1 |⊕⊕⊕○)

Remarks

Persons considering hormone use for gender affirmation need adequate information about this treatment in general and about fertility effects of hormone treatment in particular to make an informed and balanced decision (67, 68). Because young adolescents may not feel qualified to make decisions about fertility and may not fully understand the potential effects of hormonal interventions, consent and protocol education should include parents, the referring MHP(s), and other members of the adolescent's support group. To our knowledge, there are no formally evaluated decision aids available to assist in the discussion and decision regarding the future fertility of adolescents or adults beginning gender-affirming treatment.

Treating early pubertal youth with GnRH analogs will temporarily impair spermatogenesis and oocyte maturation. Given that an increasing number of transgender youth want to preserve fertility potential, delaying or temporarily discontinuing GnRH analogs to promote gamete maturation is an option. This option is often not preferred, because mature sperm production is associated with later stages of puberty and with the significant development of secondary sex characteristics.

For those designated male at birth with GD/gender incongruence and who are in early puberty, sperm production and the development of the reproductive tract are insufficient for the cryopreservation of sperm. However, prolonged pubertal suppression using GnRH analogs is reversible and clinicians should inform these individuals that sperm production can be initiated following prolonged gonadotropin suppression. This can be accomplished by spontaneous gonadotropin recovery after 3880 Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869–3903

cessation of GnRH analogs or by gonadotropin treatment and will probably be associated with physical manifestations of testosterone production, as stated above. Note that there are no data in this population concerning the time required for sufficient spermatogenesis to collect enough sperm for later fertility. In males treated for precocious puberty, spermarche was reported 0.7 to 3 years after cessation of GnRH analogs (69). In adult men with gonadotropin deficiency, sperm are noted in seminal fluid by 6 to 12 months of gonadotropin treatment. However, sperm numbers when partners of these patients conceive are far below the "normal range" (70, 71).

In girls, no studies have reported long-term, adverse effects of pubertal suppression on ovarian function after treatment cessation (72, 73). Clinicians should inform adolescents that no data are available regarding either time to spontaneous ovulation after cessation of GnRH analogs or the response to ovulation induction following prolonged gonadotropin suppression.

In males with GD/gender incongruence, when medical treatment is started in a later phase of puberty or in adulthood, spermatogenesis is sufficient for cryopreservation and storage of sperm. *In vitro* spermatogenesis is currently under investigation. Restoration of spermatogenesis after prolonged estrogen treatment has not been studied.

In females with GD/gender incongruence, the effect of prolonged treatment with exogenous testosterone on ovarian function is uncertain. There have been reports of an increased incidence of polycystic ovaries in transgender males, both prior to and as a result of androgen treatment (74-77), although these reports were not confirmed by others (78). Pregnancy has been reported in transgender males who have had prolonged androgen treatment and have discontinued testosterone but have not had genital surgery (79, 80). A reproductive endocrine gynecologist can counsel patients before genderaffirming hormone treatment or surgery regarding potential fertility options (81). Techniques for cryopreservation of oocytes, embryos, and ovarian tissue continue to improve, and oocyte maturation of immature tissue is being studied (82).

2.0 Treatment of Adolescents

During the past decade, clinicians have progressively acknowledged the suffering of young adolescents with GD/gender incongruence. In some forms of GD/gender incongruence, psychological interventions may be useful and sufficient. However, for many adolescents with GD/ gender incongruence, the pubertal physical changes are unbearable. As early medical intervention may prevent psychological harm, various clinics have decided to start treating young adolescents with GD/gender incongruence with puberty-suppressing medication (a GnRH analog). As compared with starting gender-affirming treatment long after the first phases of puberty, a benefit of pubertal suppression at early puberty may be a better psychological and physical outcome.

In girls, the first physical sign of puberty is the budding of the breasts followed by an increase in breast and fat tissue. Breast development is also associated with the pubertal growth spurt, and menarche occurs ~ 2 years later. In boys, the first physical change is testicular growth. A testicular volume ≥ 4 mL is seen as consistent with the initiation of physical puberty. At the beginning of puberty, estradiol and testosterone levels are still low and are best measured in the early morning with an ultrasensitive assay. From a testicular volume of 10 mL, daytime testosterone levels increase, leading to virilization (83). Note that pubic hair and/or axillary hair/odor may not reflect the onset of gonadarche; instead, it may reflect adrenarche alone.

- 2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment (Table 5), and are requesting treatment should initially undergo treatment to suppress pubertal development. (2 I⊕⊕○○)
- 2.2. We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty (Tanner stages G2/B2). (2 |⊕⊕○○)

Evidence

Pubertal suppression can expand the diagnostic phase by a long period, giving the subject more time to explore options and to live in the experienced gender before making a decision to proceed with gender-affirming sex hormone treatments and/or surgery, some of which is irreversible (84, 85). Pubertal suppression is fully reversible, enabling full pubertal development in the natal gender, after cessation of treatment, if appropriate. The experience of full endogenous puberty is an undesirable condition for the GD/gender-incongruent individual and may seriously interfere with healthy psychological functioning and well-being. Treating GD/gender-incongruent adolescents entering puberty with GnRH analogs has been shown to improve psychological functioning in several domains (86).

Another reason to start blocking pubertal hormones early in puberty is that the physical outcome is improved compared with initiating physical transition after puberty has been completed (60, 62). Looking like a man or woman when living as the opposite sex creates difficult

barriers with enormous life-long disadvantages. We therefore advise starting suppression in early puberty to prevent the irreversible development of undesirable secondary sex characteristics. However, adolescents with GD/gender incongruence should experience the first changes of their endogenous spontaneous puberty, because their emotional reaction to these first physical changes has diagnostic value in establishing the persistence of GD/gender incongruence (85). Thus, Tanner stage 2 is the optimal time to start pubertal suppression. However, pubertal suppression treatment in early puberty will limit the growth of the penis and scrotum, which will have a potential effect on future surgical treatments (87).

Clinicians can also use pubertal suppression in adolescents in later pubertal stages to stop menses in transgender males and prevent facial hair growth in transgender females. However, in contrast to the effects in early pubertal adolescents, physical sex characteristics (such as more advanced breast development in transgender boys and lowering of the voice and outgrowth of the jaw and brow in transgender girls) are not reversible.

Values and preferences

These recommendations place a high value on avoiding an unsatisfactory physical outcome when secondary sex characteristics have become manifest and irreversible, a higher value on psychological well-being, and a lower value on avoiding potential harm from early pubertal suppression.

Remarks

Table 6 lists the Tanner stages of breast and male genital development. Careful documentation of hallmarks of pubertal development will ensure precise timing when initiating pubertal suppression once puberty has started. Clinicians can use pubertal LH and sex steroid levels to confirm that puberty has progressed sufficiently before starting pubertal suppression (88). Reference ranges for sex steroids by Tanner stage may vary depending on the assay used. Ultrasensitive sex steroid and gonadotropin assays will help clinicians document early pubertal changes.

Irreversible and, for GD/gender-incongruent adolescents, undesirable sex characteristics in female puberty are breasts, female body habitus, and, in some cases, relative short stature. In male puberty, they are a prominent Adam's apple; low voice; male bone configuration, such as a large jaw, big feet and hands, and tall stature; and male hair pattern on the face and extremities.

2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones. (1 |⊕⊕○○)

Evidence

Clinicians can suppress pubertal development and gonadal function most effectively via gonadotropin suppression using GnRH analogs. GnRH analogs are long-acting agonists that suppress gonadotropins by GnRH receptor desensitization after an initial increase of gonadotropins during ~ 10 days after the first and (to a lesser degree) the second injection (89). Antagonists immediately suppress pituitary gonadotropin secretion (90, 91). Long-acting GnRH analogs are the currently preferred treatment option. Clinicians may consider longacting GnRH antagonists when evidence on their safety and efficacy in adolescents becomes available.

During GnRH analog treatment, slight development of secondary sex characteristics may regress, and in a later phase of pubertal development, it will stop. In girls, breast tissue will become atrophic, and menses will stop. In boys, virilization will stop, and testicular volume may decrease (92).

An advantage of using GnRH analogs is the reversibility of the intervention. If, after extensive exploration of his/her transition wish, the individual no longer desires transition, they can discontinue pubertal suppression. In subjects with

Table 6. Tanner Stages of Breast Development and Male External Genitalia

- 4. Areola and papilla form secondary mound
- 5. Mature; nipple projects, areola part of general breast contour
- For penis and testes:
 - 1. Prepubertal, testicular volume <4 mL
 - 2. Slight enlargement of penis; enlarged scrotum, pink, texture altered, testes 4-6 mL
 - 3. Penis longer, testes larger (8–12 mL)
 - 4. Penis and glans larger, including increase in breadth; testes larger (12–15 mL), scrotum dark
 - 5. Penis adult size; testicular volume > 15 ml

Adapted from Lawrence (56).

The description of Tanner stages for breast development:

^{1.} Prepubertal

^{2.} Breast and papilla elevated as small mound; areolar diameter increased

^{3.} Breast and areola enlarged, no contour separation

precocious puberty, spontaneous pubertal development has been shown to resume after patients discontinue taking GnRH analogs (93).

Recommendations 2.1 to 2.3 are supported by a prospective follow-up study from The Netherlands. This report assessed mental health outcomes in 55 transgender adolescents/young adults (22 transgender females and 33 transgender males) at three time points: (1) before the start of GnRH agonist (average age of 14.8 years at start of treatment), (2) at initiation of gender-affirming hormones (average age of 16.7 years at start of treatment), and (3) 1 year after "gender-reassignment surgery" (average age of 20.7 years) (63). Despite a decrease in depression and an improvement in general mental health functioning, GD/gender incongruence persisted through pubertal suppression, as previously reported (86). However, following sex hormone treatment and genderreassignment surgery, GD/gender incongruence was resolved and psychological functioning steadily improved (63). Furthermore, well-being was similar to or better than that reported by age-matched young adults from the general population, and none of the study participants regretted treatment. This study represents the first longterm follow-up of individuals managed according to currently existing clinical practice guidelines for transgender youth, and it underscores the benefit of the multidisciplinary approach pioneered in The Netherlands; however, further studies are needed.

Side effects

The primary risks of pubertal suppression in GD/ gender-incongruent adolescents may include adverse effects on bone mineralization (which can theoretically be reversed with sex hormone treatment), compromised fertility if the person subsequently is treated with sex hormones, and unknown effects on brain development. Few data are available on the effect of GnRH analogs on BMD in adolescents with GD/gender incongruence. Initial data in GD/gender-incongruent subjects demonstrated no change of absolute areal BMD during 2 years of GnRH analog therapy but a decrease in BMD z scores (85). A recent study also suggested suboptimal bone mineral accrual during GnRH analog treatment. The study reported a decrease in areal BMD z scores and of bone mineral apparent density z scores (which takes the size of the bone into account) in 19 transgender males treated with GnRH analogs from a mean age of 15.0 years (standard deviation = 2.0 years) for a median duration of 1.5 years (0.3 to 5.2 years) and in 15 transgender females treated from 14.9 (± 1.9) years for 1.3 years (0.5 to 3.8 years), although not all changes were statistically significant (94). There was incomplete catch-up at age 22 years after sex hormone treatment from age 16.6 (± 1.4)

years for a median duration of 5.8 years (3.0 to 8.0 years) in transgender females and from age 16.4 (\pm 2.3) years for 5.4 years (2.8 to 7.8 years) in transgender males. Little is known about more prolonged use of GnRH analogs. Researchers reported normal BMD z scores at age 35 years in one individual who used GnRH analogs from age 13.7 years until age 18.6 years before initiating sex hormone treatment (65).

Additional data are available from individuals with late puberty or GnRH analog treatment of other indications. Some studies reported that men with constitutionally delayed puberty have decreased BMD in adulthood (95). However, other studies reported that these men have normal BMD (96, 97). Treating adults with GnRH analogs results in a decrease of BMD (98). In children with central precocious puberty, treatment with GnRH analogs has been found to result in a decrease of BMD during treatment by some (99) but not others (100). Studies have reported normal BMD after discontinuing therapy (69, 72, 73, 101, 102). In adolescents treated with growth hormone who are small for gestational age and have normal pubertal timing, 2-year GnRH analog treatments did not adversely affect BMD (103). Calcium supplementation may be beneficial in optimizing bone health in GnRH analog-treated individuals (104). There are no studies of vitamin D supplementation in this context, but clinicians should offer supplements to vitamin D-deficient adolescents. Physical activity, especially during growth, is important for bone mass in healthy individuals (103) and is therefore likely to be beneficial for bone health in GnRH analog-treated subjects.

GnRH analogs did not induce a change in body mass index standard deviation score in GD/genderincongruent adolescents (94) but caused an increase in fat mass and decrease in lean body mass percentage (92). Studies in girls treated for precocious puberty also reported a stable body mass index standard deviation score during treatment (72) and body mass index and body composition comparable to controls after treatment (73).

Arterial hypertension has been reported as an adverse effect in a few girls treated with GnRH analogs for precocious/early puberty (105, 106). Blood pressure monitoring before and during treatment is recommended.

Individuals may also experience hot flashes, fatigue, and mood alterations as a consequence of pubertal suppression. There is no consensus on treatment of these side effects in this context.

It is recommended that any use of pubertal blockers (and subsequent use of sex hormones, as detailed below) include a discussion about implications for fertility (see recommendation 1.3). Transgender adolescents may

want to preserve fertility, which may be otherwise compromised if puberty is suppressed at an early stage and the individual completes phenotypic transition with the use of sex hormones.

Limited data are available regarding the effects of GnRH analogs on brain development. A single crosssectional study demonstrated no compromise of executive function (107), but animal data suggest there may be an effect of GnRH analogs on cognitive function (108).

Values and preferences

Our recommendation of GnRH analogs places a higher value on the superior efficacy, safety, and reversibility of the pubertal hormone suppression achieved (as compared with the alternatives) and a relatively lower value on limiting the cost of therapy. Of the available alternatives, depot and oral progestin preparations are effective. Experience with this treatment dates back prior to the emergence of GnRH analogs for treating precocious puberty in papers from the 1960s and early 1970s (109-112). These compounds are usually safe, but some side effects have been reported (113-115). Only two recent studies involved transgender youth (116, 117). One of these studies described the use of oral lynestrenol monotherapy followed by the addition of testosterone treatment in transgender boys who were at Tanner stage B4 or further at the start of treatment (117). They found lynestrenol safe, but gonadotropins were not fully suppressed. The study reported metrorrhagia in approximately half of the individuals, mainly in the first 6 months. Acne, headache, hot flashes, and fatigue were other frequent side effects. Another progestin that has been studied in the United States is medroxyprogesterone. This agent is not as effective as GnRH analogs in lowering endogenous sex hormones either and may be associated with other side effects (116). Progestin preparations may be an acceptable treatment for persons without access to GnRH analogs or with a needle phobia. If GnRH analog treatment is not available (insurance denial, prohibitive cost, or other reasons), postpubertal, transgender female adolescents may be treated with an antiandrogen that directly suppresses androgen synthesis or action (see adult section).

Remarks

Measurements of gonadotropin and sex steroid levels give precise information about gonadal axis suppression, although there is insufficient evidence for any specific short-term monitoring scheme in children treated with GnRH analogs (88). If the gonadal axis is not completely suppressed—as evidenced by (for example) menses, erections, or progressive hair growth—the interval of GnRH analog treatment can be shortened or the dose increased. During treatment, adolescents should be monitored for negative effects of delaying puberty, including a halted growth spurt and impaired bone mineral accretion. Table 7 illustrates a suggested clinical protocol.

Anthropometric measurements and X-rays of the left hand to monitor bone age are informative for evaluating growth. To assess BMD, clinicians can perform dualenergy X-ray absorptiometry scans.

- 2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule (see Table 8) after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years (Table 5). (1 l⊕⊕○○)
- 2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/ gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 |⊕000)
- 2.6. We suggest monitoring clinical pubertal development every 3 to 6 months and laboratory parameters every 6 to 12 months during sex hormone treatment (Table 9). (2 l⊕⊕○○)

Table 7. Baseline and Follow-Up Protocol During Suppression of Puberty

Every 3–6 mo Anthropometry: height, weight, sitting height, blood pressure, Tanner stages Every 6–12 mo Laboratory: LH, FSH, E2/T, 25OH vitamin D Every 1–2 y Bone density using DXA Bone age on X-ray of the left hand (if clinically indicated)

Adapted from Hembree et al. (118).

Abbreviations: DXA, dual-energy X-ray absorptiometry; E2, estradiol; FSH, follicle stimulating hormone; LH, luteinizing hormone; T, testosterone;

3884 Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3869–3903

Table 8. Protocol Induction of Puberty

Induction of female puberty with oral 17β -estradiol, increasing the dose every 6 mo: 5 µg/kg/d 10 µg/kg/d 15 µg/kg/d 20 µg/kg/d Adult dose = 2-6 mg/dIn postpubertal transgender female adolescents, the dose of 17β -estradiol can be increased more rapidly: 1 mg/d for 6 mo 2 mq/dInduction of female puberty with transdermal 17β -estradiol, increasing the dose every 6 mo (new patch is placed every 3.5 d): 6.25-12.5 µg/24 h (cut 25-µg patch into quarters, then halves) 25 µg/24 h 37.5 µg/24 h Adult dose = 50–200 μ g/24 h For alternatives once at adult dose, see Table 11. Adjust maintenance dose to mimic physiological estradiol levels (see Table 15). Induction of male puberty with testosterone esters increasing the dose every 6 mo (IM or SC): 25 mg/m²/2 wk (or alternatively, half this dose weekly, or double the dose every 4 wk) 50 mg/m²/2 wk 75 mg/m²/2 wk 100 mg/m²/2 wk Adult dose = 100-200 mg every 2 wk In postpubertal transgender male adolescents the dose of testosterone esters can be increased more rapidly: 75 mg/2 wk for 6 mo 125 mg/2 wk For alternatives once at adult dose, see Table 11. Adjust maintenance dose to mimic physiological testosterone levels (see Table 14).

Adapted from Hembree et al. (118).

Abbreviations: IM, intramuscularly; SC, subcutaneously.

Evidence

Adolescents develop competence in decision making at their own pace. Ideally, the supervising medical professionals should individually assess this competence, although no objective tools to make such an assessment are currently available.

Many adolescents have achieved a reasonable level of competence by age 15 to 16 years (119), and in many countries 16-year-olds are legally competent with regard to medical decision making (120). However, others believe that although some capacities are generally achieved before age 16 years, other abilities (such as good risk assessment) do not develop until well after 18 years (121). They suggest that health care procedures should be divided along a matrix of relative risk, so that younger adolescents can be allowed to decide about low-risk procedures, such as most diagnostic tests and common therapies, but not about high-risk procedures, such as most surgical procedures (121).

Currently available data from transgender adolescents support treatment with sex hormones starting at age 16 years (63, 122). However, some patients may incur potential risks by waiting until age 16 years. These include the potential risk to bone health if puberty is suppressed

Table 9. Baseline and Follow-up Protocol During Induction of Puberty

Every 3-6 mo

•Anthropometry: height, weight, sitting height, blood pressure, Tanner stages Every 6–12 mo

In transgender males: hemoglobin/hematocrit, lipids, testosterone, 250H vitamin D

In transgender females: prolactin, estradiol, 250H vitamin D

Every 1–2 y

BMD using DXA

Bone age on X-ray of the left hand (if clinically indicated)

BMD should be monitored into adulthood (until the age of 25–30 y or until peak bone mass has been reached). For recommendations on monitoring once pubertal induction has been completed, see Tables 14 and 15.

Adapted from Hembree et al. (118).

Abbreviation: DXA, dual-energy X-ray absorptiometry.

for 6 to 7 years before initiating sex hormones (*e.g.*, if someone reached Tanner stage 2 at age 9-10 years old). Additionally, there may be concerns about inappropriate height and potential harm to mental health (emotional and social isolation) if initiation of secondary sex characteristics must wait until the person has reached 16 years of age. However, only minimal data supporting earlier use of gender-affirming hormones in transgender adolescents currently exist (63). Clearly, long-term studies are needed to determine the optimal age of sex hormone treatment in GD/gender-incongruent adolescents.

The MHP who has followed the adolescent during GnRH analog treatment plays an essential role in assessing whether the adolescent is eligible to start sex hormone therapy and capable of consenting to this treatment (Table 5). Support of the family/environment is essential. Prior to the start of sex hormones, clinicians should discuss the implications for fertility (see recommendation 1.5). Throughout pubertal induction, an MHP and a pediatric endocrinologist (or other clinician competent in the evaluation and induction of pubertal development) should monitor the adolescent. In addition to monitoring therapy, it is also important to pay attention to general adolescent health issues, including healthy life style choices, such as not smoking, contraception, and appropriate vaccinations (e.g., human papillomavirus).

For the induction of puberty, clinicians can use a similar dose scheme for hypogonadal adolescents with GD/gender incongruence as they use in other individuals with hypogonadism, carefully monitoring for desired and undesired effects (Table 8). In transgender female adolescents, transdermal 17 β -estradiol may be an alternative for oral 17 β -estradiol. It is increasingly used for pubertal induction in hypogonadal females. However, the absence of low-dose estrogen patches may be a problem. As a result, individuals may need to cut patches to size themselves to achieve appropriate dosing (123). In transgender male adolescents, clinicians can give testosterone injections intramuscularly or subcutaneously (124, 125).

When puberty is initiated with a gradually increasing schedule of sex steroid doses, the initial levels will not be high enough to suppress endogenous sex steroid secretion. Gonadotropin secretion and endogenous production of testosterone may resume and interfere with the effectiveness of estrogen treatment, in transgender female adolescents (126, 127). Therefore, continuation of GnRH analog treatment is advised until gonadectomy. Given that GD/gender-incongruent adolescents may opt not to have gonadectomy, long-term studies are necessary to examine the potential risks of prolonged GnRH analog treatment. Alternatively, in transgender male adolescents, GnRH analog treatment can be discontinued once an adult dose of testosterone has been reached and the individual is well virilized. If uterine bleeding occurs, a progestin can be added. However, the combined use of a GnRH analog (for ovarian suppression) and testosterone may enable phenotypic transition with a lower dose of testosterone in comparison with testosterone alone. If there is a wish or need to discontinue GnRH analog treatment in transgender female adolescents, they may be treated with an antiandrogen that directly suppresses androgen synthesis or action (see section 3.0 "Hormonal Therapy for Transgender Adults").

Values and preferences

The recommendation to initiate pubertal induction only when the individual has sufficient mental capacity (roughly age 16 years) to give informed consent for this partly irreversible treatment places a higher value on the ability of the adolescent to fully understand and oversee the partially irreversible consequences of sex hormone treatment and to give informed consent. It places a lower value on the possible negative effects of delayed puberty. We may not currently have the means to weigh adequately the potential benefits of waiting until around age 16 years to initiate sex hormones vs the potential risks/ harm to BMD and the sense of social isolation from having the timing of puberty be so out of sync with peers (128).

Remarks

Before starting sex hormone treatment, effects on fertility and options for fertility preservation should be discussed. Adult height may be a concern in transgender adolescents. In a transgender female adolescent, clinicians may consider higher doses of estrogen or a more rapid tempo of dose escalation during pubertal induction. There are no established treatments yet to augment adult height in a transgender male adolescent with open epiphyses during pubertal induction. It is not uncommon for transgender adolescents to present for clinical services after having completed or nearly completed puberty. In such cases, induction of puberty with sex hormones can be done more rapidly (see Table 8). Additionally, an adult dose of testosterone in transgender male adolescents may suffice to suppress the gonadal axis without the need to use a separate agent. At the appropriate time, the multidisciplinary team should adequately prepare the adolescent for transition to adult care.

3.0 Hormonal Therapy for Transgender Adults

The two major goals of hormonal therapy are (1) to reduce endogenous sex hormone levels, and thus reduce

the secondary sex characteristics of the individual's designated gender, and (2) to replace endogenous sex hormone levels consistent with the individual's gender identity by using the principles of hormone replacement treatment of hypogonadal patients. The timing of these two goals and the age at which to begin treatment with the sex hormones of the chosen gender is codetermined in collaboration with both the person pursuing transition and the health care providers. The treatment team should include a medical provider knowledgeable in transgender hormone therapy, an MHP knowledgeable in GD/gender incongruence and the mental health concerns of transition, and a primary care provider able to provide care appropriate for transgender individuals. The physical changes induced by this sex hormone transition are usually accompanied by an improvement in mental well-being (129, 130).

- 3.1. We recommend that clinicians confirm the diagnostic criteria of GD/gender incongruence and the criteria for the endocrine phase of gender transition before beginning treatment. (1 |⊕⊕⊕○)
- 3.2. We recommend that clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment (Table 10). (1 l⊕⊕⊕○)
- 3.3. We suggest that clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex steroids are maintained in the normal physiologic range for the affirmed gender. (2 I⊕⊕○○)

Evidence

It is the responsibility of the treating clinician to confirm that the person fulfills criteria for treatment. The treating clinician should become familiar with the terms and criteria presented in Tables 1-5 and take a thorough history from the patient in collaboration with the other members of the treatment team. The treating clinician must ensure that the desire for transition is appropriate; the consequences, risks, and benefits of treatment are well understood; and the desire for transition persists. They also need to discuss fertility preservation options (see recommendation 1.3) (67, 68).

Transgender males

Clinical studies have demonstrated the efficacy of several different androgen preparations to induce masculinization in transgender males (Appendix A) (113, 114, 131–134). Regimens to change secondary sex characteristics follow the general principle of hormone replacement treatment of male hypogonadism (135). Clinicians can use either parenteral or transdermal preparations to achieve testosterone values in the normal male range (this is dependent on the specific assay, but is typically 320 to 1000 ng/dL) (Table 11) (136). Sustained supraphysiologic levels of testosterone increase the risk of adverse reactions (see section 4.0 "Adverse Outcome Prevention and Long-Term Care") and should be avoided.

Similar to androgen therapy in hypogonadal men, testosterone treatment in transgender males results in increased muscle mass and decreased fat mass, increased facial hair and acne, male pattern baldness in those genetically predisposed, and increased sexual desire (137).

Table 10. Medical Risks Associated With Sex Hormone Therapy

Transgender female: estrogen	
Very high risk of adverse outcomes:	
 Thromboembolic disease 	
Moderate risk of adverse outcomes:	
Macroprolactinoma	
Breast cancer	
Coronary artery disease	
Cerebrovascular disease	
•Cholelithiasis	
Hypertriglyceridemia	
Transgender male: testosterone	
Very high risk of adverse outcomes:	
•Erythrocytosis (hematocrit $>$ 50%)	
Moderate risk of adverse outcomes:	
 Severe liver dysfunction (transaminases > threefold upper limit of normal) 	
Coronary artery disease	
Cerebrovascular disease	
Hypertension	
Breast or uterine cancer	

Transgender females ^a	
Estrogen	
Oral	
Estradiol	2.0–6.0 mg/d
Transdermal	
Estradiol transdermal patch	0.025–0.2 mg/d
(New patch placed every 3–5 d)	
Parenteral	
Estradiol valerate or cypionate	5–30 mg IM every 2 wk
	2–10 mg IM every week
Anti-androgens	
Spironolactone	100–300 mg/d
Cyproterone acetate ^b	25–50 mg/d
GnRH agonist	3.75 mg SQ (SC) monthly
	11.25 mg SQ (SC) 3-monthly
Transgender males	
Testosterone	
Parenteral testosterone	
Testosterone enanthate or cypionate	100–200 mg SQ (IM) every 2 wk or SQ (SC) 50% per week
Testosterone undecanoate ^c	1000 mg every 12 wk
Transdermal testosterone	
Testosterone gel 1.6% ^d	50–100 mg/d
Testosterone transdermal patch	2.5–7.5 mg/d

Abbreviations: IM, intramuscularly; SQ, sequentially; SC, subcutaneously

^aEstrogens used with or without antiandrogens or GnRH agonist.

^bNot available in the United States.

^cOne thousand milligrams initially followed by an injection at 6 wk then at 12-wk intervals.

^dAvoid cutaneous transfer to other individuals.

In transgender males, testosterone will result in clitoromegaly, temporary or permanent decreased fertility, deepening of the voice, cessation of menses (usually), and a significant increase in body hair, particularly on the face, chest, and abdomen. Cessation of menses may occur within a few months with testosterone treatment alone, although high doses of testosterone may be required. If uterine bleeding continues, clinicians may consider the addition of a progestational agent or endometrial ablation (138). Clinicians may also administer GnRH analogs or depot medroxyprogesterone to stop menses prior to testosterone treatment.

Transgender females

The hormone regimen for transgender females is more complex than the transgender male regimen (Appendix B). Treatment with physiologic doses of estrogen alone is insufficient to suppress testosterone levels into the normal range for females (139). Most published clinical studies report the need for adjunctive therapy to achieve testosterone levels in the female range (21, 113, 114, 132–134, 139, 140).

Multiple adjunctive medications are available, such as progestins with antiandrogen activity and GnRH agonists (141). Spironolactone works by directly blocking androgens during their interaction with the androgen receptor (114, 133, 142). It may also have estrogenic activity (143). Cyproterone acetate, a progestational compound with antiandrogenic properties (113, 132, 144), is widely used in Europe. 5α -Reductase inhibitors do not reduce testosterone levels and have adverse effects (145).

Dittrich *et al.* (141) reported that monthly doses of the GnRH agonist goserelin acetate in combination with estrogen were effective in reducing testosterone levels with a low incidence of adverse reactions in 60 transgender females. Leuprolide and transdermal estrogen were as effective as cyproterone and transdermal estrogen in a comparative retrospective study (146).

Patients can take estrogen as oral conjugated estrogens, oral 17β -estradiol, or transdermal 17β -estradiol. Among estrogen options, the increased risk of thromboembolic events associated with estrogens in general seems most concerning with ethinyl estradiol specifically (134, 140, 141), which is why we specifically suggest that it not be used in any transgender treatment plan. Data distinguishing among other estrogen options are less well established although there is some thought that oral routes of administration are more thrombogenic due to the "first pass effect" than are transdermal and parenteral routes, and that the risk of thromboembolic events is dose-dependent. Injectable estrogen and sublingual
estrogen may benefit from avoiding the first pass effect, but they can result in more rapid peaks with greater overall periodicity and thus are more difficult to monitor (147, 148). However, there are no data demonstrating that increased periodicity is harmful otherwise.

Clinicians can use serum estradiol levels to monitor oral, transdermal, and intramuscular estradiol. Blood tests cannot monitor conjugated estrogens or synthetic estrogen use. Clinicians should measure serum estradiol and serum testosterone and maintain them at the level for premenopausal females (100 to 200 pg/mL and <50 ng/dL, respectively). The transdermal preparations and injectable estradiol cypionate or valerate preparations may confer an advantage in older transgender females who may be at higher risk for thromboembolic disease (149).

Values

Our recommendation to maintain levels of genderaffirming hormones in the normal adult range places a high value on the avoidance of the long-term complications of pharmacologic doses. Those patients receiving endocrine treatment who have relative contraindications to hormones should have an in-depth discussion with their physician to balance the risks and benefits of therapy.

Remarks

Clinicians should inform all endocrine-treated individuals of all risks and benefits of gender-affirming hormones prior to initiating therapy. Clinicians should strongly encourage tobacco use cessation in transgender females to avoid increased risk of VTE and cardiovascular complications. We strongly discourage the unsupervised use of hormone therapy (150).

Not all individuals with GD/gender incongruence seek treatment as described (*e.g.*, male-to-eunuchs and individuals seeking partial transition). Tailoring current protocols to the individual may be done within the context of accepted safety guidelines using a multidisciplinary approach including mental health. No evidencebased protocols are available for these groups (151). We need prospective studies to better understand treatment options for these persons.

3.4. We suggest that endocrinologists provide education to transgender individuals undergoing treatment about the onset and time course of physical changes induced by sex hormone treatment. (2 I⊕○○○)

Evidence

Transgender males

Physical changes that are expected to occur during the first 1 to 6 months of testosterone therapy include cessation of menses, increased sexual desire, increased facial and body hair, increased oiliness of skin, increased muscle, and redistribution of fat mass. Changes that occur within the first year of testosterone therapy include deepening of the voice (152, 153), clitoromegaly, and male pattern hair loss (in some cases) (114, 144, 154, 155) (Table 12).

Transgender females

Physical changes that may occur in transgender females in the first 3 to 12 months of estrogen and antiandrogen therapy include decreased sexual desire, decreased spontaneous erections, decreased facial and body hair (usually mild), decreased oiliness of skin, increased breast tissue growth, and redistribution of fat mass (114, 139, 149, 154, 155, 161) (Table 13). Breast development is generally maximal at 2 years after initiating hormones (114, 139, 149, 155). Over a long period of time, the prostate gland and testicles will undergo atrophy.

Although the time course of breast development in transgender females has been studied (150), precise information about other changes induced by sex hormones is lacking (141). There is a great deal of variability among individuals, as evidenced during pubertal development. We all know that a major concern for transgender females is breast development. If we work with estrogens, the result will be often not what the transgender female expects.

Alternatively, there are transgender females who report an anecdotal improved breast development, mood, or sexual desire with the use of progestogens. However, there have been no well-designed studies of the role of progestogens in feminizing hormone regimens, so the question is still open.

Our knowledge concerning the natural history and effects of different cross-sex hormone therapies on breast

Table 12.	Masculinizing	Effects in	Transgender
Males			

Effect	Onset	Maximum	
Skin oiliness/acne	1–6 mo	1-2 y	
Facial/body hair growth	6-12 mo	4-5 v	
Scalp hair loss	6-12 mo	a^	
Increased muscle mass/strength	6-12 mo	2-5 y	
Fat redistribution	1-6 mo	2-5 y	
Cessation of menses	1–6 mo	b	
Clitoral enlargement	1–6 mo	1–2 y	
Vaginal atrophy	1–6 mo	1-2 y	
Deepening of voice	6–12 mo	1-2 y	

Estimates represent clinical observations: Toorians *et al.* (149), Asscheman *et al.* (156), Gooren *et al.* (157), Wierckx *et al.* (158).

^aPrevention and treatment as recommended for biological men.

^bMenorrhagia requires diagnosis and treatment by a gynecologist.

doi: 10.1210/jc.2017-01658

Table 13.	Feminizing Effects in Transgender	
Females		

Effect	Onset	Maximum	
Redistribution of body fat	3–6 mo	2-3 y	
Decrease in muscle mass and strength	3-6 mo	1-2 y	
Softening of skin/decreased oiliness	3-6 mo	Unknown	
Decreased sexual desire	1-3 mo	3–6 mo	
Decreased spontaneous erections	1–3 mo	3–6 mo	
Male sexual dysfunction	Variable	Variable	
Breast growth	3-6 mo	2-3 y	
Decreased testicular volume	3-6 mo	2-3 y	
Decreased sperm production	Unknown	>3 v	
Decreased terminal hair growth	6-12 mo	$>3 y^a$	
Scalp hair	Variable	В́	
Voice changes	None	C	

Estimates represent clinical observations: Toorians et al. (149), Asscheman et al. (156), Gooren et al. (157).

^aComplete removal of male sexual hair requires electrolysis or laser treatment or both

^bFamilial scalp hair loss may occur if estrogens are stopped.

^cTreatment by speech pathologists for voice training is most effective.

development in transgender females is extremely sparse and based on the low quality of evidence. Current evidence does not indicate that progestogens enhance breast development in transgender females, nor does evidence prove the absence of such an effect. This prevents us from drawing any firm conclusion at this moment and demonstrates the need for further research to clarify these important clinical questions (162).

Values and preferences

Transgender persons have very high expectations regarding the physical changes of hormone treatment and are aware that body changes can be enhanced by surgical procedures (e.g., breast, face, and body habitus). Clear expectations for the extent and timing of sex hormone-induced changes may prevent the potential harm and expense of unnecessary procedures.

4.0 Adverse Outcome Prevention and Long-Term Care

Hormone therapy for transgender males and females confers many of the same risks associated with sex hormone replacement therapy in nontransgender persons. The risks arise from and are worsened by inadvertent or intentional use of supraphysiologic doses of sex hormones, as well as use of inadequate doses of sex hormones to maintain normal physiology (131, 139).

4.1. We suggest regular clinical evaluation for physical changes and potential adverse changes in response to sex steroid hormones and laboratory monitoring of sex steroid hormone levels every https://academic.oup.com/jcem 3889

3 months during the first year of hormone therapy for transgender males and females and then once or twice yearly. $(2 \mid \oplus \oplus \bigcirc \bigcirc)$

Evidence

Pretreatment screening and appropriate regular medical monitoring are recommended for both transgender males and females during the endocrine transition and periodically thereafter (26, 155). Clinicians should monitor weight and blood pressure, conduct physical exams, and assess routine health questions, such as tobacco use, symptoms of depression, and risk of adverse events such as deep vein thrombosis/pulmonary embolism and other adverse effects of sex steroids.

Transgender males

Table 14 contains a standard monitoring plan for transgender males on testosterone therapy (154, 159). Key issues include maintaining testosterone levels in the physiologic normal male range and avoiding adverse events resulting from excess testosterone therapy, particularly erythrocytosis, sleep apnea, hypertension, excessive weight gain, salt retention, lipid changes, and excessive or cystic acne (135).

Because oral 17-alkylated testosterone is not recommended, serious hepatic toxicity is not anticipated with parenteral or transdermal testosterone use (163, 164). Past concerns regarding liver toxicity with testosterone have been alleviated with subsequent reports that indicate the risk of serious liver disease is minimal (144, 165, 166).

Transgender females

Table 15 contains a standard monitoring plan for transgender females on estrogens, gonadotropin suppression, or antiandrogens (160). Key issues include avoiding supraphysiologic doses or blood levels of estrogen that may lead to increased risk for thromboembolic disease, liver dysfunction, and hypertension. Clinicians should monitor serum estradiol levels using laboratories participating in external quality control, as measurements of estradiol in blood can be very challenging (167).

VTE may be a serious complication. A study reported a 20-fold increase in venous thromboembolic disease in a large cohort of Dutch transgender subjects (161). This increase may have been associated with the use of the synthetic estrogen, ethinyl estradiol (149). The incidence decreased when clinicians stopped administering ethinyl estradiol (161). Thus, the use of synthetic estrogens and conjugated estrogens is undesirable because of the inability to regulate doses by measuring serum levels and the risk of thromboembolic disease. In a German gender clinic, deep vein thrombosis occurred in 1 of 60 of transgender females treated with a GnRH analog and oral

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Table 14. Monitoring of Transgender Persons on Gender-Affirming Hormone Therapy: Transgender Male

- 1. Evaluate patient every 3 mo in the first year and then one to two times per year to monitor for appropriate signs of virilization and for development of adverse reactions.
- 2. Measure serum testosterone every 3 mo until levels are in the normal physiologic male range:^a
- a. For testosterone enanthate/cypionate injections, the testosterone level should be measured midway between injections. The target
- level is 400–700 ng/dL to 400 ng/dL. Alternatively, measure peak and trough levels to ensure levels remain in the normal male range.
- b. For parenteral testosterone undecanoate, testosterone should be measured just before the following injection. If the level is <400 ng/dL, adjust dosing interval.
- c. For transdermal testosterone, the testosterone level can be measured no sooner than after 1 wk of daily application (at least 2 h after application).
- Measure hematocrit or hemoglobin at baseline and every 3 mo for the first year and then one to two times a year. Monitor weight, blood pressure, and lipids at regular intervals.
- Screening for osteoporosis should be conducted in those who stop testosterone treatment, are not compliant with hormone therapy, or who develop risks for bone loss.
- 5. If cervical tissue is present, monitoring as recommended by the American College of Obstetricians and Gynecologists.
- 6. Ovariectomy can be considered after completion of hormone transition.
- Conduct sub- and periareolar annual breast examinations if mastectomy performed. If mastectomy is not performed, then consider mammograms as recommended by the American Cancer Society.

^aAdapted from Lapauw et al. (154) and Ott et al. (159).

estradiol (141). The patient who developed a deep vein thrombosis was found to have a homozygous C677 T mutation in the methylenetetrahydrofolate reductase gene. In an Austrian gender clinic, administering genderaffirming hormones to 162 transgender females and 89 transgender males was not associated with VTE, despite an 8.0% and 5.6% incidence of thrombophilia (159). A more recent multinational study reported only 10 cases of VTE from a cohort of 1073 subjects (168). Thrombophilia screening of transgender persons initiating hormone treatment should be restricted to those with a personal or family history of VTE (159). Monitoring D-dimer levels during treatment is not recommended (169).

4.2. We suggest periodically monitoring prolactin levels in transgender females treated with estrogens. (2 l⊕⊕○○)

Evidence

Estrogen therapy can increase the growth of pituitary lactrotroph cells. There have been several reports of prolactinomas occurring after long-term, high-dose estrogen therapy (170–173). Up to 20% of transgender females treated with estrogens may have elevations in prolactin levels associated with enlargement of the pituitary gland (156). In most cases, the serum prolactin levels will return to the normal range with a reduction or discontinuation of the estrogen therapy or discontinuation of cyproterone acetate (157, 174, 175).

The onset and time course of hyperprolactinemia during estrogen treatment are not known. Clinicians should measure prolactin levels at baseline and then at least annually during the transition period and every 2 years thereafter. Given that only a few case studies reported prolactinomas, and prolactinomas were not reported in large cohorts of estrogen-treated persons, the risk is likely to be very low. Because the major presenting findings of microprolactinomas (hypogonadism and sometimes gynecomastia) are not apparent in transgender females, clinicians may perform radiologic examinations of the pituitary in those patients whose prolactin levels persistently increase despite stable or reduced estrogen levels. Some transgender individuals receive psychotropic medications that can increase prolactin levels (174).

Table 15. Monitoring of Transgender Persons on Gender-Affirming Hormone Therapy: Transgender Female

- 1. Evaluate patient every 3 mo in the first year and then one to two times per year to monitor for appropriate signs of feminization and for development of adverse reactions.
- 2. Measure serum testosterone and estradiol every 3 mo. a. Serum testosterone levels should be <50 ng/dL.
- b. Serum estradiol should not exceed the peak physiologic range: 100-200 pg/mL.
- For individuals on spironolactone, serum electrolytes, particularly potassium, should be monitored every 3 mo in the first year and annually thereafter.
- 4. Routine cancer screening is recommended, as in nontransgender individuals (all tissues present).

Consider BMD testing at baseline (160). In individuals at low risk, screening for osteoporosis should be conducted at age 60 years or in those who are not compliant with hormone therapy.

This table presents strong recommendations and does not include lower level recommendations.

4.3. We suggest that clinicians evaluate transgender persons treated with hormones for cardiovas-cular risk factors using fasting lipid profiles, diabetes screening, and/or other diagnostic tools. (2 I⊕⊕○○)

Evidence

Transgender males

Administering testosterone to transgender males results in a more atherogenic lipid profile with lowered high-density lipoprotein cholesterol and higher triglyceride and low-density lipoprotein cholesterol values (176-179). Studies of the effect of testosterone on insulin sensitivity have mixed results (178, 180). A randomized, open-label uncontrolled safety study of transgender males treated with testosterone undecanoate demonstrated no insulin resistance after 1 year (181, 182). Numerous studies have demonstrated the effects of sex hormone treatment on the cardiovascular system (160, 179, 183, 184). Long-term studies from The Netherlands found no increased risk for cardiovascular mortality (161). Likewise, a meta-analysis of 19 randomized trials in nontransgender males on testosterone replacement showed no increased incidence of cardiovascular events (185). A systematic review of the literature found that data were insufficient (due to very low-quality evidence) to allow a meaningful assessment of patient-important outcomes, such as death, stroke, myocardial infarction, or VTE in transgender males (176). Future research is needed to ascertain the potential harm of hormonal therapies (176). Clinicians should manage cardiovascular risk factors as they emerge according to established guidelines (186).

Transgender females

A prospective study of transgender females found favorable changes in lipid parameters with increased high-density lipoprotein and decreased low-density lipoprotein concentrations (178). However, increased weight, blood pressure, and markers of insulin resistance attenuated these favorable lipid changes. In a meta-analysis, only serum triglycerides were higher at \geq 24 months without changes in other parameters (187). The largest cohort of transgender females (mean age 41 years, followed for a mean of 10 years) showed no increase in cardiovascular mortality despite a 32% rate of tobacco use (161).

Thus, there is limited evidence to determine whether estrogen is protective or detrimental on lipid and glucose metabolism in transgender females (176). With aging, there is usually an increase of body weight. Therefore, as with nontransgender individuals, clinicians should monitor and manage glucose and lipid metabolism and blood pressure regularly according to established guidelines (186).

4.4. We recommend that clinicians obtain BMD measurements when risk factors for osteoporosis exist, specifically in those who stop sex hormone therapy after gonadectomy. (1 l⊕⊕○○)

Evidence

Transgender males

Baseline bone mineral measurements in transgender males are generally in the expected range for their pretreatment gender (188). However, adequate dosing of testosterone is important to maintain bone mass in transgender males (189, 190). In one study (190), serum LH levels were inversely related to BMD, suggesting that low levels of sex hormones were associated with bone loss. Thus, LH levels in the normal range may serve as an indicator of the adequacy of sex steroid administration to preserve bone mass. The protective effect of testosterone may be mediated by peripheral conversion to estradiol, both systemically and locally in the bone.

Transgender females

A baseline study of BMD reported T scores less than -2.5 in 16% of transgender females (191). In aging males, studies suggest that serum estradiol more positively correlates with BMD than does testosterone (192, 193) and is more important for peak bone mass (194). Estrogen preserves BMD in transgender females who continue on estrogen and antiandrogen therapies (188, 190, 191, 195, 196).

Fracture data in transgender males and females are not available. Transgender persons who have undergone gonadectomy may choose not to continue consistent sex steroid treatment after hormonal and surgical sex reassignment, thereby becoming at risk for bone loss. There have been no studies to determine whether clinicians should use the sex assigned at birth or affirmed gender for assessing osteoporosis (e.g., when using the FRAX tool). Although some researchers use the sex assigned at birth (with the assumption that bone mass has usually peaked for transgender people who initiate hormones in early adulthood), this should be assessed on a case-by-case basis until there are more data available. This assumption will be further complicated by the increasing prevalence of transgender people who undergo hormonal transition at a pubertal age or soon after puberty. Sex for comparison within risk assessment tools may be based on the age at which hormones were initiated and the length of exposure to hormones. In some cases, it may be

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reasonable to assess risk using both the male and female calculators and using an intermediate value. Because all subjects underwent normal pubertal development, with known effects on bone size, reference values for birth sex were used for all participants (154).

- 4.5. We suggest that transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for those designated female at birth. (2 |⊕⊕○○)
- 4.6. We suggest that transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer. (2 I⊕○○○)

Evidence

Studies have reported a few cases of breast cancer in transgender females (197–200). A Dutch study of 1800 transgender females followed for a mean of 15 years (range of 1 30 years) found one case of breast cancer. The Women's Health Initiative study reported that females taking conjugated equine estrogen without progesterone for 7 years did not have an increased risk of breast cancer as compared with females taking placebo (137).

In transgender males, a large retrospective study conducted at the U.S. Veterans Affairs medical health system identified seven breast cancers (194). The authors reported that this was not above the expected rate of breast cancers in cisgender females in this cohort. Furthermore, they did report one breast cancer that developed in a transgender male patient after mastectomy, supporting the fact that breast cancer can occur even after mastectomy. Indeed, there have been case reports of breast cancer developing in subareolar tissue in transgender males, which occurred after mastectomy (201, 202).

Women with primary hypogonadism (Turner syndrome) treated with estrogen replacement exhibited a significantly decreased incidence of breast cancer as compared with national standardized incidence ratios (203, 204). These studies suggest that estrogen therapy does not increase the risk of breast cancer in the short term (<20 to 30 years). We need long-term studies to determine the actual risk, as well as the role of screening mammograms. Regular examinations and gynecologic advice should determine monitoring for breast cancer.

Prostate cancer is very rare before the age of 40, especially with androgen deprivation therapy (205). Childhood or pubertal castration results in regression of the prostate and adult castration reverses benign prostate hypertrophy (206). Although van Kesteren *et al.* (207) reported that estrogen therapy does not induce hypertrophy or premalignant changes in the prostates of transgender females, studies have reported cases of benign prostatic hyperplasia in transgender females treated with estrogens for 20 to 25 years (208, 209). Studies have also reported a few cases of prostate carcinoma in transgender females (210–214).

Transgender females may feel uncomfortable scheduling regular prostate examinations. Gynecologists are not trained to screen for prostate cancer or to monitor prostate growth. Thus, it may be reasonable for transgender females who transitioned after age 20 years to have annual screening digital rectal examinations after age 50 years and prostate-specific antigen tests consistent with U.S. Preventive Services Task Force Guidelines (215).

4.7. We advise that clinicians determine the medical necessity of including a total hysterectomy and oophorectomy as part of gender-affirming surgery. (Ungraded Good Practice Statement)

Evidence

Although aromatization of testosterone to estradiol in transgender males has been suggested as a risk factor for endometrial cancer (216), no cases have been reported. When transgender males undergo hysterectomy, the uterus is small and there is endometrial atrophy (217, 218). Studies have reported cases of ovarian cancer (219, 220). Although there is limited evidence for increased risk of reproductive tract cancers in transgender males, health care providers should determine the medical necessity of a laparoscopic total hysterectomy as part of a genderaffirming surgery to prevent reproductive tract cancer (221).

Values

Given the discomfort that transgender males experience accessing gynecologic care, our recommendation for the medical necessity of total hysterectomy and oophorectomy places a high value on eliminating the risks of female reproductive tract disease and cancer and a lower value on avoiding the risks of these surgical procedures (related to the surgery and to the potential undesirable health consequences of oophorectomy) and their associated costs.

Remarks

The sexual orientation and type of sexual practices will determine the need and types of gynecologic care required following transition. Additionally, in certain countries, the approval required to change the sex in a birth certificate for transgender males may be dependent on having a complete hysterectomy. Clinicians should help patients research nonmedical administrative criteria and doi: 10.1210/jc.2017-01658

provide counseling. If individuals decide not to undergo hysterectomy, screening for cervical cancer is the same as all other females.

5.0 Surgery for Sex Reassignment and Gender Confirmation

For many transgender adults, genital gender-affirming surgery may be the necessary step toward achieving their ultimate goal of living successfully in their desired gender role. The type of surgery falls into two main categories: (1) those that directly affect fertility and (2) those that do not. Those that change fertility (previously called sex reassignment surgery) include genital surgery to remove the penis and gonads in the male and removal of the uterus and gonads in the female. The surgeries that effect fertility are often governed by the legal system of the state or country in which they are performed. Other genderconforming surgeries that do not directly affect fertility are not so tightly governed.

Gender-affirming surgical techniques have improved markedly during the past 10 years. Reconstructive genital surgery that preserves neurologic sensation is now the standard. The satisfaction rate with surgical reassignment of sex is now very high (187). Additionally, the mental health of the individual seems to be improved by participating in a treatment program that defines a pathway of gender-affirming treatment that includes hormones and surgery (130, 144) (Table 16).

Surgery that affects fertility is irreversible. The World Professional Association for Transgender Health Standards of Care (222) emphasizes that the "threshold of 18 should not be seen as an indication in itself for active intervention." If the social transition has not been satisfactory, if the person is not satisfied with or is ambivalent about the effects of sex hormone treatment, or if the person is ambivalent about surgery then the individual should not be referred for surgery (223, 224).

Gender-affirming genital surgeries for transgender females that affect fertility include gonadectomy, penectomy, and creation of a neovagina (225, 226). Surgeons often invert the skin of the penis to form the wall of the vagina, and several literatures reviews have reported on outcomes (227). Sometimes there is inadequate tissue to form a full neovagina, so clinicians have revisited using intestine and found it to be successful (87, 228, 229). Some newer vaginoplasty techniques may involve autologuous oral epithelial cells (230, 231).

The scrotum becomes the labia majora. Surgeons use reconstructive surgery to fashion the clitoris and its hood, preserving the neurovascular bundle at the tip of the penis as the neurosensory supply to the clitoris. Some surgeons are also creating a sensate pedicled-spot adding a G spot to the neovagina to increase sensation (232). Most recently, plastic surgeons have developed techniques to fashion labia minora. To further complete the feminization, uterine transplants have been proposed and even attempted (233).

Neovaginal prolapse, rectovaginal fistula, delayed healing, vaginal stenosis, and other complications do sometimes occur (234, 235). Clinicians should strongly remind the transgender person to use their dilators to maintain the depth and width of the vagina throughout the postoperative period. Genital sexual responsivity and other aspects of sexual function are usually preserved following genital gender-affirming surgery (236, 237).

Ancillary surgeries for more feminine or masculine appearance are not within the scope of this guideline. Voice therapy by a speech language pathologist is available to transform speech patterns to the affirmed gender (148). Spontaneous voice deepening occurs during testosterone treatment of transgender males (152, 238). No studies have compared the effectiveness of speech therapy, laryngeal surgery, or combined treatment.

Breast surgery is a good example of gender-confirming surgery that does not affect fertility. In all females, breast size exhibits a very broad spectrum. For transgender females to make the best informed decision, clinicians should delay breast augmentation surgery until the patient has completed at least 2 years of estrogen therapy, because the breasts continue to grow during that time (141, 155).

Another major procedure is the removal of facial and masculine-appearing body hair using either electrolysis or

Table 16. Criteria for Gender-Affirming Surgery, Which Affects Fertility

- 1. Persistent, well-documented gender dysphoria
- 2. Legal age of majority in the given country

- 4. Successful continuous full-time living in the new gender role for 12 mo
- 5. If significant medical or mental health concerns are present, they must be well controlled
- 6. Demonstrable knowledge of all practical aspects of surgery (e.g., cost, required lengths of hospitalizations, likely complications, postsurgical rehabilitation)

^{3.} Having continuously and responsibly used gender-affirming hormones for 12 mo (if there is no medical contraindication to receiving such therapy)

laser treatments. Other feminizing surgeries, such as that to feminize the face, are now becoming more popular (239–241).

In transgender males, clinicians usually delay gender-affirming genital surgeries until after a few years of androgen therapy. Those surgeries that affect fertility in this group include oophorectomy, vaginectomy, and complete hysterectomy. Surgeons can safely perform them vaginally with laparoscopy. These are sometimes done in conjunction with the creation of a neopenis. The cosmetic appearance of a neopenis is now very good, but the surgery is multistage and very expensive (242, 243). Radial forearm flap seems to be the most satisfactory procedure (228, 244). Other flaps also exist (245). Surgeons can make neopenile erections possible by reinervation of the flap and subsequent contraction of the muscle, leading to stiffening of the neopenis (246, 247), but results are inconsistent (248). Surgeons can also stiffen the penis by imbedding some mechanical device (e.g., a rod or some inflatable apparatus) (249, 250). Because of these limitations, the creation of a neopenis has often been less than satisfactory. Recently, penis transplants are being proposed (233).

In fact, most transgender males do not have any external genital surgery because of the lack of access, high cost, and significant potential complications. Some choose a metaoidioplasty that brings forward the clitoris, thereby allowing them to void in a standing position without wetting themselves (251, 252). Surgeons can create the scrotum from the labia majora with good cosmetic effect and can implant testicular prostheses (253).

The most important masculinizing surgery for the transgender male is mastectomy, and it does not affect fertility. Breast size only partially regresses with androgen therapy (155). In adults, discussions about mastectomy usually take place after androgen therapy has started. Because some transgender male adolescents present after significant breast development has occurred, they may also consider mastectomy 2 years after they begin androgen therapy and before age 18 years. Clinicians should individualize treatment based on the physical and mental health status of the individual. There are now newer approaches to mastectomy with better outcomes (254, 255). These often involve chest contouring (256). Mastectomy is often necessary for living comfortably in the new gender (256).

5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being. $(1 \mid \oplus \oplus \bigcirc \bigcirc)$

- 5.2. We advise that clinicians approve genital genderaffirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)
- 5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)
- 5.4. We recommend that clinicians refer hormone-treated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 □000)
- 5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. (2 I⊕⊕○○).
- 5.6. We suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement. (2 I⊕○○○)

Evidence

Owing to the lack of controlled studies, incomplete follow-up, and lack of valid assessment measures, evaluating various surgical approaches and techniques is difficult. However, one systematic review including a large numbers of studies reported satisfactory cosmetic and functional results for vaginoplasty/neovagina construction (257). For transgender males, the outcomes are less certain. However, the problems are now better understood (258). Several postoperative studies report significant long-term psychological and psychiatric pathology (259-261). One study showed satisfaction with breasts, genitals, and femininity increased significantly and showed the importance of surgical treatment as a key therapeutic option for transgender females (262). Another analysis demonstrated that, despite the young average age at death following surgery and the relatively larger number of individuals with somatic morbidity, the study does not allow for determination of doi: 10.1210/jc.2017-01658

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causal relationships between, for example, specific types of hormonal or surgical treatment received and somatic morbidity and mortality (263). Reversal surgery in regretful male-to-female transsexuals after sexual reassignment surgery represents a complex, multistage procedure with satisfactory outcomes. Further insight into the characteristics of persons who regret their decision postoperatively would facilitate better future selection of applicants eligible for sexual reassignment surgery. We need more studies with appropriate controls that examine long-term quality of life, psychosocial outcomes, and psychiatric outcomes to determine the long-term benefits of surgical treatment.

When a transgender individual decides to have genderaffirming surgery, both the hormone prescribing clinician and the MHP must certify that the patient satisfies criteria for gender-affirming surgery (Table 16).

There is some concern that estrogen therapy may cause an increased risk for venous thrombosis during or following surgery (176). For this reason, the surgeon and the hormone-prescribing clinician should collaborate in making a decision about the use of hormones before and following surgery. One study suggests that preoperative factors (such as compliance) are less important for patient satisfaction than are the physical postoperative results (56). However, other studies and clinical experience dictate that individuals who do not follow medical instructions and do not work with their physicians toward a common goal do not achieve treatment goals (264) and experience higher rates of postoperative infections and other complications (265, 266). It is also important that the person requesting surgery feels comfortable with the anatomical changes that have occurred during hormone therapy. Dissatisfaction with social and physical outcomes during the hormone transition may be a contraindication to surgery (223).

An endocrinologist or experienced medical provider should monitor transgender individuals after surgery. Those who undergo gonadectomy will require hormone replacement therapy, surveillance, or both to prevent adverse effects of chronic hormone deficiency.

Financial Disclosures of the Task Force*

Wylie C. Hembree (chair)—financial or business/ organizational interests: none declared, significant financial interest or leadership position: none declared. Peggy T. Cohen-Kettenis—financial or business/organizational interests: none declared, significant financial interest or leadership position: none declared. Louis Gooren—financial or business/ organizational interests: none declared, significant financial

interest or leadership position: none declared. Sabine E. Hannema-financial or business/organizational interests: none declared, significant financial interest or leadership position: Ferring Pharmaceuticals Inc. (lecture/conference), Pfizer (lecture). Walter J. Meyer-financial or business/organizational interests: none declared, significant financial interest or leadership position: none declared. M. Hassan Murad**-financial or business/organizational interests: Mayo Clinic, Evidence-based Practice Center, significant financial interest or leadership position: none declared. Stephen M. Rosenthal-financial or business/organizational interests: AbbVie (consultant), National Institutes of Health (grantee), significant financial interest or leadership position: Pediatric Endocrine Society (immediate past president). Joshua D. Safer, FACP-financial or business/organizational interests: none declared, significant financial interest or leadership position: none declared. Vin Tangpricha-financial or business/organizational interests: Cystic Fibrosis Foundation (grantee), National Institutes of Health (grantee), significant financial interest or leadership position, Elsevier Journal of Clinical and Translational Endocrinology (editor). Guy G. T'Sjoen-financial or business/organizational interests: none declared, significant financial interest or leadership position: none declared.* Financial, business, and organizational disclosures of the task force cover the year prior to publication. Disclosures prior to this time period are archived.**Evidence-based reviews for this guideline were prepared under contract with the Endocrine Society.

Acknowledgments

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Disclosure Summary: See Financial Disclosures.

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

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

EXPERT REPORT OF JOHANNA OLSON-KENNEDY, M.D., M.S.

I, Johanna Olson-Kennedy, M.D., M.S., hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I am over the age of 18. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

BAKCGROUND AND QUALIFICATIONS

3. I have been retained by counsel for Plaintiffs in the above-captioned lawsuit to provide an expert opinion on gender identity; the treatment and diagnosis of gender dysphoria; the *Florida Medicaid Generally Accepted*

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Professional Medical Standards (GAPMS) Determination on the Treatment of Gender Dysphoria published by Florida's Agency for Health Care Administration (AHCA) in June 2022, along with its attachments; and Fla. Admin. Code. R. 59G-1.050(7) which prohibits Medicaid coverage of puberty blockers, hormone and hormone antagonists, "sex reassignment" surgeries, and any other procedures that alter primary or secondary sexual characteristics.

A. **Qualifications and Experience**

4. I am a Double Board Certified Physician in Pediatrics and Adolescent Medicine. I specialize in the care of transgender youth and gender diverse children. I am a recognized expert in this field.

5. The information provided regarding my professional background, experiences, publications, and presentations is further detailed in my curriculum vitae ("CV"). A true and correct copy of my most up-to-date CV is attached as **Exhibit A**.

6. I received my Doctor of Medicine (M.D.) degree from the Chicago Medical School in 1997. In 2000, I completed my residency in pediatrics at the Children's Hospital of Orange County, California, and from 2000 to 2003, I was a Fellow in adolescent medicine at the Children's Hospital of Los Angeles. 7. I have been a licensed physician in California since 2000. I am currently the Medical Director of the Center for Transyouth Health and Development, in the Division of Adolescent Medicine at the Children's Hospital in Los Angeles, California. The Center is the largest clinic in the United States for transgender youth and provides gender diverse youth with both medical and mental health services, including consultation for families with gender diverse children and routine use of medications to suppress puberty in peri-pubertal youth (i.e., youth at the onset of puberty), gender-affirming hormone use for masculinization and feminization, as well as surgical referrals. Under my direction, the Center conducts rigorous research aimed at understanding the experience of gender diversity and gender dysphoria from childhood through early adulthood.

8. Over the course of my work with this population during the past 16 years, I have provided services for approximately 1000 young people and their families, and currently have an active panel of around 650 patients of varying ages, up to 25 years old.

9. I have been awarded research grants to examine the impact of early interventions including puberty-delaying medication (commonly known as puberty blockers) and gender-affirming hormones on the physiological and

psychosocial development of gender diverse and transgender youth. I have lectured extensively, across the United States and internationally on the treatment and care of gender diverse children and transgender adolescents, the subjects including pubertal suppression, gender-affirming hormone therapy, transitioning teens and the adolescent experience, age considerations in administering hormones, and the needs, risks, and outcomes of hormonal treatments. I have published numerous articles and chapters, both peer reviewed, and non-peer reviewed, on transgender health-related issues.

10. I am currently the principal investigator on a multisite National Institutes of Health grant to continue, for an additional 5 years, an ongoing study examining the impact of gender-affirming medical care for transgender youth on physiologic and psychological health and well-being. The first five years have already been completed. This is the first study of its kind in the U.S. to determine longitudinal outcomes among this population of vulnerable youth. The study to date has yielded approximately 26 manuscripts.

11. I am an Associate Professor at the Keck School of Medicine at the University of Southern California and attending physician at Children's Hospital of Los Angeles. I have been a member of the World Professional Association for Transgender Health (WPATH) since 2010, and a Board Member of the U.S. Professional Association for Transgender Health (USPATH) since 2017. I was recently appointed to the Executive Board of the USPATH. I am also a member of the Society for Adolescent Health and Medicine and the American Academy of Pediatrics. In addition, I am a member of the LGBT Special Interest Group of the Society for Adolescent Health and Development.

12. I am the 2014 Recognition Awardee for the Southern California Regional Chapter of the Society for Adolescent Health and Medicine.

13. In 2019, I was invited by the University of Bristol as a Benjamin Meaker visiting professor, the purpose of which is to bring distinguished researchers from overseas to Bristol in order to enhance the research activity of the university.

B. <u>Previous Testimony</u>

14. In the last four years, I have testified as an expert at trial or by deposition in the following cases: *Fain v. Crouch*, No. 3:20-cv-00740 (S.D. W.Va.); *Kadel v. Folwell*, Case No. 1:19-cv-00272-LCB-LPA (M.D.N.C.); *Miller v. Purdue* (Colorado); *In the interest of JA.D.Y. and JU.D.Y., Children*, Case No. DF-15-09887 (255th Jud. District Ct., Dallas Cty., Tex.); and *Paul E. v. Courtney F.*, No. FC2010-051045 (Superior Ct., Maricopa Cty., Ariz.).

C. Compensation

15. I am being compensated for my work on this matter at a rate of \$200.00 per hour for preparation of declarations and expert reports, as well as any pre-deposition and/or pre-trial preparation and any deposition testimony or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

D. Bases for Opinions

16. In preparing this report, I have relied on my training and years of research and clinical experience, as set out in my curriculum vitae, and on the materials listed therein. *See* **Exhibit A**. It documents my education, training, research, and years of experience in this field and includes a list of publications.

17. I have also reviewed the materials listed in the attached bibliography. *See* **Exhibit B**. The sources cited therein are authoritative, scientific peer-reviewed publications. I generally rely on these materials when I provide expert testimony, and they include the documents specifically cited as supportive examples in particular sections of this declaration.

18. In addition, I have reviewed the Florida Medicaid Generally Accepted Professional Medical Standards (GAPMS) Determination on the Treatment of Gender Dysphoria published by Florida's Agency for Health Care Administration (AHCA) in June 2022, along with its attachments, including the "assessments" of Dr. Romina Brignardello-Petersen and Dr. Wojtek Wiercioch (Attachment C), Dr. James Cantor (Attachment D), Dr. Quentin Van Meter (Attachment E), Dr. Patrick Lappert (Attachment F), and Dr. G. Kevin Donovan (Attachment G) (hereinafter, "GAPMS Memo"); and Fla. Admin. Code. R. 59G-1.050(7) which prohibits Medicaid coverage of puberty blockers, hormone and hormone antagonists, "sex reassignment" surgeries, and any other procedures that alter primary or secondary sexual characteristics. I may rely on these documents, as well as those cited in my curriculum vitae and the attached bibliography, as additional support for my opinions.

19. 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 the subject. I reserve the right to revise and supplement the opinions expressed in this report or the bases for them if any new information becomes available in the future, including as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

EXPERT OPINIONS

A. Gender Identity

1. The term gender identity was originally coined in 1964 by American psychiatrist Robert J. Stoller, a noted psychoanalyst who studied sexual orientation, gender identity, and differences in sexual development.¹ Gender identity is a distinct characteristic and is defined as one's internal sense of being male or female (or rarely, both or neither). It has a strong biological basis. Every person has a gender identity.

2. The concept of gender identity is contemporaneously understood both colloquially and within the domain of science and medicine to denote someone's gender. It is a concept well-understood and accepted in medicine and science. Indeed, gender identity information is commonly collected and reported on within the context of scientific research.²

3. The term cisgender refers to a person whose gender identity matches their sex assigned at birth. The term transgender refers to a person whose gender identity does not match their sex assigned at birth.

¹ Stoller, R.J. (1964). A Contribution to the Study of Gender Identity, *The International journal of psycho-analysis*, 45, 220–226.

² Clayton JA, Tannenbaum C. (2016). Reporting Sex, Gender, or Both in Clinical Research? *JAMA*. 316(18): 1863–1864.

4. Historically, "gender" was equated with a person's sex assigned at birth, which refers to the sex assigned to a person when they are born, generally based on external genitalia. However, a more contemporary understanding of gender shows that one's gender identity may differ from one's sex assigned at birth.

5. While both gender identity and sex are often assumed and treated as binary and oppositional, they are more accurately experienced as along a spectrum. For example, there are multiple sex characteristics, such as genitalia, chromosomal makeup, hormones, and variations in brain structure and function. For some of these characteristics there is significant variance as reflected by the dozens of intersex mechanisms and varying gender identities. Additionally, not all sex characteristics, including gender identity, are always in alignment. Accordingly, the Endocrine Society Guidelines state that, "As these may not be in line with each other (e.g., a person with XY chromosomes may have femaleappearing genitalia), the terms biological sex and biological male or female are imprecise and should be avoided."³

³ Hembree, W.C., Cohen-Kettenis, P.T., Gooren, L., et al. (2017). Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, 102(11): 3869–3903.

6. As early as 1966 it has been understood that gender identity cannot be changed.⁴ Efforts to do so have been shown to be unsuccessful and harmful.

B. Gender Dysphoria and its Treatment

7. Gender Dysphoria (GD) is a serious medical condition characterized by distress due to a mismatch between assigned birth sex and a person's internal sense of their gender. GD was formerly categorized as Gender Identity Disorder (GID) but the condition was renamed in May 2013, with the release of the American Psychiatric Association (APA)'s fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5).⁵ In announcing this change, the APA explained that in addition to the name change, the criteria for the diagnosis were revised "to better characterize the experiences of affected children, adolescents, and adults."⁶ The APA further stressed that "gender nonconformity is not in itself a mental disorder. The critical element of gender dysphoria is the presence of clinically significant distress associated with the condition."⁷

⁴ Benjamin, H. (1966). The Transsexual Phenomenon. New York: The Julian Press, Inc. Publishers.

⁵ A text revision to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition was published in 2022 ("DSM-5-TR").

⁶ DSM-5.

⁷ Id.

8. On May 25, 2019, the World Health Assembly approved International Classification of Diseases (ICD) version 11 that had been published by the World Health Organization in 2018.⁸ In this newest version of the ICD, all trans-related diagnostic codes were removed from the chapter "Mental and Behavioral Disorders," and the code "Gender incongruence" was included in a new chapter "Conditions related to sexual health." These codes replaced the outdated "Gender Identity Disorder of childhood" (F64.2), "Gender Identity Disorder not otherwise specified" (F64.9), "transsexualism" (F64.0), and "Dualrole transvestism" (F64.1), which perpetuated the idea that patients seeking and undergoing medical interventions for a medical condition are mentally ill.⁹

9. For a person to be diagnosed with GD, there must be a marked difference between the individual's expressed/experienced gender and the gender others would assign to the individual, present for at least six months. In children, the desire to be of the other gender must be present and verbalized.¹⁰ The

⁸ World Health Organization. (2018). Gender Incongruence. In International Classification of Diseases, 11th Revision.

⁹ Suess Schwend A. (2020). Trans health care from a depathologization and human rights perspective. *Public health reviews*, *41*, 3.

¹⁰ Notably, the DSM-IV included a separate diagnosis for GID in children, which required the child to display a number of behaviors stereotypical of the non-natal gender. That diagnosis, and its list of behavioral requirements, have been deleted from the DSM-5 and replaced by updated and more precise diagnostic criteria.

condition must cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

The World Professional Association of Transgender Health 10. (WPATH) has clear recommendations for the health of transsexual, transgender, and gender non-conforming people in what is now the Standards of Care version 8 (SOC 8).¹¹ The SOC are based on the best available science and expert professional consensus. Importantly, SOC 8 is based on the best available science and expert professional consensus in transgender health; its recommendation statements were developed based on data derived from independent systematic literature reviews, background reviews, and expert opinions; and its grading of recommendations was based on the available evidence supporting interventions, a discussion of risks and harms, as well as the feasibility and acceptability of these. SOC 8 continues to recommend the provision of medical interventions, such as puberty blockers, hormone therapy, and surgery, as treatment for gender dysphoria, based on an individual patient's needs.

11. The WPATH SOC have been endorsed and cited as authoritative by most major medical associations in the United States, including the American

¹¹ Coleman, et al. (2022) (SOC 8).

Medical Association, the American Psychiatric Association, the American Psychological Association, the Endocrine Society, the Pediatric Endocrine Society, the American College of Physicians, and the American Academy of Family Physicians, among others.

12. The UCSF Center for Excellence in Transgender Care as well as the Endocrine Society have both published comprehensive guidelines for the care of transgender and non-binary individuals that are largely consistent with the WPATH SOC.¹²

13. The GAPMS Memo and some its attached "assessments" discuss a number of approaches to care, though they fail to properly describe them and to discuss their limitations.

14. One of the approaches discussed by Dr. Van Meter is "**reparative**" or "corrective" therapy. *See* Attachment E to GAPMS Memo, at 6 ("Van Meter"). "Conversion" or "reparative" therapy refers to the practice of attempting to change an individual's sexual orientation and attractions from members of the same sex to those of the opposite sex. A similar model of therapy

¹² 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> (UCSF Guidelines); Hembree, et al. (2017) (Endocrine Society Guidelines).

for individuals with a transgender identity or experience has historically been an approach promoted by some individuals, notwithstanding its ineffectiveness and harmful effects. Accordingly, 20 states and the District of Columbia have banned reparative therapy for youth, and major medical organizations have issued statements deeming the practice to be unethical.¹³

15. A Williams Institute report published in 2019 estimates that just under 700,000 LGBT individuals in the United States have undergone "conversion therapy" at some point in their lifetime, about half of those during adolescence.¹⁴ Because some psychiatrists and sexologists working in the 1960's and 70's perpetuated the idea that being transgender was likely the result of a pathological early childhood experience, many professionals and lay community members continue to believe that gender is malleable. Tactics have ranged from simple redirection, thought pattern alteration or hypnosis to aversion techniques including induction of vomiting, nausea, paralysis or electric shock, have been employed in order to change the expression, behavior, and assertion of one's

¹³ Movement Advancement Proj., *Conversion "Therapy" Laws,* <u>https://www.lgbtmap.org/equality-maps/conversion_therapy</u> (last updated Jan. 30, 2023).

¹⁴ Mallory, C., Brown, T. N.T., Conron, K.J. (2019). Conversion Therapy and LGBT Youth: Update. Los Angeles, CA: The Williams Institute, UCLA School of Law.

authentic gender.¹⁵ However, multiple studies show that gender identity has a strong biological basis and cannot be changed. As such, reparative therapy is both ineffective and harmful for transgender and gender diverse youth.

16. **"Redirection"** – Under this approach, advocated by people like Dr. Van Meter, a mental health therapist would encourage caregivers to use positive reinforcement to try to "redirect" children toward behavior that is more typical of their birth-designated sex or less gender specific. Underlying this approach is the assumption that a child's gender identity is malleable through social interventions. The goal of redirection is thus to eliminate gender-diverse desires and expressions over time, and to try to prevent the transgender child from being transgender. This approach is not recommended because negative reinforcement (e.g., shaming the child for gender diverse expression) has substantial negative mental and social health consequences.¹⁶ It also ignores that gender identity is innate and cannot be changed.

17. **Wait-and-see** – The wait-and-see approach (also called watchful waiting) involves waiting to see if the child's gender identity will change as the

¹⁵ *Id*.

¹⁶ Turban, J.L., & Ehrensaft, D. (2018). Research Review: Gender identity in youth: treatment paradigms and controversies. *Journal of child psychology and psychiatry, and allied disciplines*, *59*(12), 1228–1243; Ehrensaft, D. (2017). Gender nonconforming youth: current perspectives. *Adolescent health, medicine and therapeutics*, *8*, 57–67.

child gets older. This approach typically recommends that caregivers prohibit a prepubertal social transition but may allow cross-gender play and clothing within the home or support both masculine and feminine activities as the child explores their interests in other social settings. The wait-and-see approach assumes that gender is binary and becomes fixed at a certain age; it pathologizes gender diversity and fluidity. It is distinguished from following the child's lead, an affirming approach that allows the child to present in the gender role that feels correct and moves at a pace that is largely directed by the child. This approach ignores evidence that young children thrive when given permission to live in the gender that is most authentic to them and are at risk for symptomatic behaviors if prevented from doing so.¹⁷

18. Affirmation – The affirmative approach considers no gender identity outcome: transgender, cisgender, or otherwise, to be preferable.¹⁸ It permits a child to explore gender development and self-definition within a safe setting. A fundamental concept of this approach is that gender diversity is not a mental illness. The gender-affirmative model is defined as a method of therapeutic care that includes allowing children to speak for themselves about

¹⁷ Ehrensaft (2017).

¹⁸ Turban and Ehrensaft (2018).

their self-experienced gender identity and expressions and providing support for them to evolve into their authentic gender selves, no matter at what age. Under this model, a child's self-report is embedded within a collaborative model with the child as subject and the collaborative team including the child, parents, and professionals. Support is not characterized by "encouraging" children or youth to be transgender or not, but rather by allowing children who express a desire to undergo a social transition (which may include changing names, pronouns, clothing, hairstyles, etc.) to do so. For children who have not yet reached puberty, medical intervention is unnecessary and unwarranted. After the onset of puberty, medical interventions such as puberty blockers, and later hormones and surgery, may be appropriate.

19. While some argue that gender affirmation leads a child or adolescent down a path of inevitable transgender identity, no such evidence exists, either in the scientific or the clinical setting. To the contrary, studies show that gender identification does not meaningfully differ before and after social transition.¹⁹

¹⁹ Rae, J. R., Gülgöz, S., Durwood, L., DeMeules, M., Lowe, R., Lindquist, G., & Olson, K. R. (2019). Predicting early-childhood gender transitions. *Psychological Science*, 30(5), 669-681.

20. Under both the "wait and see" and affirmative care models, as understood in the scientific literature, medical care is recommended following the onset of puberty.²⁰

21. The most effective treatment for adolescents and adults with GD, in terms of both their mental and medical health, contemplates an individualized approach. Medical and surgical treatment interventions are determined by the care team (usually a medical and mental health professional) in collaboration with the patient, and the patient's family, if the patient is a minor. These medical decisions are made by the care team in conjunction with the patient and, if the patient is a minor, the patient's family, and consider the patient's social situation, level of gender dysphoria, developmental stage, existing medical conditions, and other relevant factors. Sometimes treatment begins with puberty delaying medications (also referred to as puberty blockers), later followed by gender-affirming hormones. Most youth, and certainly all adults, accessing treatment are already well into or have completed puberty.

²⁰ Ehrensaft (2017).

1) Puberty Blockers

22. The beginning signs of puberty in transgender youth (the development of breast buds in assigned birth females and increased testicular volume in assigned birth males) is often a painful and sometimes traumatic experience that brings increased body dysphoria and the potential development of a host of comorbidities including depression, anxiety, substance abuse, self-harming behaviors, social isolation, high-risk sexual behaviors, and increased suicidality.

23. Puberty suppression, which involves the administration of gonadotrophin-releasing hormone analogues (GnRHa), essentially pauses puberty, thereby allowing the young person the opportunity to explore gender without having to experience the anxiety and distress associated with developing the undesired secondary sexual characteristics. In addition, for parents/guardians who are uneducated about gender diversity and/or who have only recently become aware of their child's transgender identity, puberty blockers provide additional time and opportunity to integrate this new information into their own experience and to develop skills to support their child. Puberty suppression also has the benefit of potentially rendering obsolete some gender-affirming surgeries down the line, such as male chest reconstruction, tracheal shave, facial

feminization, and vocal cord alteration, which otherwise would be required to correct the initial "incorrect" puberty.

24. Puberty suppression has been used safely for decades in children with other medical conditions, including precocious puberty, and is a reversible intervention.²¹ If the medication is discontinued, the young person continues their endogenous puberty. The "Dutch protocol," developed from a study conducted in the Netherlands and published in 2006, calls for the commencement of puberty blockers for appropriately diagnosed and assessed gender dysphoric youth as early as 12 years of age.²² Both the Endocrine Society and the WPATH's SOC, however, recommend initiation of puberty suppression at the earliest stages of puberty (usually, Tanner 2) (assuming someone has engaged in services before or around this time), regardless of chronological age, in order to avoid the stress and trauma associated with developing secondary sex characteristics of the natal sex.

²¹ Mul, D. & Hughes, I. (2008). The use of GnRH agonists in precocious puberty. *European journal of endocrinology / European Federation of Endocrine Societies*. 159 Suppl 1. S3-8.

²² de Vries, A.L.C., McGuire, J. K., Steensma, T. D., Wagenaar, E. C. F., Doreleijers, T. A. H., & Cohen-Kettenis, P. T. (2014). Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment. *Pediatrics*, *134*(4), 696-704; Biggs M. (2022). The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence. *Journal of sex & marital therapy*, 1–21.
25. A growing body of evidence, including peer-reviewed crosssectional and longitudinal studies, demonstrates the positive impact of pubertal suppression in youth with GD on psychological functioning including a decrease in behavioral and emotional problems, a decrease in depressive symptoms, and improvement in general functioning.²³

26. The initial follow-up studies evaluating the use of puberty suppression in relation to psychological well-being in adolescents with GD came from the Netherlands and demonstrated that behavioral and emotional problems and depressive symptoms decreased and general functioning significantly improved during treatment.²⁴

²³ See for example: 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), 2276-2283; Turban, J.L., King, D., Carswell, J.M., & Keuroghlian, A.S. (2020). Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. *Pediatrics*, 145(2):e20191725; van der Miesen, A.I., Steensma, T.D., de Vries, A.L., *et al.* (2020). Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared with Cisgender General Population Peers. *Journal of Adolescent Health*, 66(6), 699-704; Achille, C., Taggart, T., Eaton, N.R., *et al.* (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), 1-5; and Costa, R., Dunsford, M., Skagerberg, E., Holt, V., Carmichael, P., & Colizzi, M. (2015). Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria. *The journal of sexual medicine*, *12*(11), 2206–2214..

²⁴ de Vries, et al. (2011); de Vries, et al. (2014).

27. A study from the United Kingdom demonstrated that psychological support and puberty suppression were associated with improved global psychosocial functioning in adolescents with gender dysphoria with a combination of psychological support and puberty suppression, attributing to a greater improvement than psychological support only.²⁵

28. A more recent cross-sectional study from the Dutch team demonstrated that transgender youth undergoing pubertal suppression had better psychological functioning than those youth who had not yet begun puberty blockade.²⁶

29. Achille et al. demonstrated a positive effect of puberty blockade on mental health in a small, prospective investigation. The study characterized a treatment cohort over progressive interventions moving from puberty blockade to GAH treatment.²⁷

30. Overall, this growing body of evidence is consistent with and supports clinical experience demonstrating a significant positive effect of puberty blockade in youth with gender dysphoria.

²⁵ Costa, et al. (2015).

²⁶ Van der Miesen, et al. (2020).

²⁷ Achille, et al. (2020).

Puberty blockers, thus, afford youth the opportunity to undergo a 31. single, congruent pubertal process and avoid many of the surgical interventions previously necessary for assimilation into an authentic gender role. It is a simple reversible intervention that has the capacity to improve health outcomes and save lives. Over the course of my work in the past sixteen years with gender diverse and transgender youth, I have prescribed hormone suppression for over 350 patients. All of those patients have benefitted from putting their endogenous puberty process on pause, even the small handful who discontinued GnRH analogues and went through their endogenous puberty. Many of these young people were able to matriculate back into school environments, begin appropriate peer relationships, and participate meaningfully in therapy and family functions. Children who had contemplated or attempted suicide or self-harm (including cutting and burning) associated with monthly menstruation or the anxiety about their voice dropping were offered respite from those dark places of despair. GnRH analogues for puberty suppression are, in my opinion, a sentinel event in the history of transgender medicine, and have changed the landscape almost as much as the development of synthetic hormones.

2) Gender-Affirming Hormones

Cross-gender or gender-affirming hormone therapy involves 32. administering steroids of the experienced sex (i.e., their gender identity) (estrogen for transfeminine individuals and testosterone for transmasculine individuals). The purpose of this treatment is to attain the appropriate masculinization or feminization of the transgender person to achieve a gender phenotype that matches as closely as possible to their gender identity. Genderaffirming hormone therapy is a partially reversible treatment in that some of the effects produced by the hormones are reversible (e.g., changes in body fat composition, decrease in facial and body hair) while others are irreversible (e.g., deepening of the voice, breast tissue development). Eligibility and medical necessity should be determined case-by-case, based on an assessment of the youth's unique cognitive and emotional maturation and ability to provide a knowing and informed consent. The decision would be made only after a careful review with the youth and parents/guardians of the potential risks and benefits of hormone therapy. The youth's primary care provider, therapist, or another experienced mental health professional can help document and confirm the patient's history of GD, the medical necessity of the intervention, and the youth's readiness to transition medically.

33. As with the use of puberty blockers, the data demonstrating the positive effects of gender affirming hormones (GAH) is well established and growing.

34. The Dutch team at The Center of Expertise on Gender Dysphoria at the VU University Medical Center Amsterdam continued to report out the improvement within their cohort of youth with gender dysphoria after GAH. De Vries et al reported in 2014 that their cohort of young adults who began care in adolescence had steadily improving mental health (including depression, anxiety, anger, internalizing and externalizing psychopathologic symptoms) following puberty blockade, GAH and gender affirming surgery.²⁸

35. A German observational study reported that among the participants at follow-up, adolescents in the gender-affirming hormone (GAH) and surgery (GAS) group reported emotional and behavioral problems and physical quality of life scores similar to the German norm mean.²⁹

²⁸ de Vries, et al. (2014).

²⁹ Becker-Hebly, I., Fahrenkrug, S., Campion, F., Richter-Appelt, H., Schulte-Markwort, M., & Barkmann, C. (2021). Psychosocial health in adolescents and young adults with gender dysphoria before and after gender-affirming medical interventions: A descriptive study from the Hamburg Gender Identity Service. *European Child & Adolescent Psychiatry*, 30(11), 1755–1767.

36. Also from Germany, Neider et al. reported that among a group of 75 adolescents with gender dysphoria satisfaction improved the further along the treatment course had progressed.³⁰

37. From the United States, Kuper et al. carried out a prospective study and reported their cohort of transgender and non-binary youth starting either pubertal blockade or GAH demonstrated improvement at follow up (around a year) in depression, anxiety and body esteem.³¹

38. While small, Grannis et al. demonstrated decreased depression and anxiety in a group of transmasculine youth taking testosterone versus an untreated control group.³²

39. Most recently our team at the Trans Youth Care United States (TYC-

US) reported in the New England Journal of Medicine an improvement among

³⁰ Nieder, T. O., Mayer, T. K., Hinz, S., Fahrenkrug, S., Herrmann, L., & Becker-Hebly, I. (2021). Individual treatment progress predicts satisfaction with transition-related care for youth with gender dysphoria: A prospective clinical cohort study. *The Journal of Sexual Medicine*, 18(3), 632–645.

³¹ Kuper, L. E., Stewart, S., Preston, S., Lau, M., & Lopez, X. (2020). Body dissatisfaction and mental health outcomes of youth on gender-affirming hormone therapy. *Pediatrics*, 145(4).

³² Grannis, C., Leibowitz, S. F., Gahn, S., Nahata, L., Morningstar, M., Mattson, W. I., Chen, D., Strang, J. F., & Nelson, E. E. (2021). Testosterone treatment, internalizing symptoms, and body image dissatisfaction in transgender boys. *Psychoneuroendocrinology*, 132, 105358, 1-8.

315 youth in positive affect and life satisfaction as well as a decrease in depressive and anxiety symptoms after two years of GAH.³³

40. The data documenting the efficacy of hormone treatment in transgender adults is as robust and goes back even further. Numerous longitudinal studies document improvement in various mental health parameters including depression, anxiety, self-confidence, body image and self-image, general psychological functioning.³⁴

³³ 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):240-250.

³⁴ See for example: Colizzi, M., et al. (2014). Transsexual patients' psychiatric comorbidity and positive effect of cross-sex hormonal treatment on mental health: results from a longitudinal study. Psychoneuroendocrinology, 39, 65-73; Colizzi, M., et al. (2013). Hormonal treatment reduces psychobiological distress in gender identity disorder, independently of the attachment style. The journal of sexual medicine, 10(12), 3049-3058; Corda, E., et al. (2016). Body image and gender role perceived in gender dysphoria: Cross-sex hormone therapy effects. European Psychiatry, 33(S1), S589-S589; Fisher, A. D., et al. (2016). Cross-Sex Hormone Treatment and Psychobiological Changes in Transsexual Persons: Two-Year Follow-Up Data. The Journal of clinical endocrinology and metabolism, 101(11), 4260-4269; Heylens, G., et al. (2014). Effects of different steps in gender reassignment therapy on psychopathology: a prospective study of persons with a gender identity disorder. The journal of sexual medicine, 11(1), 119-126; Keo-Meier, C. L., et al. (2015). Testosterone treatment and MMPI-2 improvement in transgender men: a prospective controlled study. Journal of consulting and clinical psychology, 83(1), 143-156; Manieri, C., et al. (2014) Medical Treatment of Subjects with Gender Identity Disorder: The Experience in an Italian Public Health Center, International Journal of Transgenderism, 15:2, 53-65; Motta, G., et al. (2018). Does Testosterone Treatment Increase Anger Expression in a Population of Transgender Men?. The journal of sexual medicine, 15(1), 94-101; Oda, H., & Kinoshita, T. (2017). Efficacy of hormonal and mental treatments with MMPI in FtM individuals: cross-sectional and longitudinal studies. BMC psychiatry, 17(1), 256; and Turan, S., et al. (2018). Alterations in Body Uneasiness, Eating Attitudes, and Psychopathology Before and After Cross-Sex Hormonal Treatment in Patients with Female-to-Male Gender Dysphoria. Archives of sexual behavior, 47(8), 2349-2361.

41. An established and growing body of evidence combined with decades of clinical evidence demonstrate the positive effect of gender affirming hormones in adolescents and adults with gender dysphoria.

3) Gender-Affirming Surgeries

42. Some transgender individuals need surgical interventions to help bring their phenotype into alignment with their gender. Surgical interventions may include vaginoplasty, tracheal shave, liposuction, breast implants, and orchiectomy for transfeminine individuals and chest reconstruction, hysterectomy, oophorectomy, salpingectomy, construction of a neoscrotum, and metoidioplasty or phalloplasty for transmasculine individuals.

43. The current WPATH SOC recommend that surgical interventions may occur when appropriate for an individual.

44. Decades of research confirms that gender confirmation surgery is therapeutic and therefore an effective treatment for gender dysphoria.³⁵ In a 1998

³⁵ See, e.g., Almazan, A. N., & Keuroghlian, A. S. (2021). Association Between Gender-Affirming Surgeries and Mental Health Outcomes. *JAMA surgery*, 156(7), 611–618; Almazan, et al. (2021); Murad, M. H., et al. (2010). Hormonal therapy and sex reassignment: A systematic review and meta-analysis of quality of life and psychosocial outcomes. *Clinical Endocrinology*, 72(2), 214-231; Smith, Y., et al. (2005). Sex reassignment: Outcomes and predictors of treatment for adolescent and adult transsexuals. *Psychological Medicine* 35(1): 89-99; and Pfafflin, F., & Junge, A. (1998). Sex reassignment: Thirty years of international follow-up studies after sex reassignment surgery, a comprehensive review, 1961-1991.

meta-analysis, Pfafflin and Junge reviewed data from 80 studies, from 12 countries, spanning 30 years. They concluded that "reassignment procedures were effective in relieving gender dysphoria. There were few negative consequences and all aspects of the reassignment process contributed to overwhelmingly positive outcomes."³⁶

45. Subsequent studies confirm this conclusion. Researchers reporting on a large-scale prospective study of 325 individuals in the Netherlands concluded that after surgery there was "a virtual absence of gender dysphoria" in the cohort and "results substantiate previous conclusions that sex reassignment is effective."³⁷ The authors of the study concluded that the surgery "appeared therapeutic and beneficial" across a wide spectrum of factors and "[t]he main symptom for which the patients had requested treatment, gender dysphoria, had decreased to such a degree that it had disappeared." Similarly, a recent systematic review that included data from 1,052 transmasculine patients who obtained chest surgery found that pooled overall postoperative satisfaction was 92%.³⁸

³⁶ Pfafflin & Junge (1998).

³⁷ Smith, et al. (2005).

³⁸ Bustos, V. P., Bustos, S. S., Mascaro, A., Del Corral, G., Forte, A. J., Ciudad, P., Kim, E. A., Langstein, H. N., & Manrique, O. J. (2021). Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence. *Plastic and reconstructive surgery*. *Global open*, *9*(3), e3477.

46. With regards to transgender adolescents, peer-reviewed research has also shown improvements in mental health following gender-affirming chest surgery for transgender males with gender dysphoria where medically indicated.³⁹

* * *

47. Recognizing the importance of individualized care, the SOC 8 has this to say about all gender affirming interventions: "The SOC-8 guidelines are intended to be flexible to meet the diverse health care needs of TGD people globally. While adaptable, they offer standards for promoting optimal health care and for guiding treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria put forth in this document for genderaffirming interventions are clinical guidelines; individual health care professionals and programs may modify them in consultation with the TGD person. Clinical departures from the SOC may come about because of a patient's unique anatomic, social, or psychological situation; an experienced health care

³⁹ Mehringer, J. E., et al. (2021). Experience of Chest Dysphoria and Masculinizing Chest Surgery in Transmasculine Youth. *Pediatrics*, *147*(3), e2020013300; Olson-Kennedy, J., et al. (2018). Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. *JAMA pediatrics*, *172*(5), 431–436.

protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies. These departures should be recognized as such, explained to the patient, and documented for quality patient care and legal protection."

48. Gender-affirming medical interventions are considered medically necessary and are recognized as such by many major professional organizations. The denial of this care results in negative health consequences.

49. There are those (see GAPMS Memo at 12-13) who would make the argument that the recent uptick in youth presenting for services related to GD is the result of "social contagion." But if social contagion theory applied to gender and gender identity, there would be zero transgender people, because of the consistent exposure to an overwhelming majority of cisgender people. The social contagion argument that is posited by some confuses the relationship between one's recognition of their gender and their exposure to gender related information and community, particularly with regard to internet activity, asserting that youth are declaring themselves to be transgender or gender diverse because they were exposed to this online, or they have multiple friends who are also experiencing GD. Adolescent development includes finding like groups of peers, which extends to finding friend groups who are also gender diverse. Finally, attributing

GD to "social contagion" is a simplistic perspective that discounts that the process of doing something about one's gender dysphoria is complex and difficult and involves parental consent for minors.

50. There is no scientific evidence that one develops gender dysphoria from being exposed to people with GD. To the contrary, most evidence shows that gender identity has a biological basis⁴⁰ and is affixed by early childhood.⁴¹

C. <u>Critiques of the GAPMS Memo and the Attached "Assessments"</u>

51. The GAPMS Memo and the attached assessments contain a number of inaccurate assertions or misrepresentations, in addition to those noted above.

Misunderstandings and Misrepresentations of Desistance

52. The GAPMS Memo falsely states that "the majority of young adolescents who exhibit signs of gender dysphoria eventually desist and conform to their natal sex and that the puberty suppression can have side effects." (GAPMS Memo at 14). This is a blatant misrepresentation of the scientific literature. The studies pertaining to desistance upon which the GAPMS Memo

 ⁴⁰ Korpaisarn, S., & Safer, J. D. (2019). Etiology of Gender Identity. Endocrinology and metabolism clinics of North America, 48(2), 323–329. https://doi.org/10.1016/j.ecl.2019.01.002; Saraswat, A., Weinand, J.D., & Safer, J. (2015). Evidence supporting the biologic nature of gender identity. Endocrine practice, 21 2, 199-204.

⁴¹ Slaby, R., Frey, K. (1975). Development of Gender Constancy and Selective Attention to Same Sex Models, *Child Development*, 46(4): 849-856.

relies pertain to *pre-pubertal* youth, not adolescents. In fact, contrary to the GAPMS Memo's assertion, studies show that if gender dysphoria is present in adolescence, it usually persists.⁴²

53. To be sure, there are a significant number of *pre-pubertal* children who demonstrate an interest or preference for clothing, toys, and games that are stereotypically of interest to members of the "other" gender. Some of these children are transgender and some are not. It is the study of such *pre-pubertal* children that has created confusion about the persistence of gender dysphoria into adolescence and adulthood. Specifically, the *pre-pubertal* children who were the subject of research endeavors in the late 20th century included both children who are transgender and children who are not, i.e., those who would have met current criteria for a diagnosis of "Gender Dysphoria in Children" and those who would be considered "sub-threshold" for this diagnosis.

54. At the time of these studies, the diagnosis of "Gender Dysphoria in Children" did not exist and therefore the study subjects did not need to meet criteria B, which is "the presence of clinically significant distress associated with the condition." In addition, the criteria for the then-used "gender identity disorder

⁴² de Vries, et al. (2011).

in children" diagnosis did not require a child to have "a strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender)," which the current "Gender Dysphoria in Children" diagnosis requires.

55. Thus, given the broader criteria used at the time, it is unsurprising that some of the research undertaken toward the end of the 20th century demonstrated that most children who exhibited gender-nonconforming behavior did not go on to have a transgender identity in adolescence. Yet, notwithstanding its inapplicability and faulty underpinnings, this "evidence" has been used to argue against gender affirmation for children and adolescents.

56. What is more, these arguments about desistance in *pre-pubertal* children are wholly irrelevant to the question of coverage and provision of medical care as treatment for GD. That is because research to date shows that if transgender identification persists into adolescence, then desistance is incredibly rare, and no medical or surgical treatments are recommended for *pre-pubertal* children.

57. Additionally, no studies have ever demonstrated that gender affirmation in childhood "leads to" a child being transgender who otherwise might not have been. Studies have demonstrated that the majority of youth whose

GD and cross-gender identity continue to be present, or those whose GD emerges in adolescence, are highly unlikely to identify and live as cisgender individuals. Youth with GD, particularly those who are unaffirmed and denied care, are at high risk for depression, anxiety, isolation, self-harm and suicidality at the onset of puberty-related changes that feel wrong to them.

The Myth of Social Contagion and Rapid-Onset Gender Dysphoria (ROGD)

58. The GAPMS memo asserts that gender-affirming care should not be provided because the causes of GD are uncertain. It suggests that "exposure to 'social and peer contagion" accounts for the rise in numbers of adolescents who identify as transgender, pointing to research that has identified so-called "rapid-onset gender dysphoria" (ROGD). (GAPMS Memo at 12-13; see also Cantor ¶ 48-49). However, ROGD is not a diagnosis recognized by any medical or scientific institution, and there is no scientific evidence in support of it.

59. The concept of ROGD originated from a single article authored by Lisa Littman, a researcher who had no experience in the field of gender medicine, transgender issues, or gender dysphoria, prior to the publication of her article.⁴³

⁴³ Littman L. (2018). Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. *PloS one*, *13*(8), e0202330.

60. Littman's article was heavily criticized for its flawed methodology, potential for bias, and overrepresentation of its findings.⁴⁴ For example, Littman's study was based solely on "parent observations and interpretations." But parental reports are not necessarily a reliable basis for understanding a particular youth's experience with their gender, let alone whether the youth has gender dysphoria.⁴⁵ Moreover, most of the parents who participated in the study were recruited from websites targeted to parents likely to question their child's gender self-identification and the current best health care approaches. In addition, the study also failed to collect data from the adolescents and young adults (AYAs) or clinicians, which would have been necessary in order to come up with and validate ROGD as a new phenomenon.

⁴⁴ See, e.g., Brandelli Costa, A. (2019) Formal comment on: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLoS ONE 14(3): e0212578; Restar A. J. (2020). Methodological Critique of Littman's (2018) Parental-Respondents Accounts of "Rapid-Onset Gender Dysphoria". *Archives of sexual behavior*, 49(1), 61–66.

⁴⁵ See, e.g., Kennedy, N. (2022) Deferral: the sociology of young trans people's epiphanies and coming out. *Journal of LGBT Youth*, 19:1, 53-75; Brandelli Costa (2019).

61. Following the numerous critiques of the Littman study, the journal that published the study retracted it, ordered a post-publication review, and republished the article with a correction notice,⁴⁶ along with an apology.⁴⁷

- 62. The correction notice acknowledged, among other things, that: ⁴⁸
 - a. "there is some information about the AYAs that the parents would not have access to and the answers might reflect parent perspectives" and that "consideration of what information parents may or may not have access to is an important element of the findings";
 - b. "the study's output was hypothesis-generating rather than hypothesis-testing";
 - c. "three of the sites that posted recruitment information expressed cautious or negative views about medical and surgical interventions for gender dysphoric adolescents and young adults

⁴⁶ Littman L. (2019) Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. *PLoS ONE*, 14(3): e0214157.

⁴⁷ Heber, J. Correcting the scientific record on gender incongruence – and an apology, PLoS ONE (Mar. 19, 2019), <u>https://everyone.plos.org/2019/03/19/correcting-the-scientific-record-and-anapology/</u>.

⁴⁸ Littman (2019).

and cautious or negative views about categorizing gender dysphoric youth as transgender"; and

d. "There is expected variation in how objective parents can be about their own children" and that the "descriptive study was not designed to explore or measure the objectivity of participants."

63. Thus, the correction notice ultimately acknowledged that the study "does not validate the phenomenon" of ROGD and that the term ROGD "should not be used in a way to imply that it explains the experiences of all gender dysphoric youth nor should it be used to stigmatize vulnerable individuals." ⁴⁹ In the end, aside from the correction notice, the journal that published the study issued an apology "for oversights that occurred during the original assessment of the study." ⁵⁰

64. To date, no study has been published that validates or proves the hypothesis of ROGD presented by the Littman study. Indeed, Lisa Littman herself said at the GenSpect 2021 Conference that ROGD was not a new phenomenon, but rather a re-naming of late onset GD.

⁴⁹ Id.

⁵⁰ Heber (2019).

The GAPMS Memo, Dr. Cantor, and Dr. Van Meter incorrectly 65. allege that an increase in numbers of youth presenting for care related to GD provides support for the social contagion theory. (See GAPMS Memo at 12-13; Van Meter at 9-10). For one, varying estimates of prevalence are the result of inconsistent measures of transgender populations. Some studies have assessed the fraction of a population which had received the DSM-IV diagnosis of GID or the ICD 10 diagnosis of transsexualism, both of which were limited to clinical populations who sought a binary transition (male-to-female or female-to-male). For example, the prevalence reported in DSM-5 (0.005-0.014% for birthassigned males; 0.002–0.003% for birth-assigned females) are based on people who received a diagnosis of GID or transsexualism and were seeking hormone treatment and surgery from gender specialty clinics, and, therefore, do not reflect the number of all individuals with gender dysphoria or who identify as transgender.⁵¹ Other studies have reported on those who self-identified as transgender or gender incongruent and found that measuring self-identity yields much higher numbers. In 2016, data from the Center for Disease Control's Behavioral Risk Factor Surveillance System suggested that 0.6% of U.S. adults

⁵¹ Coleman, et al. (2022).

identify as transgender, double the estimate utilizing data from the previous decade.⁵² Ultimately, there is nothing surprising about the fact that more transgender people have begun identifying themselves to others as societal stigma has started to abate, and nothing about that lends support to the "social contagion" theory.

Dr. Cantor's False Assertion of Transition-on-Demand

66. In his "assessment," Dr. Cantor, a psychologist with no clinical experience in treating gender dysphoria in minors and no experience monitoring patients receiving drug treatments for gender dysphoria, states that "transition-on-demand" increases the probability of unnecessary transition and unnecessary medical risks. (Cantor \P 21).

67. His claim is wholly divorced from the reality of care for transgender people. First, like all health care, gender-affirming care for every transgender person is individualized. There simply is no one specific route.

68. Second, Dr. Cantor inaccurately assumes that every transgender person wants and receives rapid access to services. For most transgender individuals seeking care, nothing about their process has been rapid, even when

⁵² Byne, W., Karasic, D. H., Coleman, E., Eyler, A. E., Kidd, J. D., Meyer-Bahlburg, H. F. L., ... Pula, J. (2018). Gender dysphoria in adults: An overview and primer for psychiatrists. *Transgender Health*, *3*(1), 57-70.

they are young. Most individuals with gender dysphoria have engaged in a long, arduous and private process of understanding their gender to be different from the one assumed at birth. Dr. Cantor gives no credibility to transgender patients regarding their right to bodily autonomy nor their capacity to make sound and informed decisions.

69. Finally, Dr. Cantor is wrong to assert that affirmation "increases the probability of unnecessary transition and unnecessary medical risks." (Cantor ¶ 21). There is no evidence to support the notion that affirmation of gender in prepubertal children, or at any age, leads to transition. Medical interventions are not recommended and are not appropriate for pre-pubertal children. If one's gender could be impacted by the role of rearing, there would be few transgender people who transition in adulthood, as most were reared in the gender role that corresponded with their sex assigned at birth. It is not logical to think that while we have been epically failing at convincing transgender people to be cisgender, we would be able to make someone who is cisgender into someone who is transgender, a directionality that may correspond with higher rates of discrimination, harassment, and even violence. There is no data to support any such notion that children who are socially transitioned in a pre-pubertal time

period who then go on to embrace their assumed gender at birth are damaged. I know several such young people who are healthy and happy.

The Quality of the Evidence and Lack of Randomized Controlled Trials

70. The care of transgender individuals has a long history. As with all medical care, there is a range of quality in the existing data regarding the treatment of gender dysphoria,⁵³ and there is certainly a need for additional studies of a longitudinal nature. But again, that is true with most medical care.

71. Between 1963 and 1979, over 20 university-based gender identity clinics opened in the United States.⁵⁴ These clinics provided interdisciplinary care that included psychiatrists and other mental health professionals and played an important role in the provision of medical services to transgender people and in promoting research to improve their care. The majority of these clinics closed following a 1981 decision of the U.S. Department of Health and Human Services (HHS) that labeled sex reassignment surgery as experimental, in large part due to advocacy by Dr. Paul McHugh.⁵⁵ That decision was overturned by HHS in 2014 in a determination that concluded that the 1981 decision was "not

⁵³ See Deutsch (ed.) (2016) (UCSF Guidelines).

⁵⁴ Byne, et al. (2018).

⁵⁵ In this way, Dr. McHugh actively attempted to suppress the research that he complains is lacking in this field of care.

reasonable" and found that gender-affirming surgery is "a safe and effective treatment option."⁵⁶

72. Over the last four decades: research has continued to occur in the United States and internationally; WPATH (formerly the Henry Benjamin International Gender Dysphoria Association) published the first iteration of the Standards of Care in 1979, which is now in its 8th version; the DSM and ICD stopped classifying transgender identification as a mental disorder; the American Psychological Association and Endocrine Society, as well as other medical organizations, adopted clinical guidelines consistent with the WPATH Standards of Care; and dozens of interdisciplinary gender clinics associated with research institutions and teaching hospitals have been providing gender-affirming care for transgender youth and adults across the United States.

73. Drs. Brignardello-Petersen and Wiercioch repeatedly refer to an apparent lack of data comparing treated vs. untreated individuals with gender dysphoria. Their report continually places emphasis on data that they rated as "low certainty" based on GRADE criteria. These observations about the data do not mean that gender-affirming care is experimental or investigational.

⁵⁶ U.S. Dep't Health & Hum. Servs., NCD 140.3, Transsexual Surgery 18, 21 (2014); Byne, et al. (2018).

74. One of the intrinsic elements of rating the quality of evidence is the study design. Randomized controlled trials (RCTs) are considered the highest quality in the grading of evidence. Many of the research studies on gender-affirming care get a "low quality" grade due to the lack of RCTs.

75. But it is well-established that utilizing an untreated control group is unethical in this context – gender-affirming medical interventions have been used for decades, resulting in a vast amount of clinical knowledge about their efficacy. That said, we have a large de facto group of untreated individuals with gender dysphoria who experience significant psychiatric symptoms because of widespread barriers to access to care.

76. Clinicians who are competent in the care of transgender individuals practice according to a "first do no harm" ethic which understands that doing nothing is not a neutral option for those with gender dysphoria. Multiple studies have demonstrated the safety of gender-affirming hormones, and a growing body

of evidence does the same with regards to the safety of GnRH analogues.⁵⁷ The same is true with regards to surgery.⁵⁸

77. In addition, RCTs are ill-suited to studying the effects of genderaffirming interventions on psychological wellbeing and quality of life of trans people. Adequate masking, adherence, and generalizability are severely impeded in transgender care, thereby negating the superior scientific value of RCTs.

78. Gender-affirming interventions have physiologically evident effects, making it impossible to mask RCTs. The purpose of puberty blockers, hormone therapy, and transition-related surgeries is to inhibit or produce visible bodily changes.

79. In an RCT, adolescents who are on puberty blockers would notice that their endogenous pubertal development had stopped, whereas those not on puberty blockers will notice that they had not. Hormonal suppression is achieved

⁵⁷ Kuper, et al. (2020); Chew, D., Anderson, J., Williams, K., May, T., & Pang, K. (2018). Hormonal Treatment in Young People With Gender Dysphoria: A Systematic Review. *Pediatrics*, 141(4), e20173742; Colton-Meier, S. L., Fitzgerald, K. M., Pardo, S. T., & Babcock, J. (2011). The effects of hormonal gender affirmation treatment on mental health in female-to-male transsexuals. *Journal of Gay & Lesbian Mental Health*, 15(3), 281-299.

⁵⁸ Marano, A. A., Louis, M. R., & Coon, D. (2021). Gender-Affirming Surgeries and Improved Psychosocial Health Outcomes. *JAMA surgery*, *156*(7), 685–687; Olson-Kennedy, et al. (2018); Murad, et al. (2010); Smith, et al. (2005); Pfafflin & Junge (1998).

around four weeks after treatment is initiated, but it may take multiple months before participants notice that pubertal development has ceased.

80. Similarly, transgender people given hormone therapy would notice bodily changes from taking estrogen or testosterone, whereas transgender people in the control arm would notice no such changes. The onset of visible effects from hormone therapy varies from person-to-person. The first changes typically appear between one and six months of initiation, whereas other desired changes may not begin for up to a year.

81. Although it may take some time before participants are able to ascertain which treatment they were allocated to due to the delayed effect of puberty blockers and the progressive effect of and hormone therapy, large-scale unmasking is inevitable. Because the physiological changes are the primary purpose of gender-affirming care, meaningful effects on psychological wellbeing and quality of life are not expected until unmasking occurs. As such, while RCTs can be utilized to examine the effects of gender-affirming care on physiology, using RCTs to measure the effect of gender-affirming care on psychological wellbeing and quality of life would be inappropriate.

82. Unmasking an RCT of gender-affirming care would lead to noncompliance, cross-over, and response bias in the control arm of the study. Transgender people with gender dysphoria who pursue gender-affirming care are typically insistent and persistent in seeking the interventions. They are not ambivalent as to whether they are assigned to the intervention or control arm of the study. Upon realizing that they are in the control arm due to physiological effects or lack thereof, a large proportion of the study participants would likely withdraw from the study or pursue alternative sources of gender-affirming interventions.

83. Withdrawing from the study and noncompliance with the study protocol is most likely among people who have alternative means of securing gender-affirming care and who experience more severe bodily gender dysphoria, raising grave concerns of systematic bias. Gender-affirming interventions can be obtained from parents, peers, illicit or unauthorized sources, other providers within or outside of the health care system, and through medication-sharing with participants from the active arm of the study. Some of these options are associated with elevated safety risks, giving rise to additional ethical concerns about the use of RCTs. Intentional withdrawal with the goal of forcing the study to end is also possible. Resentment towards researchers for not allowing all participants to receive gender-affirming interventions may also increase the risk of response bias compared to observational studies, and the experimental design may motivate youths to engage in self-harm or suicidal behavior to influence the study results, aggravating scientific and ethical concerns.

84. Given that withdrawal rates could be high enough for studies to be terminated before they are concluded, RCTs may prove impossible to conduct altogether. The likelihood of withdrawal, non-adherence, and response bias in the context of transgender care undermines RCTs' ability to detect true associations and avoid specious associations between the intervention and the outcomes.

85. Many disciplines and areas of research rely on observational studies because RCTs are considered impracticable or unethical. This is especially common when studying the mental health outcomes of physiologically evident interventions due to the impossibility of masking, and when studying the outcomes of highly desired interventions due to the risks of de-randomization. Psychological and psychosocial interventions are most commonly studied using observational methodologies, and many research questions remain unstudied with RCTs.

86. Thus, while the GAPMS Memo correctly notes that "[p]resently, no RCTs that evaluate puberty suppression as a method to treat gender dysphoria are available," the lack of RCTs is easily understood considering the above

observations about RCTs in this context. (See GAPMS Memo at 15). And, the GAPMS Memo fails to mention that "[d]espite GnRH analogue treatment being used in precocious puberty for more than 20 years, there are no randomized controlled trials to evaluate the effect of GnRHa on a final height compared with untreated controls."⁵⁹

87. In addition, the GAPMS Memo's focus on RCTs reveals AHCA's fundamental misunderstanding of "evidence-based medicine." (GAPMS Memo at 9).

88. Evidence-based medicine, which originated in the second half of the 19th Century, means the conscientious, explicit, judicious, and reasonable use of current best evidence in making decisions about the care of individual patients. Since its inception, evidence-based medicine has included an element of clinician expertise. Indeed, the modern understanding of evidence-based medicine is a systematic approach to clinical problem solving which allows the integration of the best available research evidence with *clinical expertise and patient values*.⁶⁰

⁵⁹ Mul & Hughes (2008).

⁶⁰ Masic, I., Miokovic, M., & Muhamedagic, B. (2008). Evidence based medicine - new approaches and challenges. *Acta informatica medica : AIM : journal of the Society for Medical Informatics of Bosnia & Herzegovina : casopis Drustva za medicinsku informatiku BiH*, 16(4), 219–225.

89. Contemporaneous evidence-based medicine is defined by the *integration of clinical knowledge and skills* with the best critically-appraised-evidence available *as well as patient values and preferences in order to make a clinical decision*. The research literature is continually growing as new discoveries unravel.

90. The GAPMS Memo assigns no value to clinician expertise, experience, and skill, nor to the desires of the individual seeking services. In fact, the GAPMS Memo repeatedly and broadly asserts that recommendations for treatment of GD by well-established professional associations do not rely on evidence-based medicine, but rather on the recommendations outlined by WPATH, the Endocrine Society or others. But these two organizations not only examine best available evidence, but the guidelines and standards of care are updated by clinicians and scientists at the top of the field.

The Use of "Off-Label" Medications

91. Both the GAPMS Memo and Dr. Van Meter repeatedly express concern that the U.S. Food and Drug Administration (FDA) has not approved puberty blockers or hormone therapy for the treatment of GD. (See, e.g., GAPMS Memo at 8, 19; Van Meter at 8). Indeed, Dr. Van Meter asserts that the mere use of these medications "off-label" amounts to "uncontrolled, non-consentable experimentation on children." (Van Meter at 8). These concerns are misleading and false.

92. The use of "off-label" medications is extremely common across all fields in medicine and there are many medications that are used "off-label" in the pediatric population. Most of the therapies prescribed to children are on an off-label or unlicensed basis.⁶¹ Common medications that are used "off-label" in pediatrics include antibiotics, antihistamines, and antidepressants. That is because the majority of drugs prescribed have not been tested in children and safety and efficacy of children's medicines are frequently supported by low quality evidence. This is explained by the lack of clinical research in this population, caused by ethical, scientific, and technical issues, as well as commercial priorities.

93. "From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient."⁶² Indeed, for

⁶¹ Allen, H.C., Garbe, M.C., Lees, J., Aziz, N., Chaaban, H., Miller, J.L., Johnson, P., & DeLeon, S. (2018). Off-Label Medication use in Children, More Common than We Think: A Systematic Review of the Literature. *The Journal of the Oklahoma State Medical Association*, *111*(8), 776–783.

⁶² U.S. Food and Drug Admin. Understanding Unapproved Use of Approved Drugs "Off Label" (Feb. 5, 2018), <u>https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatmentoptions/understanding-unapproved-use-approved-drugs-label</u>.

over 40 years, the FDA has informed the medical community that "once a [drug] product has been approved ..., a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling."⁶³ Accordingly, the American Academy of Pediatrics has stated that "off-label use of medications is neither experimentation nor research."⁶⁴ Thus, "[t]he administration of an approved drug for a use that is not approved by the FDA is not considered research and does not warrant special consent or review if it is deemed to be in the individual patient's best interests."

Concerns about the Diagnosis of Gender Dysphoria and the Use of Self-Reports

94. The GAPMS Memo and Dr. Cantor criticize that the diagnosis of gender dysphoria is based, at least in part, on a patient's self-report. (GAPMS Memo at 19, 24, 28; Cantor $\P\P$ 42, 49). This critique demonstrates a fundamental misunderstanding of how gender-affirming care is provided.

95. While we have continued to attain a greater understanding about the etiology of gender incongruence, patients do not self-diagnose, as Dr. Cantor

⁶³ U.S. Food and Drug Admin, "Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments," 59 Fed. Reg. 59,820 (Nov. 18, 1994).

⁶⁴ Frattarelli, D. A., Galinkin, J. L., Green, T. P., Johnson, T. D., Neville, K. A., Paul, I. M., Van Den Anker, J. N., & American Academy of Pediatrics Committee on Drugs (2014). Offlabel use of drugs in children. *Pediatrics*, *133*(3), 563–567.

suggests. (Cantor ¶¶ 42, 49). However, it is not unusual or extraordinary in medicine for a provider to consider patients' reports of their symptoms as part of the medical assessment. Much like the diagnosis of many clinical conditions, providers rely on self-report to ascertain accurate diagnoses. Consider the diagnosis of chronic fatigue. The diagnostic criteria for this diagnosis include the following: fatigue so severe that it interferes with the ability to engage in preillness activities; of new or definite onset (not lifelong); not substantially alleviated by rest; worsened by physical, mental or emotional exertion. Like gender dysphoria, these diagnostic criteria are a subjective telling of an individual's personal experience. It is incumbent upon providers of genderaffirming care to acquire skills that help them ascertain many details about their patient's gender experience including but not limited to the history, developmental trajectory, and expectations regarding treatment options.

96. The provision of gender-affirming care occurs in multi-disciplinary settings, and indeed, the WPATH SOC recommend such an approach.⁶⁵ The

⁶⁵ Chen, D., Hidalgo, M. A., Leibowitz, S., Leininger, J., Simons, L., Finlayson, C., & Garofalo, R. (2016). Multidisciplinary Care for Gender-Diverse Youth: A Narrative Review and Unique Model of Gender-Affirming Care. *Transgender health*, *1*(1), 117–123; Coleman, et al. (2022); Coleman, E., Bockting, W., Botzer, M., Cohen-Kettenis, P., DeCuypere, G., Feldman, J., ... & Zucker, K. (2012). Standards of care for the health of transsexual, transgender, and gendernonconforming people, version 7. *International Journal of Transgenderism*, 13(4), 165-232.

multiple health providers involved, from various fields, are well trained to conduct clinical interviews and to assess a patient's report to determine whether they meet the diagnostic criteria for GD.

Particular Concerns about the Use of Puberty Delaying Medications

97. The GAPMS Memo and Dr. Cantor allege that the provision of puberty delaying medications for the treatment of GD is not effective. This is not true.

98. A substantial body of evidence shows that gender-affirming medical interventions improve mental health outcomes for transgender persons with GD, who, without treatment, experience higher levels of depression, anxiety, and suicidality. Each of these studies—as with all studies in medicine—has strengths and limitations, and no one study design can answer all questions regarding an intervention. But taken together, these studies indicate that gender-affirming medical care improves mental health for adolescents who require such care.

99. Keeping this in mind, peer-reviewed cross-sectional and longitudinal studies have found that pubertal suppression is associated with a range of improved mental health outcomes for transgender adolescents, including statistically significant improvements in internalizing psychopathology (*e.g.*,

anxiety and depression), externalizing psychopathology (*e.g.*, disruptive behaviors), global functioning, and suicidality.⁶⁶

100. For example, in the realm of cross-sectional studies, Turban et al. *Pediatrics* 2020 found that, after controlling for a range of other variables, those who accessed pubertal suppression had lower odds of lifetime suicidal ideation than those who desired but were unable to access this intervention during adolescence. A similar study by van der Miesen et al. in the *Journal of Adolescent Health*, noted above, compared 272 adolescents who had not yet received pubertal suppression with 178 adolescents who had been treated with pubertal suppression. Those who had received pubertal suppression had statistically significant lower "internalizing psychopathology" scores (a measure of anxiety and depression).⁶⁷

101. Longitudinal studies have yielded similar results. For example, de Vries et al. in the *Journal of Sexual Medicine* (discussed above) found statistically significant improvements in symptoms of depression and general

⁶⁶ See, e.g., Tordoff, D. M., Wanta, J. W., Collin, A., Stepney, C., Inwards-Breland, D. J., & Ahrens, K. (2022). Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care. *JAMA network open*, *5*(2), e220978; Turban, et al. (2020); van der Miesen, et al. (2020); Achille, et al. (2020); de Vries, et al. (2014); de Vries, et al. (2011). *See also* paragraphs 25-30, *supra*.

⁶⁷ van der Miesen, et al. (2020).

functioning following pubertal suppression for adolescents with gender dysphoria.⁶⁸

102. The GAPMS Memo, as well as the "assessments" by Dr. Brignardello-Petersen and Dr. Wiercioch and by Dr. Cantor, emphasize the possible risks and side effects associated with the provision of gender-affirming care. Every single medication, however, has potential negative side effects, in addition to the possibility of new side effects that have not been historically documented. This is one of the reasons that evidence-based medicine relies heavily on experienced clinicians to exercise their expertise and judgement.

103. The risks associated with the provision of GnRH analogues are comparable when used for transgender and non-transgender patients alike. For example, many of the side effects and risks associated with the provision of GnRH analogues have been well-studied with regards to the use of these medications for the treatment of central precocious puberty (CPP).⁶⁹

104. Given than puberty blockers are reversible, permanent sterility is not a side effect. There is no data to support that patients who have been treated with

⁶⁸ de Vries, et al. (2011).

⁶⁹ Eugster E. A. (2019). Treatment of Central Precocious Puberty. *Journal of the Endocrine Society*, *3*(5), 965–972.
blockers for central precocious puberty are "sterilized" following its use. To the contrary, information regarding long-term outcomes of patients treated with GnRH analogues with respect to gonadal function are reassuring. In fact, some studies have shown that assigned males had normal sperm function following treatment and cisgender women treated as children did not need assisted reproductive techniques.

105. In addition, while during the course of treatment with pubertal delaying medication, there is some loss in bone density, which is a side effect that we discuss with all patients and their families, studies show that with removal of the blocking agent or addition of gender affirming hormone therapy, bone mineral density begins to improve.⁷⁰ Studies regarding the use of GnRH analogues for the treatment of CPP document that following cessation of therapy with puberty delaying medications bone mineral accrual appears to be within the normal range compared with population norms. Indeed, patients treated with pubertal suppression for CPP are on pubertal blockades without affirming

⁷⁰ Vlot, M. C., et al. (2017). Effect of pubertal suppression and cross-sex hormone therapy on bone turnover markers and bone mineral apparent density (BMAD) in transgender adolescents. *Bone*, *95*, 11–19; Klink, D., et al. (2015). Bone mass in young adulthood following gonadotropin-releasing hormone analog treatment and cross-sex hormone treatment in adolescents with gender dysphoria. *The Journal of clinical endocrinology and metabolism*, *100*(2), E270–E275.

hormones for longer periods of time than patients treated with puberty blockers for the treatment of gender dysphoria and the same risks are present.⁷¹

Particular Concerns about the Use of Cross-Sex Hormones

106. The claim that treating gender dysphoria with medically supervised and recommended hormone treatment is particularly risky or causes serious mental health effects is not supported by data.

107. Peer-reviewed research studies have found improved mental health outcomes following gender-affirming hormone treatment (*e.g.*, estrogen or testosterone) for individuals with gender dysphoria, including adolescents.⁷² These include statistically significant improvements in internalizing psychopathology (*e.g.*, anxiety and depression), general well-being, and suicidality. For example, Allen et al. followed a cohort of 47 adolescents with gender dysphoria, and found statistically significant improvements in general well-being and suicidality, as measured by the National Institutes of Health "Ask Suicide Screening Questions" instrument.⁷³

⁷¹ Eugster (2019).

⁷² See, e.g., Achille, et al. (2020); de Lara, D.L., Rodríguez, O.P., Flores, I.C., *et al.* (2020). Psychosocial Assessment in Transgender Adolescents. *Anales de Pediatría (English Edition)*, 93(1), 41-48; Grannis, et al. (2021); 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), 302-311.

⁷³ Allen, et al. (2019).

108. What is more, the side effects and risks associated with these treatments are not unique to transgender individuals placed on these therapies.

109. The WPATH SOC require that fertility preservation is offered to all transgender patients prior to the initiation of gender affirming hormones. However, data shows that treatment with testosterone is not sterilizing.⁷⁴ And many transgender men become pregnant on their own.

110. It is also important to note that when these risks are reported, they are rare risks. While starting a transgender individual with GD on gender affirming hormones can raise their risk, their risk profile remains similar to their cisgender counterparts. Many times, the lipid profiles, hematologic profiles, and findings are equivalent to that of the gender these individuals identify with, as opposed to that of their sex assigned at birth.

<u>The Misconceived Notion that Psychotherapy Alone Is Sufficient for the</u> <u>Treatment of Gender Dysphoria</u>

111. Dr. Cantor describes several studies and claims that because the study subjects who were recipients of both gender-affirming hormones or puberty blockers, on the one hand, and psychotherapy, on the other hand, demonstrated

⁷⁴ Yaish, I., et al. (2021). Functional ovarian reserve in transgender men receiving testosterone therapy: evidence for preserved anti-Müllerian hormone and antral follicle count under prolonged treatment. *Human reproduction (Oxford, England)*, *36*(10), 2753–2760.

improvements in mental health, that the medical interventions could not be differentiated as responsible for the improvement. (Cantor $\P\P$ 40-41).

112. Historically the psychotherapy professional world advocated for a "therapy only" model to address gender dysphoria. As early as the 1920's and 1930's it became evident to the preeminent scholars in the field that gender dysphoria (named something else at that time) was refractory to psychotherapy. As noted in 1966 in Harry Benjamin's The Transsexual Phenomenon, "Allegedly, transsexualism, although basically a psychiatric condition, is paradoxically resistant to psychiatric help."⁷⁵ In this statement, Harry Benjamin acknowledges that psychiatric intervention cannot alter people's gender, nor does it lead to a diminishing of the distress that arises from gender incongruence. There has been an abundance of opportunity to demonstrate unequivocally that gender dysphoria is best treated with psychotherapy alone, and yet it never has been. To suggest this is now an appropriate approach simply because transgender people are coming out at younger ages is illogical.

⁷⁵ Benjamin (1966).

Dr. Lappert's Critique of My Published Work

113. In his "assessment," Dr. Lappert criticizes a 2018 article I co-wrote that was published in JAMA Pediatrics, which he acknowledges to be a "leading journal." He refers to the article as "reckless" and using "low-quality data." (Lappert, p. 7).

114. Dr. Lappert takes issue with the claim in this article that regret for surgery is "rare." (Lappert p. 7). The manuscript describes that no individual who had undergone chest reconstruction in this cohort regretted this decision. While no single study can capture all experiences, the data reported in this study and clinical experience support the claim that regret after chest surgery is rare.

115. Dr. Lappert additionally calls surgery on minors a "reckless, experimental practice" and, without citing any evidence to support his claims, states that it has "apparently been abandoned as unethical" in England, Sweden, and Finland. (Lappert p. 7). Chest surgery for transmasculine youth younger than the age of majority is not experimental. While the scientific study of the care of transgender youth is still ongoing and growing, this does not make such care experimental. By its very nature, science is ever growing and ongoing. Moreover, Dr. Lappert's claim completely discounts the clinical experiences of both community members and providers of such care.

116. Dr. Lappert seems to take issue with the methods my study used to recruit participants, which he terms "convenience sampling" and suggests constitutes "self-selection" and confirmation bias. (Lappert p. 7). While it is true that the participants were recruited from our practice, individuals seeking such a surgical intervention will also be enrolled in care at clinics familiar with gender affirming care, therefore, they are "self-selecting" to become patients. As noted in my manuscript, we made an attempt to reach all patients in our clinic who had been referred for chest surgery.

117. Dr. Lappert emphasizes that 26% of study participants who had undergone surgery could not be reached during follow-up phone calls. (Lappert p. 7). He further highlights that of the individuals we were able to reach by phone, 72% completed our survey. Again Dr. Lappert bemoans these facts as demonstrating self-selection and confirmation bias. Our Center provides services for youth and young adults up to the age of 25. Some participants who were unable to be reached had aged out of services, moved, changed their phone numbers, or simply didn't answer a phone call. This is common among all research.

118. Dr. Lappert additionally criticizes our paper for using a novel measure of gender dysphoria, which he claims is "entirely unvalidated" and "junk

science." (Lappert p. 8). When no measures exist to gain understanding about an experience, measures need to be created. Chest dysphoria is a latent construct, and as such needs to be captured through a collective of questions. The chest dysphoria scale components were developed through both content and face validity. The scale was not validated, as I clearly reported in the manuscript. In a manuscript by Sood et al., Chest Dysphoria, as measured by the scale I created, among 156 transmasculine youth, showed a significant, positive association with anxiety and depression.⁷⁶

119. Dr. Lappert suggests that our findings, which looked at satisfaction with gender-affirming surgery for patients who had undergone surgery between less than 1 to 5 years prior to the survey, are "misleading" and "deceptive" because they are not completely consistent with other long-term longitudinal population studies. (Lappert p. 8). I have not seen any longitudinal studies looking at chest surgery that dispute the findings laid out in my manuscript. In a meta-analysis related to satisfaction following masculinizing chest surgery,

⁷⁶ Sood, R., Chen, D., Muldoon, A. L., Chen, L., Kwasny, M. J., Simons, L. K., Gangopadhyay, N., Corcoran, J. F., & Jordan, S. W. (2021). Association of Chest Dysphoria With Anxiety and Depression in Transmasculine and Nonbinary Adolescents Seeking Gender-Affirming Care. *The Journal of adolescent health: official publication of the Society for Adolescent Medicine*, *68*(6), 1135–1141.

Bustos et al. found that among 1,052 transmasculine patients, the overall satisfaction rate was 92%.⁷⁷

120. Based on his review of my study, Dr. Lappert concludes that it "is essentially useless in making any clinical decisions regarding who should be offered surgery, what is the likelihood they will benefit from it, and what is the likelihood they will regret their decision." (Lappert p. 8). There have been at least two studies since my manuscript that have duplicated the findings laid out in my manuscript in addition to the meta-analysis conducted by Bustos et al. described above.

CONCLUSION

121. Gender-affirming medical and surgical care is effective, beneficial, and necessary for transgender people suffering with gender dysphoria, including transgender youth after the onset of puberty. It is well documented and studied, through years of clinical experience, observational scientific studies, and even some longitudinal studies. It is also the accepted standard of care by all major medical organizations in the United States.

⁷⁷ Bustos, et al. (2021).

122. The denial of gender-affirming care, on the other hand, is harmful to transgender people. It exacerbates their dysphoria and may cause anxiety, depression, and suicidality, among other harms.

123. The GAPMS memo is misguided and informed by individuals with no experience or knowledge base regarding the provision of gender-affirming care, not to mention well-documented biases against transgender people and/or the provision of gender-affirming care. The report leans heavily on manuscripts that are not contemporaneous with our modern understanding of gender identity and gender dysphoria, demonstrated by outdated and incorrect terminology.

124. While data may be described as weak due to the lack of randomized controlled trials, many disciplines and areas of research rely on observational studies because RCTs are considered impractical or unethical. This is especially common when studying the mental health outcomes of physiologically evident interventions due to the impossibility of masking, and when studying the outcomes of highly desired interventions due to the risks of de-randomization. Psychological and psychosocial interventions are most commonly studied using observational methodologies, and many research questions remain unstudied with RCTs.

125. Finally, the reports completely overlook bodily autonomy. Given the repeated conflation of children and adolescents, it is not surprising that the "assessments" relied upon by the GAPMS Memo and the GAPMS Memo itself view adolescents as too immature to understand their own gender. However, many studies have demonstrated that cisgender children as young as age 2 know their gender. Denying medical care to adolescent youth with gender dysphoria is an act of acquiescence to the fear of what is not understood.

126. I do not disagree that, as with every field of medicine, there is more to learn in the field of transgender youth care. That is why I became an investigator. However, there is room to provide gender-affirming medical interventions in a thoughtful manner that extrapolates from relevant fields of science and medicine, existing data and clinical expertise while simultaneously carrying out necessary investigations.

127. The denial of much needed care only serves to harm transgender people.

I declare under penalty of perjury under the laws of the United States of

America that the foregoing is true and correct.

Executed this <u>16</u> day of February, 2023.

Johanna Olson-Kennedy, M.D., M.S.

EXPERT REPORT OF DR. JOHANNA OLSON-KENNEDY, M.D., M.S. Case No. 4:22-cv-00325-RH-MAF

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

<u>CURRICULUM VITAE</u> Johanna Olson-Kennedy MS, MD February 14, 2023

PERSONAL INFORMATION:

Work
4650 Sunset Blvd. MS 2
Los Angeles, CA 90027
Phone: 323-361-3128
Fax: 323-953-8116
Work Email: jolson@chla.usc.edu

EDUCATION AND PROFESSIONAL APPOINTMENTS

EDUCATION:

Year	Degree, Field, Institution, City
1992	BA, Mammalian Physiology, UC San Diego, San Diego
1993	MS, Animal Physiology, The Chicago Medical School, Chicago
1997	MD, Medical Doctor, The Chicago Medical Shool, Chicago
2015	MS, Clinical and Biomedical Investigations in Translational Science, USC, Los Angeles

POST-GRADUATE TRAINING:

Year-Year	Training Type, Field, Mentor, Department, Institution, City
1997 - 1998	Internship, Pediatrics, Children's Hospital Orange County, Orange
1998 - 2000	Residency, Pediatrics, Antonio Arrieta, Children's Hosptial Orange County, Orange
2000 - 2003	Fellowship, Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles
2012 - 2015	Master's Degree, Clinical and Biomedical Investigations in Translational Science,
	USC

ACADEMIC APPOINTMENTS:

Year-Year	Appointment	Department, Institution, City, Country	
2006 - 2016	Assistant Professor of Clinical Pediatrics	Division of Adolescent Medicine, Children's Hospital Los Angeles/USC Keck School of Medicine, Los Angeles, USA	
2016 - Present	Associate Professor of Clinical Pediatrics	Division of Adolescent Medicine, Children's Hospital Los Angeles/USC Keck School of Medicine, Los Angeles, USA	

CLINICAL/ADMINISTRATIVE APPOINTMENTS:

2008 - 2012	Fellowship Director	Division of Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles, USA	
2012 - present	Medical Director	The Center for Transyouth Health and Development, Division of Adolescent Medicine, Children's Hospital Los Angeles, Los Angeles, USA	

2021 - pro	esent Clinical consultant	arbara Neighborhood Clinics

LICENSURE, CERTIFICATIONS

LICENSURE:

Year	License number, State, Status
2000	A-67352, California, Active

BOARD CERTIFICATION OR ELIGIBILITY:

Year	Board, State, Status
2001, 2009, 2015	Pediatrics, California, active

SPECIALTY CERTIFICATION:

Year	Specialty Certification, Status
2003, 2013	Adolescent Medicine, California, active

HONORS, AWARDS:

Year	Description	Awarding agency, address, city	
2000	Health Care Advacacy Champion	Democratic Advocates for Disability Issues, Los	
2009	Health Cale Advocacy Champion	Angeles	
2010	Clinical Research Academic Career	Saban Research Center TSRI Program: Community	
	Development Award	Health Outcomes and Intervention, Los Angeles	
2012	Extraordinary Service Award	Equality California, 202 W 1st St., Suite 3-0130, Los	
2012	Extraordinary Service Award	Angeles	
2013	Top Doctor	Castle Connolly	
2014	Anne Marie Staas Ally Award	Stonewall Democratic Club; 1049 Havenhurst Drive	
2011		#325, West Hollywood	
2014	Top Doctor	Castle Connolly	
2014	Recognition Award for Outstanding,	SoCal Society for Adolescent Health and Medicine	
2011	Compassionate and Innovative Service	Regional Chapter, Los Angeles	
2015	The Champion Award	The Division of Adolescent Medicine; CHAMPION	
2015		FUND 5000 Sunset Blvd. Los Angeles	
2016	America's Most Honored Professional's –	America's Most Honored Professional's	
	Top 10%		
2016	Regional Top Doctor	Castle Connolly	
2017	Exceptional Women in Medicine	Castle Connolly	
2017	Regional Top Doctor	Castle Connolly	
2017	America's Most Honored Professional's – Top 5%	America's Most Honored Professional's	
2018	Regional Top Doctor	Castle Connolly	
2019	Benjamin Meaker Visiting Professorship	University of Bristol, Bristol UK	
2019	Regional Top Doctor	Castle Connolly	
2019	L.A's Top Docs	Los Angeles Magazine	
2019	Top Docs	Pasadena Health	
2019	America's Most Honored Professional's –	America's Most Honored Professional's	
2020	10p 1%	Contla Compa ¹¹	
2020	Kegional Top Doctor	Castle Connolly	
2020	Southern California Top Doc	Castle Connolly	

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2020	Southern California Top Doctors	
2020	L.A's Top Docs	Los Angeles Magazine
2020	America's Most Honored Professional's – Top 1%	America's Most Honored
2021	Southern California Top Doc	Castle Connolly
2021	America's Most Honored Doctors – Top 1%	America's Most Honored
2021	Top Doctors	Castle Connolly
2022	America's Most Honored Doctors – Top 1%	America's Most Honored
2022	Top Doctors	Castle Connolly

TEACHING

DIDACTIC TEACHING:

Keck School of Medicine at USC

Year-Year	Course Name	Units/Hrs	Role
2019	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth	One hour	Curriculum development and delivery
2020, 2021, 2022	Approach to the Care of Gender Non- conforming Children and Transgender Youth	One hour	Curriculum development and delivery
2023	Transgender and Non-binary Youth and Young Adults 101	One hour	Curriculum development and delivery

CalState Fullerton

Year-Year	Course Name	Units/Hrs	Role
2017	Gender Nonconforming and	One hour	Curriculum development and
	Transgender Youth		delivery

UNDERADUATE, GRADUATE AND MEDICAL STUDENT (OR OTHER) MENTORSHIP:

Year-Year	Trainee Name	Trainee Tvpe	Dissertation/Thesis/Project Title
2015 - 2016	David Lyons	MD	Transgender Youth Clinical Clerkship
2016 - 2019	Jonathan Warus	MD	Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts
2019 - 2021	Laer Streeter	MD	Comparison of Histrelin Implants
2020 - Present	Richard Mateo Mora	MD	Fertility Preservation Among Transgender Women
2022	Avery Everhart	PhD	Incomplete Data & Insufficient Methods: Transgender Population Health Research in the US

GRADUATE STUDENT THESIS, EXAM AND DISSERTATION COMMITTEES:

Year-Year	Trainee Name	Committee Type	Student Department
2022	Avery Everhart	Dissertation	Social Work

POSTGRADUATE MENTORSHIP:

Year-Year	Trainee Name	If past trainee, current position and location
2012-2013	Lisa Simons, MD	Clinical Instructor – Lurie Children's Hospital
2013	Shelley Aggarwal, MD	Clinical Instructor – Stanford University School of Medicine
2014	Julie Spencer, MD	Adolescent Medicine Provider Kaiser Hospital
2014-2015	Michael Haymer, MD	Program Director, Psychiatry Department UCLA
2015-2017	Patrick Shepherd, MD	CHLA Endocrinology Fellow
2015-2018	Jonathan Warus, MD	Faculty, CHLA/USC Keck School of Medicine
2015-2020	Shannon Dunlap, PhD	Postdoctoral Scholar - Research Associate, University of Southern California, Suzanne Dworak-Peck School of Social Work
2020-Present	Marianela Gomez-Rincon, MD	Adolescent Medicine Fellow
2020-Present	Jonathan Warus, MD	CHLA, Assistant Professor of Clinical Pediatrics
2022	Emmett Henderson, PhD, MS	USC Suzanne Dworak-Peck School of Social Work Senior mentor K99; USC

MENTORSHIP OF FACULTY:

Year-Year	Mentee Name	Mentee Department
2021 - present	Jonathan Warus, MD	Division of Adolescent Medicine, CHLA
2022	Brigid Conn, PhD	Clinical Psychologist, CHLA

SERVICE

DEPARTMENT SERVICE:

Year-Year	Position, Committee	Organization/Institution
2010-2015	Secretary, The CHAMPION	The Division of Adolescent Medicine, Children's
	Fund Executive Board	Hospital Los Angeles

HOSPITAL OR MEDICAL GROUP SERVICE:

Year-Year	Position, Committee	Organization/Institution
2021 - present	Committee Member	SOGI work group, CHLA

PROFESSIONAL SERVICE:

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	Year-Year	Position, Committee	Organization/Institution
	2012-present	Member, LGBT Special Interest	Society for Adolescent Health and Medicine
	-	Group	
	2022	Secretary, Executive Board of	US Professional Association of Transgender Health
		Directors	

CONSULTANTSHIPS AND ADVISORY BOARDS:

Year	Position, Board	Organization/Hospital/School, Institution
2010-2017	Member, Advisory Board	Transyouth Family Allies
2017-present	Member, National Medical Committee	Planned Parenthood
2017 - Present	Board Member	US Professional Association of Transgender Health
2021	Expert Panelist	Robert Wood Johnson Foundation - National
		Commission on Data Transformation for Health Equity
2021	Member, Advisory Board	The National LGBTQIA+ Health
2021		Education Center

PROFESSIONAL SOCIETY MEMBERSHIPS:

Year- Year	Society
2003 - present	Society for Adolescent Health and Medicine
2005 - present	American Academy of Pediatrics
2006 - 2011	Los Angeles Pediatric Society (Past president 2010)
2010 - present	Professional Association for Transgender Health
2014 - present	Society for Pediatric Research
2017 - present	US Professional Association for Transgender Health

MAJOR LEADERSHIP POSITIONS: (E.G., DEAN, CHAIR, INSTITUTE DIRECTOR, HOSPITAL ADMINISTRATION, ETC.)

RESEARCH AND SCHOLARSHIP

EDITORSHIPS AND EDITORIAL BOARDS:

Year-Year	Position	Journal/Board Name
2015 - present	Associate Editor	Journal of Transgender Health

MANUSCRIPT REVIEW:

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Year-Year	Journal
2014 - present	Pediatrics
2014 - present	Journal of Adolescent Health
2014 - present	LGBT Health
2014 - present	International Journal of Transgenderism
2015 - present	Journal of Transgender Health
2018 - present	Clinical Child Psychology and Psychiatry
2018 - present	Journal of Sexual Medicine
2018 - present	Journal of Transgender Health
2021 - present	JAMA Peds

GRANT REVIEWS:

Year	Description Awarding agency, City, State, Country	
2017	Cognition and Perception Study Section	National Institutes of Health, Bethesda, Maryland, USA
2017	Neurological, Aging and Musculoskeletal Epidemiology Study Section	National Institutes of Health, Bethesda, Maryland, USA
2018	Social Psychology, Personality and Interpersonal Processes Study Section	National Institutes of Health, Bethesda, Maryland, USA
2018	Neurological, Aging and Musculoskeletal Epidemiology Study Section	National Institutes of Health, Bethesda, Maryland, USA
2019	Special Emphasis Panel Review of Research Conference (R13) Grants	National Institutes of Health, Bethesda, Maryland, USA
2019	The Einstein Foundation Award for Promoting Quality in Research	Einstein Foundation, Berlin
2020	Biobehavioral and Behavioral Sciences Study Section	National Institutes of Health, Bethesda, Maryland, USA
2021	Social Psychology, Personality and Interpersonal Processes Study Section	National Institutes of Health, Bethesda, Maryland, USA

MAJOR AREAS OF RESEARCH INTEREST

Research Areas	
1. Transgender and non-binary children, adolescents and young adults	
2. HIV medication adherence	

GRANT SUPPORT - CURRENT:

Dates of Award: 2021-2026		
Percent Effort 25%		
Title: The Impact of Early Medical Treatment in Transgender Youth		

Description: This is the continuations of a multicenter study, the first of its kind in the U.S. to evaluate the long-term outcomes of medical treatment for transgender youth. This study will provide essential, evidence-based information on the physiological and psychosocial impact, as well as safety, of hormone blockers and cross-sex hormones use in this population.

Role: Principle Investigator	
<i>Fotal Direct Costs:</i> \$4,918,586	

Grant No. 1R01HD097122-01 (Hidalgo)	Dates of Award: 2019-2024
Agency: NICHD	Percent Effort 2.5%

Title: A Longitudinal Study of Gender Nonconformity in Prepubescent Children

Description: The purpose of this study is to establish a national cohort of prepubertal transgender/gender nonconforming (TGNC) children (and their parents), and longitudinally observe this cohort to expand the body of empirical knowledge pertaining to gender development and cognition in TGNC children, their mental health symptomology and functioning over time, and how family-initiated social gender transition may predict or alleviate mental health symptoms and/or diagnoses.

Role: Site PI

Total Direct Costs: \$2,884,950

GRANT SUPPORT - PAST:

Grant No. (PI) 1R01HD082554-01A1	Dates of Award: 2015-2020
Agency: NICHD	Percent Effort 45%
Title: The Impact of Early Medical Treatment in Transgender Youth	
Description: This is a multicenter study, the first of its kind in the US to e	valuate the long_term

Description: This is a multicenter study, the first of its kind in the U.S. to evaluate the long-term outcomes of medical treatment for transgender youth. This study will provide essential, evidence-based information on the physiological and psychosocial impact, as well as safety, of hormone blockers and cross-sex hormones use in this population.

Role: Principle Investigator

Total Direct Costs: \$4,631,970	
Grant No. (COI) R01AI128796-01	Dates of Award: 2/24/17-
	1/31/18
Agency: NIAID	Percent Effort: 5%

Title: Maturation, Infectibility and Trauma Contributes to HIV Susceptibility in Adolescents

Description: This proposal explores the overarching hypothesis that fluctuations in sex steroid levels and mucosal trauma (sexual activity) are key determinants of mucosal immune activation and epithelial integrity, and that microbial communities are central to these processes. We will pursue this hypothesis by examining longitudinal changes in the anogenital microbiome as well as protein expression at these mucosal sites during sexual maturation (cisgender youth) and in hormonally-controlled sexual maturation (transgender youth). Associations between sex steroid levels, microbial community composition, mucosal trauma, and vaginal proteins will be determined and modeled.

Role: Co-Investigator Total Direct Costs: \$44,816

Grant No. (PI) U01HD040463	Dates of Award 2006 – 2016	
Agency: NIH/NICHD	Percent Effort: 10%	
Title: Adolescent Medicine Trials Network for HIV/AIDS		
Description: Adolescent Medicine Trials Network for HIV/AIDS		

Role: Co-Investigator
Total Direct Costs: 2,225,674

Grant No. (PI) SC CTSI	Dates of Award: 2012-2014	
8KL2TR000131	Dates 6/ 11/4/4. 2012 2017	
Agency: KL2 Mentored Career Research Development	Percent Effort: 37.5%	
Program of the Center for Education, Training and Career		
Development		
<i>Title:</i> The Impact of Hormone Blockers on the Physiologic and Psychosocial Development of Gender		
Non-Conforming Peri-Pubertal Youth		
Description: This study aimed to understand the impact of puberty blocking medications on mental health		
and physiolgic parameters in peri-pubertal transgender youth.		
Role: Principal Investigator		
Total Direct Costs: 191,525		

Invited Lectures, Symposia, keynote addresses

Date	Туре	Title, Location
2014	Invited Lecture	Transgender Youth; Needs, Risks, Outcomes and the Role of the System, Including Permanency and Inclusion for Our Youth, Administrative Office of the Courts, Center for Families and Children, San Diego, California
2015	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Lopez Family Foundation Special Lecture for Puerto Rico and Panama, Lopez Family Foundation, Children's Hospital Los Angeles, Los Angeles, California
2015	Symposium	Transgender Youth – An Overview of Medical and Mental Health Needs of Gender Non-Conforming Children and Transgender Adolescents, Public Child Welfare Training Academy, Academy for Professional Excellence at San Diego State University School of Social Work, San Diego, California
2015	Invited Lecture	Meeting the Needs of Transgender Adolescents; 1 st Annual Southern California LGBT Health Symposium; USC/UCLA, Los Angeles, California
2015	Symposium	Transgender Youth; An Overview of Medical and Mental Health Needs of Gender Non-conforming Children and Transgender Adolescents; GetReal California's Initiative; "Integrating Sexual Orientation, Gender Identity, and Expression (SOGIE) into California's Child Welfare System," Oakland, California
2016	Invited Symposium	Caring for Gender Nonconforming and Transgender Youth; Idyllwild, California
2016	Educational symposium	Gender 101: A Primer; Vista Mar, California
2016	Invited Lecture	Caring for Gender Non-conforming Children and Teens in the New Millennium - A Multidisciplinary Team Approach, California Association of Marriage and Family Therapists, Los Angeles, California
2016	Invited Lecture	Caring for Gender Nonconforming Children and Transgender Youth, California Psychological Association, Continuing Education Institute, Irvine, California
2016	Invited Lecture	Health Issues Related to Transgender Youth; LA City Health Commission, Los Angeles, California

2016	Invited Lecture	Caring for Gender Nonconforming and Transgender Youth, Medical Directors 12th Annual Update on Reproductive Health and Medical Leadership, Planned Parenthood, Steamboat Springs, Colorado
2016	Invited Lecture	Caring For Transgender Teens, UCLA Meet the Professor, Los Angeles, CA
2017	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Santa Barbara, CA
2017	Invited Lecture	Healthcare for TGNC Youth, Expanding Competency for LGBT Youth in the System, Washington DC
2017	Invited Lecture	Gender Non-conforming and Transgender Children and Youth; Center for Early Education, West Hollywood, CA
2017	Invited Lecture	Rethinking Gender, University of Massachusetts, Annual Convocation Welcome Luncheon, Worcester, MA
2017	Invited Lecture	Gender Non-Conforming Children and Transgender Youth, Board of Behavioral Sciences, Orange, CA
2017	Invited Lecture	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth, Santa Monica Rape Treatment Center, Santa Monica, CA
2017	Invited Lecture	Transgender Youth Care in the New Millennium, USC Law and Global Health Initiative, Los Angeles, CA
2018	Invited Lecture	Supporting Gender Diverse and Transgender Youth: A Deeper Look at Gender Dysphoria, Studio City, CA
2018	Invited Lecture	Working with Trans and Gender Non-Conforming Youth, Children's Hospital Orange County, CA
2018	Invited Lecture	Caring for gender Non-conforming and Transgender Youth and Young Adults, Ascend Residential, Encino CA
2018	Invited Lecture	Caring for gender Non-conforming and Transgender Youth and Young Adults, California State University Northridge, Northridge, CA
2018	Invited Lecture	Gender Dysphoria; School Nurse Organization of Idaho Annual Conference, Idaho
2018	Invited Lecture	Gender and What You Should Know, Archer School for Girls, Brentwood, CA
2018	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Oceanside, CA
2018	Invited Lecture	Gender Dysphoria: Beyond the Diagnosis, Advance LA, Los Angeles, CA
2018	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Andrology Society of America Clinical Symposium, Portland, OR
2018	Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Los Angeles, CA
2018	Invited Lecture	Caring for Gender Non-Conforming and Transgender Youth, Center for Early Education, Los Angeles, CA
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Cal State Los Angeles, California
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Claremont Colleges, California
2019	Symposium	TransYouth Care; Flagstaff, AZ
2019	Invited Lecture	Transgender and Gender Non-conforming Youth, Ascend Residential Treatment, Utah
2019	Invited Lecture	Gender Diverse and Transgender Youth; What Pediatricians Should Know, Common Problems in Pediatrics Conference, Utah AAP, Utah

2019	Invited Lecture	Gender Diverse and Transgender Youth; What Pediatricians Should Know, Common Problems in Pediatrics Conference, Utah AAP, Utah
2019	Invited Lecture	Caring for Gender Diverse and Transgender Youth, Grand Rounds, UCLA Olive View, CA
2019	Invited Lecture	Caring for Gender Diverse and Transgender Youth, Grand Rounds, Good Samaritan, CA
2019	Invited Lecture	Puberty Suppression in Youth with Gender Dysphoria, Fenway Trans Health Program, Boston
2019	Invited Lecture	Recognizing the Needs of Transgender Youth, California Department of Corrections and Rehabilitation, Ventura, CA
2019	Invited Lecture	Gender Dysphoria; Beyond the Diagnosis, Gender Education Demystification Symposium, GA
2019	Invited Lecture	Caring for Gender Nonconforming and Transgender Youth, Los Angeles Superior Court/Los Angeles Bar Association Training, CA
2019	Invited Lecture	Supporting Gender Diverse and Transgender Youth; A Deeper Look at Gender Dysphoria, Oakwood School, CA
2020	Symposium	Trans Youth Care, Chico Transgender Week, Virtual Presentation
2020	Invited Lecture	Gender Nonconforming and Transgender Youth, Novartis, Virtual Presentation
2020	Invited Lecture	Advanced Hormones; More than Just T and E, CHLA, Virtual Presentation
2020	Invited Lecture	Video Telehealth and Transgender Youth, Telehealth Best Practices for the Trans Community, The Central Texas Transgender Health Coalition, Virtual Presentation
2020	Invited Lecture	Gear Talk, Transforming Families, Virtual Lecture
2020 2020	Invited Lecture Invited Lecture	Gear Talk, Transforming Families, Virtual Lecture Tips for Parenting a Trans or Gender Diverse Youth, Models of Pride, Virtual Presentation
2020 2020 2020	Invited Lecture Invited Lecture Invited Lecture	Gear Talk, Transforming Families, Virtual Lecture Tips for Parenting a Trans or Gender Diverse Youth, Models of Pride, Virtual Presentation Caring for Gender Diverse and Transgender Youth, LGBTQ+ Clinical Academy, Palo Alto University, Virtual presentation
2020 2020 2020 2020	Invited Lecture Invited Lecture Invited Lecture Invited Lecture	Gear Talk, Transforming Families, Virtual LectureTips for Parenting a Trans or Gender Diverse Youth, Models of Pride, Virtual PresentationCaring for Gender Diverse and Transgender Youth, LGBTQ+ Clinical Academy, Palo Alto University, Virtual presentationUSC Medical School, Los Angeles, CA
2020 2020 2020 2020 2020 2020	Invited Lecture Invited Lecture Invited Lecture Invited Lecture Invited Lecture	Gear Talk, Transforming Families, Virtual Lecture Tips for Parenting a Trans or Gender Diverse Youth, Models of Pride, Virtual Presentation Caring for Gender Diverse and Transgender Youth, LGBTQ+ Clinical Academy, Palo Alto University, Virtual presentation USC Medical School, Los Angeles, CA Medical Interventions for transgender youth, Cal State Los Angeles, Los Angeles
2020 2020 2020 2020 2020 2020 2020	Invited Lecture Invited Lecture Invited Lecture Invited Lecture Invited Lecture Plenary Session	Gear Talk, Transforming Families, Virtual LectureTips for Parenting a Trans or Gender Diverse Youth, Models of Pride, Virtual PresentationCaring for Gender Diverse and Transgender Youth, LGBTQ+ Clinical Academy, Palo Alto University, Virtual presentationUSC Medical School, Los Angeles, CAMedical Interventions for transgender youth, Cal State Los Angeles, Los Angeles Understanding Issues Involving Gender Non-Conforming and Transgender Individuals Coming to a Courtroom Near You, Mid-Winter Workshop for Judges of the Ninth Circuit, Palm Springs, CA
2020 2020 2020 2020 2020 2020 2020 202	Invited Lecture Invited Lecture Invited Lecture Invited Lecture Invited Lecture Plenary Session Invited Lecture	Gear Talk, Transforming Families, Virtual LectureTips for Parenting a Trans or Gender Diverse Youth, Models of Pride, Virtual PresentationCaring for Gender Diverse and Transgender Youth, LGBTQ+ Clinical Academy, Palo Alto University, Virtual presentationUSC Medical School, Los Angeles, CAMedical Interventions for transgender youth, Cal State Los Angeles, Los AngelesUnderstanding Issues Involving Gender Non-Conforming and Transgender Individuals Coming to a Courtroom Near You, Mid-Winter Workshop for Judges of the Ninth Circuit, Palm Springs, CAGender Affirmation through a Social Justice Lens; Center for Gender Equity in Medicine and Science (GEMS) at Keck School of Medicine, Los Angeles
2020 2020 2020 2020 2020 2020 2021 2021	Invited Lecture Invited Lecture Invited Lecture Invited Lecture Invited Lecture Plenary Session Invited Lecture Invited Lecture	Gear Talk, Transforming Families, Virtual LectureTips for Parenting a Trans or Gender Diverse Youth, Models of Pride, Virtual PresentationCaring for Gender Diverse and Transgender Youth, LGBTQ+ Clinical Academy, Palo Alto University, Virtual presentationUSC Medical School, Los Angeles, CAMedical Interventions for transgender youth, Cal State Los Angeles, Los AngelesUnderstanding Issues Involving Gender Non-Conforming and Transgender Individuals Coming to a Courtroom Near You, Mid-Winter Workshop for Judges of the Ninth Circuit, Palm Springs, CAGender Affirmation through a Social Justice Lens; Center for Gender Equity in Medicine and Science (GEMS) at Keck School of Medicine, Los AngelesIntroduction to the Care of Gender Diverse and Transgender Youth, Providence Medical Group – South Bay Pediatrics (Torrance, San Pedro, Redondo Beach), virtual lecture
2020 2020 2020 2020 2020 2020 2021 2021	Invited Lecture Invited Lecture Invited Lecture Invited Lecture Invited Lecture Plenary Session Invited Lecture Invited Lecture Invited Lecture	Gear Talk, Transforming Families, Virtual LectureTips for Parenting a Trans or Gender Diverse Youth, Models of Pride, Virtual PresentationCaring for Gender Diverse and Transgender Youth, LGBTQ+ Clinical Academy, Palo Alto University, Virtual presentationUSC Medical School, Los Angeles, CAMedical Interventions for transgender youth, Cal State Los Angeles, Los AngelesUnderstanding Issues Involving Gender Non-Conforming and Transgender Individuals Coming to a Courtroom Near You, Mid-Winter Workshop for Judges of the Ninth Circuit, Palm Springs, CAGender Affirmation through a Social Justice Lens; Center for Gender Equity in Medicine and Science (GEMS) at Keck School of Medicine, Los AngelesIntroduction to the Care of Gender Diverse and Transgender Youth, Providence Medical Group – South Bay Pediatrics (Torrance, San Pedro, Redondo Beach), virtual lectureCaring for Gender Diverse and Transgender Youth. SLO Acceptance, Cal Poly, Virtual Presentation
2020 2020 2020 2020 2020 2020 2021 2021	Invited Lecture Invited Lecture Invited Lecture Invited Lecture Invited Lecture Plenary Session Invited Lecture Invited Lecture Invited Lecture Invited Lecture	Gear Talk, Transforming Families, Virtual LectureTips for Parenting a Trans or Gender Diverse Youth, Models of Pride, Virtual PresentationCaring for Gender Diverse and Transgender Youth, LGBTQ+ Clinical Academy, Palo Alto University, Virtual presentationUSC Medical School, Los Angeles, CAMedical Interventions for transgender youth, Cal State Los Angeles, Los AngelesUnderstanding Issues Involving Gender Non-Conforming and Transgender Individuals Coming to a Courtroom Near You, Mid-Winter Workshop for Judges of the Ninth Circuit, Palm Springs, CAGender Affirmation through a Social Justice Lens; Center for Gender Equity in Medicine and Science (GEMS) at Keck School of Medicine, Los AngelesIntroduction to the Care of Gender Diverse and Transgender Youth, Providence Medical Group – South Bay Pediatrics (Torrance, San Pedro, Redondo Beach), virtual lectureCaring for Gender Diverse and Transgender Youth. SLO Acceptance, Cal Poly, Virtual PresentationTransgender and Non-binary children and youth, Board of Behavioral Sciences

2022	Invited Lecture	Gender Dysphoria in Children, Adolescents and Young Adults, MedLambda and PsychSIG Keck USC School of Medicine, Virtual Lecture
2022	Invited Lecture	Caring for Transgender and Gender Nonconforming Youth, Presbyterian Healthcare Services, New Mexico, Virtual lecture
2022	Invited Lecture	Transgender and Non-Binary Youth, Rogers Behavioral Health, Virtual Lecture
2023	Invited Lecture	Transgender and Non-binary Youth and Young Adults 101, When Healthcare Gets Political; Health Justice and Systems of Care course, Keck USC School of Medicine, Los Angeles

Invited Grand Rounds, CME Lectures

Date	Туре	Title, Location
2014	Grand Rounds	Caring for Gender Non-conforming Children and Teens in the New Millennium - A Multidisciplinary Team Approach; Seattle Children's Hospital, Seattle, Washington
2014	CME lecture	Transgender Youth; An Overview of Medical and Mental Health Needs of Gender Non-conforming Children and Transgender Adolescents; Eisenhower Medical Center Transgender Health Symposium, Palm Springs, California
2014	Grand Rounds	Toddlers to Teens: Comprehensive Health Care for the Transgender Child, Cultural Psychiatry Lecture Series, University of Iowa Carver College of Medicine, Iowa City, Iowa
2014	Grand Rounds	Caring for Gender Non-conforming Children and Teens in the New Millennium; A Multidisciplinary Team Approach, Children's Hospital Los Angeles, Los Angeles, California
2014	CME lecture	Difficult Cases, Gender Spectrum Family Conference, Gender Spectrum, Moraga, California
2014	CME lecture	Difficult Cases, Gender Spectrum Family Conference, Gender Spectrum, Moraga, California
2014	CME lecture	Cross-sex Hormones for Teenagers, How Young is Too Young? Philadelphia Trans Health Conference, Philadelphia, Pennsylvania
2014	CME lecture	Pediatric Update, Philadelphia Trans Health Conference, Philadelphia, Pennsylvania
2015	Grand Rounds	Caring for Gender Nonconforming and Transgender Youth, Stanford Division of Adolescent Medicine, Palo Alto, CA
2015	CME Educational Lecture	The Transgender Experience, St. Joseph's Providence, Burbank, CA
2015	CME Educational Lecture	Update on the Transgender Patient for the PCP, St. Joseph's Providence, Burbank, CA
2015	CME Educational Lecture	Caring for Gender Non-Conforming Children and Transgender Teens, Providence Tarzana, CA
2015	Grand Rounds	Caring for Gender Nonconforming and Transgender Youth, University of Southern California, Los Angeles, California

2015	Grand Rounds	Puberty Blockers and Cross Sex Hormones, Pediatric Endocrinology, Children's Hospital Los Angeles, Los Angeles, California
2015	CME lecture	Youth and Hormones, 2015 Gender Expansion Conference, University of Montana, Missoula Montana
2015	CME lecture	Transyouth Healthcare, 2015 Gender Expansion Conference, University of Montana, Missoula Montana
2015	CME lecture	Supporting Transgender Youth, Southern Oregon University Student Health and Wellness Center Workshop, Southern Oregon University, Ashland, Oregon
2015	PCS Grand Rounds	Caring for Gender Nonconforming Children and Transgender Youth, Children's Hospital Los Angeles, Los Angeles, California
2015	CME lecture	Medical Care for Gender Non-Conforming Children, Transgender Adolescents and Young Adults in the New Millennium, Continuing Medical Education of Southern Oregon, Medford, Oregon
2015	Grand Rounds	Medical Care for Gender Non-Conforming Children and Transgender Youth, Olive View Medical Center-UCLA, Sylmar, California
2015	Grand Rounds	Caring for Gender Non-conforming Children and Transgender Teens, Harbor-UCLA Department of Pediatrics, Torrance, California
2015	CME lecture	Caring for Gender Non-conforming Children and Teens in the New Millennium, Healthcare Partners Pediatric Town Hall Meeting, Healthcare Partners CME, Glendale, California
2016	Pediatric Grand Rounds	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth; Children's Hospital Los Angeles, Los Angeles, California
2016	Endocrine Grand Rounds	Approach to Care of Gender Non-Conforming Children and Transgender Adolescents; Cedars Sinai Hospital, Los Angeles, California
2016	Pediatric Grand Rounds	Care of Gender Non-Conforming Children and Transgender Adolescents in the New Millennium, Stanford Lucille Packard Children's Hospital, Palo Alto, California
2016	Pediatric Update	Caring for Gender Variant Children and Adolescents, St. Louis, Missouri
2016	Grand Rounds	Care of Gender Non-Conforming Children and Transgender Adolescents in the New Millennium, St. Jude's Grand Rounds, Memphis, Tennessee
2016	CME Educational Lecture	Transgender and Gender Non-Conforming Youth: Innovative Approaches to Care in 2016; Integrating Substance Use, Mental Health, and Primary Care Services: Courageous and Compassionate Care, Los Angeles, California
2016	CME; professional conference	Caring for Gender Non-conforming Children and Teens in the New Millennium - A Multidisciplinary Team Approach, Arizona Psychiatric Society, Tempe, Arizona
2016	CME/Educati onal Symposium	Caring for Gender Nonconforming and Transgender Youth, San Diego, California
2016	CME/CEU Educational Training	Medical Interventions for Transgender Youth and Young Adults, San Diego State University, San Diego, California
2016	Grand Rounds	Caring for Gender Nonconforming Children and Transgender Youth, Mt. Sinai Hospital Pediatric Grand Rounds George J. Ginandes Lecture, New York, New York

2016	CME Educational Lecture	The Transgender Experience, Providence Tarzana, CA
2017	CME Educational Seminar	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, San Diego, CA
2017	CME Educational Seminar	The Care of Gender Non-Conforming children and Transgender Youth; Orange County Health Care Agency, Orange County, CA
2017	CME Educational Lecture	Rethinking Gender, Adolescent Grand Rounds, Children's Hospital Los Angeles, Los Angeles, CA
2017	CME Educational Lecture	Gender Non-Conforming Children and Transgender Youth, Pasadena CA
2017	CME Educational Lecture	Gender Non-Conforming and Transgender Children and Adolescents, Developmental Pediatrics continuing education lecture, Children's Hospital Los Angeles, CA
2017	CME Educational Lecture	Care of Gender Non-Conforming Children and Transgender Adolescents, Lopez Family Foundation Educational Lecture, Los Angeles, CA
2017	CME Educational Lecture	Puberty Suppression and Hormones; Medical Interventions for Transgender Youth, USC Keck School of Medicine Reproductive Health, Los Angeles, CA
2017	CME Educational Seminar	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, San Diego, CA
2018	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Glendale Unified School District, CA
2018	CME Educational Lecture	Caring for Gender Non-Conforming Children and Transgender Youth, CME by the Sea, CA
2018	CME Symposium	Caring for Gender Non-Conforming and Transgender Youth, TransYouth Care, Austin, TX
2018	CME Educational Lecture	Approach to the Care of Gender Non-Conforming Children and Transgender Youth, Desert Oasis Healthcare, Palm Desert, CA
2018	CME Workshop	Mental and Medical Healthcare for Transgender Adolescents, California Association of Marriage and Family Therapists, Garden Grove, CA
2018	CME Educational Lecture	Approach to the Care of Gender Non-Conforming Children and Transgender Youth, Keck School of Medicine, Los Angeles, CA
2018	Grand Rounds	Caring for Gender Non-Conforming Children and Transgender Adolescents, Primary Children's Hospital, Salt Lake City, UT
2018	CME Educational Lecture	Caring for Transgender Youth, Chico Trans Week, Chico, CA

2018	CME Educational Lecture	Rethinking Gender, UCSD Medical School, San Diego, CA
2018	CME Educational Lecture	Rethinking Gender, UCLA Medical School, Los Angeles, CA
2019	Symposium	Recognizing the Needs of Transgender Youth, California Department of Corrections and Rehabilitation, Stockton, CA
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Cal State Los Angeles, California
2019	Symposium	The Care of Trans and Gender Non-Conforming Youth and Young Adults, Claremont Colleges, California
2019	CME Lecture	Gender Diverse and Transgender Youth, Harbor UCLA Medical Center Grand Rounds, Torrance, CA
2019	CME Lecture	Gender Dysphoria – Beyond the Diagnosis, Gender Odyssey San Diego, San Diego, CA
2019	Grand Rounds	Transgender Youth; What's New in 2019?, Children's Hospital Los Angeles, CA
2019	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Children's Hospital Orange County, CA
2019	CME Symposium	Caring for Gender Nonconforming and Transgender Youth, Stanislaus County Behavioral Health and Recovery Services, CA
2019	CME Eduational Lecture	Rethinking Gender, Olive View Medical Center Grand Rounds, CA
2020	CME Lecture	Gender Affirmation Through a Social Justice Lens, SAHM Conference, Virtual Presentation
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, AAP Conference, Virtual Lecture
2020	CME Lecture	Conversations with LGBTQ youth; the role of the pediatrician, AAP Conference, Virtual Lecture
2020	Grand Rounds	Creating Affirming Environments for Trans and Gender Diverse Patients, USC OB/Gyn Grand Rounds, Virtual Presentation
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Resident Lecture, CHLA
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Facey Medical Group, Los Angeles, CA
2020	Plenary Lecture	Reframing Gender Dysphoria, LEAH Conference, Los Angeles, CA
2020	CME Lecture	Gender Affirming Care for Pre and Peri-pubertal Trans and Gender Diverse Youth, LEAH Conference, Los Angeles, CA
2020	CME Lecture	Introduction to the Care of Gender Diverse and Transgender Youth, Division of Endocrinology, USC, Los Angeles, CA
2021	CME Lecture	Transitioning: From Invalidation and Trauma to Gender Affirming Care; Department of Anesthesiology at CHLA

2021	CME Lecture	Transitioning from Invalidation and Trauma to Gender Affirming Care; ACCM Grand Rounds, Children's Hospital Los Angeles, Virtual presentation
2021	CME Symposium	TransYouth Care; Transfamily Support San Diego, Virtual Symposium
2021	Symposium	TransYouth Care for Parents; Santa Clara, CA
2022	CME Lecture	Gender affirming medical interventions; An Evolving landscape, Critical Issues in Child and Adolescent Mental Health Conference, San Diego, California
2022	CME Symposium	TransYouth Care for Mental Health Providers; Santa Clara, CA
2022	CME Symposium	TransYouth Care; Transfamily Support San Diego, Virtual Symposium

International Lectures

Date	Туре	Title, Location
2013	Keynote	Caring for Gender Non-conforming Children and Adolescents in the New Millennium, Vancouver, Canada
2016	CME; professional conference	Social Transitions in Pre-pubertal Children; What do we know? World Professional Association of Transgender Health, Amsterdam, The Netherlands
2016	CME; professional conference	Beyond Male and Female; Approach to Youth with Non-Binary Gender Identities, World Professional Association of Transgender Health, Amsterdam, The Netherlands
2016	CME; professional conference	Workgroup on Gender Nonconforming/Transgender Youth: Biopsychosocial Outcomes and Development of Gender Identity, World Professional Association of Transgedner Health, Amsterdam, The Netherlands
2017	Invited Lecture	Gender Dysphoria, Beyond the Diagnosis, Pink Competency, Oslo Norway
2017	Invited Lecture	Caring for Gender Non-Conforming Children and Transgender Adolescents: A United States Perspective, Pink Competency, Oslo Norway
2017	Invited Lecture	Caring for Gender Non-conforming and Transgender youth and Young Adults, Diverse Families Forum: The Importance of Family Support in The Trans And LGBT Children, Organized by COPRED and The International Association Of Families For Diversity (FDS), Mexico City, Mexico
2018	Invited Lecture	Chest Reconstruction and Chest Dysphoria in Transmasculine Adolescents and Young Adults: Comparison of Nonsurgical and Postsurgical Cohorts, Buenos Aires, Argentina
2018	Invited Lecture	Transgender Youth and Gender Affirming Hormones; A 6-8 year follow- up, Buenos Aires, Argentina
2018	Invited Lecture	Transyouth Care – An NIH Multisite Study About the Impact of Early Medical Treatment in Transgender Youth in the US, Buenos Aires, Argentina

2018	Invited Lecture	Uso de Hormonas Reaffirmantes de Genero en Adolescentes Transgenero, Trans Amor Congreso Nacional de Transexualidad Juvenil y Infantos, Monterey, Mexico
2018	Invited Lecture	Bloquedores de la Pubertad, Trans Amor Congreso Nacional de Transexualidad Juvenil y Infantos, Monterey, Mexico
2018	CME Educational Lecture	Puberty Blockers and Gender Affirming Hormones for Transgender Youth: What Do We Know, and What Have We Learned, Pediatric Academic Societies, Toronto, Canada
2019	Grand Rounds	Rethinking Gender, Grand Rounds, The Hospital for Sick Children, Toronto, Canada
2019	Keynote	<i>Gender Dysphoria; Beyond the Diagnosis,</i> Promoting Innovation and Collaboration to Support Gender Diverse Youth Conference, The Hospital for Sick Children, Toronto, Canada, December 2019
2019	Invited Lecture	Hormonas que Affirman el Genero pasa Juventud y Adultos Menores Trans, Transformando Desde el Amor y Las Familias, Colombia
2019	Invited Lecture	Infancia Trans y da Genero Diverso, Transformando Desde el Amor y Las Familias, Colombia
2019	Invited Lecture	Transgender Youth: Medical and Mental Health Needs, Bristol, United Kingdom
2019	Invited Lecture	Rethinking Gender, University of Bristol, United Kingdom
2019	CME; professional conference	Male Chest Reconstruction and Chest Dysphoria in Transmasculine Adolescents and Young Adults, European Professional Association of Transgender Health, Rome Italy
2019	CME; professional conference	Transgender Youth and Gender Affirming Hormones; 5-7 Year Follow Up, European Professional Association of Transgender Health, Rome Italy
2019	CME Educational Lecture	Gender Dysphoria; Beyond the Diagnosis, European Professional Association of Transgender Health, Rome Italy
2022	Plenary Session	The Landscape of Gender Affirming Care for Youth in the US, AusPATH, Virtual
2022	CME; professional conference	Emotional Functioning of Adolescents with Gender Dysphoria After Two Years of Treatment; WPATH Conference, Montreal, Canada
2022	CME; Professional Conference	Creating Enduring Materials; WPATH Conference, Montreal, Canada
2023		

Keynote/Plenary Presentations

Date	Туре	Title, Location
2015	Keynote	The Future of Trans Care in the New Millennium, Gender Infinity
2013		Conference, Houston, Texas
2016	Plenary Session	Caring for Trans Youth and Gender Non-Conforming Children,
2010		Transgender Spectrum Conference, St. Louis, Missouri
2018	Keynote	Future Directions, USPATH, Washington DC
2010	Varmata	Gender Dysphoria; A Deeper Dive Beyond the Diagnosis, Inaugural
2019	Keynote	LGBTQ summit, Santa Clara CA
	CME;	Advances and Challenges in the Care of Transgender/Gender Diverse
2021	professional	Vouth: USPATH Conference, Virtual presentation
	conference	Touth, OSTATT Conference, Virtual presentation
2022	Keynote	Gender Affirmation Through a Social Justice Lens, Indiana University
2022		School of Medicine
		Transgender and Non-Binary Youth, Supporting the Well-Being of
2022	Invited Lecture	LGBTQ Youth Certificate Program Center for Juvenile Justice Reform
		Georgetown University, virtual training
2022	Invited Lecture	Transgender and Non-Binary Youth, Young Women's Career Conference
2022	Invited Lecture	(YWCC) for the Girls Academic Leadership Academy; virtual lecture

PUBLICATIONS:

* INDICATES TRAINEES ** INDICATE YOURSELF AS CO-FIRST OR CO-CORRESPONDING OR SENIOR AUTHORS

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

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

EXPERT REPORT OF DANIEL SHUMER, M.D.

I, Daniel Shumer, M.D., hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection

with the above-captioned litigation.

2. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

I. BACKGROUND AND QUALIFICATIONS

A. Qualifications

3. 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.

4. 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.

5. 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. Concurrent with the 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.

6. I have extensive experience in working with and treating children and adolescents 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.

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

8. 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 the treatment of gender dysphoria, and research articles on a variety of topics with a focus on mental health in transgender adolescents.

9. I am involved in 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."

10. 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.

11. 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.

12. 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 21 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 actively conduct research related to transgender medicine, gender dysphoria treatment, and mental health concerns specific to transgender youth.

13. I also provide care in in the Differences/Disorders of Sex Development (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 influence 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.

14. 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.

15. 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

16. In the past four years, I have been retained as an expert and provided testimony at trial or by deposition in the following cases: *Roe et al v. Utah High School Activities Association et al* (Third District Court in and for Salt Lake County, UT); and *Menefee v. City of Huntsville Bd. of Educ.*, No. 5:18-cv-01481 (N.D. Ala.). 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

17. 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

18. This report sets forth my opinions in this case and the bases for my opinions.

19. In preparing this report, I reviewed the text of *Florida Medicaid* – *Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria*, including the attachments, as well as the Complaint in this case.

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 Plaintiffs or their parents. 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. <u>EXPERT OPINIONS</u>

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).

28. A person's understanding of their gender identity may evolve over time in the natural course of their life, however, attempts to "cure" transgender individuals by forcing their gender identity into alignment with their birth sex (sometimes descried as "conversion therapy") 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

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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; Savic, et al., 2011). In one such study, the volume of the bed nucleus of the *stria terminalis* (a collection of cells in the central brain) in transgender women was equivalent to the volume found in cisgender women (Chung, et al., 2002).

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 cisgender 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 ADOLECENTS AND ADULTS

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

There are several studies demonstrating positive results of gender-35. affirming care in adolescents and adults (de Vries, et al., 2014; de Vries, et al., 2011; Green, et al., 2022; Smith, et al., 2005; Turban, et al., 2022). 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-affirming treatment allowed transgender adolescents to make ageappropriate 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 gender-affirming hormone therapy is correlated with reduced rates of depression and suicidality among transgender adolescents. Turban et al. (2022) documented that access to gender-affirming 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, ADOLESCENTS, AND ADULTS

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 both 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 sex assigned at birth. 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.

In children and adolescents, the diagnosis of gender dysphoria is made 38. 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.

39. In transgender adults, the WPATH SOC recommends that a health care provider assessing and treating a transgender patient should ensure diagnostic criteria are met prior to initiating gender-affirming treatments and ensure that any health conditions that could negatively impact the outcome of treatment are assessed, with risks and benefits discussed, before a decision is made regarding treatment. The capacity of the adult. to consent for the specific treatment should be confirmed prior to initiation (Coleman, et al., 2022).

D. EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES FOR THE TREATMENT OF GENDER DYSPHORIA IN CHILDREN, ADOLESCENTS AND ADULTS

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

41. 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).

42. 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).

43. 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).

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

45. 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.

46. 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.

47. 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.

48. 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).

49. 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.

50. 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. 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).

51. The previous version (SOC 7), published in 2012 (Coleman, et al., 2012), was the most recent version at the time of the adoption of Florida Administrative Code, 59G-1.050(7) (the "Challenged Exclusion"). SOC 7 was similar to SOC 8 in the basic tenets of management for transgender adolescents and adults; however, SOC 8 further reinforces these guidelines with data published since the release of SOC 7.

52. 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).

53. 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 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).

54. 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).

55. 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).

56. 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

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 (e.g., GAPMS Memo at 14; Attachment D (Cantor) to GAPMS Memo at 6-9). 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.

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60. Puberty-delaying medication and hormone-replacement therapy—both individually and in combination—can significantly improve a transgender young 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. Designed benefit of treatment is to reduce the risk of worsening gender dysphoria and mental health deterioration. More specifically, use of GnRHa in transmasculine adolescents allows for decreased chest development, reducing the need for breast binding and surgical intervention in adulthood. For transfeminine adolescents GnRHa limits facial and body hair growth, voice deepening, and masculine bone structure development, which greatly reduce distress both at the time of treatment and later in life and reduce the need for later interventions such as voice therapy, hair removal, and facial feminization surgery.

67. The goal in using GnRHa is to minimize the patient's dysphoria related to progression of puberty and allow for later initiation of puberty consistent with gender identity. When a patient presents to care, the provider assesses the patient's pubertal stage, pubertal history, and individual needs. A patient may present prior to the onset of puberty (Tanner Stage 1), at the onset of puberty (Tanner Stage 2), or further along in puberty (Tanner Stages 3-5). The pubertal stage and individual needs of the patient then direct conversations regarding care options. A patient at Tanner Stage 2 may benefit from GnRHa, while an older patient who has completed puberty may benefit from pubertal initiation with hormones, as described below. I have observed that providing individualized care based on individual patient characteristics, using the WPATH Standards of Care as the foundation of this care, provides significant benefit to patients, minimizes gender dysphoria, and can eliminate the need for surgical treatments in adulthood.

68. 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.

69. 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

70. 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. In adult patients, use of GnRHa is uncommon, but rather medical decisions are focused more on testosterone or estrogen therapy.

71. These hormone therapies are used to treat gender dysphoria in adolescents and adults to facilitate development of sex-specific physical changes congruent with their gender identity. For example, a transgender man prescribed testosterone will develop a lower voice as well as facial and body hair, while a

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transgender woman prescribed estrogen will experience breast growth, female fat distribution, and softer skin.

72. 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).

73. Under the Endocrine Society Clinical Guidelines and SOC 8, hormone therapy is an appropriate treatment for transgender adults with gender dysphoria when the experience of dysphoria is marked and sustained, other possible causes of apparent gender dysphoria are excluded, any mental and physical health conditions that could negatively impact the outcome of treatment are assessed, the adult has capacity to understand risks and benefits of treatment and provide consent for treatment (Coleman, et al., 2022; Hembree, et al., 2017).

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74. 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.

75. 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).

F. SAFETY AND EFFICACY OF PUBERTY-DELAYING MEDICATIONS AND HORMONE THERAPY TO TREAT GENDER DYSPHORIA

76. 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.

77. 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.

78. 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.

79. 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).

80. 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).

81. 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.

82. 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-affirming 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).

83. 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.

84. Hormone therapy (testosterone or estrogen) is prescribed to older 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 times 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 minimized with this monitoring. Additionally, side effects are considered, discussed, and easily managed in all individuals needing hormone therapy regardless of the diagnosis necessitating these medications.

85. 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. 86. 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 gender-affirming hormone therapy is correlated with reduced rates of depression and suicidality among transgender adolescents. Turban et al. (2022) documented that access to gender-affirming 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.

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

88. The efficacy of hormone treatment in transgender adults is similarly robust. At least 11 longitudinal studies document improvement in various mental health parameters including depression, anxiety, self-confidence, body image and self-image, general psychological functioning (e.g., Colizzi, et al., 2013; Colizzi, et al., 2014; Corda, et al., 2016; Defreyne, et al., 2018; Fisher, et al., 2016; Heylens, et

al., 2014; Keo-Meier, et al., 2015; Manieri, et al., 2014; Motta, et al., 2018; Oda, et al., 2017; Turan, et al., 2018).

89. In sum, the use of GnRHa and hormones in adolescents, and hormones in adults 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 adolescent and adult age groups. 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

90. Prohibition of gender-affirming care, or coverage thereof, for adolescents and adults is likely to have devastating consequences. I am concerned that the Challenged Exclusion might lead to a staggering increase in mental health problems including suicidality for transgender Floridians. One study which highlights my concern is a study of over 21,000 patients who report ever desiring gender-affirming 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).

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

III. <u>CONCLUSION</u>

92. In summary, banning coverage of gender-affirming care runs counter to evidence-based best practices and standards of care for the treatment of gender dysphoria in adolescence and adulthood.

93. 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.

94. Lack of access to these treatments will result in worse outcomes for countless individuals in Florida. Furthermore, banning coverage for evidence-based treatment for gender dysphoria sends a message that transgender people are not valid and should be stigmatized.

95. 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. Adult patients, and 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.

96. Banning coverage of effective treatment for gender dysphoria will not eliminate transgender people, but will, unfortunately, lead to an increase in mental health problems and suicidality in an already vulnerable population.

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

Executed this 16th day of February 2023.

Daniel Shumer, M.D.

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

EXPERT REPORT OF DR. DANIEL SHUMER Case No. 4:22-cv-00325-RH-MAF

Daniel Shumer, MD MPH

Clinical Associate Professor in Pediatrics - Endocrinology

Email: dshumer@umich.edu

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

Michigan, Medical License Michigan, Controlled Substance

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

<u>Clinical Appointments</u>

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 PI 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

Institutional

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
2010	Lecturer of the Month Department of Pediatrics Michigan

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

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

Institutional

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

Peer-Reviewed 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 (17OHD) 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 (17OHD) 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

<u>Notes</u>

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

<u>Reviews</u>

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*

EXPERT REPORT OF DR. DANIEL SHUMER Case No. 4:22-cv-00325-RH-MAF

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Allen, N. G., Krishna, K. B., & Lee, P. A. (2021). Use of gonadotropin-releasing hormone analogs in children. *Current opinion in pediatrics*, *33*(4), 442–448.

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), 302-311.

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>

American Psychological Association. (2015). Guidelines for psychological practice with transgender and gender nonconforming people. American Psychologist, 70, 832-864.

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), 387–397.

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

AUGUST DEKKER, et al.,

Plaintiffs,

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

v.

JASON WEIDA, et al.,

Defendants.

EXPERT REPORT OF KELLAN E. BAKER, MA, MPH, PhD

I, Kellan E. Baker, MA, MPH, PhD, declare and state as follows:

1. I have been retained by counsel for Plaintiffs in connection with the above-captioned litigation.

2. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

BACKGROUND AND QUALIFICATIONS

A. Qualifications

3. I am the Executive Director and Chief Learning Officer of the Whitman-Walker Institute. In this role I oversee the Whitman-Walker Institute, which is the research, policy, and educational arm of Whitman-Walker, a community health system that includes Whitman-Walker Health, a federally qualified

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community health center with 50 years of expertise in serving diverse communities across the Washington, D.C. metro area, particularly LGBTQ+ people and people living with HIV.

4. In 2021, I received my Doctor of Philosophy in Health Policy and Management from the Johns Hopkins Bloomberg School of Public Health, where I focused on Health Services Research and Policy as a Centennial Scholar and a Robert Wood Johnson Health Policy Research Scholar. I also completed a three-year Certificate Program in Public Health Economics at the Johns Hopkins Bloomberg School of Public Health and received an Executive Certificate in Health Care Leadership and Management from the Johns Hopkins Carey Business School.

5. In 2011, I received my Master of Public Health in Global Health Policy from The George Washington University Milken Institute School of Public Health and in the same year received my Master of Arts in International Development Studies from The George Washington University Elliott School of International Affairs.

6. Through my academic training and professional experience, I have extensive experience as a researcher and health policy expert regarding topics such as insurance reform and the Patient Protection and Affordable Care Act ("Affordable Care Act"), federal and state regulatory policy, public health, and government statistics. I have expertise in developing and analyzing health policy; conducting,

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synthesizing, and communicating scientific research; and working with government, philanthropy, and other partners toward health policy objectives.

7. A significant part of my scholarship, research, and experience has focused on ensuring health equity for medically underserved populations, including sexual and gender minority communities, communities of color, and people with disabilities. My work has a particular emphasis on health care access and insurance issues in relation to the transgender population.

8. I have also worked with the National Academies of Sciences, Engineering, and Medicine ("National Academies") in several capacities. In 2017-2018, I served as a Steering Committee Member for the National Academies Project on Demography of Sexual and Gender Minority Populations. In 2019-2021, I served as a consultant to the National Academies Committee on Population on the convening of a National Academies Consensus Study Committee to assess the health and well-being of sexual and gender diverse populations. In this capacity, I advised on the preparation, creation, and dissemination of the Consensus Study Report "Understanding the Well-Being of LGBTQI+ Populations," which was published in 2020. As part of my role I participated in Consensus Study Committee discussions and authored and edited report components related to physical and mental health, health services access and use, health policy, data collection, and demography.¹ As a consensus study report by the National Academies, the report documents the evidence-based consensus on the study's statement of task, was subjected to a rigorous and independent peer-review process, and represents the position of the National Academies on the statement of task.

9. Of relevance to this case, the National Academies 2020 consensus study report states that:

- a. "Clinicians who provide gender-affirming psychosocial and medical services in the United States are informed by expert evidence-based guidelines";
- b. Each of the guidelines published by the World Professional Association for Transgender Health ("WPATH") (Coleman et al., 2012); the Endocrine Society (Hembree et al., 2017); and the Center of Excellence for Transgender Health (UCSF Transgender Care, 2016) "is informed by the best available data and is intended to be flexible and holistic in application to individual people"; and
- c. "Mental and physical health problems need not be resolved before a person can begin a process of medical gender affirmation, but they

¹ National Academies of Sciences, Engineering, and Medicine. (2020). Understanding the Well-Being of LGBTQI+ Populations. Washington, DC: The National Academies Press. https://doi.org/10.17226/25877.

should be managed sufficiently such that they do not interfere with treatment."

10. In 2021, I was appointed as a member of the National Academies Consensus Study Committee on Measuring Sex, Gender Identity, and Sexual Orientation, which was charged with developing recommendations for the National Institutes of Health on the measurement of sex, gender identity, and sexual orientation. In March 2022, the Committee published the report "Measuring Sex, Gender Identity and Sexual Orientation."²

11. In 2013, I co-founded Out2Enroll, which is a nationwide nonprofit initiative focused on connecting low- and middle-income LGBT people with health insurance coverage under the Affordable Care Act. Over the last decade, Out2Enroll has provided technical assistance to enrollment organizations, federal and state governments, and other stakeholders on insurance coverage issues related to LGBT populations; trained more than 15,000 enrollment assisters in all 50 states; and conducted annual research on the content of coverage sold through the Health Insurance Marketplaces.

² National Academies of Sciences, Engineering, and Medicine. 2022. Measuring Sex, Gender Identity, and Sexual Orientation. Washington, DC: The National Academies Press. https://doi.org/10.17226/26424.

12. For the last two years, I have been an appointed consumer representative to the National Association of Insurance Commissioners (NAIC), where I bring expert and consumer perspectives to inform the activities and policy positions of the NAIC.

13. I am the author of 22 peer-reviewed journal articles, 42 non-peerreviewed articles and reports, and three book chapters. My peer-reviewed journal articles have been published in high-impact journals such as the *Journal of the American Medical Association, New England Journal of Medicine*, and *American Journal of Public Health*, among others.

14. Among my peer-reviewed publications are the following: "Utilization and Costs of Gender-Affirming Care in a Commercially Insured Transgender Population," published in 2022 in the *Journal of Law, Medicine, and Ethics*; "Health and Health Care Among Transgender Adults in the United States," published in 2021 in the *Annual Review of Public Health*; "Hormone Therapy, Mental Health, and Quality of Life among Transgender People: A Systematic Review," published in 2021 in the *Journal of the Endocrine Society*; "The Future of Transgender Coverage," published in 2017 in the *New England Journal of Medicine*; and "Coverage for Gender Affirmation: Making Health Insurance Work for Transgender Americans," published in 2017 in *LGBT Health*.

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15. I am also a senior researcher with the What We Know Project, a Cornell University–based initiative that conducts scoping reviews of the evidence in relation to complex legal and social issues involving LGBTQ populations in order to present the public and other stakeholders with primary source materials and summary findings. In 2018, I was the lead author of the What We Know Project's review of the effects of gender affirmation on the well-being of transgender people.³

16. This project included a systematic literature review of all peer-reviewed articles published in English between 1991 and June 2017 that assessed the effects of gender-affirming medical care on health-related outcomes among transgender people. We identified 55 studies that consisted of primary research on this topic, of which 51 (93%) found that gender-affirming medical care improves outcomes for transgender people, while 4 (7%) reported mixed or null findings. We found no studies concluding that gender-affirming care causes overall harm.

17. In addition, I am an author of multiple policy statements and technical reports, and I have served as a reviewer for 30 peer-reviewed journals, including the *New England Journal of Medicine, Journal of the American Medical Association*, and *Transgender Health*.

³ What We Know Project. (2018). What Does the Scholarly Research Say About the Effect of Gender Transition on Transgender Wellbeing? Cornell University Center for the Study of Inequality. https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people/

18. I have taught courses in LGBTQ health policy and health equity, as well as given dozens of invited lectures, presentations, keynotes, and plenaries related to health policy, health coverage, health disparities, and transgender health.

19. More detailed information regarding my professional background, experiences, publications, and presentations is outlined in my curriculum vitae, a true and correct copy of which is attached as **Exhibit B**.

B. Prior Testimony

20. I have not testified as an expert at deposition or trial within the last four years.

C. Compensation

21. I am being compensated at an hourly rate of \$200 per hour for preparation of expert declarations and reports and time spent preparing for or giving deposition or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

BASES FOR OPINIONS

22. This report sets forth my opinions in this case and the bases for my opinions.

23. In preparing this report, I reviewed Florida's Administrative Rule governing the determination of generally accepted professional medical standards under Florida Medicaid coverage (Fla. Admin. Code R. 59G-1.035); the text of

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"Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria" ("GAPMS Memo"),⁴ including all attachments; Fla. Admin. Code. R. 59G-1.050(7), which prohibits Medicaid coverage of puberty-delaying medications (commonly referred to as "puberty blockers"), hormone and hormone antagonists, "sex reassignment" surgeries, and any other procedures that alter primary or secondary sexual characteristics, on the basis that the services do not meet Florida's definition of "medical necessity" for purposes of its Medicaid program; and the Complaint in this Case.

24. I also reviewed the materials listed in the attached Bibliography (Exhibit A), as well as the materials listed within my curriculum vitae (attached as Exhibit B). I may rely on those documents as additional support for my opinions.

25. In addition, I have relied on my education, training, and years of professional and research experience, as well as my knowledge of the scientific literature in the pertinent fields.

26. The materials I have relied upon in preparing this declaration are the same types of materials that experts in health and public policy regularly rely upon when forming opinions on this type of subject. I may wish to supplement these

⁴ June 2022. Accessed February 6, 2022. Available at

https://ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf.

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.

TRANSGENDER PEOPLE AND GENDER DYSPHORIA

27. Transgender people are individuals whose gender identity, meaning their innate, deeply seated knowledge of their own gender, is different from that typically associated with the sex they were assigned at birth.⁵

28. There are approximately 1.6 million transgender people in the United States today, comprising approximately 0.6 percent of the U.S. population.⁶ This estimate has remained steady since the authors' initial assessments of this population size in 2016⁷ and 2017.⁸ Compared to the general U.S. population, transgender people are more likely to not have health insurance coverage, to be unemployed and living in poverty, and to have a disability.⁹ Scientific studies consistently identify experiences of discrimination and a lack of access to appropriate medical care as

https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Adults-US-Aug-2016.pdf ⁸ Herman JL, Flores AR, Brown TNT, Wilson BDM, Conron KJ. (2017). *Age of Individuals Who Identify as Transgender in the United States*. Los Angeles: The Williams Institute. https://williamsinstitute.law.ucla.edu/wp-content/uploads/Age-Trans-Individuals-Jan-2017.pdf ⁹ James SE, Herman JL, Rankin S, Keisling M, Mottet L, Anafi M. (2016). *The Report of the 2015 U.S. Transgender Survey*. Washington, DC: National Center for Transgender Equality. https://www.ustranssurvey.org/reports

⁵ National Academies of Sciences, Engineering, and Medicine. (2022). *Measuring Sex, Gender Identity, and Sexual Orientation for the National Institutes of Health*. Washington, DC: National Academies Press.

⁶ Herman JL, Flores AR, O'Neill KK. (2022). *How Many Adults and Youth Identify as Transgender in the United States?* Los Angeles: The Williams Institute.

https://williamsinstitute.law.ucla.edu/publications/trans-adults-united-states/

⁷ Flores AR, Herman JL, Gates GJ, Brown TNT. (2016). *How Many Adults Identify as Transgender in the United States?* Los Angeles: The Williams Institute.

major drivers of these disparities.¹⁰ Because of these systematic and welldocumented gaps in health and overall well-being, the transgender population is designated as a health disparity population by the National Institutes of Health.¹¹

29. Many transgender people seek medical treatment to physically transition from the sex that they were assigned at birth to the sex that aligns with their gender. According to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5-TR), the diagnostic term that describes the medical necessity of transition is gender dysphoria, which refers to the distress and impairment transgender individuals may experience due to a profound misalignment between their gender and their assigned birth sex.¹²

30. Gender dysphoria is recognized as a serious medical condition by major medical associations such as the American Medical Association (AMA), the American Psychiatric Association, and the American Psychological Association, among many others.¹³ A 2008 AMA resolution notes that the consequences of gender dysphoria can include "clinically significant psychological distress,

¹¹ National Institute for Minority Health and Health Disparities. (2016). Sexual and Gender Minorities Formally Designated as a Health Disparity Population for Research Purposes. https://www.nimhd.nih.gov/about/directors-corner/messages/message_10-06-16.html ¹² American Psychiatric Association. (2013). *Diagnostic and Statistical Manual of Mental*

Disorders (5th ed. revised). Arlington, VA: American Psychiatric Publishing.

¹⁰ National Academies of Sciences, Engineering, and Medicine. (2020). *Understanding the Well-Being of LGBTQI+ Populations*. Washington, D.C.: National Academies Press.

¹³ See https://transhealthproject.org/resources/medical-organization-statements/

dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death."¹⁴

31. Treatment for gender dysphoria, which may include mental health counseling, hormone therapy, and surgeries, is provided in the United States by licensed clinicians according to expert standards developed by professional medical associations such as the Endocrine Society¹⁵ and the World Professional Association for Transgender Health (WPATH).¹⁶ Interventions to treat gender dysphoria have been linked to multiple positive health outcomes, including better quality of life; lower rates of mental health conditions such as depression, anxiety, and psychological distress; decrease in or elimination of distress associated with gender dysphoria; and mitigation of stigma and discrimination.¹⁷

INSURANCE COVERAGE OF TREATMENT FOR GENDER DYSPHORIA

32. The first U.S. clinics opened to provide treatment for gender dysphoria

to transgender individuals in the 1960s and 1970s, and the first edition of the

¹⁴ American Medical Association House of Delegates. (2008). Removing Barriers to Care for Transgender Patients. H-185.950 (Res. 122; A-08).

https://www.tgender.net/taw/ama_resolutions.pdf

¹⁵ Hembree WC, Cohen-Kettenis PT, Gooren L, et al. (2017). Endocrine treatment of genderdysphoric/gender-incongruent persons: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*, *102*(11), 3869–903.

¹⁶ Coleman E, Radix AE, Bouman WP, et al. (2022). Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *Int J Transgend Health*, *23*(Suppl 1), S1-S259.

¹⁷ National Academies of Sciences, Engineering, and Medicine. (2020). Understanding the Well-Being of LGBTQI+ Populations. Washington, DC: The National Academies Press.

WPATH Standards of Care was published in 1979.¹⁸ By the late 1970s, nationwide trends favored insurance coverage for treatment of gender dysphoria, particularly through state Medicaid programs.

Private Health Coverage

State-Regulated Individual and Group Coverage

33. In the U.S., the states are the traditional regulators of private insurance coverage sold in the individual, small group, and large group markets. Over the last two decades, many states have required plans under their jurisdiction to remove exclusions of coverage for gender dysphoria.

34. In 2005, California became the first state to prohibit discrimination against transgender individuals by state-regulated individual and group plans by enacting the Insurance Gender Nondiscrimination Act (IGNA), which bans discrimination in health insurance coverage because of gender identity.

35. In 2012, the California Department of Insurance issued a regulation under IGNA defining gender identity discrimination in health insurance coverage to mean "denying or limiting coverage, or denying a claim, for…health care services related to gender transition if coverage is available for those services under the policy when the services are not related to gender transition, including but not limited to

¹⁸ Allee KM. (2009). Harry Benjamin International Gender Dysphoria Association. In *Encyclopedia of gender and society, volume 1* (Ed. J O'Brien). Thousand Oaks, CA: SAGE.

hormone therapy, hysterectomy, mastectomy, and vocal training."¹⁹ Since 2012, 24 other states and the District of Columbia have prohibited exclusions of coverage for gender dysphoria in state-regulated individual and group plans.²⁰

36. Most recently, Colorado added new explicit coverage requirements for plans in its state-regulated individual and small group markets.²¹ Those plans in Colorado are now required to cover the following procedures for transgender people: gender-affirming hormone therapy, chest reconstruction, augmentation mammoplasty, genital surgeries, facial feminization surgeries, and laser or electrolysis hair removal. An actuarial analysis commissioned by the state to assess the cost of these procedures estimated that their long-term steady state cost is 0.04% of total allowed claims.²²

37. Similarly, in 2022, 21 state regulators wrote a joint letter to the U.S. Department of Health and Human Services (HHS) stating, "Transgender people should have equal access to the same health insurance and care as every other insured American. This includes health care related to gender affirmation, which for years

¹⁹ CAL. CODE REGS., tit. 10, § 2561.2(a)(4)(A).

²⁰ LGBT Movement Advancement Project. (2023). Equality Maps.

https://www.lgbtmap.org/equality-maps/healthcare_laws_and_policies/private_insurance ²¹ Keith K. (2021). Unpacking Colorado's New Guidance on Transgender Health. Commonwealth Fund Blog. https://www.commonwealthfund.org/blog/2021/unpackingcolorados-new-guidance-transgender-health

²² Colorado Benchmark Plan for 2023. https://www.cms.gov/files/zip/co-ehb-benchmark.zip

has been recognized by every major U.S. medical society as effective and medically necessary for many individuals."²³

38. In addition to state regulators, insurance carriers themselves have also spoken strongly about their interest in ensuring that transgender enrollees can access treatment for gender dysphoria. In 2022, America's Health Insurance Plans (AHIP), the professional trade association that represents 1,300 member companies that sell health insurance coverage for more than 200 million people nationwide, wrote in a letter to HHS that they "strongly support ensuring that appropriate gender-affirming care is available and accessible to enrollees. We [are committed] to ensuring benefit designs and coverage decisions reflect evidence-based guidelines and recommendations and do not restrict coverage related to gender identity."²⁴

Employer-Sponsored Coverage

39. Employee coverage through large employers in the U.S. is primarily regulated by the federal government under the Employee Retirement Income Security Act (ERISA), though states retain authority over the plans they offer to their employees. The federal government also oversees coverage requirements for federal

²³ Letter from state insurance commissioners to U.S. Department of Health and Human Services Secretary Xavier Becerra. (2022). http://www.insurance.ca.gov/0400-news/0100-pressreleases/2022/upload/joint-Letter-Final_ACA_SECTION_1557_NPRM_sign-on_letter_2022-2.pdf

²⁴ America's Health Insurance Plans. (2022). Letter to Dr. Ellen Montz, Administrator, Center for Consumer Information and Insurance Oversight, U.S. Department of Health and Human Services. https://ahiporg-production.s3.amazonaws.com/documents/AHIP-Letter-to-CMS-on-Nondiscrimination-2.16.22.pdf

employees nationwide through the Federal Employees Health Benefits Program (FEHBP). Trends in employer coverage of treatment for gender dysphoria parallel the expansion of coverage evident in state-regulated individual and group coverage.

40. Among state employee benefit plans, 42 states and territories do not have categorical transgender-specific exclusions in their plans; of these, 24 states and D.C. affirmatively spell out the gender-affirming services that their state employee plans cover.²⁵

41. According to the Corporate Equality Index (CEI), which has tracked the status of private employer-sponsored coverage for treatment of gender dysphoria since 2002, 67 percent of the entire Fortune 500—and 86 percent of all CEI-rated businesses (1,088 of 1,271)—offered employee benefits with no transgender-specific exclusions in 2022.²⁶ In 2015, 54 percent (421 of 781) companies offered at least one fully inclusive plan to their employees, and by 2022 that number had reached 91 percent (1,160 out of 1,271).

42. In 2016, the White House Office of Personnel Management (OPM) required all FEBHP carriers to remove blanket exclusions of services, drugs, or

²⁵ LGBT Movement Advancement Project. (2023). Equality Maps.

https://www.lgbtmap.org/equality-maps/healthcare_laws_and_policies/state_employees. West Virginia's exclusion was recently removed as a result of a settlement agreement.

²⁶ Human Rights Campaign Foundation. (2022). Corporate Equality Index.

https://reports.hrc.org/corporate-equality-index-2022

supplies related to the treatment of gender dysphoria. For plan year 2023, OPM instituted the following requirements for FEHB carriers:²⁷

- a. Have adopted one or more recognized entities in order to guide evidence-based benefits coverage and medical policies pertaining to gender affirming care and services, such as the World Professional Association of Transgender Health (WPATH) Standards of Care, the Endocrine Society, and the Fenway Institute. These entities provide evidence-based clinical guidelines for health professionals to assist transgender and gender diverse people with safe and effective pathways that maximize their overall health, including physical and psychological well-being.
- b. Will provide individuals diagnosed with and/or undergoing evaluation for gender dysphoria the option to use a Care Coordinator to assist and support them as they seek gender-affirming care and services. If network providers are not available to provide medically necessary treatment of gender dysphoria, FEHB Carriers will provide members direction on how to find qualified providers with experience delivering this specialized care.
- c. Have reviewed their formularies to ensure that transgender and gender diverse individuals have equitable access to medications and provide coverage of medically necessary hormonal therapies for gender transition care.

Health Insurance Marketplace Coverage

43. Another major source of individual and small group insurance beyond

traditional state-regulated private markets are the Health Insurance Marketplaces

established by the Patient Protection and Affordable Care Act (ACA), where

²⁷ United States Office of Personnel Management. (2022). Federal Benefits Open Season November 14, 2022 – December 12, 2022.

https://cdn.govexec.com/media/gbc/docs/pdfs_edit/093022ew1.pdf

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income-eligible consumers can purchase plans with government financial subsidies. Approximately one-third of states operate their own Marketplace, while the federal government operates the Marketplace for the remaining states, including Florida, through the HealthCare.gov platform.

44. Since 2017, the Out2Enroll initiative has conducted research on the prevalence of exclusions for gender dysphoria in plans sold through HealthCare.gov. Over the past seven years, this research has documented that the vast majority of plans sold through HealthCare.gov do not have transgender-specific exclusions.²⁸

45. In 2023, for instance, 92% of 1,429 HealthCare.gov plans reviewed from 33 states, including Florida, did not have categorical exclusions of gender dysphoria treatment. Almost half (47%) of all plans reviewed explicitly stated that medically necessary treatment for gender dysphoria is covered.

46. Of the eight carriers selling coverage through HealthCare.gov in Florida, seven (88%) expressly cover medical care related to gender affirmation. The remaining carrier excludes coverage only for some gender-affirming services, and no carriers offer plans with categorical exclusions of the type established in Fla. Admin. Code R. 59G-1.035.²⁹

²⁸ Out2Enroll. (2022). Summary of Findings: 2023 Marketplace Plan Compliance with Section 1557 of the Affordable Care Act. https://out2enroll.org/2023-cocs/

²⁹ Out2Enroll. (2022). Transgender Health Insurance Guide to the Marketplace: Florida. https://drive.google.com/file/d/1XliTnjuwi_6pCQuOj3Nm9vlGalAdTOaE/view

Public Health Coverage

Medicare

47. An exclusion of Medicare coverage for "transsexual surgery" was introduced in 1981 and codified in a 1989 National Coverage Determination. In 2014, the HHS Departmental Appeals Board (DAB) ruled that this exclusion of treatment for gender dysphoria was invalid on the grounds that it was based on outdated evidence that was not complete or adequate to support the determination that this treatment was never medically necessary.³⁰

48. In its ruling, the DAB rejected the assertion that gender-affirming surgeries are "experimental" and "controversial," finding instead that current evidence "indicates a consensus among researchers and mainstream medical organizations that transsexual surgery is an effective, safe and medically necessary treatment for transsexualism." Following the rescinding of the exclusion, Medicare covers surgeries and other gender-affirming care for transgender individuals according to case-by-case assessments of medical necessity.

49. An example of this coverage policy in practice is a 2016 ruling by the Medicare Appeals Council ("the Council"), which is part of the DAB, finding that a Medicare Advantage plan's decision to deny coverage for gender-affirming surgery

³⁰ Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Div., Decision No. 2676 (May 30, 2014), hhs.gov/sites/default/files/static/dab/decisions/board-decisions/2014/dab2576.pdf.

to a transgender Medicare beneficiary did not comport with Medicare's statutory "reasonable and necessary" coverage criterion.³¹

50. The Council asserted that the WPATH Standards of Care are "reasonable guidelines to determine medical necessity" and found that, inasmuch as the enrollee "satisfies all of the WPATH clinical requirements for gender reassignment surgery...the requested vaginoplasty is medically reasonable and necessary for treatment of this enrollee's gender dysphoria under Section 1862(a)(1)(A) of the [Social Security] Act and is covered under existing [Centers for Medicare & Medicaid Services] guidance."

Medicaid

51. Medicaid coverage for gender-affirming care predates the first iteration of WPATH's Standards of Care. For example, Medicaid coverage for such care in California can be documented as far back as the 1970s. In a pair of cases decided in 1978 (*J.D. v. Lackner* and *G.B. v. Lackner*) pertaining to Medicaid coverage of vaginoplasty for transgender women, a California court found that the plaintiff "has an illness and … as far as her illness affects her, the proposed surgery is medically reasonable and necessary and…there is no other effective treatment method." The judges further asserted that "the proposed surgery is medically reasonable and

³¹ In the Case of United Health Care / AARP Medicare Complete, No. M-15-1069 at 8 (Jan. 21, 2016), https://www.hhs.gov/sites/default/files/static/dab/decisions/council-decisions/m-15-1069.pdf.

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necessary" and should thus be covered by Medicaid, and they added that "we do not believe, by the wildest stretch of the imagination, that such surgery can reasonably and logically be characterized as cosmetic."

52. Other states likewise provided Medicaid coverage for gender-affirming care as far back as the 1970s and 1980s.³² When the federal Medicare program instituted its exclusion in 1981, however, many Medicaid programs followed suit.

53. Beginning in the early 2000s and over the course of the next 20 years, categorical exclusions of coverage in many state Medicaid programs began to be removed—whether administratively, by statute, or after court orders—in response to successive iterations of the standards of care and increasingly sophisticated clinical practice guidelines for the treatment of gender dysphoria.

54. As of present, the overwhelming majority of states do not exclude coverage of gender-affirming care from Medicaid. As of early 2023, 47 states and territories, as well as D.C., no longer have categorical exclusions of gender dysphoria treatment in their Medicaid programs. Of these, 27 states and D.C. explicitly and affirmatively delineate coverage of a range of gender-affirming services.

³² See, e.g., *Pinneke v. Preisser*, 623 F.2d 546 (8th Cir. 1980) (pertaining to Iowa's Medicaid program); *Doe v. State, Dep't of Pub. Welfare*, 257 N.W.2d 816 (Minn. 1977) (pertaining to Minnesota's Medicaid program).

55. The GAPMS Memo outlines that there are eight states that explicitly ban coverage for treatment of gender dysphoria. However, these limitations are typically not as broad or all-encompassing as Fla. Admin. Code. R. 59G-1.050(7). For example, the exclusions in Missouri, Nebraska, and Texas are limited to surgery and do not extend to coverage for puberty delay medications and hormone therapy, while the exclusion in Arkansas is limited to minors.³³ Meanwhile, the exclusion in Ohio appears to be inoperative, as officials in Ohio do not appear to be enforcing the exclusion and managed care organizations operating under Ohio's Medicaid program have clinical policy guidelines for covering gender-affirming care; thus, the scope of coverage is unclear. Finally, the GAPMS Memo erroneously states that Georgia excludes coverage of gender-affirming care in Medicaid.

56. Taking stock of Medicaid coverage policies requires assessment not just of a state's regulations and statutes, but also operative guidance, managed care organizations' policies, and relevant administrative and court decisions in the state.

57. When one does so, Florida stands apart as one of less than a handful of states with exclusions of similar breadth and scope among the 56 jurisdictions in the United States that operate Medicaid programs (i.e., the 50 states, five U.S. territories, and D.C.). Florida's recently adopted exclusion therefore runs counter to the clear and overwhelming trend among Medicaid programs to remove such exclusions and, as

³³ Ark. Code § 20-9-1503(d).

outlined further below, to affirmatively provide guidance on coverage for treatment of gender dysphoria.

58. Some states have recently explicitly broadened and clarified the scope of Medicaid coverage for gender dysphoria. In Washington State, for instance, 2021 legislation codified that the state's Medicaid program covers a range of "surgical and ancillary services," as well as puberty-delaying medications, for transgender people.³⁴ The legislation indicates that the list of covered services is not exhaustive and requires that a "health care provider with experience prescribing and/or delivering gender affirming treatment must review and confirm the appropriateness of any adverse benefit determination.³⁵

COSTS AND UTILIZATION OF TREATMENT FOR GENDER DYSPHORIA

59. While the number of people with transgender-specific diagnostic codes in commercial insurance claims databases has increased over the last decade, the increase is attributable to national policy trends that have made coverage for genderaffirming care more accessible. As such, more transgender people are now able to access coverage for treatment of gender dysphoria, and more providers are able to appropriately code for these encounters without triggering coverage exclusions.

³⁴ Washington State Legislature. SB 5313 (2021-2022).

https://app.leg.wa.gov/billsummary?BillNumber=5313&Initiative=false&Year=2021 ³⁵ Washington State Healthcare Authority. (2022). Transhealth Program. https://www.hca.wa.gov/billers-providers-partners/programs-and-services/transhealth-program

60. Even as coverage has become more accessible, utilization rates remain low. Moreover, evidence indicates that insurance coverage of treatment for gender dysphoria is low-cost and highly cost-effective. The impact of gender-affirming care on payer budgets has thus remained nominal even as coverage has become more available, standardized, and routine.

61. A California Department of Insurance assessment of IGNA, the state law that broadly prohibited insurance discrimination against transgender beneficiaries, for instance, showed that a major state university-sponsored plan had a utilization rate of only 0.062 per 1,000 covered persons for this care over the 6.5 years following the law's enactment; across the state, impacts on premium costs were "immaterial," leading the Department to conclude that "the benefits of eliminating discrimination far exceed the insignificant costs."³⁶

62. A 2016 economic model evaluating the cost-effectiveness of care for transgender men that included hormone replacement therapy, mastectomy, abdominoplasty, hysterectomy, genital reconstruction, and other services underscores this conclusion, finding that the incremental cost-effectiveness ratio

³⁶ State of California Department of Insurance. (2012). Economic Impact Assessment: Gender Nondiscrimination in Health Insurance. http://transgenderlawcenter.org/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf

(ICER) of these services was less than \$8,000 per quality-adjusted life year (QALY) gained over a ten-year time horizon.³⁷

63. This is far below a typical U.S. "willingness to pay" threshold of \$100,000 per QALY.³⁸ This study also found that, on a per member per month (PMPM) basis, coverage of surgical and other services for transgender men and women together cost \$0.016.

64. My own recent research indicates that each covered transgender person in a major national commercial insurance database incurred an average of less than \$1,800 in costs per year for hormone therapy (including puberty delay medications) and surgeries (including facial surgeries) combined to treat gender dysphoria.³⁹ Considered on a PMPM basis, the budget impact of covering this care was \$0.73 per year, or \$0.06 PMPM.

³⁷ Padula, W. V., Heru, S., & Campbell, J. D. (2016). Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis. Journal of General Internal Medicine, 31(4), 394–401. https://doi.org/10.1007/s11606-015-3529-6

³⁸ Cameron, D., Ubels, J., & Norström, F. (2018). On what basis are medical cost-effectiveness thresholds set? Clashing opinions and an absence of data: a systematic review. Global health action, 11(1), 1447828. https://doi.org/10.1080/16549716.2018.1447828

³⁹ Baker, K., & Restar, A. (2022). Utilization and Costs of Gender-Affirming Care in a Commercially Insured Transgender Population. Journal of Law, Medicine & Ethics, 50(3), 456-470. doi:10.1017/jme.2022.87

65. Similarly, an actuarial assessment conducted for the North Carolina State Health Plan estimated a PMPM cost range of \$0.06-\$0.15 (0.011% to 0.027% of premiums).⁴⁰

66. Estimates from other states show equally low utilization and related low costs, with Alaska estimating that coverage for gender dysphoria would result in increases of 0.03% to 0.04% of total costs for its state employee plan⁴¹ and Wisconsin noting costs to its state employee plan are "immaterial, since it represents less than 0.1% of the overall costs of medical care."⁴²

67. Cost estimates of coverage for gender-affirming care under Wisconsin Medicaid were "actuarially immaterial, as they are equal to approximately 0.008% to 0.03%" of Wisconsin's share of its Medicaid budget.⁴³

68. An analysis in the military context concluded that the cost of covering gender-affirming care was "too low to matter"⁴⁴ or, as military leadership noted, "'budget dust,' hardly even a rounding error.⁴⁵

https://www.shpnc.org/media/22/download

⁴¹ Plaintiffs' Motion for Partial Summary Judgment, Fletcher v. Alaska, No. 1:18-cv-00007-HRH (D. Alaska July 1, 2019), https://www.lambdalegal.org/sites/default/files/legaldocs/downloads/fletcher_ak_20190701_plaintiffs-motion-for-partial-summary-judgment.pdf.

⁴⁰ Schatten, K. R., & Viera, K. C. (2016). Memorandum to Mona Moon, Administrator, North Carolina State Health Plan, re: Transgender Cost Estimate.

⁴² Boyden v. Conlin, 341 F. Supp. 3d 979, 1000 (W.D. Wis. 2018).

⁴³ Flack v. Wis. Dept of Health Servs., 395 F. Supp. 3d 1001, 1008 (W.D. Wis. 2019).

 ⁴⁴ Belkin A. (2015). Caring for our transgender troops – The negligible cost of transition-related care. *New Eng J Med*, *373*, 1089–1092. https://www.nejm.org/doi/full/10.1056/NEJMp1509230
⁴⁵ Declaration of Raymond Edwin Mabus, Jr., Former U.S. Secretary of the Navy, in Support of Plaintiff's Motion for Preliminary Injunction, Doe v. Trump, No. 17-cv-1597-CKK (D.D.C.) filed Aug. 31, 2017, at 41). http://files.eqcf.org/wp-content/uploads/2017/09/13-Ps-App-PI.pdf

69. Overall, the actuarial evidence indicates that gender-affirming care is not expensive when considered from a payer or societal perspective, but it can easily be beyond the individual reach of transgender people, particularly those who rely on public coverage programs such as Medicaid.

CONCLUSION

70. The transgender population, at a steady 0.6% of the U.S. population, is a small and medically vulnerable population for whom decades of scientific research and medical practice have established a robust consensus on the appropriateness of gender-affirming care. Over the last 20 years, state regulators, Medicaid programs, insurance carriers, and employers have increasingly taken affirmative action to ensure that transgender people do not face barriers to coverage for the medically necessary treatment of gender dysphoria. The exclusion recently instituted at Fla. Admin. Code. R. 59G-1.050(7) thus is both out-of-step with expert medical standards used by both public and private health insurance programs and runs counter to prevailing nationwide trends in every form of insurance, including Medicaid, Medicare, and private coverage. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 17th day of February 2023.

mu p _____

KELLAN E. BAKER, MA, MPH, PhD

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Effect of Gender Transition on Transgender Wellbeing? Cornell University
Center for the Study of Inequality.

https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-
the-scholarly-research-say-about-the-well-being-of-transgender-people/.

EXHIBIT B

KELLAN E. BAKER, PhD, MPH, MA

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EDUCATION

Johns Hopkins Bloomberg School of Public Health Doctor of Philosophy in Health Policy and Management Concentration in Health Services Research and Policy <u>Dissertation</u> : Clinically Documented Social Risk Factors, Health Care Utilization, and Expenditures in a Commercially Insured Transgender Population Activities: Centennial Scholar, Health Policy Research Scholar, Gordis Teaching Fellow	2016-2021
Johns Hopkins Bloomberg School of Public Health Certificate in Public Health Economics	2016-2019
Johns Hopkins Carey Business School Executive Certificate in Health Care Leadership and Management	2018
University of the South School of Theology Certificate in Theological Education	2008-2012
George Washington University School of Public Health and Health Services Master of Public Health Concentration in Global Public Health Policy <u>Thesis</u> : <i>Transforming Health: International Rights-Based Advocacy for Transgender Health</i> <u>Activities</u> : Delta Omega Public Health Honors Society	2008-2011
George Washington University Elliott School of International Affairs Master of Arts in International Development Thesis: Security, Development, and Sexual and Gender-Based Violence in Conflict Settings	2008-2011
Diplomatic Academy of Vienna Graduate study in International Economics	2007-2008
University of Vienna Certificate of Advanced Proficiency in German Language	2007-2008
Swarthmore College Bachelor of Arts with High Honors in Astrophysics and Russian Literature Activities: External Honors Program	2000-2004

PROFESSIONAL EXPERIENCE

Whitman-Walker Institute

Executive Director and Chief Learning Officer

- Lead the research, policy, and education activities of Whitman-Walker, a community health system in Washington, DC that also includes Whitman-Walker Health, a Federally Qualified Health Center with 50+ years of experience serving diverse patient populations across the DC metro area, with a particular focus on people living with HIV and sexual and gender minority populations.
- Oversee daily operations for the Institute, including personnel, grants management, financial reporting and fiscal accountability, strategic planning, quality assurance for training and research activities, and development of internal and external partnerships.
- Oversee a 55-person team of researchers, policy analysts, and administrative staff in conducting epidemiologic, econometric, clinical, and policy research; translating research findings into policy, practice, and programming recommendations; and advancing methodology for research centering the impact of structural factors on individual and population health.
- Partner with clinicians and clinic management at Whitman-Walker on health services research using clinical data for quality assessment and practice improvement.
- Represent Whitman-Walker in interactions with media, government, academic institutions, public and private payers, professional societies, community members, and other stakeholders.

2021-present
Johns Hopkins School of Public Health Affiliate Faculty, Department of Health Policy and Management	2021-present
George Washington University School of Public Health and Health Services Affiliate Faculty, Department of Health Policy and Management	2021-present
 National Academy of Sciences, Division of Behavioral and Social Sciences and Education <i>Consultant</i> Advised the Committee on Population on the development, funding, and coordination of a consensus study project on health and other domains of well-being in sexual and gender diverse populations 	2019-2021
 Authored and edited report components related to physical and mental health; health services access and use; health policy; data collection; and demography. Led report dissemination to policy, academic, medical, media, and community audiences. 	
Johns Hopkins Evidence-Based Practice Center Research Associate	2018-2021
Designed and conducted systematic reviews to support the revision of the leading expert treatment guidelines in the field of transgender health.	
Cornell University Center for the Study of Inequality Senior Researcher Designed and conducted systematic reviews of social inequality and health policy issues	2017-2019
Johns Hopkins School of Public Health, Department of Epidemiology	
Research Associate Built economic models assessing the cost-effectiveness of integrating HIV testing, prevention, and treatment into primary care in low-resource settings.	2017-2018
Center for American Progress Senior Fellow	2014-2017
 Designed and implemented strategies to advance policy goals around health equity, Affordable Care Act (ACA) implementation, health system transformation, health insurance reform, appropriations and budget, nondiscrimination, and data collection and research at all levels of government and with hospitals, health insurance carriers, and other private stakeholders. With Fenway Community Health, co-founded and directed a project that secured new data elements in the federal regulations governing the Meaningful Use of Electronic Health Records program. Coordinated and represented coalitions of diverse organizations focusing on civil rights, health care, and public health in regulatory and legislative policymaking activities with decisionmakers and staff at all levels of government. 	2011 2017
 Developed and published original research, policy analyses, and policy and practice recommendations for audiences such as the White House, the federal agencies, the Presidential Advisory Council on HIV/AIDS, congressional and other legislative staff, state and local health departments, and state and federal insurance regulators. Regularly quoted and published in venues such as <i>Washington Post</i>, <i>New York Times</i>, <i>Reuters</i>, <i>Time</i>, 	
Scientific American, US News and World Report, and National Public Radio.	
 Out2Enroll Founding Steering Committee Member Conceived and co-led Out2Enroll, a \$1-million national communications, training, and policy partnership with the U.S. Department of Health & Human Services (HHS) and the White House to connect low-income sexual and gender minority people with insurance coverage under the ACA. Managed strategic and daily operations, including overseeing a coalition of more than 70 partners, developing communications strategies, fundraising, and grants management. Created the training "Reaching and Assisting LGBT Communities" (in-person and online) and trained more than 15,000 enrollment assisters in all 50 states, the US territories, and Washington, DC. At the request of the HHS Office for Civil Rights, created and presented trainings on the ACA and civil rights to the HHS Regional Offices. 	2013-2017
 Associate Director Led the health policy portfolio of the Federal Agencies Project, a national funder collaborative pursuing health reform and health equity objectives via federal regulatory policy. Managed a staff of research and policy analysts. 	2013-2014

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Senior Policy AnalystConducted policy analyses and wrote reports, memos, regulatory comments, and media pieces on	2011-2013
 issues such as health reform, HIV/AIDS, health disparities, and health information technology. Created and oversaw the LGBT State Exchanges Project, a training and technical assistance partnership with five states to address coverage gaps through the implementation of the ACA. 	
Astraea Lesbian Foundation for Justice	
<i>Consultant</i> Managed strategic planning activities of the Global Philanthropy Project, a group of 15 international funders supporting the human rights of sexual and gender minorities.	2014
Kaiser Foundation Health Plan	
Consultant	2013-2014
Advised on the development of Kaiser's industry-leading LGBTI Health Equity Program.	
The Joint Commission	
Consultant	2010
Co-authored "Advancing Effective Communication, Cultural Competence, and Patient- and Family- Centered Care for the LGBT Community: A Field Guide."	
Open Society Foundations	2010 2012
Consultant Authored "Transforming Health: International Rights-Based Advocacy for Trans Health," featuring case studies from nine countries and the World Health Organization.	2010-2013
Danish Refugee Council	
<i>Fellow</i> Conducted French-language focus group research in the Central African Republic and wrote a needs assessment about addressing sexual and gender-based violence in conflict situations.	2010
National Coalition for LGBT Health	
Policy Analyst	2009-2011
In coordination with 75 member organizations in 22 states and other stakeholders, developed and implemented a national policy strategy for advancing LGBT health equity.	
The White House	
Intern	2009
Staffed the Special Assistant to the President for Disability Policy.	
Wonder Sprachinstitut (Vienna, Austria)	2007 2000
TOEFL Preparation Instructor Taught beginning and advanced English	2007-2008
Vienna University of Economics and Proinces (Vienna, Austria)	
Executive MBA Program Tutor	2007-2008
Tutored students on English and economics topics.	2007 2000
Kommersant Newspaper (Moscow, Russia)	
Russian–English Translator	2006-2007
Translated international news, politics, business, and editorial content for a leading daily newspaper.	
Nauka/Interperiodica (Moscow, Russia)	
Russian–English Translation Editor	2004-2005
Edited translated scientific journal articles in the areas of physics, chemistry, geology, and biology under a contract with the Russian Academy of Sciences.	

SERVICE TO PROFESSIONAL ORGANIZATIONS

National Institutes of Health Appointed Member, Sexual and Gender Minority Working Group of the NIH Council of Councils	2022-present
Public Health AmeriCorps Member, Technical Working Group for National Process, Outcomes, and Impact Evaluation	2022-present
AcademyHealth Member, Advisory Group on Health Services Research Innovation, Inclusion, and Impact	2022-present

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UnitedHealthcare Member, Ambassadors for the Community (health equity initiative focused on dual eligibles in DC)	2022-present
Personalized Medicine Coalition Member, Health Equity Task Force	2022-present
National Association of Insurance Commissioners Appointed Consumer Representative	2022-present
California Health Interview Survey Member, Sexual Orientation and Gender Identity Working Group	2022-present
National Academies of Sciences, Engineering, and Medicine Appointed Member, Consensus Study Committee on Measuring Sex, Gender Identity, and Sexual Orientation for the National Institutes of Health	2021-present
Agency for Healthcare Research and Quality Invited Participant, AHRQ Health Equity Summits	2021-present
National Institutes of Health, Inter-Society Coordinating Committee for Practitioner Education in Genomics	2021-present
Founder and Co-Chair, Project on LGBTQI+ Issues in Genomics and Genomics Education	
European Research Council Grant Reviewer	2021-present
National Academies of Sciences, Engineering, and Medicine Partner, Assessing Meaningful Community Engagement in Health & Health Care Leadership Consortium	2021-present
AcademyHealth Appointed Member, National Advisory Group on Diversity, Equity, and Inclusion	2020-present
Harvard Medical School Professional Advisory Council Member, Sexual and Gender Minority Health Equity Initiative	2020-present
National Center for Transgender Equality Scientific Advisory Council Member, 2022 US Transgender Survey	2019-present
National Institutes of Health Community Engagement Working Group Member, National Human Genome Research Institute	2016-present
American Councils for International Education Flagship Program Orientation Facilitator (Russia, Kazakhstan, Azerbaijan, Tajikistan)	2016-present
Equality Federation Board of Directors (current Immediate Past Chair, past Treasurer)	2015-present
TEDMED Invited Health Equity Expert	2020
Biden-Harris Presidential Campaign Equity Review Board Member, Health Policy Committee	2020
Biden-Harris Presidential Campaign Co-Chair, LGBTO Health Policy Committee	2020
Congressional Tri-Caucus, Families USA, and UnidosUS Steering Committee Member, Health Equity and Accountability Act	2016-2020
10.10.10 Cities: Health Social Entrepreneurship Program Health Start-Up Team "Ninja"	2019
Community Catalyst and the Robert Wood Johnson Foundation National Advisory Council Member, Consumer Advocacy for Health System Transformation	2017-2019
Gilead Sciences Transgender Advisory Council Member	2017-2019
American Association for the Advancement of Science Selection Committee Member, Executive Branch Science and Technology Policy Fellowship	2016-2019
Centers for Medicare & Medicaid Services, U.S. Department of Health & Human Services Appointed Member, Advisory Panel on Outreach and Education	2014-2019

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National Academies of Sciences, Engineering, and Medicine Steering Committee Member, Project on Demography of Sexual and Gender Minority Populations	2017-2018
Johns Hopkins Bloomberg School of Public Health Member, Schoolwide Honors and Awards Committee	2018
National Institutes of Health Invited Participant, Expert Workshop on Methods in Sexual & Gender Minority Health Research	2018
Johns Hopkins Medicine and Harvard University School of Medicine Member, EQUALITY Study Stakeholder Advisory Board	2013-2018
Robert Wood Johnson Foundation Application Reviewer, Culture of Health Program	2017
U.S. Professional Association for Transgender Health Scientific Program Committee Member, Inaugural USPATH Scientific Conference	2016-2017
AcademyHealth Advisory Council Member and Grant Reviewer, Community Health Peer Learning Program	2015-2017
Center for Consumer Information & Insurance Oversight, U.S. Department of Health & Human Services Grant Reviewer, HealthCare.gov Enrollment Navigator Program	2015
Robert Carr Civil Society Networks Grant Reviewer	2015
University of California at San Francisco Center of Excellence for Transgender Health Policy Track Co-Chair, National Transgender Health Summit	2013, 2015
National Action Alliance for Suicide Prevention Member, LGBT Task Force	2012
The Fenway Institute Affiliated Faculty for LGBT Health Policy	2011-2016
U.S. Department of State National Security Language Initiative for Youth Program Orientation Facilitator (Russia)	2009-2013
The DC Center for the LGBT Community Board of Directors (DC for Marriage Campaign Co-Chair)	2009-2011

OTHER PROFESSIONAL ACTIVITIES

Ad Hoc Journal Reviews

- New England Journal of Medicine
- Journal of the American Medical Association
- JAMA Psychiatry
- JAMA Internal Medicine
- Health Affairs
- American Journal of Public Health
- Journal of the American Medical Informatics Association
- Medical Informatics
- Milbank Quarterly
- Journal of Official Statistics
- Social Science & Medicine
- American Journal of Epidemiology
- American Journal of Preventive Medicine
- Preventive Medicine
- Quality of Life Research

- Sexuality Research and Social Policy
- Sexual and Reproductive Health Matters
- Journal of Homosexuality
- Journal of Public Health Dentistry
- Frontiers in Oncology
- Psychology of Sexual Orientation and Gender Diversity
- LGBT Health
- Transgender Health
- BMC Health Services Research
- Family Practice
- Journal of Patient Safety and Risk Management
- Progress in Community Health Partnerships: Research, Education, and Action
- Media and Communication
- Patient Education & Counseling
- The Physician and Sports Medicine

Memberships

- DC Center for AIDS Research (2021-present)
- Johns Hopkins Center for AIDS Research (2020-present)
- Association for Public Policy Analysis and Management (2018-present)
- International Society for Pharmacoeconomics and Outcomes Research (2018-present)
- World Professional Association for Transgender Health (2018-present)
- Society for Medical Decision Making (2017-present)
- AcademyHealth (2012-present)
- American Public Health Association (2009-present)

Conference Abstract Reviews

- International Society for Pharmacoeconomics and Outcomes Research
- AcademyHealth (theme reviewer for "Disparities and Health Equity" track)
- American Public Health Association
- Society for Medical Decision Making
- U.S. Professional Association for Transgender Health

HONORS AND AWARDS

First Place, Research and OptumLabs	l Translation Virtual Ideas Exchange Competition	2020
Golden Apple Award for P Public Health Studies Progr Awarded for the class "Policy, F	Excellence in Teaching ram, Johns Hopkins University <i>Politics, and Power in Health Equity," designed through the Gordis Teaching Fellowsh</i>	2020
Alice S. Hersh Scholarshi AcademyHealth	ip	2020
Victor P. Raymond Mem Department of Health Police	orial Fund Award cy and Management, Johns Hopkins Bloomberg School of Public Health	2019
Delta Omega Policy and Johns Hopkins Bloomberg	Practice Scholarship Award School of Public Health	2019
Out to Innovate Award National Organization of G	Gay & Lesbian Scientists and Technical Professionals	2019
Distinguished Service Aw 10.10.10 Cities: Health	vard	2019
Science Writing Fellowsh Johns Hopkins Bloomberg	iip School of Public Health	2019
Gordis Teaching Fellows Public Health Studies Progr	h ip ram, Johns Hopkins University	2018
Health Policy Research S Robert Wood Johnson Fou Health Policy Research Scholars underrepresented in graduate pro	Scholarship undation s is a national leadership program that invests in scholars from populations traditional grams whose work will inform and influence policy for building a Culture of Health	2017 Ży
Featured Speaker National March for Science	e (Washington, DC)	2017
Centennial Scholarship Department of Health Polic <i>Awarded to the outstanding ente</i>	cy and Management, Johns Hopkins Bloomberg School of Public Health ering doctoral student in each department to mark the school's centennial in 2016	2016
Achievement Award GLMA: Health Professiona	als Advancing LGBT Equality	2015
Curriculum Vitae	Baker, Kellan E. (2023)	Page 6 of 23

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Andrew Cray Memorial Transgender Health Advocacy Award National Center for Transgender Equality	2015
LGBTQ Leadership Fellowship The Rockwood Institute	2011-2012
Delta Omega Public Health Honors Society George Washington University School of Public Health and Health Sciences	2010
Eric Rofes Memorial Scholarship National Gay & Lesbian Task Force	2009
High Honors Swarthmore College Honors Program	2004

PUBLICATIONS

Journal Articles (Peer-Reviewed)

- Baker KE, Restar A. (2022). Utilization and Costs of Gender-Affirming Care in a Commercially Insured Transgender Population. J Law Med Ethics, 50, 456–470.
- Baker KE, Compton D, Fechter-Leggett ED, Grasso C, Kronk CA. (2022). Will clinical standards not be part of the choir? Harmonization between the HL7 gender harmony project model and the NASEM measuring sex, gender identity, and sexual orientation report in the United States. *JAMLA*, 30(1), 83–93.
- Restar A, Dusic E, Garrison-Desany H, Lett E, Everhart A, **Baker KE**, Scheim A, Beckham SW, Reisner S, Rose A, Mimiaga M, Radix A, Operario D, Hughto J. (2022) Gender Affirming Hormone Therapy Dosing Behaviors among Transgender and Nonbinary Adults. *Humanit Soc Sci Commun, 9*(304).
- Tran NK, Baker KE, Lett E, Scheim AI. (2022). State-level heterogeneity in associations between structural stigma and individual healthcare access: A multilevel analysis of transgender adults in the United States. J Health Serv Res Policy. doi:10.1177/13558196221123413.
- Scheim AI, **Baker KE**, Restar AJ, Sell RL. (2021). Health and Health Care Among Transgender Adults in the United States. *Annual Review of Public Health*. doi:10.1146/annurev-publhealth-052620-100313
- Restar A, Garrison-Desany HM, Baker KE, Adamson T, Howell S, Baral SD, Operario D, Beckham W. (2021). Prevalence and associations of COVID-19 testing in an online sample of transgender and non-binary individuals. *British Medical Journal - Global Health*, 6, e006808.
- **Baker KE**, Durso LE, Streed CG. (2021). Ensuring that LGBTQI+ People Count: Collecting Data on Sexual Orientation, Gender Identity, and Intersex Status. *New England J Med*, *384*, 1184–1186.
- **Baker KE**, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. (2021). Hormone Therapy, Mental Health, and Quality of Life among Transgender People: A Systematic Review. *J Endocr Soc*, *5*(4), bvab001.
- Wiegmann AL, Young EI, **Baker KE**, Khalid SI, Shenaq DS, Dorafshar AH, Schechter LS. (2021). The Affordable Care Act and Its Impact on Plastic and Gender-Affirmation Surgery. *Plastic Reconstr Surg*, 147(1), 135e–153e.
- **Baker KE**, Harris AC. (2020). Terminology should accurately reflect complexities of sexual orientation and identity. *Am J Public Health*, 110(11), 1668–1669.
- Lett E, Dowshen NL, **Baker KE**. (2020). Intersectionality and Health Inequities for Gender Minority Blacks in the U.S. *Am J Prev Med*, *59*(5), 639–647.
- Wilson LM, Baker KE, Sharma R, Dukhanin V, McArthur K, Robinson KA. (2020). Effects of antiandrogens on prolactin levels among transgender women on estrogen therapy: A systematic review. Int J Transgend Health, 21(4), 391–402.
- Baker KE. (2019). Findings from the Behavioral Risk Factor Surveillance System on Health-Related Quality of Life among U.S. Transgender Adults, 2014-2017. JAMA Intern Med, 179(8), 1141–1144.
- Tabaac AR, Sutter ME, Wall CSJ, **Baker KE**. (2018). Gender Identity Disparities in Cancer Screening. *Am J Prev Med*, 54(3), 385–393.

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- Baker KE. (2017). The Future of Transgender Coverage. New England J Med, 376(19), 1801–1804.
- Padula WV, **Baker KE**. (2017). Coverage for Gender Affirmation: Making Health Insurance Work for Transgender Americans. *LGBT Health*, 4(4), 244–247.
- Cahill S, **Baker KE**, Deutsch MB, Keatley J, Makadon HJ. (2016). Inclusion of Sexual Orientation and Gender Identity in Stage 3 Meaningful Use Guidelines: A Huge Step Forward for LGBT Health. *LGBT Health*, *3*(2), 100–102.
- Reisner SL, Conron KJ, Scout Nfn, **Baker KE**, et al. (2015). Counting transgender and gender nonconforming adults in health research: Recommendations from the Gender Identity in U.S. Surveillance (GenIUSS) Group. *Transgender Studies Quarterly*, 2(1), 34–57.
- Cahill S, Singal R, Grasso C, King D, Mayer K, **Baker KE**, Makadon H. (2014). Do ask, do tell: High levels of acceptability by patients of routine collection of sexual orientation and gender identity data in four diverse American community health centers. *PLaS ONE*, *9*(9), e107104.
- Baker KE, Minter S, Wertz K. (2012). Nondiscrimination in Insurance: The Case of California's Insurance Gender Nondiscrimination Act. *Harvard University LGBTQ Policy Journal, 2*.
- Baker KE. (2012). Where Do We Go from Here: LGBT-Inclusive Health Policy in Affordable Care Act Implementation. *Harvard University LGBTQ Policy Journal*, 2.
- Baker KE, Krehely J. (2011). How Health Care Reform Will Help LGBT Elders. Public Policy & Aging Report, 21(3), 19–23.

Book Chapters

- Baker KE. (2019). The Politics of LGBT Health. In: Schneider JS and V Silenzio, eds. *Gay & Lesbian Medical Association Handbook on LGBT Health.* Washington, DC: ABC-CLIO Press.
- Bau I and **Baker KE**. (2016). Legal and Policy Issues in LGBTI Health. In: Ehrenfeld J and K Eckstrand, eds. *Lesbian, Gay, Bisexual, Transgender, and Intersex Healthcare: A Clinical Guide to Preventative, Primary, and Specialist Care.* Nashville: Vanderbilt University Press.
- Baker KE. (2011). Data Collection and Use. In: The Joint Commission. Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the LGBT Community: A Field Guide. Oakbrook Terrace, IL: The Joint Commission. Available at: www.jointcommission.org/assets/1/18/LGBTFieldGuide.pdf

Reports, Issue Briefs, Articles, and Editorials

- Organizing Committee for Assessing Meaningful Community Engagement in Health & Health Care Programs & Policies. (2022). Assessing Meaningful Community Engagement: A Conceptual Model to Advance Health Equity through Transformed Systems for Health. *NAM Perspectives.* Commentary, National Academy of Medicine, Washington, DC. https://doi.org/10.31478/202202c
- Frank NF, **Baker KE**. (2019). Anti-LGBT Discrimination Has a Huge Human Toll. Research Proves It. *Washington Post*. Available at: www.washingtonpost.com/outlook/2019/12/19/anti-lgbt-discrimination-has-huge-human-toll-research-proves-it/
- What We Know Project. (2019). What Does the Scholarly Research Say About the Effects of Discrimination on the Health of LGBT People? Cornell University Center for the Study of Inequality. Available at: https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-scholarly-research-say-about-the-effects-of-discrimination-on-the-health-of-lgbt-people/
- What We Know Project. (2018). What Does the Scholarly Research Say About the Effect of Gender Transition on Transgender Wellbeing? Cornell University Center for the Study of Inequality. Available at: https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people/
- **Baker KE**, Keisling MR. (2018). Two Transgender Advocates Explain Why They're Marching for Science. *Scientific American*. Available at: https://blogs.scientificamerican.com/voices/2-transgender-activists-explain-why-theyre-marching-for-science/
- **Baker KE**. (2017). Trans People in the Health Reform Fight: What's at Stake. *TheBody.com*. Available at: www.thebody.com/content/80046/trans-people-in-the-health-reform-fight-whats-at-s.html

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GRANT SUPPORT

DC Center for AIDS Research Developing Best Practices for Integrating HIV Prevention into Gender-Affirming Care for Transgender Adults <u>Amount</u> : \$49,961 Role: Principal Investigator	2022-2023
Wellspring Advisors Conducting nationwide outreach and enrollment activities through the Out2Enroll campaign <u>Amount</u> : \$200,000	2015-2017
<u>Robert Wood Johnson Foundation</u> Conducting nationwide outreach and enrollment activities through the Out2Enroll campaign <u>Amount</u> : \$199,472	2015-2016
Role: Project Co-Director Robert Wood Johnson Foundation Building the Out2Enroll online enrollment assistance tool <u>Amount</u> : \$148,800	2014-2015
<u>Role</u> : Project Co-Director Wellspring Advisors Conducting nationwide outreach and enrollment activities through the Out2Enroll campaign <u>Amount</u> : \$100,000 Role: Project Co. Director	2014-2015
Arcus Foundation Conducting nationwide outreach and enrollment activities through the Out2Enroll campaign Amount: \$100,000 Role: Project Co-Director	2014-2015
Robert Wood Johnson Foundation Establishing the "Do Ask, Do Tell" project Amount: \$84,000 Role: Co-Principal Investigator	2014-2015

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Wellspring Advisors Impact of the Affordable Care Act on LGBT Communities <u>Amount</u> : \$600,000 <u>Role</u> : Co-Principal Investigator	2013-2016
Palette Fund Launching the Out2Enroll campaign <u>Amount</u> : \$10,000 <u>Role</u> : Project Co-Director	2013-2014
Nathan Cummings Foundation Launching the Out2Enroll campaign <u>Amount</u> : \$10,000 <u>Role</u> : Project Co-Director	2013-2014
Open Society Foundations Transgender Medical Policy Reform in Russia and the Former Soviet Union <u>Amount</u> : \$88,000 <u>Role</u> : Co-Principal Investigator	2013-2014
Elliott School of International Affairs Investigating sexual- and gender-based violence in conflict situations <u>Amount</u> : \$10,000 <u>Role</u> : Co-Principal Investigator	2010

TEACHING

Classes Taught

Issues in LGBTQ Health Policy	Fall 2021, Fall 2022
Johns Hopkins School of Public Health (Baltimore, MD)	
Policy, Politics, and Power in Health Equity Johns Hopkins University (Baltimore, MD) <i>Upper-division undergraduate seminar designed and taught through the Gordis Teaching Fellowship</i>	Fall 2019, Spring 2020
Guest Lectures	
Sexuality, Gender Identity, & The Law American University Washington College of Law (Washington, DC)	02/2022
Epidemiology of LGBTQIA Health George Washington University (Washington, DC)	02/2022
O'Neill Institute for National and Global Health Law Colloquium Georgetown Law Center (Washington, DC)	11/2021
Health Equity Policy Georgetown University (Washington, DC)	10/2021
Social Epidemiology Temple University College of Public Health (Philadelphia, PA)	10/2021
Advanced Topics in Health Promotion and Behavioral Sciences University of Louisville (Louisville, KY)	04/2021
LGBT Health Law and Policy Georgetown Law School (Washington, DC)	03/2021
Health Policy and Advocacy SUNY Upstate Medical College (Syracuse, NY)	02/2021
Issues in LGBTQ Health Policy Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)	12/2020

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Epidemiology of LGBT Health Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)	11/2020
Issues in LGBTQ Health Policy Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)	11/2020
LGBTQ Politics and Policy American University (Washington, DC)	10/2020
Research Ethics and Integrity Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)	03/2020
LGBT Health Policy Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)	03/2020
LGBT Health Law and Policy Georgetown Law School (Washington, DC)	02/2020
LGBT Health Policy Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)	02/2020
Epidemiology of LGBT Health Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)	12/2019
Economic Evaluation II Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)	12/2018
Epidemiology of LGBT Health Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)	12/2018
Public Health Policy SUNY Upstate Medical College (Syracuse, NY)	11/2018
LGBTQI Health: Research, Policies, and Best Practices Mt. Sinai Icahn School of Medicine (New York, NY)	05/2018
Epidemiology of LGBT Health Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)	12/2017
LGBTQ Issues in Public Policy New York University Wagner School of Public Service (New York, NY)	11/2017
Health Policy and Public Health Baldwin Wallace University (Berea, OH)	10/2017
LGBT Health Law and Policy Georgetown Law School (Washington, DC)	09/2017
Epidemiology of LGBT Health Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)	12/2016
LGBT Health Policy and Practice Graduate Certificate Program George Washington University (Washington, DC)	01/2016
Epidemiology of LGBT Health Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)	12/2015
LGBT Health Policy and Practice Graduate Certificate Program George Washington University (Washington, DC)	01/2015
Health Policy and Public Health Baldwin Wallace University (Berea, OH)	10/2014
Teaching Assistant Positions	
 Teaching Assistant, Department of Health Policy and Management Johns Hopkins Bloomberg School of Public Health (Baltimore, MD) Economic Evaluation I and II Health Economics for Managers 	2017-2020

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- Fundamentals of Health Policy and Management
- Introduction to Bioethics in Public Health Practice and Research
- Research Ethics and Integrity: U.S. and International Issues
- Science of Patient Safety
- The Political Economy of Social Inequalities and Its Consequences for Health and Quality of Life

MPH Capstone Teaching Assistant	2019
Johns Hopkins Bloomberg School of Public Health (Baltimore, MD)	
Teaching Assistant, Pfizer Executive Program in Economic Evaluation	2018
University of Chicago (New York, NY)	

<u>Trainings</u>

"Reaching and Assisting LGBT Communities" – in-person and online training developed for Out2Enroll and presented to Health Insurance Marketplace Navigators and other enrollment assisters

Arkansans for Coverage	12/2015
Alaska Primary Care Association	11/2015
Cognosante, Cleveland, OH	11/2015
Cognosante, Miami, FL	11/2015
Cognosante, Philadelphia, PA	11/2015
Enroll Virginia Coalition	11/2015
Council on Aging of Buncombe County, Asheville, NC	11/2015
Navigators for a Healthy Louisiana, Shreveport, LA	10/2015
Navigators for a Healthy Louisiana, Baton Rouge, LA	10/2015
Navigators for a Healthy Louisiana, New Orleans, LA	10/2015
Covered California University, Sacramento, CA	09/2015
HealthCare.gov	09/2015
Nebraska Primary Care Association	08/2015
Michigan Primary Care Association	08/2015
Florida Association of Community Health Centers	07/2015
Get Covered Arkansas Coalition, Little Rock, AR	06/2015
Kentuckiana Regional Planning and Development Agency, Louisville, KY	05/2015
Kentucky Primary Care Association, Hazard, KY	05/2015
Cognosante, Cleveland, OH	01/2015
Cognosante, Philadelphia, PA	01/2015
Utah Health Policy Project, Salt Lake City, UT	12/2014
Cognosante, New Orleans, LA	12/2014
Cognosante, Miami, FL	11/2014
Planned Parenthood Federation of America	10/2014
United Way Worldwide	10/2014
Nebraska Primary Care Association	07/2014
HealthCare.gov	07/2014

"Opening the Door: Assisting LGBT People"

U.S. Department of Health and Human Services Office for Civil Rights Region IV Office, Atlanta, GA	10/2015
U.S. Department of Health and Human Services Office for Civil Rights Region II Office, New York, NY	10/2015

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U.S. Department of Health and Human Services Office for Civil Rights Region VIII Office, Denver, CO	10/2015
U.S. Department of Health and Human Services Office for Civil Rights Region IX Office, San Francisco, CA	09/2015
U.S. Department of Health and Human Services Office for Civil Rights Region III Office, Philadelphia, PA	08/2015
U.S. Department of Health and Human Services Office for Civil Rights Region I Office, Boston, MA	06/2015
U.S. Department of Health and Human Services Office for Civil Rights Region VI Office, Dallas, TX	05/2015

PRESENTATIONS

Oral Abstracts and Issue Panels

Baker, KE , Segal J. Clinically Documented Social Risk Factors and Mental and Behavioral Health Diagnoses in a Commercially Insured Transgender Population. American Public Health Association Conference (online)	10/2021
Wolfson D, Baker KE , Platt J, Fields C, Ramiah K. Rebuilding Trust in Health Care: What We Know and What We Need to Know. AcademyHealth Annual Research Meeting (online)	06/2021
Baker KE , Badgett MVL, Gates G, Patterson C, Russell S, Umberson D, White J. The Health of LGBTQI+ Populations: Findings from a New National Academy of Sciences Report. Population Association of America Annual Meeting (online)	05/2021
Baker KE , Russell S. The Health of LGBTQI+ Populations: Findings from a New National Academy of Sciences Report. American Educational Research Association Annual Meeting (online)	04/2021
Terndrup CP, Siegel J, Streed C, Ufomata E, Baker KE . Transforming General Internal Medicine for Improved LGBTQ Healthcare: Strategies from the Bedside to the Legislature. Society for General Internal Medicine Annual Meeting (online)	04/2021
Hedian H, Terndrup CP, Siegel J, McNamara M, Baker KE . Teaching about Transgender Health: How to Navigate Challenging Small Group Discussions. Society for General Internal Medicine Meeting (online)	04/2021
Baker KE , Reisner SL, Dalke K, Harris AC. The Health of LGBTQI+ Populations: Findings from a New National Academy of Sciences Report. National Health Policy Conference (online)	02/2021
Badgett MVL, Flores AR, Dibner K, Baker KE . Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report. Association for Public Policy Analysis and Management Conference (online)	11/2020
Baker KE , Russell S, Reisner SL, Dalke K, Harris AC. Violence and the Well-Being of LGBTQI+ People: A Role for Public Health. American Public Health Association Conference (online)	10/2020
Baker KE . Leveraging the Behavioral Risk Factor Surveillance System for Transgender Health Research. American Public Health Association Conference, Philadelphia, PA	11/2019
Baker KE . Cracking the Code: Using Machine Learning to Identify Transgender People in Medical Claims Data. American Public Health Association Conference, Philadelphia, PA	11/2019
Pardo S, Baker KE , Wilkinson W. Advancing Sexual Orientation and Gender Identity Cultural Humility in Public Health Care: Policy, Research, and Practice Strategies. National Trans Health Summit, Oakland, CA	04/2019
Gorton N, Baker KE , Tescher J, Jaffe JM. Transgender Health Insurance Reform. World Professional Association for Transgender Health Inaugural USPATH Scientific Conference, Los Angeles, CA	01/2017
Baker KE, Cahill SR. Sexual Orientation and Gender Identity Data in EHRs. Critical Conversation, America's Essential Hospitals VITAL 2016 Conference, Boston, MA	06/2016
Baker KE . Role of Public Health Policy in Gender Affirmation and Health Equity for Trans/Gender- Variant People in the U.S. American Public Health Association Conference, Chicago, IL	11/2015
Baker KE . Do Ask, Do Tell: Collecting and Using LGBT Data. AcademyHealth Annual Research Meeting, San Diego, CA	04/2014
Allensworth-Davies D, Badgett MVL, Baker KE , Bean-Mayberry B, Bowleg L, Mattocks K. The Role of Health Services Research and Policy in Addressing the Health and Health Care Needs of LGBT Individuals. AcademyHealth Annual Research Meeting, Baltimore, MD	06/2013

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Cain VS, Miller KS, Baker KE , Pearlman AJ. Understanding LGBT Health: Overview, Methodological Challenges, and Policy Implications. National Conference on Health Statistics, Washington, DC	08/2012
Baker KE. Not Waving, But Drowning? Barriers and Challenges in Access to Sexual Health Services for MSM. Centers for Disease Control and Prevention National STD Conference, Minneapolis, MN	03/2012
Baker KE. LGBT Health as a Tool for Social Justice. American Public Health Association Conference, Denver, CO	11/2010

Poster Abstracts

Hindorff L, Madden E, Jackson A, Akintobi T, Baker KE , et al. (2022). Advancing Health Equity in Genomics: Reflections and Recommendations for Future Research Directions from an NHGRI Workshop. American Society of Human Genetics, Los Angeles, CA	10/2022
Baker KE , Segal J. Utilization and Costs of Gender-Affirming Care in a Commercially Insured Transgender Population. AcademyHealth Annual Research Meeting (online)	06/2021
Kasaie P, Weir B, Dowdy D, Baker KE , Holmes L, Labossiere S, Beyrer C. Mobile Multi-Disease Screening at Scale: Modelling the Effects in Kenya, Nigeria, and India. 22nd International AIDS Conference, Amsterdam, Netherlands	07/2018
Baker KE , Chidambaram P, Colrick I, Padula WV. Implications of Health Insurance Coverage for Care Related to Gender Transition for Transgender Adolescents. Society for Medical Decision Making Annual Meeting, Pittsburgh, PA	10/2017
Fox RF, Baker KE . LGBT Inclusion in Health Care Reform. American Public Health Association Conference, Philadelphia, PA	11/2009
Interviews and Recordings	
"Dr. Kellan Baker and Health Equity for the LGBTQ+ Community," Inside Health Care #79, National Committee on Quality Assurance. Available at: https://www.ncqa.org/blog/inside-health-care-79-dr-kellan-baker-health-equity-for-the-lgbt-community/	05/2022
"Patient Story: Kellan Baker," American Board of Internal Medicine Foundation Forum. Available at: https://abimfoundation.org/video/patient-story-kellan-baker	10/2021
"Core to Who I Am," <i>Tradeoffs</i> Podcast, University of Pennsylvania. Available at: https://tradeoffs.org/2020/07/14/core-to-who-i-am/	07/2020
"A Conversation with Kellan Baker," Health Policy Research Scholars. Available at: www.youtube.com/watch?v=trLC992Q7bc	09/2019
"Meet the Scholars: Kellan Baker," Health Policy Research Scholars. Available at: https://healthpolicyresearch-scholars.org/meet-the-scholars-kellan-baker/	06/2019
"Transgender Health Care Access and Policy," HealthLink on Air, SUNY Upstate Medical University. Available at: www.upstate.edu/hloa/2018/1127-transgender-people-face-health-care-challenges-of-both- access-and-policy.php	11/2018
"The Future of Transgender Coverage," <i>New England Journal of Medicine</i> . Available at: https://www.nejm.org/doi/full/10.1056/NEJMp1702427	05/2017
National March for Science Speech, Washington, DC. Available at: https://www.youtube.com/watch?v=Qin3q4dp7DQ	04/2017
"A New Era of Inclusion: How to Address LGBT and HIV/AIDS Issues in Health Reform Implementation," Center for American Progress. Available at: www.c-span.org/video/?311574-1/lgbt- health-advocates-examine-afforable-care-act	03/2013
"Queery: Kellan Baker." Washington Blade. Available at: www.washingtonblade.com/2010/05/20/queery-kellan-baker/	05/2010

Testimony

Hearing on Trans Health Equity Act of 2022 (House Bill 746), Public Health and Minority Health Disparities Subcommittee, Health and Government Operations Committee, Maryland General Assembly	03/2022
Hearing on Trans Health Equity Act of 2022 (House Bill 746), Health and Government Operations Committee, Maryland General Assembly	03/2022
Hearing on Trans Health Equity Act of 2022 (Senate Bill 682), Senate Finance Committee, Maryland State Senate	03/2022
DC Health Benefit Exchange Authority Performance Oversight Hearing, Committee on Health and Human Services, Council of the District of Columbia	02/2016
Invited Lectures, Presentations, Keynotes, and Plenaries	
Public Health and Health Systems Policy for Federal Policymakers	
"Addressing Structural Factors Needed to Support Health Equity Research," Future Directions in Genomics and Health Equity Research Workshop, National Human Genome Research Institute (online)	03/2022
"Collecting Sex, Gender Identity, and Sexual Orientation Data: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," White House Office of Personnel Management (online)	03/2022
"Sexual and Gender Minority Health: Evidence and Recommendations," Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services (online)	06/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," U.S. Department of Justice (online)	06/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," Civil Rights Division, U.S. Department of Justice (online)	06/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," National Institutes of Health Bioethics Interest Group (online)	02/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," National Institutes of Health Committee on Sexual and Gender Minority Research (online)	12/2020
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," Federal Committee on Statistical Methodology (online)	12/2020
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," U.S. Department of Health and Human Services LGBT Coordinating Committee (online)	11/2020
"Access to Care for the LGBT Community," Centers for Disease Control and Prevention National STD Conference (online)	09/2020
"LGBT Populations in Cancer Clinical Trials," U.S. Food and Drug Administration (online)	06/2020
"LGBT Issues in Public Health and Genomics," National Human Genome Research Institute (online)	06/2020
Health Equity and Accountability Act Congressional Briefing, Washington, DC	04/2018
"LGBT Communities in Genomics Research and Outreach," National Institutes of Health, Bethesda, MD	03/2018
"LGBT Federal Health Policy," White House LGBT Summit, Dearborn, MI	04/2016
"Two-Spirit and Native LGBT Communities," Indian Health Service (online)	12/2015
"Enrollment Resources for LGBTQ Youth," Centers for Medicare & Medicaid Services (online)	12/2015
"Transgender Issues in Federal Policy," Health Resources and Services Administration Special Projects of National Significance Meeting, Washington, DC	10/2015
"LGBT Data Collection," White House LGBT Summit, St. Louis, MO	10/2015
"New Frontiers in Health Disparities: Medicare and Medicaid in a Post- <i>Heckler</i> World," Centers for Medicare & Medicaid Services Health Equity Conference, Baltimore, MD	09/2015

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"LGBT Outreach and Enrollment under the Affordable Care Act," The White House, Washington, DC	07/2014
Health Equity and Accountability Act Congressional Briefing, Washington, DC	07/2014
"The ACA and LGBT Individuals: Delivering Culturally Competent Quality Care in Clinical Settings," Health Resources and Services Administration, Washington, DC	05/2014
"The Out2Enroll Initiative and LGBT Priorities in Health Reform," The White House, Washington, DC	09/2013
"What Health Reform Means for LGBT Communities," U.S. Government Accountability Office, Washington, DC	06/2013
"Policy Approaches for Addressing Transgender Health Disparities," Presidential Advisory Council on HIV/AIDS, Washington, DC	02/2013
"LGBT Health Policy," White House Summit on LGBT Health, Philadelphia, PA	02/2012
"Sexual Orientation and Gender Identity Data Collection in the Youth Risk Behavior Surveillance System," Federal LGBT Youth Summit, Washington, DC	06/2011
"If You Don't Count Us, We Don't Count: Using Data for Advocacy," Federal LGBT Youth Summit, Washington, DC	06/2011
Health Disparities Research and Policy	
Measuring Sex, Gender Identity, and Sexual Orientation," Sexual and Gender Minority Interest Group, National Cancer Institute Cohort Consortium (online)	03/2022
"Measuring Sex, Gender Identity, and Sexual Orientation," Sexual and Gender Minority Task Force, American Society of Clinical Oncology (online)	03/2022
"Health Policy for Transgender and Gender-Diverse Youth," Policy & Issues Forum, National Association of Community Health Centers (online)	02/2022
"End Stigma, End HIV: World AIDS Day 2021," Smithsonian Natural History Museum (online)	12/2021
"The State of Trans Men and Transmasculine Community," Brothers Obtaining and Navigating Dynamic Solidarity (online)	11/2021
"The Impact of COVID-19 on Trans Men and Transmasculine Communities," Brothers Obtaining and Navigating Dynamic Solidarity (online)	11/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," American Medical Association LGBTQ Committee (online)	11/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," American Medical Association LGBTQ and Allies Caucus	11/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," University of Minnesota Ethics Grand Rounds (online)	10/2021
Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," LGBTQIA Health Conference (online)	10/2021
"The Health of Sexual and Gender Diverse Populations: Addressing Inequities at the Intersections," National Academies of Sciences, Engineering, and Medicine (online)	07/2021
"LGBTQI+ Communities in the COVID-19 Pandemic," National Academies of Sciences, Engineering, and Medicine (online)	06/2021
"Advancing the Well-Being of LGBTQI+ Populations," Hauser Policy Fund Webinar Series, National Academies of Sciences, Engineering, and Medicine (online)	06/2021
"Understanding the Well-Being of LGBTQI+ Populations: Findings from a New National Academies of Sciences, Engineering, and Medicine Report," American Educational Research Association Presidential Session (online)	04/2021
"2021 Opportunities for Strengthening HIV Programs and Improving Health Equity," O'Neill Institute at Georgetown School of Law (online)	02/2021
"LGBT Health Research and Policy," LGBT Litigators Roundtable (online)	12/2020
"Cancer in LGBT Populations: Differences, Disparities, and Strategies for Change," American Association for Cancer Research Conference (online)	10/2020

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"Transgender Patient Narratives," American Board of Internal Medicine Foundation Forum (online)	08/2020
"Influencing LGBT Health Policy," Columbia University Program for the Study of LGBT Health (online)	07/2020
"Challenges and Barriers in Closing the Evidence Gap for Underrepresented and Vulnerable Populations in Clinical Research," Conquer Cancer Council Meeting, Alexandria, VA	12/2019
"Public Health Issues Before the U.S. Supreme Court: LGBT Rights, Reproductive Rights, and Firearms," Johns Hopkins School of Public Health, Baltimore, MD	11/2019
"How Patients' Identities Impact Trust," National Patient Advocate Foundation Policy Consortium, Washington, DC	11/2019
"Federal LGBTQ Health Policy in the Trump Administration," US Professional Association for Transgender Health, Washington, DC	09/2019
"Barriers and Solutions to Access to Genomic Medicine: Realizing the Benefits of Genomic Medicine for All," National Patient Advocate Foundation Policy Consortium, Washington, DC	05/2019
"Challenges and Opportunities in Trans Health Policy," SUNY Upstate Medical College, Syracuse, NY	11/2018
"Challenges and Opportunities in Advancing Federal LGBTQ Health Policy in the Trump Administration," GLMA: Health Professionals Advancing LGBT Equality Conference, Las Vegas, NV	10/2018
"Together Ahead: Accelerating Progress to End HIV," US Conference on AIDS, Orlando, FL	09/2018
"Research Ethics and Policy Intersections," National Transgender Health Summit, Oakland, CA	11/2017
"SOGI Data Collection," National Transgender Health Summit, Oakland, CA	11/2017
"United States of Trans Health Policy," National Transgender Health Summit, Oakland, CA	11/2017
"Ethical Issues in the Care of LGBTQ Youth and Families," American Academy of Pediatrics National Conference, Chicago, IL	10/2017
"Rollback of Protections Impacting the Quality of Hospice and Palliative Care for LGBTQ Patients and Families," GLMA: Health Professionals Advancing LGBT Equality Conference, Philadelphia, PA	10/2017
"The Assault on Federal LGBT Health Policy in the Trump Administration," GLMA: Health Professionals Advancing LGBT Equality Conference, Philadelphia, PA	10/2017
"Sexual Orientation and Gender Identity Data Collection," National Alliance of State and Territorial AIDS Directors National Prevention and Care Technical Assistance Meeting, Arlington, VA	07/2017
"Health Privacy in the LGBTQIA Community, Electronic Health Records Systems and Sensitive Data," Health Privacy Summit, Washington, DC	06/2017
"LGBTQ Health Policy Update," Health Action, Washington, DC	02/2017
"Transgender Health Policy and Research Ethics," World Professional Association for Transgender Health Inaugural USPATH Scientific Conference, Los Angeles, CA	01/2017
"Deep Dive: What the Affordable Care Act Means for LGBT People," The Fenway Institute (online)	07/2016
"LGBT Outreach and Enrollment: New Developments," Cognosante National Training, Phoenix, AZ	07/2016
"LGBT Health under the Affordable Care Act," Equality Federation Leadership Conference, Portland, OR	07/2016
"Times of Change: The Latest Dynamics in LGBT Outreach, Enrollment, and Coverage," Enroll America National Conference, Washington, DC	05/2016
"Beyond HIV/AIDS: Reporting on the LGBT Community," American Health Journalists Association Conference, Cleveland, OH	04/2016
"SOGI Data Collection and LGBT Health," National Association of State and Territorial AIDS Directions Midwestern Regional Meeting, Detroit, MI	04/2016
"Cultural Competency and the ACA: Maximizing Outreach," American Federation of Teachers Professional Issues Conference, Washington, DC	04/2016
"LGBT Health Policy: Current Landscape and Latest News," The Fenway Institute (online)	03/2016
"Cutting Edge Issues in LGBT Health Research and Policy," Johns Hopkins Bloomberg School of Public Health LGBT Public Health Research Day, Baltimore, MD	03/2016

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"Affirmatively Transgender: The Role of Law and Policy," O'Neill Institute Colloquium at Georgetown La School, Washington, DC	w 09/2015
"Transgender Health Insurance Policy," Stanley Biber Memorial Lecture, GLMA: Health Professionals Advancing LGBT Equality Conference, Portland, OR	09/2015
"Transgender Health Insurance Coverage," Pride at Work Conference, Orlando, FL	08/2015
"Effective LGBT Outreach," Cognosante National Training, Baltimore, MD	07/2015
"Culturally Competent Outreach and Enrollment Assistance," Enroll America State of Enrollment Conference, Washington, DC	06/2015
"What LGBT Communities Need to Know about the Affordable Care Act," Equal Care for Equal Lives LGBT Health Summit, Little Rock, AR	06/2015
"LGBT Outreach and Enrollment," Southern Health Partners Meeting, Atlanta, GA	06/2015
"Healthcare Hallelujah: Trans Health and the ACA," Black Trans Advocacy Conference, Dallas, TX	05/2015
"Transgender Health Issues," Rutgers University Law School, Newark, NJ	04/2015
"Data Collection to Advance Transgender Health," National Transgender Health Summit, Oakland, CA	04/2015
"Winning Access to Trans Health Coverage and Care," National Transgender Health Summit, Oakland, CA	A 04/2015
"The ACA and LGBT Communities," EverThrive Illinois	03/2015
"Using Data to Advance Public Policy," Creating Change Conference, Denver, CO	02/2015
"Top Issues in LGBT Health Policy," Harvard School of Public Health LGBTQ Conference, Boston, MA	02/2015
"LGBT Health Disparities," Thomson Reuters, New York, NY	01/2015
"Update on LGBTQ People of Color: Focus on Transgender Health," Health Action, Washington, DC	01/2015
"LGBT Enrollment Challenges," Get Covered Illinois LGBT Marketing Campaign Launch, Chicago, IL	01/2015
"LGBT Health: Challenges and Opportunities," Diversity, Inc. Healthcare Event, New York, NY	10/2014
"LGBT People in Health System Transformation," Consumer Voices for Coverage, Philadelphia, PA	09/2014
"LGBTI Health Policy," LGBTI Health Research Conference, Cleveland, OH	08/2014
"LGBT Health Disparities and ACA Enrollment," Cognosante National Meeting, Baltimore, MD	07/2014
"Do Ask, Do Tell: LGBT Data Collection in Electronic Health Records," The Center for LGBTQ Studies the City University of New York Graduate Center, New York, NY	at 06/2014
"Understanding LGBT Health," University of Pennsylvania, Philadelphia, PA	04/2014
"Introduction to Transgender Healthcare," Medical College of Wisconsin, Milwaukee, WI	04/2014
"The Affordable Care Act: Implications for Trans Consumers," FORGE, Inc., Milwaukee, WI	04/2014
"Access to Health Care," Civil Liberties and Public Policy Conference, Amherst, MA	04/2014
"Reaching and Assisting LGBT Communities," Rutgers School of Nursing, Newark, NJ	03/2014
"Connecting with Coverage: LGBT Communities and the ACA," Pennsylvania Health Access Network	03/2014
"The Affordable Care Act and the LGBT Community," Oklahoma Equality, Tulsa, OK	03/2014
"The Affordable Care Act and the LGBT Community," The Dallas Resource Center, Dallas, TX	03/2014
"Connecting with Coverage: LGBT Communities and the ACA," Black AIDS Institute (online)	03/2014
"LGBT Federal Health Policy," National Summit on Cancer in the LGBT Communities, Memorial Sloane Kettering Cancer Center, New York, NY	01/2014
"LGBT Health Policy and Advocacy," Creating Change Conference, Houston, TX	01/2014
"Enrollment 2.0: Effective Strategies for Specific Populations," Health Action, Washington, DC	01/2014
"Implementing the Affordable Care Act," International Gay & Lesbian Leadership Conference, Denver, C	O 12/2013
"Out2Enroll: The Affordable Care Act and the LGBT Community," The Johns Hopkins Center for Health Disparities Solutions (online)	1 11/2013
"The LGBT Community and the Affordable Care Act," Marquette University, Milwaukee, WI	11/2013
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"Connecting with Coverage: LGBT Communities and the ACA," AIDS Resource Center of Wisconsin, Milwaukee, WI	11/2013
"Connecting LGBT Communities to Benefits under the ACA," Children's Hospital Los Angeles (online)	10/2013
"Nondiscrimination under the Affordable Care Act," Consumer Voices for Coverage, Philadelphia, PA	10/2013
"Outreach, Engagement and Enrollment into ACA Coverage," U.S. Conference on AIDS, New Orleans, LA	09/2013
"LGBT Community Benefits from the ACA," Q Health Initiative Conference, Salt Lake City, UT	09/2013
"Leading on Meaningful Use: Next Steps in SO/GI Data Policy," Gay & Lesbian Medical Association Conference, Denver, CO	09/2013
"Enrollment for LGBT Communities," Gay & Lesbian Medical Association Conference, Denver, CO	09/2013
"The Promise of Reform: How Obamacare Affects LGBT Communities," Federal AIDS Policy Partnership, Washington, DC	08/2013
"Optimizing LGBT Health under the ACA," National LGBT Health Education Center (online)	08/2013
"Building a Healthy and Inclusive Society," Young Elected Officials National Convening, Washington, DC	07/2013
"Transgender Health Issues in Health Care Reform," National Transgender Health Summit, Oakland, CA	04/2013
"Transgender Diagnoses in ICD-11," Global Action for Transgender Equality Strategy Meeting, Buenos Aires, Argentina	04/2013
"Organizing LGBT Communities around the ACA," Fair Wisconsin Leadership Conference, Milwaukee, WI	02/2013
"The Affordable Care Act and LGBT Consumers," Michigan Consumers for Healthcare and Equality Michigan, Kalamazoo, MI	02/2013
"LGBT Legal and Policy Issues in the Affordable Care Act," Eastern Michigan University, Ypsilanti, MI	02/2013
"LGBT Legal and Policy Issues in the Affordable Care Act," University of Michigan, Ann Arbor, MI	02/2013
"LGBT Community Health Center Advocacy and Policy," Gay & Lesbian Medical Association Conference, San Francisco, CA	09/2012
"LGBT Health in Health Care Reform," Gay & Lesbian Medical Association Conference, San Francisco, CA	09/2012
"Closing the LGBT Health Disparities Gap through Electronic Health Records," Gay & Lesbian Medical Association Conference, San Francisco, CA	09/2012
"The LGBT State Exchanges Project: Building Community and Advocacy Tools for LGBT Health," Equality Federation Summer Institute, Portland, ME	08/2012
"Transgender Health," Johns Hopkins School of Nursing, Baltimore, MD	04/2012
"LGBT Health Disparities," National Health Law Program Health Advocates Conference, Washington, DC	12/2011
"The Picture of Health: How Statistics Will Change LGBT Health Care," International Gay & Lesbian Leadership Conference, Houston, TX	12/2011
"International Transgender Health," World Professional Association for Transgender Health Conference, Atlanta, GA	11/2011
"No Data, Big Problem: LGBT Health Equity at Kaiser Permanente," Kaiser Permanente Diversity Conference, San Francisco, CA	10/2011
"2011 Federal LGBT Health Initiatives," Gay & Lesbian Medical Association Conference, Atlanta, GA	09/2011
"Transgender Health Policy Advocacy," National Transgender Health Summit, San Francisco, CA	04/2011
"Advancing LGBT Health through Health Care Reform Implementation," Gay & Lesbian Medical Association Conference, San Diego, CA	10/2010
"Health as a Social Justice Issue," Creating Change Conference, Dallas, TX	02/2010
"LGBT Federal Youth Policy," Creating Change Conference, Dallas, TX	02/2010
"Transgender Issues in Russia," Transgender Europe Conference, Berlin, Germany	05/2008
Philanthropy	
"Protections and Barriers in Access to Care," AIDS Philanthropy Summit, Washington, DC	12/2016

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"LGBT Health Policy Opportunities," OutGiving Funders Meeting, Dallas, TX	05/2015
"Expanding Coverage and Access," LGBT Health Funding Summit, New York, NY	01/2015
"International Transgender Health Priorities," Advancing Transgender Movements Worldwide Funders Conference, Berlin, Germany	12/2013
"LGBT Health Reform Priorities," Health Care for All New York and the New York State Health Foundation, New York, NY	06/2013
"The Promise of Reform: How Obamacare Affects LGBTQ Communities," LGBTQ Grantmakers Retreat, Albuquerque, NM	03/2013
"Transforming Health: International Rights Based Advocacy for Trans Health," Open Society Foundations, New York, NY	02/2013
"LGBT Health Issues in U.S. Health Reform," Rockefeller Foundation, Bellagio, Italy	05/2012
Education and Career Development	
"Health Science Policy," Health Science Communications and Policy Workshop, Office of Intramural Training and Education, National Institutes of Health (online)	03/2022
"Living Intersectionality in Academia: Emerging Scholars," Davis Center for Russian and Eurasian Studies, Harvard University (online)	01/2022
Postbac Career Exploration Series: Careers in Public Health, Office of Intramural Training and Education, National Institutes of Health (online)	10/2021
"LGBTQI+ Health Disparities: Research, Interventions, and Policy," Amgen Scholars Health Disparities Seminar, National Institutes of Health (online)	06/2021
Professional Advisory Panel on Sexual and Gender Minority Health in Medical Education, Harvard Medical School (online)	05/2021
"Innovations in Cancer Disparities Research," San Diego State University (online)	04/2021
Russian Tea, Swarthmore College (online)	04/2021
Summer Social Justice Institute, Swarthmore and Haverford Colleges, Swarthmore, PA	08/2018
"Science Outside the Lab: Science and Technology Policy Careers," Arizona State University Honors College, Washington, DC	06/2018
"Gay for Pay: Swarthmore Alumni in Queer Careers," Swarthmore College, Swarthmore, PA	03/2017
"Science Outside the Lab: Science and Technology Policy Careers," Arizona State University Honors College, Washington, DC	05/2016

VOLUNTEER ACTIVITIES

Co-Founder FtM Phoenix (Moscow, Russia) FtM Phoenix (https://www.transsovetnik.com) advocates for the health and human rights of transgender people in Russia and Eurasia. In 2013-2014, we hosted the 1 st and 2 nd Eurasian Trans Health Conferences in Moscow, which brought together health care providers, advocates, and government officials from 8 countries in the former Soviet Union.	2008-present
HIV/AIDS Peer Support Program Developer Whitman-Walker Health (Washington, DC)	2008-2009
Community Clinics Campaign Coordinator FTM Alliance of Los Angeles (Los Angeles, CA)	2006
Recreational Therapist Baskakov Center for Children with Special Needs (Moscow, Russia)	2005
English–Russian Translator and Program Assistant Special Olympics Russia (Moscow, Russia)	2004-2005
Certified Coach and Unified Team Player (basketball, bocce, long-distance running) Special Olympics USA (Thousand Oaks, CA and Philadelphia, PA)	1997-2004

Baker, Kellan E. (2023)

SKILLS AND PROFICIENCIES

Software/Programs: R, SQL, Stata, DbVisualizer, Mplus, TreeAge, heRo3, DistillerSR, AHRQ Systematic Data Review Repository, Covidence, ArcGIS, WordPress, Quickbooks, Microsoft Office **Languages:** Russian (fluent), German (working proficiency), French (working proficiency), Spanish (basic proficiency)

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

AUGUST DEKKER, et al.,

Plaintiffs, v.

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

JASON WEIDA, et al.,

Defendants.

EXPERT DECLARATION OF ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C

I, ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C, have been retained by counsel for Plaintiffs in connection with the above-captioned litigation.

1. This declaration provides the following expert opinions, which are explained in further detail below:

2. General Medicaid Policy Rule 59G-1.050 ("the Exclusion") excludes from coverage certain medical services, which I will refer to as gender-affirming medical care, when these interventions are used to treat gender dysphoria.¹

¹ Gender dysphoria is "a marked incongruence between one's experienced/expressed gender and their assigned gender" which is "associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning." American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders.* 5th ed, Text Revision. American

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3. Gender-affirming medical care is consistent with generally accepted professional medical standards and is not experimental or investigational. It is endorsed by evidence-based clinical practice guidelines that are themselves based on studies published in the peer-reviewed literature demonstrating that it improves individuals' health outcomes. Gender-affirming medical care is also supported by increasing utilization trends and coverage by other creditable insurance payors.

4. In the Exclusion and other supporting documents, the Florida Agency for Health Care Administration (AHCA) persistently mischaracterizes these treatments and singles them out for anomalous treatment by withholding Medicaid coverage for them only when they are used to treat gender dysphoria. Specifically, AHCA mischaracterizes

- a. individuals as diagnosing themselves with gender dysphoria,
- b. treatments for gender dysphoria and "off-label" treatments as experimental,
- c. treatments of gender dysphoria as "eminence-based medicine" and the evidence base supporting many medical treatments, and
- d. the informed consent process for the treatment of gender dysphoria in minors.

Psychiatric Publishing; 2022.

5. I have actual knowledge of the matters stated in this declaration. In preparing this declaration, I reviewed the Exclusion, "Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria" ("GAPMS Memo"),² including Attachment G, a commissioned, unpublished paper written by G. Kevin Donovan, MD, MA, entitled "Medical Experimentation without Informed Consent: An Ethicist's View of Transgender Treatment for Children."³ I also reviewed the materials listed in the attached Bibliography (Exhibit A), and I may rely on those documents as additional support for my opinions. I have also relied on my years of research and clinical practice, as set out in my curriculum vitae (Exhibit B), and on the materials listed therein. The materials I have relied upon in preparing this declaration are the same types of materials that experts in medicine and bioethics regularly rely upon when forming opinions on this type of subject. I may wish to supplement 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.

² June 2022. Accessed September 6, 2022. Available at https://ahca.myflorida.com/letkidsbekids/docs/AHCA GAPMS June 2022 Report.pdf. Mav September 12. 2022. Accessed 6, 2022. Available at https://ahca.myflorida.com/letkidsbekids/docs/AHCA GAPMS June 2022 Attachment G.pdf.

BACKGROUND AND QUALIFICATIONS

6. I am the Director of the Ethics Center, the Lee Ault Carter Chair of Pediatric Ethics, and an Attending Physician in the Division of Hospital Medicine at Cincinnati Children's Hospital Medical Center ("Cincinnati Children's"). I am also a Professor in the Departments of Pediatrics and Surgery at the University of Cincinnati College of Medicine.

7. In 2000, I received both my medical degree from Washington University School of Medicine in St. Louis, Missouri and my PhD in Religious Ethics from The University of Chicago Divinity School. I completed my pediatrics residency at the University of Utah in 2003.

8. I have been licensed to practice medicine since 2001 and am currently licensed to practice medicine in Ohio. I have been Board Certified in General Pediatrics since 2004 and in Pediatric Hospital Medicine since the inception of this certification in 2019. I have been certified as a Healthcare Ethics Consultant since the inception of this certification in 2019.

9. I have extensive experience as a practicing physician. I have been in clinical practice since 2003 and approximately 30 percent of my current work is dedicated to caring for hospitalized patients. Cincinnati Children's is a nonprofit pediatric academic medical center with 622 total registered beds. It admits patients up to age 25 and older patients under certain conditions, including patients in the

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Adults with Congenital Heart Disease and Young Adults with Cancer programs. I routinely admit and care for adult patients.

10. I also have extensive experience as a bioethicist. Bioethicists examine the ethical issues that arise in medicine and the life sciences. I was Chair of the Ethics Committee at Primary Children's Medical Center in Salt Lake City, Utah from 2005 to 2012 and have been Director of the Ethics Center at Cincinnati Children's since 2012.

11. I regularly consult on patients in the Transgender Health Clinic at Cincinnati Children's whose care presents unique ethical issues and participate in the Clinic's monthly multidisciplinary team meetings. I remain current with the medical and bioethics literature regarding the treatment of individuals with gender dysphoria, particularly minors. I am also the Chair of Cincinnati Children's Fetal Care Center's Oversight Committee which provides the Center with recommendations on the use of innovative treatments and experimental interventions.

12. I am a member of the American Academy of Pediatrics (AAP), the American Society for Bioethics and Humanities (ASBH), the Association of Bioethics Program Directors, and the Society for Pediatric Research. I was a member of the AAP's Committee on Bioethics from 2005 to 2011. I have also served as a member of the ASBH's Clinical Ethics Consultation Affairs Committee from 2009

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to 2014 and currently serve on its Healthcare Ethics Consultant Certification Commission.

13. I am the author of 41 peer-reviewed journal articles, 11 non-peerreviewed journal articles, six book chapters, and 28 commentaries. My peerreviewed journal articles have been published in high-impact journals including the *Journal of the American Medical Association* and *Annals of Internal Medicine*. I am also an author of 17 policy statements and technical reports, including four as lead author, by the AAP.

14. I am a member of the Executive Editorial Board and the Associate Editor for Ethics Rounds of *Pediatrics*. *Pediatrics* is the AAP's flagship journal and Ethics Rounds is a type of article in which commentators analyze cases that raise ethical issues. I am an active peer reviewer for many medical journals, including the *American Journal of Bioethics* and the *Journal of Pediatrics*. I also review abstracts for the annual meetings of professional organizations, including the Pediatric Academic Societies and ABSH. I was previously a member of the editorial boards of the *Journal of Clinical Ethics* and the *Journal of Medical Humanities*.

15. I previously testified as an expert witness at trial or deposition in the following cases: *Brant v. Rutledge*, Case No. 4:21CV450-JM (E.D. Ark.), *Doe v. Abbott*, No. D-1-GN-22-000977, 2022 WL 628912 (Tex. Dist. 353rd Judicial

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District, March 2, 2022), and *Eknes-Tucker* v *Marshall*, Case No. 2:22-cv-184-LCB (M.D. Ala. May 13, 2022).

16. I am being compensated at an hourly rate of \$250 per hour for preparation of expert declarations and reports, and \$400 per hour for time spent preparing for or giving deposition or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

GENDER-AFFIRMING MEDICAL CARE IS SUPPORTED BY EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES

17. Medical care for individuals with gender dysphoria is evidence-based and is supported by clinical practice guidelines developed by medical professional organizations including the Endocrine Society ("the Society").

18. The Society was established in 1916⁴ and is an international medical organization whose membership is comprised of over 18,000 endocrinology researchers and clinicians.⁵ It uses rigorous methods to develop guidelines on a variety of clinical conditions. Members of guideline development panels are nominated by the Society's Board of Directors, its Clinical Guidelines Committee, and any co-sponsoring organizations; they are selected based on their clinical

 ⁴ Endocrine Society. Our History. Accessed December 31, 2022. Available at https://www.endocrine.org/our-community/advancing-endocrinology-and-public-health/history/.
 ⁵ Endocrine Society. Who We Are. Accessed December 31, 2022. Available at https://www.endocrine.org/about-us.

expertise and other skills; and they are screened for conflicts of interest. Panels are multidisciplinary and include a patient representative and a methodologist— someone trained in the methods for developing clinical practice guidelines. The Society uses the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology. Guidelines undergo both internal and external review including a public comment period. After any revisions, the proposed guidelines undergo a second review by the Society's Clinical Guidelines Committee, its Board of Directors Reviewer, and an expert reviewer. If approved, they undergo peer review prior to publication. Guidelines are periodically reviewed and may be updated or retired.⁶

19. The GRADE approach is a widely utilized method for developing clinical practice guidelines.⁷ It involves both rating the quality of the evidence and the strength of the recommendations.⁸ In this context, evidence is the studies' relevant to a recommendation. It is best practice to ascertain the studies via systematic reviews of the literature.⁹ The evidence provides an estimate of the effect

⁶ Endocrine Society Guideline Methodology. Accessed November 25, 2022. Available at <u>https://www.endocrine.org/-/media/endocrine/files/cpg/methodology-page-</u>refresh/endocrine society guideline methodology links.pdf.

⁷ GRADE: Welcome to the GRADE working group. Accessed November 23, 2022. Available at <u>https://www.gradeworkinggroup.org/#pub</u>.

⁸ Guyatt G, Oxman AD, Akl EA, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. *J Clin Epidemiol*. 2011;64(4):383-394.

⁹ Systematic reviews use exhaustive, transparent, and repeatable methods to identify, select, and appraise the relevant research. For example, medical librarians may help develop strategies to search multiple databases and several investigators may screen each articles' title and abstract

of an intervention both in terms of the size of the effect and the certainty of the knowledge about it. The quality of the evidence rating reflects "the extent of our confidence that the estimates of an effect are adequate to support a particular decision or recommendation."¹⁰ The higher the quality of the evidence, the more confidence there is in our knowledge about the estimated magnitude of the effect and the more likely the true magnitude of the effect is the same as the estimate. The lower the quality of the evidence, the less confidence there is in the estimate of the effect and the more likely the true effect differs from the estimate. The GRADE approach uses four categories to rate the quality of the evidence: "high," "moderate," "low," and "very low."¹¹

20. In the rating process, randomized trials are initially rated as high quality and observational studies as low quality.¹² In randomized trials, participants are randomly assigned to an intervention or a control group. Randomization is like flipping a coin. In double blind or masked randomized trials, neither the investigators nor the participants know to which group the participants are assigned.

against inclusion and exclusion criteria. Cook DJ, Greengold NL, Ellrodt AG, Weingarten SR. The relation between systematic reviews and practice guidelines. *Ann Intern Med.* 1997;127(3):210-6.

¹⁰ Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):403.

¹¹ Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

¹² Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

Observational studies include cross-sectional and cohort studies. In cross-sectional studies, investigators collect data at a single point in time or within a short period of time. In cohort studies, researchers identify a group of participants and then make measurements over time. The measurements may be retrospective and/or prospective.¹³

21. The initial rating of the evidence may subsequently be modified based on additional factors. The rating of randomized trials may, for example, be decreased if they have serious risks of bias¹⁴ like a lack of masking.¹⁵ The rating of observational trials may be increased if they have large effects, e.g., those receiving the intervention are more than two times or less than one-half as likely to experience the outcome.¹⁶

22. The strength of a recommendation is related to the confidence that a treatment's desirable outcomes outweigh its undesirable ones. The GRADE approach conceptualizes recommendations on a continuum: "strong against," "weak against," "only in research," "weak for," and "strong for." Strong recommendations are ones where all or almost all informed people would make the recommended

¹³ Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2023.

¹⁴ Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

¹⁵ Guyatt GH, Oxman AD, Vist G, et al. GRADE guidelines: 4. Rating the quality of evidence study limitations (risk of bias). *J Clin Epidemiol*. 2011;64(4):407-415.

¹⁶ Guyatt GH, Oxman AD, Sultan S, et al. GRADE guidelines: 9. Rating up the quality of evidence. *J Clin Epidemiol*. 2011;64(12):1311-1316.

choice and weak recommendations are ones where most informed people would, but a substantial number would not, make the recommended choice.¹⁷ The strength of a recommendation is based on the balance between desirable and undesirable outcomes, confidence in the magnitude of estimates of the intervention's effect, confidence in values and preferences, and resource use.¹⁸ Low quality evidence may be sufficient to justify a strong recommendation.¹⁹ Because of the potential to confuse low quality evidence and weak recommendations, the GRADE approach offers the following alternative ways to describe a weak recommendation: "conditional," "discretionary," and "qualified."²⁰

23. The Society's clinical practice guideline for the endocrine treatment of gender-dysphoric/gender-incongruent persons makes 28 recommendations.²¹ Ten are strong, 12 are weak, and six are ungraded good practice statements; three are

¹⁷ Andrews J, Guyatt G, Oxman AD, et al. GRADE guidelines: 14. Going from evidence to recommendations: The significance and presentation of recommendations. *J Clin Epidemiol*. 2013;66(7):719-725.

¹⁸ Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

¹⁹ Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-6; Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

²⁰ Andrews J, Guyatt G, Oxman AD, et al. GRADE guidelines: 14. Going from evidence to recommendations: the significance and presentation of recommendations. *J Clin Epidemiol*. 2013;66(7):719-725.

²¹ Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of genderdysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

based on moderate, 14 on low, and five on very low-quality evidence. Table 1 (Exhibit C). The recommendation, "We suggest that adolescents who meet diagnostic criteria for [gender dysphoria]/gender incongruence, fulfill criteria for treatment, and are requesting treatment should initially undergo treatment to suppress pubertal development," for example, is a weak recommendation based on low-quality evidence. Recall that a weak recommendation is one where most informed people would make the recommended choice. The evidence includes cohort studies conducted at VU University Medical Center in the Netherlands demonstrating that gender-affirming medical care improves individuals' mental health outcomes.²² The recommendation "We recommend that clinicians confirm the diagnostic criteria of [gender dysphoria]/gender incongruence and the criteria for the endocrine phase of gender transition before beginning treatment" is a strong recommendation based on moderate quality evidence. The evidence includes a randomized trial of three different testosterone formulations in transgender men (individuals who were assigned female at birth and identify as male).²³

24. Professional associations' treatment recommendations for pediatric

²² Cohen-Kettenis PT, van Goozen SHM. Sex reassignment of adolescent transsexuals: A followup study. *J Am Acad Child Adolesc Psychiatry*. 1997;36(2):263–271; Smith YLS, Van Goozen SHM, Kuiper AJ, Cohen-Kettenis PT. Sex reassignment: Outcomes and predictors of treatment for adolescent and adult transsexuals. Psychol Med. 2005;35(1):89–99; and de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283.

²³ Pelusi C, Costantino A, Martelli V, et al. Effects of three different testosterone formulations in female-to-male transsexual persons. *J Sex Med.* 2014;11(12):3002-3011.

patients are infrequently based on well-designed and conducted randomized controlled trials due to their rarity and are frequently based on observational studies. For example, the Society has developed two other guidelines that focus on the pediatric population: guidelines on pediatric obesity and congenital adrenal hyperplasia. They contain 84 recommendations. None are based on high, 24 (29%) on moderate, and 49 (58%) on low or very low-quality evidence. Forty-three (51%) recommendations are strong and 30 (36%) weak. The remaining recommendations (11, 13%) are Ungraded Good Practice Statements.²⁴ Table 1 (Exhibit C).

25. Medical research on children is less likely to use randomized trials than is medical research for adults. Reasons for this disparity include the low prevalence of childhood disease or conditions, small market share for therapeutic agents in children, low level of National Institutes of Health funding, and difficulty enrolling children in research.²⁵

26. It may also, at times, be unethical to conduct randomized trials. For randomized trials to be ethical, clinical equipoise must exist; there must be uncertainty about whether the efficacy of the intervention or the control is greater.

²⁴ Speiser PW, Arlt W, Auchus RJ, et al. Congenital adrenal hyperplasia due to steroid 21hydroxylase deficiency: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2018;103(11):4043-4088; Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesityassessment, treatment, and prevention: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(3):709-757.

²⁵ Martinez-Castaldi C, Silverstein M, Baucher H. Child versus adult research: The gap in highquality study design. *Pediatrics*. 2008;122(1):52-57.

It would be unethical to knowingly expose some participants to an inferior intervention. Trials must also be feasible. It would be unethical to expose individuals to the risks of trial participation without the benefit of the trial generating generalizable knowledge. A randomized trial that is unlikely to enroll enough participants because they believe they might be randomized to an inferior intervention would be unethical because it could not generate generalizable knowledge due to an inadequate sample size.²⁶

27. Under the applicable ethical standards, randomized, placebo-controlled trials (trials that compare pharmacological treatment to no pharmacological treatment) of individuals with gender dysphoria are currently unethical. Potential investigators no longer have equipoise between pharmacological treatment and no pharmacological treatment; they believe that pharmacological treatment is superior. It is also highly unlikely that enough participants would enroll in such randomized controlled trials for them to be informative.²⁷

28. Even if randomized, placebo-controlled trials of gender-affirming health care were ethical, they would provide a lower quality of evidence because of intrinsic limitations in their design. For example, it would be impossible to mask

²⁶ Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA*. 2000;283(20):2701-2711.

²⁷ Chew D, Anderson J, Williams K, May T, Pang K. Hormonal treatment in young people with gender dysphoria: A systematic review. *Pediatrics*. 2018;141(4):e20173742; Reisner SL, Deutsch MB, Bhasin S, et al. Advancing methods for US transgender health research. *Curr Opin Endocrinol Diabetes Obes*. 2016;23(2):198-207.
which participants were receiving an active medication or a placebo; the investigators and the participant would know if the participant was in the intervention or control group due to the physical changes in the participant's body, or the lack thereof, over time. This might bias their perception of the outcomes and lower the rating of the study's quality.²⁸

29. Gender-affirming medical care is also recommended by the World Professional Association for Transgender Health's (WPATH's) Standards of Care for the Health of Transgender and Gender Diverse People which is currently in its 8th version ("SOC-8").²⁹ WPATH is an international interdisciplinary professional and educational organization³⁰ whose over 2,500 members include physicians, psychologists, lawyers, and social workers.³¹ The SOC-8 revision committee included subject matter experts, stakeholders, and an expert in developing clinical practice guidelines each of whom completed conflict of interest declarations. An independent, evidence review team conducted selected systematic reviews of the literature. Consensus on recommendations was attained using a Delphi process; a voting process requiring approval by 75% of participating committee members. If

²⁸ Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64(4):401-406.

²⁹ Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, Version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259.

³⁰ WPATH. Mission and Vision. Accessed December 31, 2022. Available at <u>https://www.wpath.org/about/mission-and-vision</u>.

³¹ WPATH. Member Search. Accessed February 13, 2023. Available at https://www.wpath.org/member/search/results?showAll=1.

a recommendation was not approved, it was revised and was removed if not approved in 3 rounds of voting. Approved recommendations were subsequently graded. A draft of the revision was reviewed by an International Advisory Committee and open to public comment.³²

30. In addition to these clinical practice guidelines, gender-affirming medical care is endorsed by other types of statements by numerous medical professional associations including the American Academy of Family Physicians,³³ the AAP, ³⁴ the American College of Obstetricians and Gynecologists, ³⁵ the American Medical Association, ³⁶ the American Psychiatric Association, ³⁷ the

³² Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, Version 8. *Int J Transgend Health*. 2022;23(Suppl 1): S1-S259.

³³ American Academy of Family Physicians. Care for the transgender and gender nonbinary patient. Accessed January 8, 2023. Available at <u>https://www.aafp.org/about/policies/all/transgender-</u>

nonbinary.html#:~:text=The%20American%20Academy%20of%20Family,patients%2C%20incl uding%20children%20and%20adolescents.

³⁴ Rafferty J, Committee on Psychosocial Aspects of Child and Family Health, Committee on Adolescence, et al. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. *Pediatrics*. 2018;142(4): e20182162.

³⁵ American College of Obstetricians and Gynecologists. ACOG Committee Opinion Number 823: Health care for transgender and gender diverse individuals. March 2021. Accessed January 8, 2023. Available at <u>https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals/;</u> American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice and Committee on Health Care for Underserved Women. Health Care for Transgender and Gender Diverse Individuals: ACOG Committee Opinion, Number 823. *Obstet Gynecol.* 2021;137(3):e75-e88.

³⁶ American Medical Association. Removing financial barriers to care for transgender patients H-185.950. 2022. Accessed January 8, 2023. Available at <u>https://policysearch.amaassn.org/policyfinder/detail/H-185.950?uri=%2FAMADoc%2FHOD.xml-0-1128.xml;</u> Madara JL to McBride B. April 26, 2021. Accessed January 8, 2023. Available at <u>https://searchlf.amaassn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2</u> <u>F2021-4-26-Bill-McBride-opposing-anti-trans-bills-Final.pdf</u>.

³⁷ American Psychiatric Association. Position statement on treatment of transgender (trans) and

American Psychological Association, ³⁸ the Endocrine Society and Pediatric Endocrine Society, ³⁹ and WPATH.⁴⁰

GENDER-AFFIRMING MEDICAL CARE IS NOT EXPERIMENTAL

31. Clinical practice and research are distinguished by their goals and methods. The goal of clinical practice is to benefit individual patients, and its method is individualized decision-making. The goal of research is to contribute to generalizable knowledge, and its method uses formal protocols that describe the research study's objectives and procedures.⁴¹

32. To the extent that the GAPMS Memo uses the term "experimental" or "investigational" to convey that gender-affirming medical care is new, untested, or different, that suggestion is baseless. GAPMS Memo at 29, 30; Attachment G at 1, 4. Hormone treatment for gender dysphoria began after estrogen and testosterone

gender diverse youth. July 2020. Accessed January 8, 2023. Available at <u>https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-</u> Policies/Policies/Position-Transgender-Gender-Diverse-Youth.pdf.

³⁸ American Psychological Association. Transgender, gender identity, and gender expression nondiscrimination. August 2008. Accessed January 8, 2023, Available at <u>https://www.apa.org/about/policy/transgender.pdf</u>.

³⁹ Endocrine Society and Pediatric Endocrine Society. Transgender health: Position Statement. December 2020. Accessed January 8, 2023. Available at <u>https://www.endocrine.org/advocacy/position-statements/transgender-health</u>; Anton BS. Proceedings of the American Psychological Association for the legislative year 2008: Minutes of the annual meeting of the Council of Representatives. *Am Psychol.* 2009;64:372-453.

⁴⁰ WPATH. Position statement on medical necessity of treatment, sex reassignment, and insurance coverage in the U.S.A. December 21, 2016. Accessed January 8, 2023. Available at <u>https://www.wpath.org/newsroom/medical-necessity-statement</u>.

⁴¹ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* The Commission; 1978.

became commercially available in the 1930's. The first documented male to female gender-affirming genital surgery was performed in 1931 and Christine Jorgensen famously underwent gender-affirming surgery in 1952.⁴² The use of gonadotropin releasing hormone analogues, also known as puberty blockers or puberty-delaying medications, to treat gender dysphoria in adolescents, while a somewhat more recent treatment, is also not new. The first reference to this treatment in the medical literature was in 1998, approximately 25 years ago.⁴³ Observational studies of puberty blockers began recruiting participants in 2000.⁴⁴ As described above, gender-affirming medical care is supported by clinical studies, the same type of studies that support many other widely accepted medical treatments.

33. The clinical use of puberty blockers, gender-affirming hormone treatment and surgeries are not research or experimentation. When administering these treatments, clinicians seek to benefit individual patients and adjust the treatment based on individual patients' responses.

34. The GAPMS Memo's suggestion that, because puberty blockers and gender-affirming hormone treatment are being used "off-label," they are experimental, untested, or unsafe is also misleading. GAPMS Memo at 8, 14, 16, 19,

⁴² Stryker S. *Transgender History*. 2nd ed. Seal Press; 2017.

⁴³ Cohen-Kettenis PT, van Goozen SH. Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent. *Eur Child Adolesc Psychiatry*. 1998;7(4):246-248.

⁴⁴ de Vries AL, Steensma TD, Doreleijers TA, Cohen- Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med.* 2011;8(8):2276-2283.

21; Attachment G at 4. Off-label use of medications is legal, common, and often evidence-based.

35. Approval by the United States (US) Food and Drug Administration (FDA) is not required for all uses of a medication. Once the FDA has approved a medication for one indication,⁴⁵ thereby agreeing that it is safe (i.e., its benefits outweigh its potential risks) and effective for this intended use, as is the case with the medications at issue here, prescribers are generally free to prescribe it for other indications.⁴⁶ Prescribing an approved medication for an unapproved indication is colloquially referred to as "off-label" use. The AAP Committee on Drugs states, "[i]t is important to note that the term 'off-label' does not imply an improper, illegal, contraindicated, or investigational use" and "[t]he administration of an approved drug for a use that is not approved by the FDA is not considered research and does

⁴⁵ According to the FDA, an indication includes several factors: the particular disease or condition or the manifestation or symptoms of the disease or condition for which the drug is approved; whether the drug is approved for treatment, prevention, mitigation, cure, or diagnosis; and the population, including age group, for which the drug is safe and effective. Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, Food and Drug Administration, U.S. Department of Health and Human Services. Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products-Content and Format: Guidance for Industry. July 2018. Accessed August 25, 2022. Available at https://www.fda.gov/files/drugs/published/Indications-and-Usage-Section-of-Labeling-for-Human-Prescription-Drug-and-Biological-Products-%E2%80%94-Content-and-Format-Guidance-for-Industry.pdf. A medication approved for the treatment of asthma in adults would, for example, be prescribed off label if used to treat a different disease, like pneumonia, or a different age group, like children.

⁴⁶ U.S. Food & Drug Administration. Understanding unapproved use of approved drugs "off label." February 5, 2018. Accessed August 25, 2022. Available at <u>https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label</u>.

not warrant special consent or review if it is deemed to be in the individual patient's best interest."⁴⁷

36. The AAP Committee on Drugs further states "in no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children."⁴⁸ Among the reasons for this is that, even if there is substantial evidence of safety and efficacy for a new indication, a sponsor may not seek FDA approval for it because the sponsor does not expect that the future revenue will offset the costs of obtaining approval.⁴⁹

37. "Off-label" use of drugs is common in many areas of medicine, including pediatrics. For example, magnesium sulfate is only approved by the FDA for replacement therapy in magnesium deficiency, in nutrition given by vein to correct or prevent low magnesium levels, or to prevent or control seizures due to high blood pressure during pregnancy.⁵⁰ It is, nonetheless, recommended for the short-term prolongation of pregnancy and to prevent neurologic injuries to the fetus and newborn ⁵¹ and as an adjunct treatment in severe, unresponsive asthma

⁴⁷ Frattarelli DA, Galinkin JL, Green TP, et al. Off-label use of drugs in children. *Pediatrics*. 2014; 133(3): 563, 565.

⁴⁸ Frattarelli DA, Galinkin JL, Green TP, et al. Off-label use of drugs in children. *Pediatrics*. 2014; 133(3): 564.

⁴⁹ Wittich CM, Burkle CM, Lanier WL. Ten common questions (and their answers) about off-label drug use. *Mayo Clin Proc.* 2012;87(10):982-990.

⁵⁰ Magnesium Sulfate. February 2016. Accessed August 31, 2022. Available at <u>https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019316s024lbl.pdf</u>.

⁵¹ Committee Opinion No 652: Magnesium sulfate use in obstetrics. *Obstet Gynecol*. 2016;127(1): e52-e53.

exacerbations.⁵² A recent study of children's hospitals found that in 28.1% of encounters, at least one off-label drug was prescribed.⁵³ Examples of medications used off-label in this study included: albuterol, which is used to treat asthma; morphine, which is used to treat pain; and lansoprazole (Prevacid®), which is used to treat gastrointestinal reflux. The rate of off-label use may be significantly higher in certain age groups, categories of drugs, and clinical settings.

38. The GAPMS Memo misleadingly notes that testosterone is a Schedule III controlled substance because of its "high probability of abuse." GAPMS Memo at 19. But there is no evidence of abuse or dependence of anabolic-androgenic steroids from therapeutic use. And Schedule III drugs have a moderate to low potential for physical and psychological dependence.⁵⁴ Dependence has only been reported among weightlifters and bodybuilders receiving non-therapeutic, supraphysiologic doses.⁵⁵

SUBSTANTIAL INCREASES IN THE UTILIZATION OF GENDER-AFFIRMING MEDICAL CARE

 ⁵² National Heart, Lung, and Blood Institute. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. 2007. Accessed August 31, 2022. Available at https://www.nhlbi.nih.gov/sites/default/files/media/docs/EPR-3_Asthma_Full_Report_2007.pdf.
⁵³ Yackey K, Stukus K, Cohen D, Kline D, Zhao S, Stanley R. Off-label medication prescribing

patterns in pediatrics: An update. Hosp Pediatr. 2019;9(3):186-193.

⁵⁴ United States Drug Enforcement Administration. Drug scheduling. July 10, 2018. Accessed August 25, 2022. Available at <u>https://www.dea.gov/drug-information/drug-scheduling</u>.

⁵⁵ Brower KJ. Anabolic steroid abuse and dependence. *Curr Psychiatry Rep.* 2002;4(5):377-387.

In addition to evidence-based clinical practice guidelines, utilization 39. trends and insurance coverage policies provide further evidence that genderaffirming medical care is a consistent with generally accepted medical standards. The peer-reviewed evidence of the efficacy of gender-affirming medical care and the recommendations of it by clinical practice guidelines are likely to increase the utilization of gender-affirming medical care and coverage by insurance companies. There have been substantial increases in the utilization of gender-affirming medical care in the last 30 years. This has included increases in referrals for care as well as the use of different forms of care. Evidence for these changes comes from a variety of sources and investigators use different ways to describe the increases in utilization. Studies demonstrate increasing referrals to children's hospitals and specialized gender clinics.⁵⁶ Handler and colleagues, for example, report that between February 2015 and June 2018 there was a significant increase in the volume of pediatric referrals to the specialized gender clinic at Kaiser Permanente North California; the average number of monthly referrals increased from 5.1 to 25.7 individuals per month which is an increase of 504%.⁵⁷

⁵⁶ Spack NP, Edwards-Leeper L, Feldman HA, et al. Children and adolescents with gender identity disorder referred to a pediatric medical center. *Pediatrics*. 2012;129(3):418-425; Chen M, Fuqua J, Eugster EA. Characteristics of referrals for gender dysphoria over a 13-year period. *J Adolesc Health*. 2016;58(3):369-371.

⁵⁷ Handler T, Hojilla JC, Varghese R, Wellenstein W, Satre DD, Zaritsky E. Trends in referrals to a pediatric transgender clinic. *Pediatrics*. 2019;144(5): e20191368.

40. Studies have also demonstrated significant increases in the utilization of various forms of gender-affirming medical care including puberty blockers,⁵⁸ hormone therapy,⁵⁹ and surgery.⁶⁰ Baker and colleagues, for example, conducted a study using the OptumLabs Data Warehouse. The Warehouse includes de-identified administrative claims data for commercially insured enrollees in a large, private US health plan. They found that the percentage of transgender people who were receiving hormone therapy or underwent surgery increased from 17% and 0.5% respectively in 2011 to 65% and 8% by 2019. This percentile increase represents a substantial number of individuals as the number of transgender people with coverage increased from 71 per million enrollees in 1993 to 411 per million in 2019.⁶¹ The Society for Plastic Surgery reports also that the number of gender-affirming

⁵⁸ Lopez CM, Solomon D, Boulware SD, Christison-Lagay ER. Trends in the use of puberty blockers among transgender children in the United States. *J Pediatr Endocrinol Metab.* 2018;31(6):665-670.

⁵⁹ Leinung MC, Joseph J. Changing demographics in transgender individuals seeking hormonal therapy: Are trans women more common than trans men? *Transgend Health*. 2020;5(4):241-245. ⁶⁰ Das RK, Perdikis G, Al Kassis S, Drolet BC. Gender-affirming chest reconstruction among transgender and gender-diverse adolescents in the US from 2016 to 2019. *JAMA Pediatr*. 2023;177(1):89-90.

⁶⁰ Canner JK, Harfouch O, Kodadek LM, et al. Temporal trends in gender-affirming surgery among transgender patients in the United States. *JAMA Surg.* 2018;153(7):609-616; Lane M, Ives GC, Sluiter EC, et al. Trends in gender-affirming surgery in insured patients in the United States. *Plast Reconstr Surg Glob Open.* 2018;6(4):e1738; Das RK, Evans AG, Kalmar CL, Al Kassis S, Drolet BC, Perdikis G. Nationwide estimates of gender-affirming chest reconstruction in the United States, 2016-2019. *Aesthet Surg J.* 2022;42(12):NP758-NP762; Das RK, Perdikis G, Al Kassis S, Drolet BC. Gender-affirming chest reconstruction among transgender and gender-diverse adolescents in the US from 2016 to 2019. *JAMA Pediatr.* 2023;177(1):89-90; Tang A, Hojilla JC, Jackson JE, et al. Gender-affirming mastectomy trends and surgical outcomes in adolescents. *Ann Plast Surg.* May 2022;88(4 Suppl): S325-S331.

⁶¹ Baker K, Restar A. Utilization and costs of gender-affirming care in a commercially insured transgender population. *J Law Med Ethics*. 2022;50(3):456-470.

surgeries performed by its members increased from 2,470 in 2015^{62} to 16,353 in 2020,⁶³ which is an increase of 562%.

COVERAGE BY OTHER CREDITABLE INSURANCE PAYORS

41. Coverage of gender-affirming medical care is provided by other creditable insurance payors. In 2014, the Department of Health and Human Services' Departmental Appeals Board determined that the National Coverage Determination denying Medicare coverage of gender-affirming surgery was invalid.⁶⁴ A 2018 analysis of Medicare prescription drug plans found that the proportion of plans providing coverage of hormone therapy varied by hormone with 100/75% providing coverage/unrestricted coverage of testosterone-cypionate, 89/89% estradiol-valerate, and 100/100% spironolactone.⁶⁵ A study of state Medicaid programs published in 2021 found that 67% covered gender affirming

⁶² American Society of Plastic Surgeons. Plastic surgery statistics report 2016. Accessed January 8, 2023. Available at <u>https://www.plasticsurgery.org/documents/News/Statistics/2016/plastic-surgery-statistics-full-report-2016.pdf</u>.

⁶³ American Society of Plastic Surgeons. Plastic surgery statistics report 2020. Accessed January 8, 2023. Available at <u>https://www.plasticsurgery.org/documents/News/Statistics/2020/plastic-surgery-statistics-full-report-2020.pdf</u>.

⁶⁴ Department of Health and Human Services Departmental Appeals Board Appellate Division. NCD 140.3 Transexual Surgery. May 30, 2014. Accessed January 8, 2023. Available at https://www.hhs.gov/sites/default/files/static/dab/decisions/board-decisions/2014/dab2576.pdf;

Centers for Medicare & Medicaid Services. National coverage determination: Gender dysphoria and gender reassignment surgery 140.9. August 30, 2016. Accessed January 8, 2023. Available at <u>https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=368</u>.

⁶⁵ Solotke MT, Liu P, Dhruva SS, Gulanski B, Shah ND, Ross JS. Medicare prescription drug plan coverage of hormone therapies used by transgender individuals. *LGBT Health*. 2020;7(3):137-145. Spironolactone is an anti-androgen used in the treatment of transgender women in conjunction with estrogen to reduce testosterone production.

hormone treatment, 18% did not cover it, and 16% were indeterminate. With respect to gender affirming surgery, the results were 51%, 43%, and 8% respectively.⁶⁶

42. Gender-affirming medical care is also covered by private health insurance plans. A study of self-insured, corporate health insurance benefit plans conducted in 2019 found that 56.4% covered transition care, 8.8% did not cover it, 5.8% were ambiguous, and 29.1% were silent. The investigators did not differentiate between gender-affirming hormone treatment and surgery.⁶⁷ Coverage for surgery is highest for bilateral mastectomy for transgender men and genital surgery for transgender men and women (transgender women are individuals assigned male at birth who identify as female). National surveys of private insurance plans found 96% covered mastectomy⁶⁸ and 91% genital surgery.⁶⁹ Private insurance plans cover other types of gender-affirming surgery,⁷⁰ such as breast augmentation,⁷¹

⁶⁶ Zaliznyak M, Jung EE, Bresee C, Garcia MM. Which U.S. states' Medicaid programs provide coverage for gender-affirming hormone therapy and gender-affirming genital surgery for transgender patients?: A state-by-state review, and a study detailing the patient experience to confirm coverage of services. *J Sex Med*. 2021;18(2):410-422.

⁶⁷ Kirkland A, Talesh S, Perone AK. Transition coverage and clarity in self-insured corporate health insurance benefit plans. *Transgend Health*. 2021;6(4):207-216.

⁶⁸ Ngaage LM, Knighton BJ, McGlone KL, et al. Health insurance coverage of gender-affirming top surgery in the United States. *Plast Reconstr Surg*. 2019;144(4):824-833.

 ⁶⁹Ngaage LM, Knighton BJ, Benzel CA, et al. A review of insurance coverage of gender-affirming genital surgery. *Plast Reconstr Surg.* 2020;145(3):803-812.
⁷⁰Ngaage LM, McGlone KL, Xue S, et al. Gender surgery beyond chest and genitals: Current

⁷⁰ Ngaage LM, McGlone KL, Xue S, et al. Gender surgery beyond chest and genitals: Current insurance landscape. *Aesthet Surg J.* 2020;40(4):NP202-NP210.

⁷¹ Ngaage LM, Knighton BJ, McGlone KL, et al. Health insurance coverage of gender-affirming top surgery in the United States. *Plast Reconstr Surg.* 2019;144(4):824-833.

facial feminization surgery,⁷² voice surgery,⁷³ and hair removal procedures⁷⁴ for transgender women albeit at lower rates.

GENDER DYSPHORIA IS A MEDICAL DIAGNOSIS

43. Several other mischaracterizations of gender-affirming medical care in the GAPMS Memo should be addressed. While the GAPMS Memo correctly acknowledges that gender dysphoria is a medical diagnosis contained in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders (DSM)* 5th ed,⁷⁵ it falsely characterizes individuals with gender dysphoria as "self-diagnosing." GAPMS Memo at 30; Attachment G at 5. The diagnosis of gender dysphoria in adolescents and adults, like many other common medical diagnoses, relies on individuals' self-report of their symptoms. The diagnosis of migraine headaches, for example, depends on individuals' report of the number, duration, and characteristics of their headaches. The characteristics include the

⁷² Gorbea E, Gidumal S, Kozato A, Pang JH, Safer JD, Rosenberg J. Insurance coverage of facial gender affirmation surgery: A review of Medicaid and commercial insurance. *Otolaryngol Head Neck Surg.* 2021;165(6):791-797; Gadkaree SK, DeVore EK, Richburg K, et al. National variation of insurance coverage for gender-affirming facial feminization surgery. *Facial Plast Surg Aesthet Med.* 2021;23(4):270-277.

⁷³ DeVore EK, Gadkaree SK, Richburg K, et al. Coverage for gender-affirming voice surgery and therapy for transgender individuals. *Laryngoscope*. 2021;131(3):E896-E902.

⁷⁴ Peloza K, Kahn B, Stoff BK, Yeung H. Insurance coverage for hair removal procedures in the treatment of gender dysphoria. *Dermatol Surg*. 2021;47(2):306-308.

⁷⁵ American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed. American Psychiatric Publishing; 2013. A text revision, which contains the same diagnosis and diagnostic criteria, has subsequently been published. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed, Text Revision. American Psychiatric Publishing; 2022.

headaches' location, quality, intensity, and aggravating factors as well as the presence of nausea and/or vomiting, and light and sound sensitivity. It is common for diagnostic criteria to utilize qualitative terms, e.g., the intensity of migraine headaches is moderate to severe.⁷⁶ Like gender dysphoria, there is no confirmatory laboratory or radiographic study for the diagnosis of migraine headaches. Radiographic studies and electroencephalograms (EEG) are only used if the history and physical examination suggest that the headache is secondary to another condition, e.g., meningitis or subarachnoid hemorrhage.⁷⁷

44. Individuals with symptoms of gender dysphoria may anticipate their diagnosis in the same way that individuals with fever, cough, and difficulty breathing may reasonably suspect that they have pneumonia. It is, however, incorrect to suggest that these patients "self-diagnose," or that such suspicions serve as the basis for the diagnosis or subsequent treatment. Only licensed healthcare providers or teams of providers, based on patient reports and, in the case of minors, parent reports, make the diagnosis of gender dysphoria and any subsequent treatment recommendations.

⁷⁶ Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211.

⁷⁷ Steiner TJ, Jensen R, Katsarava Z, et al. Aids to management of headache disorders in primary care, 2nd edition. *J Headache Pain*. 2019;20(1):57.

PARENTS AND LEGAL GUARDIANS ARE CAPABLE OF PROVIDING INFORMED CONSENT FOR GENDER-AFFIRMING MEDICAL CARE

45. The GAPMS Memo and attachments incorrectly claim that parents or legal guardians are unable to understand and appreciate the potential risks of genderaffirming health care and, therefore, are incapable of providing informed consent. GAPMS Memo at 18, 29; Attachment G at 3-4.

46. First and foremost, the current standard of care for treating gender dysphoria in minors is consistent with general ethical principles instantiated in the practices of informed consent and shared decision-making.

47. Parents or legal guardians generally must provide informed consent for medical treatment for their minor children, including for gender-affirming medical care. AHCA and Dr. Donovan cite no evidence in support of the assertion that parents or guardians of adolescents with gender dysphoria, nor the adolescents themselves, are unable to understand or appreciate the potential risks of gender-affirming medical care. ACHA and Dr. Donovan also cite to no evidence that clinicians are not sufficiently disclosing the risks of gender-affirming medical care to parents or legal guardians, or to minor patients. GAPMS Memo p. 29-30; Attachment G at 2-4.

48. Parents and legal guardians frequently consent to medical treatments for minors unrelated to gender dysphoria which have comparable risks, uncertainty,

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or levels of evidence. For example, parents and legal guardians consent to the treatment of nonmalignant medical conditions for their minor children, including some rheumatologic disorders and hematologic conditions, which may impair fertility.⁷⁸

49. Adolescents generally possess comparable medical decision-making capacity to adults.⁷⁹ There is evidence that most adolescents with gender dysphoria have sufficient medical decision-making capacity to make decisions regarding puberty blockers.⁸⁰ And there are steps that healthcare providers take to promote adolescents' decision-making capacity.⁸¹

50. The Society's clinical practice guideline extensively discusses the potential benefits, risks, and alternatives to gender-affirming medical care, and its recommendations regarding the timing of interventions are based in part on the treatment's potential risks and the adolescent's decision-making capacity. The guideline recommends that informed consent for pubertal blockers and gender-

⁷⁸ Hirshfeld-Cytron J, Gracia C, Woodruff TK. Nonmalignant diseases and treatments associated with primary ovarian failure: An expanded role for fertility preservation. *J Womens Health (Larchmt)*. 2011;20(10):1467-77.

⁷⁹ Weithorn LA, Campbell SB. The competency of children and adolescents to make informed treatment decisions. *Child Dev.* 1982;53(6):1589-98.

⁸⁰ Vrouenraets L, de Vries ALC, de Vries MC, van der Miesen AIR, Hein IM. Assessing medical decision-making competence in transgender youth. *Pediatrics*. 2021;148(6): e2020049643.

⁸¹ Katz AL, Webb SA, Committee on Bioethics. Informed consent in decision-making in pediatric practice. *Pediatrics*. 2016;138(2): e20161485.

affirming hormones include a discussion of the implications for fertility and options for fertility preservation.⁸²

51. The Society's clinical guideline also advises delaying gender-affirming hormone treatment, which results in partly irreversible physical changes, until an adolescent has developed sufficient medical decision-making capacity. The guideline states clinicians should individualize decision-making for chest surgery in transgender males and that chest surgery may be considered in some instances for individuals under 18 years old. The guideline recommends gender-affirming genital surgery involving gonadectomy and/or hysterectomy only in individuals 18 years old or older. ⁸³

THE EXCLUSION SINGLES OUT GENDER-AFFIRMING CARE FOR ANOMALOUS TREATMENT

52. The Exclusion does not provide a basis for excluding coverage of the provision of gender-affirming medical care to individuals with gender dysphoria and treating it differently from other comparable medical interventions. For example, while the Exclusion would eliminate coverage of chest surgery for the treatment of gender dysphoria for transgender Medicaid beneficiaries, cisgender Medicaid

⁸² Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of genderdysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

⁸³Or the legal age of majority in his or her country. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

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beneficiaries are provided coverage for comparable surgeries, such as those for gynecomastia.⁸⁴ Gynecomastia is the proliferation of ductal or glandular breast tissue, as opposed to adipose tissue or fat, in individuals whose sex assigned at birth is male. While surgery to treat gynecomastia may at times lessen pain, it also commonly reduces psychosocial distress. The surgery has the effect of affirming cisgender male patients' gender identity, that is, to help individuals assigned male at birth feel their bodies are more typically masculine. Risks associated with the procedure include bruising, bleeding, infection, scarring, poor cosmetic outcome, and loss of sensation.⁸⁵

53. There is nothing unique about chest surgery for gender dysphoria that justifies singling this treatment, or other medical treatments for gender dysphoria, out for non-coverage based on a concern regarding evidence of safety or efficacy; adult patients', or parents' or guardians' ability to consent; or adolescents' ability to assent. As with other conditions, medical decisions regarding treatment for gender dysphoria should continue to be left to the discretion of adult patients, or parents or legal guardians and their minor children, and their healthcare providers.

⁸⁴ State of Florida Agency for Health Care Administration. Florida Medicaid's Covered Services and HCBS Waivers: Integumentary Services. Accessed February 16, 2023. Available at https://ahca.myflorida.com/medicaid/Policy_and_Quality/Policy/behavioral_health_coverage/primary_care_policy/Integumentary.shtml.

⁸⁵ Nordt CA, DiVasta AD. Gynecomastia in adolescents. *Curr Opin Pediatr*. 2008;20(4):375-382.

CONCLUSION

54. Based on my research and experience as a physician and bioethicist, treatment for gender dysphoria is not experimental and is consistent with generally accepted professional medical standards including standards for informed consent. There is not a sound medical or ethical basis for excluding such care from coverage by Florida Medicaid and so doing is inconsistent with the program's other medical coverage decisions.

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

Executed on February 16, 2023

ND H. MATHENY ANTOMMARIA, MD, PhD

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EXHIBIT A

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EXHIBIT B

Curriculum Vitae

Last Updated: January 24, 2023

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EDUCATION

1983-1987	BSEE	Valparaiso University, with High Distinction
		Valparaiso, IN
1983-1987	BS	Valparaiso University (Chemistry), with High Distinction
		Valparaiso, IN
1987-1989	MD	Washington University School of Medicine
1998-2000		Saint Louis, MO
1989-2000	PhD	The University of Chicago Divinity School (Religious Ethics)
		Chicago, IL
2000-2003	Resident	University of Utah (Pediatrics)
		Salt Lake City, UT
2005-2006	Certificate	Conflict Resolution Certificate Program, University of Utah
		Salt Lake City, UT

BOARD CERTIFICATION

- 2019 Pediatric Hospital Medicine, American Board of Pediatrics
- 2019 Healthcare Ethics Consultant-Certified, Healthcare Ethics Consultation Certification Commission
- 2004 General Pediatrics, American Board of Pediatrics

PROFESSIONAL LICENSES

- 2012-Present Doctor of Medicine, Ohio
- 2006-2010 Alternative Dispute Resolution Provider—Mediator, Utah
- 2001-2014 Physician and Surgeon, Utah
- 2001-2014 Physician and Surgeon Controlled Substance, Utah

PROFESSIONAL EXPERIENCE

Full Time Positions

2019-Present *Professor* Cincinnati Children's Hospital Medical Center, Cincinnati, OH Department of Surgery

2019-Present	Professor of Clinical-Affiliated
	University of Cincinnati, Cincinnati, OH
	Department of Surgery
2017-Present	Professor
	Cincinnati Children's Hospital Medical Center, Cincinnati, OH
	Division of Pediatric Hospital Medicine
2017-Present	Professor of Clinical-Affiliated
	University of Cincinnati, Cincinnati, OH
	Department of Pediatrics
2016-2017	Associate Professor of Clinical-Affiliated
	University of Cincinnati, Cincinnati, OH
	Department of Pediatrics
2012-2017	Associate Professor
	Cincinnati Children's Hospital Medical Center, Cincinnati, OH
	Division of Pediatric Hospital Medicine
2012-Present	Lee Ault Carter Chair in Pediatric Ethics
	Cincinnati Children's Hospital Medical Center
2012-2016	Associate Professor-Affiliated
	University of Cincinnati, Cincinnati, OH
	Department of Pediatrics
2010-2012	Associate Professor of Pediatrics (with Tenure)
	University of Utah School of Medicine, Salt Lake City, UT
	Divisions of Inpatient Medicine and Medical Ethics
2010-2012	Adjunct Associate Professor of Medicine
	University of Utah School of Medicine, Salt Lake City, UT
	Division of Medical Ethics and Humanities
2004-2010	Assistant Professor of Pediatrics (Tenure Track)
	University of Utah School of Medicine, Salt Lake City, UT
	Divisions of Inpatient Medicine and Medical Ethics
2004-2010	Adjunct Assistant Professor of Medicine
	University of Utah School of Medicine, Salt Lake City, UT
	Division of Medical Ethics and Humanities
2003-2004	Instructor of Pediatrics (Clinical Track)
	University of Utah School of Medicine, Salt Lake City, UT
	Divisions of Inpatient Medicine and Medical Ethics
2003-2004	Adjunct Instructor of Medicine
	University of Utah School of Medicine, Salt Lake City, UT
	Division of Medical Ethics

Part Time Positions

2022- Present *Expert Witness*, Testimony Eknes-Tucker, et al., v. Marshall, et al., United States District Court Middle District of Alabama Northern Division, Case No. 2:22-cv0-184-LCB.

2022-Present	Expert Witness, Testimony
	Jane Doe, et al., v. Greg Abbott, et al., District Court of Travis County, Texas 353rd
	Judicial District, Case No. D-1-GN-22-000977
2021-2022	Expert Witness, Deposition and Testimony
	Dylan Brandt, et al., v. Leslie Rutledge, et al., United States District Court, Eastern
	District of Arkansas, Case No.: 5:21-CV-00450-JM-1
2021	Consultant
	Proctor & Gamble, Cincinnati, OH
2019	Consultant
	Sanofi Genzyme, Cambridge, MA
2018-Present	Consultant
	Center for Conflict Resolution in Healthcare, Memphis, TN
2017-2020	Consultant
	Amicus Therapeutics, Cranbury, NJ
2017	Consultant
	Sarepta Therapeutics, Cambridge, MA
2014	Consultant
	Genzyme, A Sanofi Company, Cambridge, MA

Editorial Experience

Editorial Board

2020-Present *Pediatrics,* Associate Editor for Ethics Rounds and Member of the Executive Editorial Board
2015-2020 *Journal of Clinical Ethics* 2009-2020 *Journal of Medical Humanities*

Guest Academic Editor

 $2017 \qquad PLOS|ONE$

Ad Hoc Reviewer: Academic Medicine, Academic Pediatrics, AJOB Primary Research, American Journal of Bioethics, American Journal of Law & Medicine, American Journal of Medical Genetics, American Journal of Transplantation, BMC Medical Ethics, BMJ Open, Canadian Journal of Bioethics, CHEST, Clinical Transplantation, European Journal of Human Genetics, European Journal of Pediatrics, Frontiers in Genetics, Hospital Medicine, International Journal of Health Policy and Management, International Journal of Nursing Studies, Journal of Adolescent and Young Adult Oncology, Journal of Clinical Ethics, Journal of Empirical Research on Human Research Ethics, Journal of General Internal Medicine, Journal of Healthcare Leadership, Journal of Hospital Medicine, Journal of the Kennedy Institute of Ethics, Journal of Law, Medicine & Ethics, Journal of Medical Ethics, Journal of Medical Humanities, Journal of Medicine and Life, Journal of Palliative Care, Journal of Pediatrics, Journal of Pediatric Surgery, Mayo Clinic Proceedings, Medicine, Healthcare and Philosophy, Molecular Diagnosis & Therapy, New England Journal of Medicine, Patient Preference and Adherence, Pediatrics, Pediatrics in Review, Personalized Medicine, PLOS|ONE, Risk Management and Healthcare Policy, Saudi Medical Journal, SSM - Qualitative Research in Health, and Theoretical Medicine and Bioethics

SCHOLASTIC AND PROFESSIONAL HONORS

2021	Hidden Gem Award, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2019-2022	Presidential Citation, American Society for Bioethics and Humanities, Chicago, IL
2016	Laura Mirkinson, MD, FAAP Lecturer, Section on Hospital Medicine, American
	Academy of Pediatrics, Elk Grove Village, IL
2016, 2018	Certificate of Excellence, American Society for Bioethics and Humanities, Glenview, IL
2013, 2016	Senior Resident Division Teaching Award, Cincinnati Children's Hospital Medical
	Center, Cincinnati, OH
2012	Role Model, Quality Review Committee, Primary Children's Medical Center, Salt Lake
	City, UT
2011	Member, Society for Pediatric Research, The Woodlands, TX
2011	Presidential Citation, American Society for Bioethics and Humanities, Glenview, IL
2009	Role Model, Quality Review Committee, Primary Children's Medical Center, Salt Lake
	City, UT
2008	Nominee, Physician of the Year, Primary Children's Medical Center, Salt Lake City, UT
2005-2006	Fellow, Medical Scholars Program, University of Utah School of Medicine, Salt Lake
	City, UT
1995-1997	Doctoral Scholar, Crossroads, A Program of Evangelicals for Social Action, Philadelphia
	PA
1989-1992	Fellow, The Pew Program in Medicine, Arts, and the Social Sciences, University of
	Chicago, Chicago, IL

ADMINISTRATIVE EXPERIENCE

Administrative Duties

2019-Present	Chair, Oversight Committee, Cincinnati Fetal Center, Cincinnati, OH
2014-Present	Chair, Ethics Committee, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2012-Present	Director, Ethics Center, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2012-Present	Chair, Ethics Consultation Subcommittee, Cincinnati Children's Hospital Medical
	Center, Cincinnati, OH
2010	Co-Chair, Ethics Subcommittee, Work Group for Emergency Mass Critical Care in
	Pediatrics, Centers for Disease Control and Prevention, Atlanta, GA
2009	Chair, Ethics Working Group, H1N1 and Winter Surge, Primary Children's Medical
	Center, Salt Lake City, UT
2005-2012	Chair, Ethics Committee, Primary Children's Medical Center, Salt Lake City, UT
2005-2012	Chair, Ethics Consultation Subcommittee, Primary Children's Medical Center, Salt Lake
	City, UT
2003-4	Chair, Clinical Pertinence Committee, Primary Children's Medical Center, Salt Lake
	City, UT

Professional & Scientific Committees

Committees	
2021	Member, EMCO Capacity Collaboration, Ohio Hospital Association, Columbus, OH
2020-2021	Member, Allocation of Scarce Resources Work Group, Ohio Hospital Association, Columbus, OH
2020-Present	<i>Member,</i> Literature Selection Technical Review Committee, National Library of Medicine, Bethesda, MD
2020 2019-Present	<i>Member</i> , Crisis Standards of Care Workgroup, The Health Collaborative, Cincinnati, OH <i>Member</i> , Healthcare Ethics Consultant Certification Commission, Oak Park, IL

2019	<i>Member</i> , Expert Panel, Pediatric Oncology End-of-Life Care Quality Markers, Institute for Cancer Outcomes & Survivorship, University of Alabama at Birmingham, Birmingham, AL
2018	<i>Member</i> , Resource Planning and Allocation Team Implementation Task Force, Ohio Department of Health, Columbus, OH
2012-Present 2009-2014	<i>Member</i> , Gaucher Initiative Medical Expert Committee, Project HOPE, Millwood, VA <i>Member</i> , Clinical Ethics Consultation Affairs Committee, American Society for Bioethics and Humanities, Glenview, IL
2005-2011	Member, Committee on Bioethics, American Academy of Pediatrics, Oak Park, IL
Data Safety and	Monitoring Boards
2019-Present	<i>Member</i> , Data and Safety Monitoring Board, Sickle Cell Domestic Trials, National Heart, Lung, and Blood Institute, Bethesda, MD
2018-2019	<i>Member</i> , Standing Safety Committee for P-188-NF (Carmeseal-MD TM) in Duchenne Muscular Dystrophy, Phrixus Pharmaceuticals, Inc., Ann Arbor, MI
2017-Present	<i>Member</i> , Observational Study Monitoring Board, Sickle Cell Disease Observational Monitoring Board, National Heart, Lung, and Blood Institute, Bethesda, MD
2016-2018	Member, Observational Study Monitoring Board, Long Term Effects of Hydroxyurea in Children with Sickle Cell Anemia, National Heart, Lung, and Blood Institute, Bethesda, MD
Reviewer	
2020-Present 2020 2018	Abstract Reviewer, American Society for Bioethics and Humanities Annual Meeting Grant Reviewer, The Croatian Science Foundation, Hvatska zaklada za znanost (HRZZ) Book Proposal Reviewer, Elsevier
2018-2019	<i>Category Leader,</i> Religion, Culture, and Social Sciences, American Society for Bioethics and Humanities Annual Meeting
2017	Timekeeper, American Society for Bioethics and Humanities Annual Meeting
2017-Present	Abstract Reviewer, Pediatric Academic Societies Annual Meeting
2016-2021	Workshop Reviewer, Pediatric Academic Societies Annual Meeting
2010	for Health Research and Development
2016-2017	Abstract Reviewer, American Society for Bioethics and Humanities Annual Meeting
2014, 2016	External Peer Reviewer, PSI Foundation, Toronto, Ontario, Canada
2014	<i>Member</i> , Scientific Committee, International Conference on Clinical Ethics and Consultation
2013 2013	Abstract Reviewer, American Society for Bioethics and Humanities Annual Meeting Reviewer, Open Research Area Plus, Agence Nationale de la Research, Deutsche Forschungsgemeinschaft, Economic and Social Research Council, National Science Foundation, and Organization for Scientific Research
2011-2012	Abstract Reviewer, Pediatric Academic Societies Annual Meeting
2011-2013	Workshop Reviewer, Pediatric Academic Societies Annual Meeting
2011-2014	Abstract Reviewer, Pediatric Hospital Medicine Annual Meeting
2011-2012	<i>Religious Studies Subcommittee Leader,</i> Program Committee, American Society for Bioethics and Humanities Annual Meeting
2010	Abstract Reviewer, American Society for Bioethics and Humanities Annual Meeting
Other	
2021	Timekeeper, American Society for Bioethics and Humanities Annual Meeting
2021	<i>Mentor</i> , Early Career Advisor Professional Development Track, American Society for Bioethics and Humanities.

- 2021 *Mentor*, Early Career Advisor Paper or Project Track, American Society for Bioethics and Humanities.
- 2109 *Mentor*, Early Career Advising Program, American Society for Bioethics and Humanities 2018 *Passing Point Determination*, Healthcare Ethics Consultant-Certified Examination,

Healthcare Ethics Consultant Certification Commission

- 2018 *Member*, Examination Committee, Healthcare Ethics Consultant-Certified Examination, Healthcare Ethics Consultant Certification Commission
- 2018 *Item Writer*, Healthcare Ethics Consultant-Certified Examination, Healthcare Ethics Consultant Certification Commission

UNIVERSITY COMMUNITY ACTIVITIES

Cincinnati Children's Hospital Medical Center

2020-Present	Member, Faculty Diversity and Inclusion Steering Committee
2020-Present	Member, Medical Management of COVID-19 Committee
2020-2021	Member, Caregiver Refusal Team
2020-2021	Member, COVID-19 Vaccine Allocation Committee
2020	Member, Personal Protective Equipment Subcommittee of the COVID-19 Steering.
	Committee
2018-2019	Member, Planning Committee, Center for Clinical & Translational Science & Training
	Research Ethics Conference
2017-Present	Member, Donor Selection Committee
2017-2020	Member, Employee Emergency Fund Review Committee
2017	Member, Root Cause Analysis Team
2016-2017	Member, Planning Committee, Center for Clinical & Translational Science & Training
	Research Ethics Conference
2015-2019	Member, Destination Excellence Medical Advisory Committee
2015-Present	Member, Disorders of Sexual Development Case Review Committee
2015-2019	Member, Destination Excellence Case Review Committee
2014-2018	Member, Genomics Review Group, Institutional Review Board
2014-2017	Member, Center for Pediatric Genomics Leadership Committee
2013-2017	Member, Genetic Testing Subcommittee, Health Network
2013-2016	Member, Schwartz Center Rounds Planning Committee
2013-2014	Member, Genomics Ad Hoc Subcommittee, Board of Directors
2012-Present	Member, Cincinnati Fetal Center Oversight Committee
2012-Present	Member, Ethics Committee
2012-Present	Member, G-23
2012-2016	Member, Integrated Solid Organ Transplant Steering Committee

University of Utah

2009-2012 *Member*, Consolidated Hearing Committee

University of Utah School of Medicine

2010-2012 *Member*, Medical Ethics, Humanities, and Cultural Competence Thread Committee 2008-2010 *Member*, Fourth Year Curriculum Committee

University of Utah Department of Pediatrics

- 2010-2011 *Member*, Planning Committee, 25th Annual Biological Basis of Children's Health Conference, "Sex, Gender, and Sexuality"
- 2009-2012 *Member*, Medical Executive Committee
- 2005-2012 *Member,* Retention, Promotion, and Tenure Committee
- 2004-2012 *Interviewer*, Residency Program

2003-2012 *Member*, Education Committee

Intermountain Healthcare

2009-2012	Member, System-Wide Bioethics Resource Service
2009-2012	Member, Pediatric Guidance Council

Primary Children's Medical Center

2012-2012	Member, Shared	Accountability	Organization	Steering	Committee
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- 2009 *Member*, H1N1 and Winter Surge Executive Planning Team
- 2005-2010 *Member*, Continuing Medical Education Committee
- 2005-2010 *Member*, Grand Rounds Planning Committee
- 2003-2012 *Member*, Ethics Committee

ACTIVE MEMBERSHIPS IN PROFESSIONAL SOCIETIES

2012-Present	Association of Bioethics Program Directors
2011-Present	Society for Pediatric Research
2000-Present	American Academy of Pediatrics
1999-Present	American Society of Bioethics and Humanities

FUNDING

Past Grants

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- 2013-2014 "Better Outcomes for Children: GWAS & PheWAS in eMERGEII Percent Effort: 5% National Human Genome Research Institute Grant Number: 3U01HG006828-0251 Role: <u>Investigator</u>
- 2004-2005 "Potential Patients' Knowledge, Attitudes, and Beliefs Regarding Participating in Medical Education: Can They be Interpreted in Terms of Presumed Consent?" Direct Costs: \$8,000 Interdisciplinary Research in Applied Ethics and Human Values, University Research Committee, University of Utah Role: <u>Principal Investigator</u>

TEACHING RESPONSIBILITIES/ASSIGNMENTS

Course and Curriculum Development

2003-2012 Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100

Course Lectures

- 2018, 2021 Introduction to Biotechnology, "Ethics and Biotechnology" and "Clinical Ethics," BIOL 3027, University of Cincinnati, Taught 1 time per year, Taken by undergraduate students, Enrollment 25.
- 2018-Present Biomedical Ethics, "Conscientious Objection in Healthcare" and "Ethical Issues in the Care of Transgender Adolescents," MEDS 4035 & MEDS 4036, University of Cincinnati College of Medicine, Taught 1 time per year, Taken by senior undergraduate students, Enrollment 52.
- 2016 Foundations of Healthcare Ethics and Law, "Clinical Ethics," HESA 390, Xavier University.
- 2014-Present Physicians and Society, "Transfusion and the Jehovah's Witness Faith," "Obesity Management: Ethics, Policy, and Physician Implicit Bias," "Embryos and Ethics: The Ethics of Designer Babies," "Ethics and Genetic Testing," and "Ethics and Direct to Consumer Genetic Testing," 26950112 and 26950116, University of Cincinnati School of Medicine, Taken by first and second year medical students, Enrollment 100.
- 2014-Present Ethical Issues in Health Care, "Ethical Issues in Managing Drug Shortages: The Macro, Meso, and Micro Levels," HESA 583, College of Social Sciences, Health, and Education Health Services Administration, Xavier University, Taken by health services administration students, Enrollment 25.
- 2009 Physical Diagnosis II, Internal Medicine 7160, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100
- 2003-2012 Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught 1 time per year, Taken by fourth year medical students, Enrollment 100

Small Group Teaching

2018-Present	Ethics in Research, GNTD 7003-001, University of Cincinnati School of Medicine,
	Taught 1 time per year, Taken by fellows, MS, and PhD students, Enrollment 110.
2007	Physical Diagnosis I, Internal Medicine 7150, University of Utah School of Medicine,
	Taught 1 time per year, Taken by medical students, Enrollment 100
2003-2012	Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught
	1 time per year, Taken by fourth medical students, Enrollment 100
2003	Pediatric Organ System, Pediatrics 7020, University of Utah School of Medicine, Taught
	1 time per year, Taken by medical students, Enrollment 100

Graduate Student Committees

2018-2022	Chair, Scholarship Oversight Committee, William Sveen, Pediatric Critical Care
	Fellowship, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

- 2018-2020 *Member*, Scholarship Oversight Committee, Anne Heueman, Genetic Counseling, University of Cincinnati, Cincinnati, OH
- 2017-2019 *Chair*, Scholarship Oversight Committee, Bryana Rivers, Genetic Counseling, University of Cincinnati, Cincinnati, OH
- 2013-2015 *Mentor*, Sophia Hufnagel, Combined Pediatrics/Genetics Residency, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
- 2013-2015 *Co-Chair,* Scholarship Oversight Committee, Andrea Murad, Genetic Counseling, University of Cincinnati, Cincinnati, OH
- 2013-2014 *Member*, Scholarship Oversight Committee, Grace Tran, Genetic Counseling, University of Cincinnati, Cincinnati, OH
- 2011-2012 *Chair*, Scholarship Oversight Committee, Kevin E. Nelson, MD, PhD, Pediatric Inpatient Medicine Fellowship, University of Utah, Salt Lake City, UT

Continuing Education Lectures

- 2008 Choosing Healthplans All Together (CHAT) Exercise Facilitator, 18th Annual Intermountain Medical Ethics Conference, "Setting Priorities for Healthcare in Utah: What Choices are We Ready to Make?," Salt Lake City, Utah, October 3.
- 2007 *Speaker*, Infant Medical Surgical Unit, Primary Children's Medical Center, "Withholding and Withdrawing Artificial Nutrition and Hydration: Can It Be Consistent With Care?," Salt Lake City, Utah, September 6.
- 2007 *Faculty Scholar-in Residence,* Summer Seminar, "The Role of Religion in Bioethics," Utah Valley State College, Orem, Utah, May 1.
- 2006 *Workshop Leader*, Faculty Education Retreat, "Publications and Publishing in Medical Education," University of Utah School of Medicine, Salt Lake City, Utah, September 15.
- 2006 *Breakout Session*, 16th Annual Intermountain Medical Ethics Conference, "Donation after Cardiac Death: Evolution of a Policy," Salt Lake City, Utah, March 28.

Other Educational Activities

- 2008 *Instructor*, Contemporary Ethical Issues in Medicine and Medical Research, Osher Lifelong Learning Institute, University of Utah, "Religion and Bioethics: Religiously Based Demands for and Refusals of Treatment," Salt Lake City, Utah, February 7.
- 2007 *Speaker*, Biology Seminar, Utah Valley State College, "Is He Dead?: Criteria of the Determination of Death and Their Implications for Withdrawing Treatment and Recovering Organs for Transplant," Orem, Utah, September 21.

PEER-REVIEWED JOURNAL ARTICLES

- William N. Sveen, <u>Armand H. Matheny Antommaria</u>, Stephen Gilene, and Erika L. Stalets. (Forthcoming) "Adverse Events During Apnea Testing for the Determination of Death by Neurologic Criteria: A Single Center, Retrospective Pediatric Cohort." *Pediatric Critical Care Medicine*.
- Erica K. Salter, Jay R. Malone, Amanda Berg, Annie Friedrich, Alexandra Hucker, Hillary King, and <u>Armand H. Matheny Antommaria.</u> (Online ahead of print) "Triage Policies at U.S. Hospitals with Pediatric Intensive Care Units." *AJOB Empirical Bioethics*. PMID: 36576201.
- 3. <u>Armand H. Matheny Antommaria</u>, Elizabeth Lanphier, Anne Housholder, and Michelle McGowan. (2023). "A mixed methods analysis of requests for religious exemptions to a COVID-19 vaccine requirement." *AJOB Empirical Bioethics*. 14: 15-22. PMID: 36161802.

- Anne C Heuerman, Danielle Bessett, <u>Armand H. Matheny Antommaria</u>, Leandra. K. Tolusso, Nicki Smith, Alison H. Norris and Michelle L. McGowan (2022). "Experiences of reproductive genetic counselors with abortion regulations in Ohio." *Journal of Genetic Counseling*. 31: 641-652. PMID: 34755409.
- <u>Armand H. Matheny Antommaria</u> and Ndidi I. Unaka. (2021) "Counterpoint: Prioritizing Health Care Workers for Scarce Critical Care Resources is Impractical and Unjust. *Journal of Hospital Medicine*. 16: 182-3. PMID 33617445.
- Gregory A. Grabowski, <u>Armand H. Matheny Antommaria</u>, Edwin H. Kolodny, and Pramod K. Mistry. (2021) "Gaucher Disease: Basic and Translational Science Needs for More Complete Therapy and Management." *Molecular Genetics and Metabolism*. 132: 59-75. PMID: 33419694.
- <u>Armand H. Matheny Antommaria</u>, Laura Monhollen, and Joshua K. Schaffzin. (2021) "An Ethical Analysis of Hospital Visitor Restrictions and Masking Requirements During the COVID-19." *Journal* of Clinical Ethics. 32(1): 35-44. PMID 33416516.
- 8. <u>Armand H. Matheny Antommaria</u> (2020) "The Pediatric Hospital Medicine Core Competencies: 4.05 Ethics." *Journal of Hospital Medicine*. 15(S1): 120-121.
- 9. <u>Armand H. Matheny Antommaria</u>, Tyler S. Gibb, Amy L. McGuire, Paul Root Wolpe, Matthew K. Wynia, Megan K. Applewhite, Arthur Caplan, Douglas S. Diekema, D. Micah Hester, Lisa Soleymani Lehmann, Renee McLeod-Sordjan, Tamar Schiff, Holly K. Tabor, Sarah E. Wieten, and Jason T. Eberl for a Task Force of the Association of Bioethics Program Directors (2020) "Ventilator Triage Policies During the COVID-19 Pandemic at U.S. Hospitals Associated With Members of the Association of Bioethics Program Directors." *Annals of Internal Medicine*. 173(3): 188-194. PMID: 32330224.
- 10. <u>Armand H. Matheny Antommaria</u> (2020) "Conflicting Duties and Reciprocal Obligations During a Pandemic." *Journal of Hospital Medicine*. 5:284-286. PMID: 32379030.
- Mary V. Greiner, Sarah J. Beal, and <u>Armand H. Matheny Antommaria</u> (2020) "Perspectives on Informed Consent Practices for Minimal-Risk Research Involving Foster Youth." *Pediatrics*. 45:e20192845. PMID: 32156772.
- Jennifer deSante-Bertkau, Michelle McGowan, and <u>Armand H. Matheny Antommaria</u> (2018) "Systematic Review of Typologies Used to Characterize Clinical Ethics Consultations." *Journal of Clinical Ethics*. 29:291-304. PMID: 30605439.
- Andrew J. Redmann, Melissa Schopper, <u>Armand H. Matheny Antommaria</u>, Judith Ragsdale, Alessandro de Alarcon, Michael J. Jutter, Catherine K. Hart, and Charles M. Myer. (2018) "To Transfuse or Not to Transfuse? Jehovah's Witnesses and PostOperative Hemorrhage in Pediatric Otolaryngology." *International Journal of Pediatric Otorhinolaryngology*. 115:188-192. PMID: 30368384.
- Armand H. Matheny Antommaria, Kyle B. Brothers, John A. Myers, Yana B Feygin, Sharon A. Aufox, Murray H. Brilliant, Pat Conway, Stephanie M. Fullerton, Nanibaa' A. Garrison, Carol R. Horowitz, Gail P. Jarvik, Rongling Li, Evette J. Ludman, Catherine A. McCarty, Jennifer B. McCormick, Nathaniel D. Mercaldo, Melanie F. Myers, Saskia C. Sanderson, Martha J. Shrubsole, Jonathan S. Schildcrout, Janet L. Williams, Maureen E. Smith, Ellen Wright Clayton, Ingrid A. Holm. (2018) "Parents' Attitudes toward Consent and Data Sharing in Biobanks: A Multi-Site Experimental Survey." *AJOB Empirical Research*. 21:1-15. PMID: 30240342.
- Armand H. Matheny Antommaria and Cynthia A. Prows. (2018) "Content Analysis of Requests for Religious Exemptions from a Mandatory Influenza Vaccination Program for Healthcare Personnel" *Journal of Medical Ethics.* 44: 389-391. PMID: 29463693.
- Armand H. Matheny Antommaria (2017) "May Medical Centers Give Nonresident Patients Priority in Scheduling Outpatient Follow-Up Appointments?" *Journal of Clinical Ethics*. 28: 217-221. PMID: 28930708.

- Andrea M. Murad, Melanie F. Myers, Susan D. Thompson, Rachel Fisher, and <u>Armand H. Matheny</u> <u>Antommaria</u> (2017) "A Qualitative Study of Adolescents' Understanding of Biobanks and Their Attitudes Toward Participation, Re-contact, and Data Sharing." *American Journal of Medical Genetics: Part A.* 173: 930-937. PMID: 28328120.
- 18. Saskia Sanderson, Kyle Borthers, Nathaniel Mercaldo, Ellen Wright Clayton, <u>Armand Antommaria</u>, Sharon Aufox, Murray Brillant, Diego Campos, David Carrell, John Connolly, Pat Conway, Stephanie Fullerton, Nanibaa Garrison, Carol Horowitz, Gail Jarvik, David Kaufman, Terrie Kitchner, Rongling Li, Evette Ludman, Cahterine McCarty, Jennifer McCormick, Valerie McManus, Melanie Myers, Aaron Scrol, Janet Williams, Martha Shrubsole, Jonathan Schildcrout, Maureen Smith, and Ingrid Holm (2017) "Public Attitudes Towards Consent and Data Sharing in Biobank Research: A Large Multisite Experimental Survey in the US." *The American Journal of Human Genetics*. 100: 414-427. PMID: 28190457.
- Maureen E. Smith, Saskia C Sanderson, Kyle B Brothers, Melanie F Myers, Jennifer McCormick, Sharon A Aufox, Martha J Shrubsole, Nanibaa' A Garrison, Nathaniel D Mercaldo, Jonathan S Schildcrout, Ellen Wright Clayton, <u>Armand H. Matheny Antommaria</u>, Melissa Basford, Murray Brilliant, John J Connolly, Stephanie M Fullerton, Carol R Horowitz, Gail P Jarvik, Dave Kaufman, Terrie Kitchner, Rongling Li, Evette J Ludman, Catherine McCarty, Valerie McManus, Sarah C Stallings, Janet L Williams, and Ingrid A Holm (2016) "Conducting a Large, Multi-Site Survey about Patients' Views on Broad Consent: Challenges and Solutions." *BMC Medical Research Methodology*. 16: 162. PMID: 27881091.
- Angela Lorts, Thomas D. Ryan, <u>Armand H. Matheny Antommaria</u>, Michael Lake, and John Bucuvalas (2016) "Obtaining Consensus Regarding International Transplantation Continues to be Difficult for Pediatric Centers in the United States." *Pediatric Transplant.* 20: 774-777. PMID: 27477950.
- 21. Sophia B. Hufnagel, Lisa J. Martin, Amy Cassedy, Robert J. Hopkin, and <u>Armand H. Matheny</u> <u>Antommaria</u> (2016) "Adolescents' Preferences Regarding Disclosure of Incidental Findings in Genomic Sequencing That Are Not Medically Actionable in Childhood." *American Journal of Medical Genetics Part A*. 170: 2083-2088. PMID: 27149544.
- 22. Nanibaa' A. Garrison, Nila A. Sathe, <u>Armand H. Matheny Antommaria</u>, Ingrid A. Holm, Saskia Sanderson, Maureen E. Smith, Melissa McPheeters, and Ellen Wright Clayton (2016) "A Systematic Literature Review of Individuals' Perspectives on Broad Consent and Data Sharing in the United States." *Genetics in Medicine*. 18: 663-71. PMID: 26583683.
- 23. Kyle B. Brothers, Ingrid A. Holm Janet E. Childerhose, <u>Armand H. Matheny Antommaria</u>, Barbara A. Bernhardt, Ellen Wright Clayton, Bruce D. Gelb, Steven Joffe, John A. Lynch, Jennifer B. McCormick, Laurence B. McCullough, D. William Parsons, Agnes S. Sundaresan, Wendy A. Wolf, Joon-Ho Yu, and Benjamin S. Wilfond (2016) "When Genomic Research Participants Grow Up: Contact and Consent at the Age of Majority." *The Journal of Pediatrics* 168: 226-31. PMID: 26477867.
- Erin E. Bennett, Jill Sweney, Cecile Aguayo, Criag Myrick, <u>Armand H. Matheny Antommaria</u>, and Susan L. Bratton (2015) "Pediatric Organ Donation Potential at a Children's Hospital." *Pediatric Critical Care Medicine*. 16: 814-820. PMID: 26237656.
- 25. Anita J. Tarzian, Lucia D. Wocial, and the ASBH Clinical Ethics Consultation Affairs Committee (2015) "A Code of Ethics for Health Care Ethics Consultants: Journey to the Present and Implications for the Field." *American Journal of Bioethics*. 15: 38-51. PMID: 25970392.
- <u>Armand H. Matheny Antommaria</u>, Christopher A. Collura, Ryan M. Antiel, and John D. Lantos (2015) "Two Infants, Same Prognosis, Different Parental Preferences." *Pediatrics*, 135: 918-923. PMID: 25847802.
- Stefanie Benoit, <u>Armand H. Matheny Antommaria</u>, Norbert Weidner, and Angela Lorts (2015)
 "Difficult Decision: What should we do when a VAD supported child experiences a severe stroke?" *Pediatric Transplantation* 19: 139-43. PMID: 25557132.

- 28. Kyle B. Brothers, John A. Lynch, Sharon A. Aufox, John J. Connolly, Bruce D. Gelb, Ingrid A. Holm, Saskia C. Sanderson, Jennifer B. McCormick, Janet L. Williams, Wendy A. Wolf, <u>Armand H. Matheny Antommaria</u>, and Ellen W. Clayton (2014) "Practical Guidance on Informed Consent for Pediatric Participants in a Biorepository." *Mayo Clinic Proceedings*, 89: 1471-80. PMID: 25264176.
- 29. Sophia M. Bous Hufnagel and <u>Armand H. Matheny Antommaria</u> (2014) "Laboratory Policies on Reporting Secondary Findings in Clinical Whole Exome Sequencing: Initial Uptake of the ACMG's Recommendations." *American Journal of Medical Genetics Part A*, 164: 1328-31. PMID: 24458369.
- Wylie Burke, <u>Armand H. Matheny Antommaria</u>, Robin Bennett, Jeffrey Botkin, Ellen Wright Clayton, Gail E. Henderson, Ingrid A. Holm, Gail P. Jarvik, Muin J. Khoury, Bartha Maria Knoppers, Nancy A. Press, Lainie Friedman Ross, Mark A. Rothstein, Howard Saal, Wendy R. Uhlmann, Benjamin Wilfond, Susan M. Wold, and Ron Zimmern (2013) "Recommendations for Returning Genomic Incidental Findings? We Need to Talk!" *Genetics in Medicine*, 15: 854-859. PMID: 23907645.
- Armand H. Matheny Antommaria (2013) "An Ethical Analysis of Mandatory Influenza Vaccination of Health Care Personnel: Implementing Fairly and Balancing Benefits and Burdens," *American Journal of Bioethics*, 13: 30-37. PMID: 23952830.
- 32. Joseph A. Carrese and the Members of the American Society for Bioethics and Humanities Clinical Ethics Consultation Affairs Standing Committee (2012) "HCEC Pearls and Pitfalls: Suggested Do's and Don't's for Healthcare Ethics Consultants," *Journal of Clinical Ethics*, 23: 234-240. PMID: 23256404.
- 33. Christopher G Maloney, <u>Armand H Matheny Antommaria</u>, James F Bale Jr., Jian Ying, Tom Greene and Rajendu Srivastiva (2012) "Factors Associated with Intern Noncompliance with the 2003 Accreditation Council for Graduate Medical Education's 30-hour Duty Period Requirement," *BMC Medical Education* 12: 33. PMID: 22621439.
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UNPUBLISHED POSTER PRESENTATIONS

- 1. <u>Armand H. Matheny Antommaria.</u> (2018) "Ethical Issues in the Care of International Patients: A Case Study." International Conference on Clinical Ethics and Consultation, Oxford, United Kingdom.
- Jill S Sweney, Brad Poss, Colin Grissom, Brent Wallace, and <u>Armand H Matheny Antommaria</u>, (2010) "Development of a Statewide Pediatric Pandemic Triage Plan in Utah." Pediatric Academic Societies Annual Meeting, Vancouver, Canada. E-PAS20103713.147.
- Christopher G. Maloney, <u>Armand H. Matheny Antommaria</u>, James F. Bale, Thomas Greene, Jian Ying, Gena Fletcher, and Rajendu Srivastava (2010) "Why Do Pediatric Interns Violate the 30 Hour Work Rule?" Pediatric Academic Societies Annual Meeting, Vancouver, Canada. E-PAS20101500.596
- Armand H. Matheny Antommaria and Edward B. Clark (2007) "Resolving Conflict through Bioethics Mediation." 3rd International Conference on Ethics Consultation and Clinical Ethics, Toronto, Canada.
- Elizabeth Tyson, Tracy Hill, <u>Armand Antommaria</u>, Gena Fletcher, and Flory Nkoy (2007) "Physician Practice Patterns Regarding Nasogastric Feeding Supplementation and Intravenous Fluids in Bronchiolitis Patients." Pediatrics Academic Societies Annual Meeting, Toronto, Canada. E-PAS2007:61300.

ORAL PRESENTATIONS

Keynote/Plenary Lectures

International

- 1. 2021, *Panelist*, Partnership for Quality Medical Donations, Charitable Access Programming for Rare Diseases, "Ethical Issues," Webinar, April 6.
- 2. 2017, *Invited Speaker*, Spina Bifida Fetoscopic Repair Study Group and Consortium, "Ethics of Innovation and Research in Fetal Surgery," Cincinnati, Ohio, October 26.
- 3. 2014, *Invited Speaker*, CIC 2013 CCI: Canadian Immunization Conference, "Condition-of-Service Influenza Prevention in Health Care Settings," Ottawa, Canada, December 2.
- 4. 2014, *Invited Speaker*, National Conference of the Chinese Pediatric Society, "A Brief Introduction to Pediatric Research and Clinical Ethics," Chongqing, China, September 12.

National

- 1. 2020, *Panelist*, Children's Mercy Bioethics Center, "Ethical Issues in the COVID Pandemic at Children's Hospitals," Webinar, March 2.
- 2. 2019, *Invited Speaker*, North American Fetal Therapy Network (NAFTnet), "Ethics of Innovation," Chicago, Illinois, October 12.
- 3. 2019, *Panelist*, National Society of Genetic Counselors Prenatal Special Interest Group, "Fetal Intervention Ethics," Webinar, September 12.
- 4. 2017, *Invited Participant*, American College of Epidemiology Annual Meeting, Preconference Workshop, "Extreme Personal Exposure Biomarker Levels: Guidance for Study Investigators," New Orleans, Louisiana, September 24.
- 2016, *Invited Speaker*, American Academy of Pediatrics National Conference & Exhibition, Joint Program: Section on Hospital Medicine and Section on Bioethics, "Resource Allocation: Do We Spend Money to Save One Patient with Ebola or Over a 1,000?" San Francisco, California, October 23.
- 2016, *Invited Speaker*, 26th Annual Specialist Education in Extracorporeal Membrane Oxygenation (SEECHMO) Conference, "Ethical Issues in ECMO: The Bridge to Nowhere," Cincinnati, Ohio, June 5.
- 2015, *Invited Speaker*, Extracorporeal Life Support Organization (ELSO) 26th Annual Conference, "ECMO-Supported Donation after Circulatory Death: An Ethical Analysis," Atlanta, Georgia, September 20.

- 8. 2014, *Invited Speaker*, Pediatric Evidence-Based Practice 2014 Conference: Evidence Implementation for Changing Models of Pediatric Health Care, "Ethical Issues in Evidence-Based Practice," Cincinnati, Ohio, September 19.
- 9. 2014, *Invited Speaker*, 6th Annual David Kline Symposium on Public Philosophy: Exploring the Synergy Between Pediatric Bioethics and Child Rights, "Does Predictive Genetic Testing for Adult Onset Conditions that Are Not Medically Actionable in Childhood Violate Children's Rights?" Jacksonville, Florida, March 6.
- 10. 2010, *Invited Speaker*, Quest for Research Excellence: The Intersection of Standards, Culture and Ethics in Childhood Obesity, "Research Integrity and Religious Issues in Childhood Obesity Research," Denver, Colorado, April 21.
- 11. 2010, *Invited Speaker*, Symposium on the Future of Rights of Conscience in Health Care: Legal and Ethical Perspectives, J. Reuben Clark Law School at Brigham Young University and the Ave Maria School of Law, "Conscientious Objection in Clinical Practice: Disclosure, Consent, Referral, and Emergency Treatment," Provo, Utah, February 26.
- 12. 2009, *Invited Speaker*, Pediatric Organ Donation Summit, "Research Findings Regarding Variations in Pediatric Hospital Donation after Cardiac Death Policies," Chicago, Illinois, August 18.
- 13. 2008, *Meet-the-Experts*, American Academy of Pediatrics National Conference & Exhibition, "Physician Refusal to Provide Treatment: What are the ethical issues?" Boston, Massachusetts, October 11.
- 2008, *Invited Conference Faulty*, Conscience and Clinical Practice: Medical Ethics in the Face of Moral Controversy, The MacLean Center for Clinical Medical Ethics at the University of Chicago, "Defending Positions or Identifying Interests: The Uses of Ethical Argumentation in the Debate over Conscience in Clinical Practice," Chicago, IL, March 18.
- 15. 2007, *Symposium Speaker*, Alternative Dispute Resolution Strategies in End-of-Life Decisions, The Ohio State University Mortiz College of Law, "The Representation of Children in Disputes at the End-of-Life," Columbus, Ohio, January 18.
- 16. 2005, Keynote Speaker, Decisions and Families, Journal of Law and Family Studies and The University of Utah S.J. Quinney College of Law, "Jehovah's Witnesses, Roman Catholicism, and Calvinism: Religion and State Intervention in Parental, Medical Decision-Making," Salt Lake City, Utah, September 23.

Regional/Local

- 1. 2021, *Panelist*, Pediatric Residency Noon Conference, University of Tennessee Health Science Center, "Bioethics Rounds—Ethical Issues in the Care of Transgender Adolescents," Memphis, Tennessee, September 21.
- 2020, Keynote Speaker, 53rd Annual Clinical Advances in Pediatrics, "Referral to a Fetal Care Center: How You Can Help Patients' Mothers Address the Ethical Issues," Kansas City, Kansas, September 16.
- 3. 2019, *Speaker*, Patient and Family Support Services, Primary Children's Hospital, "Ethical Issues in the Care of Trans Adolescents," Salt Lake City, Utah, December 5.
- 4. 2019, *Speaker*, Evening Ethics, Program in Medical Ethics and Humanities, University of Utah School of Medicine, "Patients, Parents, and Professionals: Ethical Issues in the Treatment of Trans Adolescents," Salt Lake City, Utah, December 4.
- 5. 2019, *Speaker*, Pediatric Hospital Medicine Board Review Course, "Ethics, Legal Issues, and Human Rights including Ethics in Research," Cincinnati, Ohio, September 8.
- 6. 2019, *Speaker*, Advances in Fetology, "Evolving Attitudes Toward the Treatment of Children with Trisomies," Cincinnati, Ohio, September 6.
- 7. 2019, *Speaker*, Half-Day Ethics Training: Ethics Consultation & Ethics Committees, "Navigating the Rapids of Clinical Ethics Consultation: Intake, Recommendations, and Documentation," Salt Lake City, Utah, June 1.

- 8. 2019, *Speaker*, Scientific and Ethical Underpinnings of Gene Transfer/Therapy in Vulnerable Populations: Considerations Supporting Novel Treatments, BioNJ, "What Next? An Ethical analysis of Prioritizing Conditions and Populations for Developing Novel Therapies," Cranbury, New Jersey, March 7.
- 9. 2018, Panelist, Periviability, 17th Annual Regional Perinatal Summit, Cincinnati, Ohio, October 12.
- 2018, Speaker, Regional Advance Practice Registered Nurse (APRN) Conference, "Adults are Not Large Children: Ethical Issues in Caring for Adults in Children's Hospitals," Cincinnati, Ohio, April 26.
- 11. 2018, *Speaker*, Southern Ohio/Northern Kentucky Sigma Theta Tau International Annual Conference, "Between Hope and Hype: Ethical Issues in Precision Medicine," Sharonville, Ohio, March 2.
- 12. 2017, *Speaker*, Advances in Fetology 2017, "Ethics of Innovation and Research: Special Considerations in Fetal Therapy Centers," Cincinnati, Ohio, October 27.
- 13. 2016, *Speaker*, End-of-Life Pediatric Palliative Care Regional Conference, "Ethical/Legal Issues in Pediatric Palliative Care," Cincinnati, Ohio, September 15.
- 14. 2016, *Speaker*, 26th Annual Bioethics Network of Ohio (BENO) Conference, "When Does Parental Refusal of Medical Treatment for Religious Reasons Constitute Neglect?" Dublin, Ohio, May 29.
- 15. 2014, *Speaker*, Cincinnati Comprehensive Sickle Cell Center Symposium: Research Ethics of Hydroxyurea Therapy for Sickle Cell Disease During Pregnancy and Lactation, "Ethical Issues in Research with Pregnant and Lactating Women," Cincinnati, Ohio, October 30.
- 16. 2014, *Speaker*, Advances in Fetology 2014, "The 'Miracle Baby' and Other Cases for Discussion," Cincinnati, Ohio, September 26.
- 17. 2014, *Speaker*, Advances in Fetology 2014, "'Can you tell me ...?': Achieving Informed Consent Given the Prevalence of Low Health Literacy," Cincinnati, Ohio, September 26.
- 18. 2014, *Panelist*, Center for Clinical & Translational Science & Training, Secrets of the Dead: The Ethics of Sharing their Data, Cincinnati, Ohio, August 28.
- 2014, Speaker, Office for Human Research Protections Research Community Forum: Clinical Research ... and All That Regulatory Jazz, "Research Results and Incidental Findings: Do Investigators Have a Duty to Return Results to Participants," Cincinnati, Ohio, May 21.
- 20. 2013, *Opening Presentation*, Empirical Bioethics: Emerging Trends for the 21st Century, University of Cincinnati Center for Clinical & Translational Science & Training, "Empirical vs. Normative Ethics: A Comparison of Methods," Cincinnati, Ohio, February 21.
- 21. 2012, *Videoconference*, New York State Task Force on Life and the Law, "Pediatric Critical Care Triage," New York, New York, March 1.
- 22. 2011, *Presenter*, Fall Faculty Development Workshop, College of Social Work, University of Utah, "Teaching Ethics to Students in the Professions," Salt Lake City, Utah, November 14.
- 23. 2011, *Speaker*, 15th Annual Conference, Utah Chapter of the National Association of Pediatric Nurse Practitioners, "Ethical Issues in Pediatric Practice," Salt Lake City, Utah, September 22.
- 24. 2011, *Speaker*, Code Silver! Active Shooter in the Hospital, Utah Hospitals & Health Systems Association, Salt Lake City, Utah, March 21.
- 25. 2009, *Speaker*, Medical Staff Leadership Conference, Intermountain Healthcare, "The Ethics of Leadership," Park City, Utah, October 30.
- 26. 2008, *Speaker*, The Art and Medicine of Caring: Supporting Hope for Children and Families, Primary Children's Medical Center, "Medically Provided Hydration and Nutrition: Ethical Considerations," Salt Lake City, Utah, February 25.
- 27. 2005, *Speaker*, Utah NAPNAP (National Association of Pediatric Nurse Practitioners) Chapter Pharmacology and Pediatric Conference, "Immunization Update," Salt Lake City, Utah, August 18.
- 28. 2005, *Keynote Speaker*, 17th Annual Conference, Utah Society for Social Work Leadership in Health Care, "Brain Death: Accommodation and Consultation," Salt Lake City, March 18.
- 29. 2004, *Continuing Education Presentation*, Utah NAPNAP (National Association of Pediatric Nurse Practitioners), "Febrile Seizures," Salt Lake City, Utah, April 22.

- 30. 2004, *Speaker*, Advocacy Workshop for Primary Care Providers, "Ethics of Advocacy," Park City, Utah, April 3.
- 31. 2002, *Speaker*, 16th Annual Biologic Basis of Pediatric Practice Symposium, "Stem Cells: Religious Perspectives," Deer Valley, Utah, September 14.

Meeting Presentations

International

1. 2018, *Speaker*, International Conference on Clinical Ethics and Consultation, "A Systematic Review of Typologies Used to Characterize Clinical Ethics Consultations," Oxford, United Kingdom, June 21.

National

- 1. 2022, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "A Mixed Methods Analysis of Requests for Religious Exemptions to a COVID-19 Vaccine Requirement." Portland, Oregon, October 27.
- 2. 2022, *Panelist,* American Society for Bioethics and Humanities Annual Meeting, Pediatric Ethics Affinity Group, "When Ethical Healthcare Is Prohibited By Law, How Do We Respond?" Portland, Oregon, October 27.
- 3. 2022, *Speaker*, APPD/PAS Fellow Core Curriculum Workshop, Pediatric Academic Societies Annual Meeting, "From Idea to Implementation: Navigating the Ethical Landscape of Pediatric Clinical Research," Denver, Colorado, April 22.
- 4. 2021, *Panelist*, Pediatric Endocrine Society Annual Meeting, Difference of Sex Development Special Interest Group, Virtual Conference, April 29.
- 2020, Speaker, American Society for Bioethics and Humanities Annual Meeting, "Is This Child Dead? Controversies Regarding the Neurological Criteria for Death," Virtual Conference, October 17.
- 6. 2020, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Contemporary Ethical Controversy in Fetal Therapy: Innovation, Research, Access, and Justice," Virtual Conference, October 15.
- 2020, Speaker, American Society for Bioethics and Humanities Annual Meeting, "K-12 Schools and Mandatory Public Health Programs During the COVID-19 Pandemic," Virtual Conference, October 15.
- 8. 2019, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Ethical Issues in Translating Gene Transfer Studies Involving Children with Neurodegenerative Disorders," Pittsburgh, Pennsylvania, October 26.
- 9. 2019, *Moderator*, Pediatric Academic Societies Annual Meeting, Clinical Bioethics, Baltimore, Maryland, April 28.
- 10. 2018, *Presenter*, American Society for Bioethics and Humanities Annual Meeting, "Looking to the Past, Understanding the Present, and Imaging the Future of Bioethics and Medical Humanities" Engagement with Transgender Health," Anaheim, California, October 19.
- 11. 2018, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Should Vaccination Be a Prerequisite for Sold Organ Transplantation?" Anaheim, California, October 18.
- 12. 2018, Lindsey Douglas, <u>Armand H. Matheny Antommaria</u>, Derek Williams. *Workshop Presenter*, Pediatric Hospital Medicine Annual Meeting, "IRB Approved! Tips and Tricks to Smooth Sailing through the Institutional Review Board (IRB)." Atlanta, Georgia, July 20.
- 2018, Alan Schroeder, <u>Armand H. Matheny Antommaria</u>, Hannah Bassett, Kevin Chi, Shawn Ralston, Rebecca Blankenburg. *Workshop Speaker*, Pediatric Hospital Medicine Annual Meeting, "When You Don't Agree with the Plan: Balancing Diplomacy, Value, and Moral Distress," Atlanta, Georgia, July 20.

- 14. 2018, Alan Schroeder, Hannah Bassett, Rebecca Blankenburg, Kevin Chi, Shawn Ralston, <u>Armand H. Matheny Antommaria.</u> Workshop Speaker, Pediatric Academic Societies Annual Meeting, "When You Don't Agree with the Plan: Balancing Diplomacy, Value, and Moral Distress," Toronto, Ontario, Canada, May 7.
- 15. 2017, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Tensions in Informed Consent for Gender Affirming Hormone Therapy and Fertility Preservation in Transgender Adolescents," Kansas City, Missouri, October 19.
- 16. Lindsey Douglas, <u>Armand H. Matheny Antommaria</u>, and Derek Williams. 2017, *Workshop Leader*, PHM[Pediatric Hospital Medicine]2017, "IRB Approved! Tips and Tricks to Smooth Sailing through the Institutional Review Board (IRB) Process," Nashville, Tennessee, July 21.
- 2016, Speaker, American Society for Bioethics and Humanities Annual Meeting, "Ethical Challenges in the Care of International Patients: Organization, Justice, and Cultural Considerations," Washington, DC, October 9.
- 2015, *Coauthor*, The American Society of Human Genetics Annual Meeting, "Adolescents' Opinions on Disclosure of Non-Actionable Secondary Findings in Whole Exome Sequencing," Baltimore, Maryland, October 9.
- 19. 2012, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "A Public Health Ethics Analysis of the Mandatory Immunization of Healthcare Personnel: Minimizing Burdens and Increasing Fairness," Washington, DC, October 21.
- Armand H. Matheny Antommaria, Valerie Gutmann Koch, Susie A. Han, Carrie S. Zoubul. 2012, Moderator, American Society for Bioethics and Humanities Annual Meeting, "Representing the Underrepresented in Allocating Scarce Resources in a Public Health Emergency: Ethical and Legal Considerations," Washington, DC, October 21.
- 2012, *Platform Presentation*, Pediatric Academic Societies Annual Meeting, "Qualitative Analysis of International Variation in Donation after Circulatory Death Policies and Rates," Boston, Massachusetts, April 30. Publication 3150.4.
- 22. 2011, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "The Intersection of Policy, Medicine, and Ethics during a Public Health Disaster: Special Considerations for Children and Families," Minneapolis, Minnesota, October 13.
- 23. <u>Armand H. Matheny Antommaria</u> and Joel Frader. 2010, *Workshop Leader*, Pediatric Academic Societies Annual Meeting, "Conscientious Objection in Health Care: Respecting Conscience and Providing Access," Vancouver, British Columbia, Canada. May 1. Session 1710.
- 2009, Workshop Leader, American Society for Bioethics and Humanities Annual Meeting, "Advanced Clinical Ethics Consultation Skills Workshop: Process and Interpersonal Skills," Washington, DC, October 15.
- 25. 2009, *Platform Presentation*, Pediatric Academic Societies Annual Meeting, "Qualitative Analysis of Donation after Cardiac Death Policies at Children's Hospitals," Baltimore, Maryland, May 2. Publication 2120.6.
- 26. 2008, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Qualitative Analysis of Donation After Cardiac Death (DCD) Policies at Children's Hospitals," Cleveland, Ohio, October 26.
- 27. 2007, *Participant*, Hamline University School of Law Biennial Symposium on Advanced Issues in Dispute Resolution, "An Intentional Conversation About Conflict Resolution in Health Care," Saint Paul, Minnesota, November 8-10.
- 28. 2007, Speaker, American Society of Bioethics and Humanities Annual Meeting, "Bioethics Consultation and Alternative Dispute Resolution: Opportunities for Collaboration," Washington, DC, October 21.
- 29. 2007, *Speaker*, American Society of Bioethics and Humanities Annual Meeting, "DNAR Orders in Schools: Collaborations Beyond the Hospital," Washington, DC, October 18.

- 30. <u>Armand H. Matheny Antommaria</u> and Jeannie DePaulis. 2007, *Speaker*, National Association of Children's Hospitals and Related Institutions Annual Meeting, "Using Mediation to Address Conflict and Form Stronger Therapeutic Alliances," San Antonio, Texas, October 9.
- 31. 2006, *Speaker*, American Society of Bioethics and Humanities Annual Meeting, "Bioethics Mediation: A Critique," Denver, Colorado, October 28.
- 32. 2005, *Panelist,* American Society of Bioethics and Humanities Annual Meeting, "How I See This Case: 'He Is Not His Brain,'" Washington, DC, October 20.
- 2005, Paper Presentation, Pediatric Ethics: Setting an Agenda for the Future, The Cleveland Clinic, "'He Is Not His Brain:' Accommodating Objections to 'Brain Death," Cleveland, Ohio, September 9.
- 2004, Speaker, American Society for Bioethics and Humanities Spring Meeting, "Verification and Balance: Reporting Within the Constraints of Patient Confidentiality," San Antonio, Texas, March 13.
- 35. 2002, *Panelist*, American Society for Bioethics and Humanities Annual Meeting, "Who Should Survive?:' Mental Retardation and the History of Bioethics," Baltimore, Maryland, October 24.

Invited/Visiting Professor Presentations

- 1. 2013, Visiting Professor, "How to Listen, Speak and Think Ethically: A Multidisciplinary Approach," Norton Suburban Hospital and Kosair Children's Hospital, Louisville, Kentucky, May 22.
- 2. 2010, Visiting Professor, Program in Bioethics and Humanities and Department of Pediatrics, "What to Do When Parents Want Everything Done: 'Futility' and Ethics Facilitation," University of Iowa Carver College of Medicine, Iowa City, Iowa, September 10.

Grand Round Presentations

- 1. 2019, David Green Lectureship, "Establishing Goals of Care and Ethically Limiting Treatment," Primary Children's Hospital, Salt Lake City, Utah, December 5.
- 2. 2018, "The Ethics of Medical Intervention for Transgender Youth," El Rio Health, Tucson, Arizona, September 29.
- 3. 2018, Pediatrics, "Patient Selection, Justice, and Cultural Difference: Ethical Issues in the Care of International Patients," Cleveland Clinic, Cleveland, Ohio, April 10.
- 4. 2018, Bioethics, "Reversibility, Fertility, and Conflict: Ethical Issues in the Care of Transgender and Gender Nonconforming Children and Adolescents," Cleveland Clinic, Cleveland, Ohio, April 9.
- 5. 2017, Heart Institute, "'Have you ever thought about what you would want—if god forbid—you became sicker?': Talking with adult patients about advance directives," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 16.
- 6. 2017, Pediatrics, "Respectful, Effective Treatment of Jehovah's Witnesses," with Judith R. Ragsdale, PhD, MDiv and David Morales, MD, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, March 14.
- 7. 2017, Pediatrics, "Ethical Dilemmas about Discharging Patients When There Are Disagreements Concerning Safety," Seattle Children's Hospital, Seattle, Washington, January 19.
- 8. 2015, Pediatrics, "'Nonbeneficial' Treatment: What must providers offer and what can they withhold?," Greenville Health System, Greenville, South Carolina, May 10.
- 9. 2014, Advance Practice Providers, "Common Ethical Issues," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, August 13.
- 10. 2014, Respiratory Therapy, "Do-Not-Resuscitate (DNR) Orders," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, July 15.
- 11. 2013, Heart Institute, "No Not Months. Twenty-Two *Years*-Old: Transiting Patients to an Adult Model of Care." Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 21.
- 12. 2013, Division of Neonatology, "This Premature Infant Has a *BRCA1* Mutation!?: Ethical Issues in Clinical Whole Exome Sequencing for Neonatologists." Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 11.

- 2013, Department of Pediatrics, "Adults are Not Large Children: Ethical Issues in Caring for Adults in Children's Hospitals," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, February 26.
- 14. 2012, "Mandate or Moratorium?: Persisting Ethical Controversies in Donation after Circulatory Death," Cedars-Sinai Medical Center, Los Angeles, California, May 16.
- 15. 2011, Division of Pediatric Neurology Friday Lecture Series, "Inducing or Treating 'Seizures' with Placebos: Is It Ever Ethical?," University of Utah, Salt Lake City, Utah, October 7.
- 16. 2011, Department of Surgery, "DNR Orders in the OR and other Ethical Issues in Pediatric Surgery: Case Discussions," Primary Children's Medical Center, Salt Lake City, Utah, October 3.
- 17. 2009, Department of Pediatrics, "What to Do When Parents Want Everything Done: 'Futility' and Bioethical Mediation," Primary Children's Medical Center, Salt Lake City, Utah, September 17.
- 2008, Division of Pulmonology and Critical Care, "Futility: May Clinicians Ever Unilaterally Withhold or Withdraw Medical Treatment?" Utah Valley Regional Medical Center, Provo, Utah, April 17.
- 19. 2007, Division of Otolaryngology-Head and Neck Surgery, "Advance Directives, Durable Powers of Attorney for Healthcare, and Do Not Attempt Resuscitation Orders: Oh My!," University of Utah School of Medicine, Salt Lake City, Utah, June 20.

Outreach Presentations

- 1. 2019, *Panelist*, Cincinnati Edition, WVXU, "The Ethics of Human Gene Editing," Cincinnati, Ohio, June 13.
- 2. 2019, Speaker, Adult Forum, Indian Hill Church, "Medical Ethics," Indian Hill, Ohio, March 24.
- 3. 2016, *Speaker*, Conversations in Bioethics: The Intersection of Biology, Technology, and Faith, Mt. Washington Presbyterian Church, "Genetic Testing," Cincinnati, Ohio, October 12.
- 4. 2008, *Speaker*, Science in Society, Co-sponsored by KCPW and the City Library, "Death—Choices," Salt Lake City, Utah, November 20.
- 5. 2003, *Panelist*, Utah Symposium in Science and Literature, "The Goodness Switch: What Happens to Ethics if Behavior is All in Our Brains?" Salt Lake City, Utah, October 10.
- 6. 2002, *Respondent*, H. Tristram Englehardt, Jr. "The Culture Wars in Bioethics," Salt Lake Community College, Salt Lake City, Utah, March 29.

Podcasts

- 1. 2021, "Ethics of COVID Vaccines in Kids," PHM from Pittsburgh, August 12.
- 2. 2020, COVID Quandaries: Episode 1, "Is Getting Sick Just Part of the Job?" Hard Call, October 6.

EXHIBIT C

Strength of the Recommendation/ Quality of the Evidence ¹	Endocrine Treatment of Gender- Dysphoric/Gender-	Pediatric Obesity- Assessment, Treatment, and Prevention	Congenital Adrenal Hyperplasia Due to Steroid 21-Hydroxylase
Strong High	$0 (0)^2$	0 (0)	0 (0)
Strong Moderate	3 (11)	4 (13)	18 (33)
StrongLow	5 (18)	6 (20)	13 (25)
Strong Very Low	2 (7)	1 (3)	1 (2)
Weak High	0 (0)	0 (0)	0 (0)
Weak Moderate	0 (0)	0 (0)	2 (4)
Weak Low	9 (32)	5 (17)	4 (7)
Weak Very Low	3 (11)	12 (40)	7 (13)
Ungraded Good	6 (21)	2 (7)	9 (17)
Practice			
Statement ³			
Weak	12 (43)	17	13 (24)
		(57)	
Either Low or	19 (68)	24	25 (46)
Very Low		(80)	
Total	28	30	54

TABLE 1: Strength of Recommendation and Quality of Evidence inRecommendations Made by the Endocrine Society

¹Quality of the Evidence

High: "Consistent evidence from well-performed RCTs [Randomized Controlled Trials] or exceptionally strong evidence from unbiased observational studies" Moderate: "Evidence from RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise evidence), or unusually strong evidence from unbiased observational studies"

Low: "Evidence for at least one critical outcomes from observational studies, from RCTs with serious flaws, or indirect evidence"

Very Low: "Evidence for at least one of the critical outcomes from unsystematic

clinical observations or very indirect evidence"

See Swiglo BA, Murad MH, Schunemann HJ, et al. A case for clarity, consistency, and helpfulness: State-of-the-art clinical practice guidelines in endocrinology using the grading of recommendations, assessment, development, and evaluation system. *J Clin Endocrinol Metab.* 2008;93(3):666-73.

² n (%)

³Ungraded Good Practice Statement: "Direct evidence for these statements was either unavailable or not systematically appraised and considered out of the scope of this guideline. The intention of these statements is to draw attention to these principles." See Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

Guidelines:

Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of genderdysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity-assessment, treatment, and prevention: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(3):709-757.

Speiser PW, Arlt W, Auchus RJ, et al. Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2018;103(11):4043-4088.

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

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

EXPERT REPORT OF DAN H. KARASIC, M.D.

I, Dan H. Karasic, M.D., hereby declare and state as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection

with the above-captioned litigation.

2. I am over the age of 18. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

I. BACKGROUND AND QUALIFICATIONS

A. Qualifications

3. The information provided regarding my professional background, experiences, publications, and presentations are detailed in my curriculum vitae ("CV"). A true and correct copy of my CV is attached as **Exhibit A**.

4. I am a Professor Emeritus of Psychiatry at the University of California
– San Francisco (UCSF) Weill Institute for Neurosciences. I have been on faculty at
UCSF since 1991. I have also had a telepsychiatry private practice since 2020.

5. I received my Doctor of Medicine (M.D.) degree from the Yale Medical School in 1987. In 1991, I completed my residency in psychiatry at the University of California – Los Angeles (UCLA) Neuropsychiatric Institute, and from 1990 to 1991, I was a postdoctoral fellow in a training program in mental health services for persons living with AIDS at UCLA.

6. For over 30 years, I have worked with patients with gender dysphoria. I am a Distinguished Life Fellow of the American Psychiatric Association and currently the chair of the American Psychiatric Association Workgroup on Gender Dysphoria, as well as the sole author of the chapter on transgender care in the American Psychiatric Press's Clinical Manual of Cultural Psychiatry, Second Edition.

7. Over the past 30 years, I have provided care for thousands of transgender patients. For 17 years, I was the psychiatrist for the Dimensions Clinic for transgender youth in San Francisco. The clinic treats trans youth 12-25 years old.

8. I previously sat on the Board of Directors of the World Professional Association for Transgender Health (WPATH) and am a co-author of WPATH's Standards of Care for the Health of Transsexual, Transgender, and Gender *Nonconforming People*, Versions 7 and 8, which are the internationally accepted guidelines designed to promote the health and welfare of transgender, transsexual, and gender variant persons. For the Version 8, I was the lead author on the Mental Health chapter.

9. As a member of the WPATH Global Education Initiative, I helped develop a specialty certification program in transgender health and helped train over 2,000 health care providers.

10. At UCSF, I developed protocols and outcome measures for the Transgender Surgery Program at the UCSF Medical Center. I also served on the Medical Advisory Board for the UCSF Center of Excellence for Transgender Care and co-wrote the mental health section of the original *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People* and the revision in 2016.

11. I have also worked with the San Francisco Department of Public Health, having helped develop and implement their program for the care of transgender patients and for mental health assessments for gender-affirming surgery. I served on the City and County of San Francisco Human Rights Commission's LGBT Advisory Committee, and I have been an expert consultant for California state agencies and on multiple occasions for the United Nations Development Programme on international issues in transgender care.

12. I have held numerous clinical positions concurrent to my clinical professorship at UCSF. Among these, I served as an attending psychiatrist for San Francisco General Hospital's consultation-liaison service for AIDS care, as an outpatient psychiatrist for HIV-AIDS patients at UCSF, as a psychiatrist for the Transgender Life Care Program and the Dimensions Clinic at Castro Mission Health Center, and the founder and co-lead of the UCSF Alliance Health Project's Transgender Team. In these clinical roles, I specialized in the evaluation and treatment of transgender, gender dysphoric, and HIV-positive patients. I also regularly provide consultation on challenging cases to psychologists and other psychotherapists working with transgender and gender dysphoric patients. I have been a consultant in transgender care to the California Department of State Hospitals and am currently a consultant for the California Department of Corrections and Rehabilitation on the care of incarcerated transgender people.

13. As part of my psychiatric practice treating individuals diagnosed with gender dysphoria and who receive other medical and surgical treatment for that condition, as well as a co-author of the WPATH Standards of Care and UCSF's *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People*, I am and must be familiar with additional aspects of medical care for the diagnosis of gender dysphoria, beyond mental health treatment, assessment, and diagnosis.

14. In addition to this work, I have done research on the treatment of depression. I have authored many articles and book chapters and edited the book *Sexual and Gender Diagnoses of the Diagnostic and Statistical Manual (DSM): A Reevaluation.*

15. Since 2018, I have performed over 100 independent medical reviews for the State of California to determine the medical necessity of transgender care in appeals of denial of insurance coverage.

B. Compensation

16. I am being compensated for my work on this matter at a rate of \$400.00 per hour for preparation of declarations and expert reports. I will be compensated \$3,200.00 per day for any deposition testimony or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

C. Previous Testimony

17. Over the past four years, I have given expert testimony at trial or by deposition in the following cases: *C.P. v. Blue Cross Blue Shield of Illinois*, No. 3:20-cv-06145-RJB (W.D. Wash.); *Kadel v. Folwell*, No. 1:19-cv-00272 (M.D.N.C.); *Fain v. Crouch*, 3:20-cv-00740 (S.D.W. Va.); and *Brandt v. Rutledge*, No. 4:21-cv-00450 (E.D. Ark.). To the best of my recollection, I have not given expert testimony at a trial or at a deposition in any other case during this period.

II. BASES FOR OPINIONS

18. In preparing this report, I have relied on my training and years of research and clinical experience, as set out in my curriculum vitae, and on the materials listed therein, as documented in my curriculum vitae, which is attached hereto as **Exhibit A**.

19. I have also reviewed the materials listed in the bibliography attached hereto as **Exhibit B**. 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.

20. Additionally, I have reviewed Florida's Administrative Rule governing the determination of generally accepted professional medical standards under Florida Medicaid coverage (Fla. Admin. Code R. 59G-1.035); the Florida Medicaid Generally Accepted Professional Medical Standards (GAPMS) Determination on the Treatment of Gender Dysphoria published by Florida's Agency for Health Care Administration (AHCA) in June 2022, along with its attachments, including the reports of Dr. Romina Brignardello-Petersen and Dr. Wojtek Wiercioch (Attachment C), Dr. James Cantor (Attachment D), Dr. Quentin Van Meter (Attachment E), Dr. Patrick Lappert (Attachment F), and Dr. G. Kevin Donovan (Attachment G) (hereinafter, "GAPMS Memo"); and Fla. Admin. Code. R. 59G-1.050(7) which prohibits Medicaid coverage of puberty-delaying medications (commonly referred to as "puberty blockers"), hormone and hormone antagonists, "sex reassignment" surgeries, and any other procedures that alter primary or secondary sexual characteristics, on the basis that the services do not meet Florida's definition of "medical necessity" for purposes of its Medicaid program.

21. 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 the subject. I reserve the right to revise and supplement the opinions expressed in this report or the bases for them if any new information becomes available in the future, including as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

III. EXPERT OPINIONS

A. Gender Identity

22. Sex assigned at birth refers to the sex assigned to a person at the time of their birth, typically based on the appearance of external genital characteristics. While the terms "male sex" and "female sex" are sometimes used in reference to a person's genitals, chromosomes, and hormones, the reality is that sex is complicated and multifactorial. Aside from external genital characteristics, chromosomes, and endogenous hormones, other factors related to sex include gonads, gender identity, and variations in brain structure and function. Because these factors may not always be in alignment as typically male or typically female, "the terms biological sex and

biological male or female are imprecise and should be avoided." (Hembree, et al., 2017).

23. Gender identity is "a person's deeply felt, inherent sense of being a girl, woman, or female; a man, or male; a blend of male or female; or an alternative gender" (American Psychological Association, 2015, at 834). Gender identity does not always align with sex assigned at birth. Gender identity, which has biological bases, is not a product of external influence and not subject to voluntary change. As documented by multiple leading medical authorities, efforts to change a person's gender identity are ineffective, can cause harm, and are unethical. (American Psychological Association, 2021; Byne, et al., 2018; Coleman, et al., 2022).

B. Gender Dysphoria

24. The term "gender dysphoria" is distress related to the incongruence between one's gender identity and attributes related to one's sex assigned at birth.

25. The diagnosis of Gender Dysphoria in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision* (DSM-5-TR) (DSM-5 released in 2013 and DSM-5-TR released in 2022), involves two major diagnostic criteria for adolescents and adults:

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as

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manifested by at least two of the following (one of which must be Criterion A1):

- A marked incongruence between one's experienced/expressed gender and primary or secondary sex characteristics.
- A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender.
- A strong desire for the primary and/or secondary sex characteristics of the other gender.
- 4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
- 5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
- A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).
- B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

26. Given that gender dysphoria can cause such distress, many transgender individuals face depression, anxiety, and higher rates of suicidality than cisgender people. This is noted both in adults and adolescents. However, gender dysphoria is a condition that is highly amenable to treatment, and the prevailing treatment for it is highly effective. These risks decline when transgender individuals are supported and live according to their gender identity. And with access to medically indicated care, transgender people can experience significant and potentially complete relief from their symptoms of gender dysphoria. Not only is this documented in scientific literature and published data, but I witness this each time I see my patients being supported by their community, family, school, and medical providers.

C. Evidence-Based Guidelines for Treatment of Gender Dysphoria

27. The World Professional Association of Transgender Health (WPATH) has issued *Standards of Care for the Health of Transgender and Gender Diverse People* ("WPATH SOC") since 1979. The current version is WPATH SOC 8, published in 2022. The WPATH SOC provide guidelines for multidisciplinary care of transgender individuals and describes criteria for medical interventions to treat gender dysphoria, including hormone treatment and surgery when medically indicated.

28. The SOC 8 is based upon a more rigorous and methodological evidence-based approach than previous versions. (Coleman, et al., 2022). This

evidence is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion. Its recommendations are evidence-based, informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. The process for development of the SOC 8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization. Its recommendations were graded using a modified GRADE methodology (Guyatt, et al., 2011), considering the available evidence supporting interventions, risks and harms, and feasibility and acceptability.

29. While SOC 8 includes important updates, it does not change the substance of any of the opinions I expressed in my previous declaration. Indeed, SOC 8 continues to recommend the provision of medical interventions, such as puberty blockers, hormone therapy, and surgery, as medically appropriate and necessary treatments for gender dysphoria, based on an individual patient's needs.

30. WPATH SOC 8 also states, "Gender identity change efforts (gender reparative or gender conversion programs aimed at making the person cisgender) are widespread, cause harm to TGD people, and (like efforts targeting sexual orientation) are considered unethical." (Coleman, et al., 2022).

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31. A clinical practice guideline from the Endocrine Society (the Endocrine Society Guidelines) provides similar protocols for the medically necessary treatment of gender dysphoria. (Hembree, et al., 2017).

32. Guidelines from other organizations, including those developed by the UCSF Center of Excellence for Transgender Care, also list similar protocols for the medically necessary treatment of gender dysphoria.

33. Each of these guidelines are evidence-based and supported by scientific research and literature, as well as extensive clinical experience.

34. The protocols and policies set forth by the WPATH Standards of Care and the Endocrine Society Guidelines are endorsed and cited as authoritative by the major professional medical and mental health associations in the United States, including the American Medical Association, the American Academy of Pediatrics, the American Psychiatric Association, the American Psychological Association, the American College of Obstetrics and Gynecology, the American College of Physicians, and the World Medical Association, among others.

35. To be sure, being transgender is widely accepted as a variation in human development and is not considered a mental illness. People who are transgender have no impairment in their ability to be productive, contributing members of society simply because of their transgender status.

- a. The American Psychiatric Association's DSM 5 states: Gender dysphoria "is more descriptive than the previous DSM-IV term 'gender identity disorder' and focuses on dysphoria as the clinical problem, not identity per se." (APA, 2013).
- b. WPATH SOC 8 states: "The expression of gender characteristics, including identities, that are not stereotypically associated with one's sex assigned at birth is a common and a culturally diverse human phenomenon that should not be seen as inherently negative or pathological. ... It should be recognized gender diversity is common to all human beings and is not pathological. However, gender incongruence that causes clinically significant distress and impairment often requires medically necessary clinical interventions." (Coleman, et al. 2022).
- c. The American Psychological Association states: "Whereas diversity in gender identity and expression is part of the human experience and transgender and gender nonbinary identities and expressions are healthy, incongruence between one's sex and gender is neither pathological nor a mental health disorder." (American Psychological Association, 2021).

d. The World Health Organization states: "Gender incongruence has thus broadly been moved out of the 'Mental and behavioural disorders' chapter and into the new 'Conditions related to sexual health' chapter. This reflects evidence that trans-related and gender diverse identities are not conditions of mental ill health, and classifying them as such can cause enormous stigma." (WHO Europe).

36. Thus, the overarching goal of treatment is to eliminate the distress of gender dysphoria by aligning an individual patient's body and presentation with their internal sense of self. The denial of medically indicated care to transgender people not only results in the prolonging of their gender dysphoria, but causes additional distress and poses other health risks, such as depression, posttraumatic stress disorder, and suicidality. In other words, lack of access to gender-affirming care directly contributes to poorer mental health outcomes for transgender people. (Owen-Smith, et al., 2018).

37. For patients for whom gender-affirming medical care is indicated, no alternative treatments have been demonstrated to be effective. The American Psychological Association states that gender identity change efforts provide no benefit and instead do harm. (American Psychological Association, 2021).

38. Accordingly, major medical organizations, such as the American Medical Association, American Psychiatric Association, the Endocrine Society, American College of Obstetricians and Gynecologists, and American Academy of Family Physicians oppose the denial of this medically necessary care and support public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician. (American Medical Association, 2021; American Psychiatric Association, 2018; Endocrine Society, 2020; American College of Obstetricians and Gynecologists, 2021; American Academy of Family Physicians, 2020).

D. Treatment of Gender Dysphoria

39. The WPATH SOC 8 and the Endocrine Society Guidelines establish authoritative protocols for the treatment of gender dysphoria.

40. In accordance with the WPATH SOC 8 and the Endocrine Society Guidelines, medical interventions to treat gender dysphoria may include treatment with pubertal suppression and/or hormones, and treatment with surgery.

41. No medical or surgical treatment for gender dysphoria is provided to pre-pubertal children.

42. Once a patient enters puberty, treatment options include pubertal suppression therapy and gender-affirming hormones. Pubertal blocking involves methods of temporarily suppressing endogenous puberty to alleviate gender dysphoria and give the patient more time to work with their mental health providers to assess treatment needs. These blockers are reversible medications and once
stopped, a patient returns to the stage of pubertal development that had begun when the treatment was initiated.

43. If a patient is assessed to have a medical need for hormone therapy, gender-affirming hormone therapy involves administering steroids of the experienced sex (i.e., their gender identity), such as testosterone in transgender male individuals and estrogen in transgender female individuals, to treat gender dysphoria later in puberty. The purpose of this treatment is to attain the appropriate masculinization or feminization of the transgender person to achieve a gender phenotype that matches as closely as possible to their gender identity. For adolescents, this treatment allows patients to have pubertal changes and development consistent with their gender identity. Gender-affirming hormone therapy is a partially reversible treatment in that some of the effects produced by the hormones are reversible (e.g., changes in body fat composition, decrease in facial and body hair) while others are irreversible (e.g., deepening of the voice, decreased testicular mass).

44. Some transgender individuals need surgical interventions to help bring their phenotype into alignment with their gender. Surgical interventions may include, *inter alia*, vaginoplasty and orchiectomy for transgender female individuals, and chest reconstruction and hysterectomy for transgender male individuals.

45. According to WPATH SOC 8, "Chest masculinization surgery can be considered in minors when clinically and developmentally appropriate as determined

by a multidisciplinary team experienced in adolescent and gender development" (Coleman, et al. 2022).

46. The treatment protocols for gender dysphoria are comparable to those for other mental health and medical conditions. Indeed, these or similar procedures are provided for cisgender people with other diagnoses.

E. Assessments of Patients with Gender Dysphoria.

47. WPATH SOC 8 recommends that health care professionals working with transgender and non-binary adolescents be licensed, hold a postgraduate degree in relevant clinical field, have received training and developed expertise in working with children and adolescents, including those with autism spectrum disorder, and have received training and developed expertise in gender identity and diversity in youth, and in the ability of youth to assent/consent to care (Coleman, et al., 2022).

48. WPATH SOC 8 recommends a "comprehensive biopsychosocial assessment" for adolescents "prior to any medically necessary medical or surgical intervention" for gender dysphoria. The assessment should include gender identity development, social development and support, diagnostic assessment of co-occurring mental health or developmental concerns, and capacity for decision-making (Coleman, et al., 2022).

49. For assessing an adult for gender-affirming medical care, WPATH SOC 8 states that the health professional should be licensed and trained in identifying

gender dysphoria as well as co-existing mental health and psychosocial concerns, and that medical or surgical treatment should only be recommended when "gender incongruence is marked and sustained," when there is capacity for consent, when other conditions that might affect outcomes have been assessed, and when diagnostic criteria for Gender Dysphoria of DSM 5-TR (in the US) or Gender Incongruence of ICD-11(outside the US) are met.

50. Before gender affirming care is provided, WPATH SOC 8 recommends that impacts on fertility of care, and fertility preservation options be discussed thoroughly with the patient, and in the case of a minor, with parents or guardians.

51. Affirming care for transgender youth does not mean steering them in any particular direction, but rather supporting them through their period of exploration of gender expression and increasing self-awareness of their identity (Ehrensaft, 2017). WPATH SOC 8 states, "We recommend health professionals working with gender diverse adolescents facilitate the exploration and expression of gender openly and respectfully so that no one particularly in favored." (Coleman, et al., 2022). WPATH SOC 8 states "For some youth, obtaining gender-affirming medical care is important while for others these steps might not be necessary." (Coleman, et al., 2022). In my clinical experience, some adolescent patients have a critical need for medical interventions at or at some point after the onset of puberty and others do not. As with all medical interventions, it is highly individualized and responsive to the particular medical and mental health needs of each patient.

52. The Endocrine Society Guidelines state that only "[mental health professionals] who ha[ve] training/experience in child and adolescent gender development (as well as child and adolescent psychopathology) should make the diagnosis," which usually includes "a complete psychodiagnostic assessment." (Hembree, et al., 2017, at 3877). It further provides that because gender dysphoria "may be accompanied with psychological or psychiatric problems" it is necessary that clinicians involved in diagnosis and psychosocial assessment meet specific competency requirements and that they undertake or refer for appropriate psychological or psychiatric treatment. *Id.*, at 3876. And "in cases in which severe psychopathology" "interfere[s] with diagnostic work or make[s] satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues." *Id.*

F. Gender-Affirming Medical and Surgical Care Is Safe and Effective.

53. Gender-affirming medical and surgical interventions in accordance with the WPATH SOC and Endocrine Society Guidelines are widely recognized in the medical community as safe, effective, and medically necessary for many transgender people with gender dysphoria. (See American Academy of Pediatrics, 2018; the American Medical Association, 2021; the Endocrine Society, 2020; the 19 EXPERT REPORT OF DR. DAN H. KARASIC Pediatric Endocrine Society, 2021; the American Psychiatric Association, 2018; the American Psychological Association, 2021; the American Congress of Obstetricians and Gynecologists, 2021; the American Academy of Family Physicians, 2020; WPATH, 2016).

54. There is substantial evidence that gender-affirming medical and surgical care is effective in treating gender dysphoria. This evidence includes scientific studies assessing mental health outcomes for transgender people who are treated with these interventions, including adolescents, and decades of clinical experience.

55. The research and studies supporting the necessity, safety, and effectiveness of medical and surgical care for gender dysphoria are the same type of evidence-based data that the medical community routinely relies upon when treating other medical conditions.

56. Medical treatment for gender dysphoria has been studied for over half a century, and there is substantial evidence that it improves quality of life and measures of mental health. (Aldridge et al., 2021; Almazan, et al., 2021; Baker et al., 2021; Murad, et al., 2010; Nobili et al., 2018; Pfafflin & Junge, 1998; T'Sjoen et al. 2019; van de Grift et al., 2018; White Hughto and Reisner, 2016; Wierckx et al., 2014).

57. A systematic review of 20 studies showed improved quality of life, decreased depression, and decreased anxiety with hormonal treatment in transgender people. (Baker, et al., 2021). Another systematic review showed improvement in mental health and quality of life measures in transgender people with hormonal treatment (White Hughto and Reisner, 2016). In the United Kingdom, one study demonstrated that depression and anxiety were substantially reduced over 18 months of gender-affirming hormonal treatment. (Aldridge, et al., 2021). In a secondary analysis of data from the US Transgender Survey, having had genital surgery was associated with decreased psychological distress and suicidal ideation. (Almazan, et al., 2021). In transgender patients followed 4-6 years after surgery, satisfaction was very high (over 90%) and regret was low. (van de Grift et al., 2018). The Cornell "What We Know" systematic review of 55 studies from 1991-2017 strongly supported that gender-affirming hormone and surgical treatment improved the wellbeing of transgender individuals. (What We Know, 2018).

58. Transgender people have been benefiting from gender-affirming medical and surgical care for decades. Researchers interviewed fifteen transgender people 40 years after they had received gender-affirming surgical care at University of Virginia. Participants reported continued benefits over 40 years from gender affirming care, including improved mental health, reduced suicidality, reduced gender dysphoria, and high patient satisfaction, with no reported cases of regret (Park, et al. 2022).

59. The studies on gender-affirming medical care for treatment of dysphoria are consistent with decades of clinical experience of mental health providers across the U.S. and around the world. At professional conferences and other settings in which I interact with colleagues, clinicians report that gender-affirming medical care, for those for whom it is indicated, provides great clinical benefit. In my 30 years of clinical experience treating gender dysphoric patients, I have seen the benefits of gender-affirming medical care on my patients' health and well-being. I have seen many patients show improvements in mental health, as well as in performance in school, in social functioning with peers, and in family relationships when they experience relief from gender dysphoria with gender-affirming medical care.

60. Accordingly, treatments for gender dysphoria are not considered elective or cosmetic. Indeed, as WPATH (2016) states, "The medical procedures attendant to gender-affirming/confirming surgeries are not 'cosmetic' or 'elective' or 'for the mere convenience of the patient.' These reconstructive procedures are not optional in any meaningful sense but are understood to be medically necessary for the treatment of the diagnosed condition. In some cases, such surgery is the only

effective treatment for the condition, and for some people genital surgery is essential and life-saving."

As part of the treatment process for gender dysphoria, patients provide 61. informed consent to their care. In addition, a treating doctor will not offer genderaffirming medical treatments unless they have concluded after weighing the risks and benefits of care for the specific patient that treatment is appropriate. The risks and benefits of care are discussed with the transgender patient, who must consent or assent, as appropriate. This process is no different than the informed consent process for other medical treatments. However, for gender-affirming medical care, there is the additional safeguard of the recommended assessments by a health care professional, who must not only be experienced in the assessment of gender dysphoria, but also in the assessment of a patient's capacity to consent/assent to treatment and ability to understand the risks and benefits of treatment. Indeed, SOC 8 notes that mental health professionals are the best positioned practitioners to conduct these assessments for adolescents and also recommends, for all patients, that a mental health professional address any mental health issues that may interfere with a patient's ability to consent prior to the initiation of gender-affirming care.

62. Regret among those who are treated with gender-affirming medical care is rare. For example, in one study in the Netherlands, none of the youth who received puberty-delaying treatment, hormones, and surgery, and were followed over an 8year period expressed regret. (DeVries, 2014.) Zucker, et al., (2010), summarizing key studies on regret for adolescents referred for surgery when they reached the age of majority in the Netherlands, states, "there was virtually no evidence of regret, suggesting that the intervention was effective."

63. A study of 209 gender-affirming mastectomies in transmasculine adolescents aged 12-17, performed at Kaiser Permanente Northern California from 2013 to 2020, showed a regret rate of 1%. (Tang, et al 2022).

64. Regret rates for gender-affirming surgery in adults are also very low. A pooled review across multiple studies of 7,928 patients receiving gender-affirming surgery showed a regret rate of 1%. (Bustos, et al., 2021). Over 50 years of gender-affirming surgery in Sweden, the regret rate, as measured by legal gender change reversal, was 2%. (Dhejne, et al., 2014). These are very low regret rates for surgery. For example, 47% of women expressed at least some regret after reconstructive breast surgery following mastectomy for breast cancer. (Sheehan, et al., 2008).

65. For all the reasons above, I am aware of no basis in medicine or science for categorical exclusion of coverage for gender-affirming care.

66. One misperception is that puberty-delaying medications and hormone therapy are experimental because they are not FDA-approved for the specific application of treating Gender Dysphoria. Medications very commonly are prescribed for off-label uses. All gender-affirming hormone treatments are approved for treatment of other conditions and have been used to treat those conditions, as well as for gender-affirming care, for many years, supporting their safety and efficacy. The U.S. Department of Health and Human Services Agency for Healthcare Research and Quality states, "[Off-label prescribing] is legal and common. In fact, one in five prescriptions written today are for off-label use."¹

67. Finally, the cost of providing coverage for gender-affirming care is generally very low. To begin, transgender people constitute a small percentage of the overall population, approximately 0.5%. (Crissman, et. al., 2017). Furthermore, the fraction of the population receiving clinical care for Gender Dysphoria is much smaller, well under one in a thousand patients (Zhang, et al., 2020). As a result, one study estimated an average cost of \$0.016 cents per member per month to provide gender-affirming care (Padula, et al., 2016). A study by Herman (2013) similarly found low costs to providing health coverage for gender-affirming care. Additionally, when a form of treatment is covered for cisgender people under an insurance plan, it is generally not disproportionately costly to cover the same treatment for transgender people simply because it is provided to treat gender dysphoria.

¹ See <u>https://www.ahrq.gov/patients-consumers/patient-involvement/off-label-drug-usage.html</u>.

G. Harms of Denying Gender-Affirming Care

68. The overarching goal of treatment is to eliminate the distress of gender dysphoria by aligning an individual patient's body and presentation with their internal sense of self. The denial of medically indicated care to transgender people not only results in the prolonging of their gender dysphoria, but causes additional distress and poses other health risks, such as depression, posttraumatic stress disorder, and suicidality. The prevalence of these mental health conditions is also thought to be a consequence of minority stress, the chronic stress from coping with societal stigma and discrimination because of one's identity, including gender identity and gender expression. (American Medical Association, 2019). In other words, lack of access to gender-affirming care directly contributes to poorer mental health outcomes for transgender people. (Owen-Smith, et al., 2018).

69. Accordingly, major medical organizations, such as the American Medical Association, American Psychiatric Association, and American College of Obstetricians and Gynecologists, oppose the denial of this medically necessary care and support public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician. (American Medical Association, 2019).

70. Denial of this appropriate care for transgender adolescents is also opposed by mainstream organizations responsible for the care of youth, including the American Academy of Pediatrics, the Academy of Child and Adolescent Psychiatry, and the Pediatric Endocrine Society.

71. Familial and social support and the provision of gender-affirming medical treatment have been associated with dramatically less suicidal ideation in transgender people. (Bauer, et al., 2015). Provision of puberty blockers and gender-affirming hormones for transgender youth likewise decreases suicidality (Tordoff, et al., 2022; Turban, et al., 2020; Green, et al., 2022; Allen, et al., 2019). The American Academy of Child and Adolescent Psychiatry states, "Research consistently demonstrates that gender diverse youth who are supported to live and/or explore the gender role that is consistent with their gender identity have better mental health outcomes than those who are not." (AACAP, 2019).

72. In a multicenter NIH-funded study, 315 transgender and nonbinary youth followed over two years showed a decrease in anxiety and depression and an improvement in appearance congruence and life satisfaction with gender affirming medical treatment. (Chen, et al., 2023).

73. In a University of Washington study of 104 transgender and nonbinary youth, treatment with puberty blockers or hormones was associated with 60% less moderate to severe depression and 73% less suicidal ideation over 12 months, compared to youth not treated. (Tordoff, et al. 2022).

74. In a University of Texas Southwestern study, treatment with genderaffirming hormones in transgender youth was associated with a substantial reduction in body dissatisfaction, as well as improvement on measures of depression and anxiety. (Kuper, et al., 2020).

75. In a University of Southern California and Children's Hospital Los Angeles study of 136 transgender male youth, the half that had received chest masculinizing surgery had far less gender dysphoria than those who had not yet had surgery. (Olson-Kennedy, et al., 2018).

76. In a University of Pennsylvania and University of Rochester study, transgender male youth aged 13-21 suffered substantial emotional distress and functional impairment from dysphoria related to their chest. Chest dysphoria resolved with surgery. Youth reported improvement functionally and in quality of life (Mehringer, et al., 2021).

77. In the past 10 years, there has been a reversal in longstanding coverage policies that had excluded reimbursement of gender-affirming care for transgender people. There are many more clinics providing care to transgender youth and adults in academic medical centers than a decade ago, because funding is now available. This change is allowing clinical researchers to expand the body of research in the United States, as well as increasing access to care.

H. The GAPMS Memo and AHCA's Decision to Prohibit Medicaid Coverage of Gender-Affirming Care

78. According to criteria of the Florida Administrative Code 59G-1.035, the Agency for Health Care Administration (AHCA) makes coverage determinations based on "Generally accepted professional medical standards—standards based on reliable scientific evidence published in peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations' recommendations." It is my understanding that AHCA purports to have used the standards set forth in this rule to reach the conclusion set forth in its June 2022 GAPMS Memo that gender-affirming care, including puberty blockers, hormone replacement therapy, and gender-affirming surgery does not meet generally accepted professional medical standards and is therefore, experimental and investigational.

79. To craft the GAPMS Memo (which served as the basis for AHCA's decision to ban gender-affirming care in accordance with Fla. Admin. Code R. 59G-1.050(7)), AHCA enlisted Drs. Romina Brignardello-Petersen and Wojtek Wiercioch. Dr. Brignardello-Petersen is a dentist who is an assistant professor in the Department of Health Research Methods, Evidence, and Impact at McMaster University in Canada. Dr. Wiercioch is a post-doctoral research fellow in the same department as Dr. Brignardello-Petersen. Both authors report no academic interests in the care of people with gender dysphoria.

80. Drs. Brignardello-Petersen and Wiercioch performed a manual search of websites that includes only one non-governmental organization site: the Society for Evidence-Based Gender Medicine (SEGM). The fact that SEGM was chosen instead of much larger and more established organizations representing the mainstream of care, e.g., the American Psychological Association, the American Medical Association, or the American Psychiatric Association, raises a concern for bias, as SEGM is a small group founded recently specifically in opposition to genderaffirming care.

81. To support the conclusions provided to AHCA, Drs. Brignardello-Petersen and Wiercioch preferentially relied on studies that only included participants under age 25. Drs. Brignardello-Petersen and Wiercioch do not provide a basis to support their selection of only these studies, or of leaving out a multitude of other studies that include participants that are over age 25. In my experience working with patients with gender dysphoria, many of those who seek genderaffirming surgery are over 25. The average age of 7,905 transgender patients who had gender-affirming surgery in the US from 2009-2015, identified by insurance data, was 29.8 years old (Lane, et al., 2018). Thus, reliance on studies related preferentially to those under age 25 does not accurately capture the full body of scientific evidence pertaining to this form of care. This is especially important given that the GAPMS memo concludes that gender-affirming care is not a generally accepted professional medical standard for individuals at any age.

82. Brignardello-Petersen and Wiercioch excluded from consideration the vast majority of studies on transgender health. They state, "After screening 1854 records found through our searches, we found 10 eligible studies."

83. Drs. Brignardello-Petersen and Wiercioch relied on an overview of a very small sample of systematic reviews of studies of transgender care (they looked at only 10 of 61 systematic reviews), for which they purported to rank the quality of evidence using GRADE criteria. GRADE criteria assigns low quality scores to studies not performed by randomized, blinded clinical trials. However, randomly selecting people to receive or not receive gender-affirming medical or surgical interventions is impossible, for practical and ethical reasons. Notably, many treatments for other conditions are in widely accepted use without having been studied through randomized, controlled clinical trials. Many drugs for cancer and hematologic disorders have been FDA approved without a randomized controlled trial (Hatswell, et al., 2016). Many other drugs have been FDA approved with randomized controlled trials for one indication but are commonly used for another condition or in a different population than the one for which it was approved (Wittich, et. al., 2012).

84. People have been receiving gender-affirming medical and surgical treatment for well over half a century, with very low regret rates (Dhejne, et al., 2014), and there is substantial research and clinical experience that supports gender-affirming care as treatment for gender dysphoria. The scientific evidence "published in peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations" led the American Medical Association, the American Academy of Pediatrics, the American Psychiatric Association, the American Psychological Association, and other mainstream medical organizations to conclude that the provision of gender-affirming medical and surgical interventions falls within generally accepted professional medical standards.

85. Another person enlisted to provide an opinion to AHCA in drafting its GAPMS memo is James Cantor, PhD, a forensic psychologist in Toronto, Canada. Dr. Cantor's report indicates that his work at the University of Toronto from 1998 to 2018 was limited to its adult forensic program, that is, Dr. Cantor worked with people with paraphilias,² and in particular with pedophiles. Dr. Cantor is well known for this work, but not for his work with transgender people. In testimony in *Eknes-Tucker v. Marshall*, Dr. Cantor stated that he had not personally diagnosed any child or

² Paraphilias are persistent and recurrent sexual interests, urges, fantasies, or behaviors of marked intensity involving objects, activities, or even situations that are atypical in nature. Being transgender is not a paraphilic disorder.

adolescent with gender dysphoria, and that he had personally never treated any child or adolescent for gender dysphoria.

86. Dr. Cantor agrees that transgender adults "adjust well to life as the opposite sex" if they are otherwise mentally healthy. Dr. Cantor is also correct to report that regret rates are low.

87. Dr. Cantor focuses on desistance rates of prepubertal children brought into clinics in Toronto and Amsterdam. However, given that these prior longitudinal studies included gender nonconforming children who were not transgender due to the broad criteria for the since-abandoned "gender identity disorder in children" diagnosis, or who did not qualify even for the gender identity disorder in children diagnosis, these studies shed little light into questions of persistence and desistance of gender dysphoria in pre-pubertal children. In fact, a more recent study, which is the only large American prospective study that has been published in the past 35 years, showed much lower desistance rates (Olson, et al., 2022). Specifically, only 2.5% of the youth studied identified with their sex assigned at birth.³

88. In any event, longitudinal studies show that gender dysphoria in adolescence usually persists (DeVries, et al., 2011; van der Loos, et al., 2022). And

³ Of these, youth with cisgender identities were more common among youth whose initial social transition occurred before age 6 years; their retransitions often occurred before age 10 years. And, again, no medical treatment is recommended for any transgender person prior to the onset of puberty.

no medical treatment, let alone irreversible medical and surgical interventions, is used prior to puberty. Even in the clinics with higher desistance rates for *pre-pubertal* children upon which Dr. Cantor relies, puberty blockers and hormones were used when gender dysphoria persisted after the onset of puberty. In sum, the desistance statistics of *pre-pubertal* children do not inform the decision whether to initiate these treatments in adolescents and adults.

89. The WPATH Standards of Care and the American Psychiatric Association each recommend that transgender people who also suffer from depression, anxiety, and other mental health symptoms should seek out treatment for these symptoms. However, in most cases, having a history of mental illness should not prevent people from receiving gender-affirming medical and surgical treatment. (Coleman, et al., 2022; Byne, et al., 2018).

90. Dr. Cantor's uses the term "affirmation on demand" as a straw man. The WPATH Standards of Care require a comprehensive mental health assessment for patients who are minors, and clinical assessments are also required for adults. (Coleman, et al., 2022).

91. Dr. Cantor cites a Finnish study as evidence for his conclusion that adolescents should not be prescribed gender-affirming hormones because they are supposedly not effective in the treatment of gender dysphoria. (Kaltiala, et al., 2020). However, in that study, the need for treatment for depression dropped from 54% of the youth to 15%; the need for treatment for anxiety dropped from 48% of the youth to 15%; and the need for treatment for suicidality/self-harm dropped from 35% to 4%. All of these were statistically highly significant changes.

92. Dr. Cantor states that the study by Kuper, et al. 2020 did not show benefit from treatment. This statement is misleading at best. The article concludes, "Youth reported large improvements in body dissatisfaction (P < .001), small to moderate improvements in self-report of depressive symptoms (P < .001), and small improvements in total anxiety symptoms (P < .01)." Dr. Cantor further states that the study by Achille et al. does not show that those studied benefitted from endocrine treatment. Again, Cantor's characterization of this study's conclusion is misleading. The results of the paper show that, "Mean depression scores and suicidal ideation decreased over time while mean quality of life scores improved over time. When controlling for psychiatric medications and engagement in counseling, regression analysis suggested improvement with endocrine intervention. This reached significance in male-to-female participants."

93. In reviewing the international health care consensus regarding genderaffirming care, Dr. Cantor refers to an interim report on care of transgender youth in the United Kingdom's National Health System which is currently being compiled by Dr. Hilary Cass. The interim report states that the final report will synthesize published evidence with expert opinion and stakeholder input. Notably, the interim report recommends increasing the number of health providers, shortening wait times, and increasing the number of centers across the country providing care to transgender youth.

94. Swedish and Finnish national health authorities, which Dr. Cantor also references, have recommended caution and more research but have not banned care for transgender youth. In these countries, gender-affirming care for adults and for youth who qualify is fully paid for by the national health system of each country.

95. There remains strong international support for the continued provision of gender-affirming medical and surgical care. Experts from the around the world collaborated on the new WPATH Standards of Care Version 8. I was chapter lead of the Mental Health chapter of this version, and the authors of that chapter included psychiatrists who are leaders of transgender health programs in Belgium, Sweden, and Turkey. There is broad agreement in philosophy of care, including support for gender-affirming care and opposition to conversion therapy.

96. The ethics of providing transgender care are discussed by one expert, Dr. G. Kevin Donovan. Dr. Donovan ignores the larger ethical question raised by Florida's actions to terminate Medicaid coverage of gender-affirming care for those who were previously approved for that same coverage. Florida's actions amount to forced detransition. As Dr. Donovan states, the principles of ethical care include autonomy, beneficence, and justice. There has been little research on those forced to

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detransition, but abruptly terminating Medicaid coverage for low-income and disabled Floridians will force these Medicaid recipients into detransition, an experiment to which they did not consent. Autonomy, beneficence, and justice are entirely ignored in this experiment, with no respect for the autonomy of the individual to decide their course, no concern for "do no harm" or maximizing benefits and minimizing harm, and no justice—fairness in distribution of risks and benefits—as the poor and those with disabilities will be forced into this detransition experiment while those with resources will be spared.

97. I have only had a few patients over the years who have been forced to detransition, because of incarceration or institutionalization, or other circumstances, and results have been uniformly disastrous, with suicide and self-harm attempts, depression, and deterioration of functioning. Some of my patients forced to detransition were receiving intensive mental health care at the time, on psychiatric wards. But no amount of psychotherapy could counter the deleterious effects of forced detransition and the withholding of needed gender-affirming medical and surgical care.

IV. CONCLUSION

98. The categorical exclusion of coverage for gender-affirming medical care adopted by Florida's Agency for Health Care Administration, which bars coverage for medical treatments for gender dysphoria, is contrary to widely accepted

medical protocols for the treatment of transgender people with gender dysphoria that are recognized by major medical and mental health professional associations in the United States.

99. The accepted protocols for the treatment of transgender people with gender dysphoria provide for mental health assessments, including of co-occurring conditions; criteria for eligibility for each treatment; and an informed consent process before medical interventions are initiated.

100. Decades of medical research and clinical experience have demonstrated that the medical treatments AHCA has barred from Medicaid coverage are safe, effective, and medically necessary to relieve gender dysphoria for transgender people. AHCA's conclusion otherwise is not supported by medical evidence or consensus.

101. Denying gender-affirming medical care to transgender people for whom it is medically indicated puts them at risk of significant harm to their health and wellbeing, including heightened risk of depression and suicidality.

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

Executed this 15th day of February 2023.

Dan H. Karasic, M.D.

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

EXPERT REPORT OF DR. DAN H. KARASIC Case No. 4:22-cv-00325-RH-MAF

University of California, San Francisco CURRICULUM VITAE

Name: Dan H. Karasic, MD

Position: Professor Emeritus Psychiatry School of Medicine

> Voice: 415-935-1511 Fax: 888-232-9336

EDUCATION

1978 - 1982	Occidental College, Los Angeles	A.B.; Summa Cum Laude	Biology
1982 - 1987	Yale University School of Medicine	M.D.	Medicine
1987 - 1988	University of California, Los Angeles	Intern	Medicine, Psychiatry, and Neurology
1988 - 1991	University of California, Los Angeles; Neuropsychiatric Institute	Resident	Psychiatry
1990 - 1991	University of California, Los Angeles; Department of Sociology	Postdoctoral Fellow	Training Program in Mental Health Services for Persons with AIDS
LICENSES, CE	RTIFICATION		
1990	Medical Licensure, California, L	icense Number (G65105
1990	Drug Enforcement Administration	on Registration N	umber BK1765354
1993	American Board of Psychiatry a	and Neurology, B	oard Certified in Psychiatry
PRINCIPAL PO	DSITIONS HELD		
1991 - 1993	University of California, San Fra	ancisco Hea Cline	alth Sciences Psychiatry cial Instructor
1993 - 1999	University of California, San Fra	ancisco Hea Assi Prof	alth Sciences Psychiatry stant Clinical essor
1999 - 2005	University of California, San Fra	ancisco Hea	alth Sciences Psychiatry

Associate Clinical Professor

2005 - present University of California, San Francisco

Health Sciences Psychiatry Clinical Professor

OTHER POSITIONS HELD CONCURRENTLY

1980 - 1980	Associated Western Universities / U.S. Department of Energy	Honors UC Undergraduate Research Fellow	CLA Medicine
1981 - 1981 Medicine	University of California, Los Angeles; e American Heart Association, California Affiliate	Summer Student Research Fellow	UCLA
1986 - 1987	Yale University School of Medicine; American Heart Association, Connection Affiliate	Medical Student cut Research Fellow	Psychiatry
1990 - 1991	University of California, Los Angeles Pos	tdoctoral Sociology	Fellow
1991 - 2001	SFGH Consultation-Liaison Service; Atte AIDS Care	ending Psychiatry Psychiatrist	,
1991 - 2001	AIDS Consultation-Liaison Medical Student Elective	Course Director	Psychiatry
1991 - presen	t UCSF Positive Health Program at San General Hospital (Ward 86) Out	HIV/AIDS Psy patient Psychiatrist	ychiatry Francisco
1991 - present	t UCSF AHP (AIDS Health Project/Allianc Health Project)	e HIV/AIDS Outpatient Psychiatrist	Psychiatry
1994 - 2002	St. Mary's Medical Center CARE Unit. The CARE Unit specializes in the care with AIDS dementia.	Consultant of patients	Psychiatry
2001 - 2010	Depression and Antiretroviral Adherer Study (The H.O.M.E. study: Health Outcomes of Mood Enhancement)	ce Clinical Director	Psychiatry and Medicine
2003 - 2020 T	ransgender Life Care Program and Psy Clinic, Castro Mission Health Clir Center	rchiatrist Dimensior nic	ns Dimensions
2013 - 2020 U	CSF Alliance Health Project, Co-lead, Transgender Team	Co-Lead and Psychiatrist	Psychiatry
HONORS AN	ID AWARDS		
1981	Phi Beta Kappa Honor Society	Phi Beta Kappa	
1990	NIMH Postdoctoral Fellowship in Mental Health Services for People with	National Institute of	Mental Health

AIDS (1990-1991)

2001	Lesbian Gay Bisexual Transgend Leadership Award, LGBT Task Fo of the Cultural Competence and Diversity Program	ler SFGH Department of Psychiatry orce
2006	Distinguished Fellow	American Psychiatric Association
2012	Chancellor's Award for Leadershi LGBT Health	ip in UCSF
2023	Alumni Seal Award for Professional Achievement	Occidental College

MEMBERSHIPS

- 1992 present Northern California Psychiatric Society
- 1992 present American Psychiatric Association
- 2000 2019 Bay Area Gender Associates (an organization of psychotherapists working with transgendered clients)
- 2001 present World Professional Association for Transgender Health

SERVICE TO PROFESSIONAL ORGANIZATIONS

1981 - 1982	The Occidental	News Editor
1984 - 1985	Yale University School of Medicine	Class President
1989 - 1991	Kaposi's Sarcoma Group, AIDS Project Los Angeles	Volunteer Facilitator
1992 - 1996	Early Career Psychiatrist Committee, Association of Gay Lesbian Psychiatrists	/ Chair and
1992 - 1996	Board of Directors, Association of Gay and Lesbian Psychiatrists	Member
1993 - 1993 Psychia	Local Arrangements Committee, Association of Gay and atrists	Chair Lesbian
1994 - 1995 1995 Ai	Educational Program, Association of Gay and Lesbian nnual Meeting	Director Psychiatrists,
1994 - 1998	Board of Directors, BAY Positives	Member
1994 - preser	nt Committee on Lesbian, Gay, Bisexual and Transgender Issues, Northern California Psychiatric Society	Member
1995 - 1997	Board of Directors, Bay Area Young Positives. BAY	President

Positives is the nation's first community-based organization providing psychosocial and recreational services to HIV-positive youth

1995 - 1997	Executive Committee, Bay Area Young Positives. C	Chair
1996 - 2004	Committee on Lesbian, Gay, Bisexual and Transgend Issues, Northern California Psychiatric Society	der Chair
1998 - 2002	City of San Francisco Human Rights Commission, Lesbian, Gay Bisexual Transgender Advisory Comr	Member mittee
2000 - 2004	Association of Gay and Lesbian Psychiatrists. V V for the organization's educational programs	ice President Responsible
2004 - 2005	Association of Gay and Lesbian Psychiatrists P	President-elect
2005 - 2007	Caucus of Lesbian, Gay, and Bisexual Psychiatrists of American Psychiatric Association	of the Chair
2005 - 2007	Association of Gay and Lesbian Psychiatrists	President
2007 - 2009	Association of Gay and Lesbian Psychiatrists	Immediate Past President
2009 - 2010	Consensus Committee for Revision of the Sexual and Gender Identity Disorders for DSM-V, GID of Adults subcommittee. (Wrote WPATH recommendations a advisory body to the APA DSM V Committee for the Sexual and Gender Identity Disorders chapter revis	d Member s as e sion.)
2010 - 2011	Scientific Committee, 2011 WPATH Biennial Sympos	ium, Member Atlanta
2010 -2022 W	orld Professional Association for Transgender Care Standards of Care Workgroup and Committee (writ seventh and eighth revisions of the WPATH Standa Care, which is used internationally for transgender	Member ing ards of care.)
2010 - 2018	ICD 11 Advisory Committee, World Professional Association for Transgender Health	Member
2012 - 2014	Psychiatry and Diagnosis Track Co-chair, Scientific 2014 WPATH Biennial Symposium, Bangkok	Member Committee,
2014 - 2016	Scientific Committee, 2016 WPATH Biennial Sympo	osium, Member Amsterdam
2014 - 2018	Board of Directors (elected to 4 year term), World Professional Association for Transgender Health	Member
2014 - 2018	Public Policy Committee, World Professional Assoc Transgender Health	ciation Chair for
2014 - 2018	WPATH Global Education Initiative: Training provid specialty certification in transgender health	ers Trainer and and Steering
		Committee Member
2014 - 2016	American Psychiatric Association Workgroup on Ge	ender Member Dysphoria

- 2016 present American Psychiatric Association Workgroup on Gender Chair Dysphoria
- 2016 USPATH: Inaugural WPATH U.S. Conference, Los Conference Chair Angeles, 2017

SERVICE TO PROFESSIONAL PUBLICATIONS

- 2011 present Journal of Sexual Medicine, reviewer
- 2014 present International Journal of Transgenderism, reviewer
- 2016 present LGBT Health, reviewer

INVITED PRESENTATIONS - INTERNATIONAL

2009	World Professional Association for Transgender Health, Oslo, Norway	Plenary Session Speaker
2009	World Professional Association for Transgender Health, Oslo, Norway	Symposium Speaker
2009	Karolinska Institutet, Stockholm Sweden	Invited Lecturer
2012	Cuban National Center for Sex Education (CENESEX), Havana, Cuba	Invited Speaker
2013	Swedish Gender Clinics Annual Meeting, Stockholm, Sweden	Keynote Speaker
2013	Conference on International Issues in Transgender care, United Nations Development Programme - The Lancet, B	Expert Consultant Beijing, China
2014	World Professional Association for Transgender Health, Bangkok, Thailand	Track Chair
2014	World Professional Association for Transgender Health, Bangkok, Thailand	Invited Speaker
2014	World Professional Association for Transgender Health, Bangkok, Thailand	Invited Speaker
2015	European Professional Association for Transgender Health, Ghent, Belgium	Invited Speaker
2015	European Professional Association for Transgender Health, Ghent, Belgium	Symposium Chair
2015	Israeli Center for Human Sexuality and Gender Identity, Aviv	Invited Speaker Tel
2016	World Professional Association for Transgender Health, Amsterdam	Symposium Chair
2016	World Professional Association for Transgender Health, Amsterdam	Invited Speaker
2016	World Professional Association for Transgender Health, Amsterdam	Invited Speaker

2017	Brazil Professional Association for Transgender Health, Sao Paulo
2017	Vietnam- United Nations Development Programme Asia Transgender Health Conference, Hanoi
2018	United Nations Development Programme Asia Conference on Transgender Health and Human Rights, Bangkok
2018	World Professional Association for Transgender Health, Invited Speaker Buenos Aires
2021	Manitoba Psychiatric Association, Keynote Speaker

INVITED PRESENTATIONS - NATIONAL

1990		Being Alive Medical Update, Century Cable Television	Televised Lecturer
1992	Institute	e on Hospital and Community Psychiatry, Toronto Sympos	sium Speaker
1992		Academy of Psychosomatic Medicine Annual Meeting, San Diego	Symposium Speaker
1994		American Psychiatric Association 150th Annual Meeting, Philadelphia	Workshop Chair
1994		American Psychiatric Association 150th Annual Meeting Philadelphia	Workshop Speaker
1994		American Psychiatric Association 150th Annual Meeting, Philadelphia	Paper Session Co- chair
1995		Spring Meeting of the Association of Gay and Lesbian Psychiatrists, Miami Beach	Symposium Chair
1996		American Psychiatric Association 152nd Annual Meeting, New York	Workshop Speaker
1997		American Psychiatric Association Annual Meeting, San Diego	Workshop Speaker
1997		Gay and Lesbian Medical Association Annual Invited	Speaker Symposium
1998		American Psychiatric Association Annual Meeting, Toronto	Workshop Chair
1998		American Psychiatric Association Annual Meeting, Toronto	Workshop Chair
1998		American Psychiatric Association Annual Meeting, Toronto	Media Session Chair
1998		American Psychiatric Association Annual Meeting, Toronto	Media Session Chair

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1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Symposium Chair
1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Symposium Presenter
1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Workshop Chair
2000	American Psychiatric Association Annual Meeting, Chicago	Workshop Chair
2000	National Youth Leadership Forum On Medicine, Invited University of California, Berkeley	Speaker
2001	American Psychiatric Association Annual Meeting, New Orleans	Workshop Chair
2001	American Psychiatric Association Annual Meeting, New Orleans	Media Program Chair
2001	Association of Gay and Lesbian Psychiatrists Symposium, New Orleans	Chair
2001	Harry Benjamin International Gender Dysphoria Invited Association Biennial Meeting, Galveston, Texas	Speaker
2002	American Psychiatric Association Annual Meeting, Philadelphia	Media Program Chair
2002	American Psychiatric Association Annual Meeting, Philadelphia	Workshop Chair
2002	American Psychiatric Association Annual Meeting, Philadelphia	Workshop Chair
2003	Association of Gay and Lesbian Psychiatrists CME	Chair Conference
2003	American Psychiatric Association Annual Meeting, San Francisco	Symposium Chair
2003	American Psychiatric Association Annual Meeting, San Francisco	Symposium Co- Chair
2003	American Psychiatric Association Annual Meeting, San Francisco	Workshop Chair
2003	American Public Health Association Annual Meeting, Sar Francisco	n Invited Speaker
2004	Mission Mental Health Clinic Clinical Conference Invited	Speaker
2004	Association of Gay and Lesbian Psychiatrists Conference, New York	Co-Chair
2004	Mental Health Care Provider Education Program: Los Angeles. Sponsored by the American Psychiatric Association Office of HIV Psychiatry	Invited Speaker

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2005	American Psychiatric Association Annual Meeting, Atlanta	Workshop Speaker
2005	Association of Gay and Lesbian Psychiatrists Saturday Symposium	Invited Speaker
2008	Society for the Study of Psychiatry and Culture, San Francisco	Invited Speaker
2009	American Psychiatric Association Annual Meeting, San Francisco	Symposium Speaker
2011	National Transgender Health Summit, San Francisco	Invited Speaker
2011	National Transgender Health Summit, San Francisco	Invited Speaker
2011	American Psychiatric Association Annual Meeting, Honolulu, HI	Symposium Chair
2011	American Psychiatric Association Annual Meeting, Honolulu, HI	Symposium Speaker
2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA	Invited Speaker
2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA	Invited Speaker

Invited Speaker

2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA	
2011	Institute on Psychiatric Services, San Francisco Invited	Speaker
2012	Gay and Lesbian Medical Association Annual Meeting	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	American Psychiatric Association Annual Meeting, San Francisco	Invited Speaker
2013	Gay and Lesbian Medical Association, Denver, CO	Invited Speaker
2014	American Psychiatric Association Annual Meeting, New	Invited Speaker York
2014	Institute on Psychiatric Services, San Francisco	Moderator
2014	Institute on Psychiatric Services, San Francisco	Invited Speaker
2014	Institute on Psychiatric Services, San Francisco Invited	Speaker
2015	National Transgender Health Summit, Oakland, CA	Invited Speaker
2015	National Transgender Health Summit, Oakland, CA	Invited Speaker
2015	American Psychiatric Association Annual Meeting, Toronto	Workshop Speaker
2015	American Psychiatric Association Annual Meeting, Toronto	Course Faculty
2016	American Psychiatric Association Annual Meeting	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Atlanta	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Springfield, MO	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Fort Lauderdale, FL	Course Faculty
2017	World Professional Association for Transgender Health, GEI, Los Angeles Course Faculty	
	World Professional Association for Transgender Health	

Surgeon's Training, Irvine, CA Course Faculty

2017	American Urological Association Annual Meeting, San Francisco CA Invited Speaker
2018	World Professional Association for Transgender Health GEI, Portland OR, Course Faculty
2018	World Professional Association for Transgender Health GEI, Palm Springs, Course Faculty
2019	American Society for Adolescent Psychiatry Annual Meeting, San Francisco, Speaker
2019	American Psychiatric Association Annual Meeting, San Francisco, Session Chair
2020	Psychiatric Congress, Invited Speaker
2022	World Professional Association for Transgender Health, Montreal, invited speaker
2023	National Transgender Health Summit, San Francisco, invited speaker
2023	American Psychiatric Association Annual Meeting, San Francisco, invited speaker

INVITED PRESENTATIONS - REGIONAL AND OTHER INVITED PRESENTATIONS

1990	Advanced Group Therapy Seminar, UCLAInvited LecturerNeuropsychiatric Institute
1991	Joint Project of the Southern California AIDS InterfaithSymposiumCouncil and UCLA School of MedicineSpeaker
1991	Joint Project of the Southern California AIDS Interfaith Workshop Panelist Council and UCLA School of Medicine
1992	Advanced Group Therapy Seminar, UCLA Invited Lecturer Neuropsychiatric Institute
1993	UCSF School of Nursing Invited Lecturer
1995	UCSF/SFGH Department of Medicine Clinical Care Invited Speaker Conference
1996	UCSF School of Nursing Invited Speaker

	Invited Speaker
1996	Psychopharmacology for the Primary Care AIDS/Clinician, Invited Lecturer series of four lectures, UCSF Department of Medicine
1996	UCSF AIDS Health Project Psychotherapy Internship Training Program
1996	UCSF/SFGH Department of Medicine AIDS Quarterly Invited Speaker Update
1996	San Francisco General Hospital, Division of Addiction Invited Speaker Medicine
1996	UCSF Langley Porter Psychiatric Hospital and Clinics Invited Speaker Grand Rounds
1997	UCSF School of Nursing Invited Speaker
1997	UCSF Department of Medicine AIDS Program Invited Speaker
1997	Northern California Psychiatric Society Annual Meeting, Workshop Speaker Monterey
1997	San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds
1997	San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds
1997	Northern California Psychiatric Society LGBT Committee Chair Fall Symposium
1997	Progress Foundation, San Francisco Invited Speaker
1998	San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds
1999	Northern California Psychiatric Society Annual Meeting, Invited Speaker Santa Rosa
1999	Northern California Psychiatric Society Annual Meeting, Invited Speaker Santa Rosa
1999	University of California, Davis, Department of Psychiatry Invited Speaker Grand Rounds
1999	California Pacific Medical Center Department of Invited Speaker Psychiatry Grand Rounds
1999	San Francisco General Hospital Department of Psychiatry Discussant Departmental Case Conference
2000	Langley Porter Psychiatric Hospital and Clinics Invited Speaker Consultation Liaison Seminar
2000	San Francisco General Hospital, Psychopharmacology Invited Speaker Seminar

2000	UCSF Transgender Health Conference, Laurel Heights Invited Speaker Conference Center
2000	Psychiatry Course for UCSF Second Year Medical Invited Lecturer Students
2000	Community Consortium Treatment Update Symposium, Invited Speaker California Pacific Medical Center, Davies Campus
2000	San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds
2001	Psychiatry Course for UCSF Second Year Medical Invited Lecturer Students
2003	Tom Waddell Health Center Inservice Invited Speaker
2003	San Francisco Veterans Affairs Outpatient Clinic Invited Speaker
2004	San Francisco General Hospital Psychiatric Emergency Invited Speaker Service Clinical Conference
2004	South of Market Mental Health Clinic, San Francisco Invited Speaker
2005	Northern Psychiatric Psychiatric Society Annual Meeting Invited Speaker
2005	Equality and Parity: A Statewide Action for Transgender Invited Speaker HIV Prevention and Care, San Francisco
2005	San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds.
2006	SFGH/UCSF Department of Psychiatry Grand Rounds Invited Speaker
2007	UCSF Department of Medicine, HIV/AIDS Grand Rounds, Invited Speaker Positive Health Program
2007	California Pacific Medical Center LGBT Health Invited Speaker Symposium, San Francisco LGBT Community Center
2007	UCSF CME Conference, Medical Management of Invited Speaker HIV/AIDS, Fairmont Hotel, San Francisco
2008	UCSF Department of Medicine, Positive Health Program, Invited Speaker HIV/AIDS Grand Rounds
2008	San Francisco General Hospital Psychiatry Grand Rounds Invited Speaker
2008	UCSF CME Conference, Medical Management of Invited Speaker HIV/AIDS, Fairmont Hotel, San Francisco
2010	Northern California Psychiatric Society Annual Meeting, Invited Speaker Monterey, CA
2011	Transgender Mental Health Care Across the Life Span, Invited Speaker Stanford University
2011	San Francisco General Hospital Department of Psychiatry Invited Speaker Grand Rounds
Invited Speaker

2012	UCSF AI Veterans	DS Health Project Affairs Medical Center.	Invited Speak	er 2012 San Francisco
2013	Associati Angeles,	on of Family and Concil CA	iation Courts Co	nference, Invited Speaker Los
2014	UCSF Tr	ansgender Health electi [,]	ve Invited	l Speaker
2014	UCSF De	epartment of Psychiatry	Grand Rounds	Invited Speaker
2014	California Grand Ro	Pacific Medical Center	Department of	Invited Speaker Psychaitry
2014	UCLA Se Rounds	mel Institute Departmer	nt of Psychiatry	Grand Invited Speaker
2015	UCSF Tr	ansgender Health electi [,]	ve Invited	l Speaker
2015	Fenway	Health Center Boston, M	1A (webinar)	Invited Speaker
2015	Transger	der Health Symposium	, Palm Springs	Invited Speaker
2015	Transger	der Health Symposium	, Palm Springs	Co-Chair
2015	Santa Cla	ara Valley Medical Cente	er Grand Round	s Invited Speaker
2016	UCSF So	hool of Medicine Transo	gender Health e	ective Invited Speaker
2016	Langley Porter P	sychiatric Institute APC	Case Conference	e Invited Speaker (2 session series)
2016	Zuckerbe Psychiati	rg San Francisco Gene y Grand Rounds	ral Department	of Invited Speaker
2016	UCSF M	ni-Medical School Lectu	ires to the Publi	c Invited Speaker
2021	Los Ang	eles County Departme	ent of Mental He	alth, Invited Speaker

CONTINUING EDUCATION AND PROFESSIONAL DEVELOPMENT ACTIVITIES

2005	Northern California Psychiatric Society
2005	Northern California Psychiatric Society Annual Meeting, Napa
2005	Association of Gay and Lesbian Psychiatrist Annual Conference
2006	Annual Meeting, American Psychiatric Association, Atlanta
2006	Annual Meeting, American Psychiatric Association, Toronto
2006	Institute on Psychiatric Services, New York
2007	Association of Gay and Lesbian Psychiatrists Annual Conference
2007	American Psychiatric Association Annual Meeting, San Diego

2007	The Medical Management of HIV/AIDS, a UCSF CME Conference
2008	Society for the Study of Psychiatry and Culture, San Francisco
2009	American Psychiatric Association, San Francisco
2009	World Professional Association for Transgender Health, Oslo, Norway
2010	Annual Meeting of the Northern California Psychiatric Society, Monterey, CA
2011	Transgender Mental Health Care Across the Life Span, Stanford University
2011	National Transgender Health Summit, San Francisco
2011	American Psychiatric Association Annual Meeting, Honolulu, HI
2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA
2011	Institute on Psychiatric Services, San Francisco
2012	Gay and Lesbian Medical Association Annual Meeting, San Francisco
2013	National Transgender Health Summit, Oakland, CA
2013	American Psychiatric Association Annual Meeting, San Francisco
2013	Gay and Lesbian Medical Association, Denver, CO
2014	American Psychiatric Association Annual Meeting, New York
2014	Institute on Psychiatric Services, San Francisco
2015	European Professional Association for Transgender Health, Ghent, Belgium
2015	National Transgender Health Summit, Oakland
2015	American Psychiatric Association Annual Meeting, Toronto
2016	American Psychiatric Association Annual Meeting, Atlanta
2016	World Professional Association for Transgender Health, Amsterdam

GOVERNMENT AND OTHER PROFESSIONAL SERVICE

1998 - 2002 City and County of San Francisco Human Rights Member Commission LGBT Advisory Committee I am the chair of the American Psychiatric Association Workgroup on Gender Dysphoria, which developed a CME course fort the 2015 and 2016 APA Annual Meetings, and is now embarking on a larger educational mission to train American psychiatrists to better care for transgender patients. I have been leading education efforts in transgender health at APA meetings since 1998. On the APA Workgroup on Gender Dysphoria, I am a co-author of a paper of transgender issues that has been approved by the American Psychiatric Association as a resource document and is in press for the American Journal of Psychiatry. I am also the sole author of the chapter on transgender care in the American Psychiatric Press's Clinical Manual of Cultural Psychiatry, Second Edition.

I have been active internationally in transgender health through my work as a member of the Board of Directors of the World Professional Association for Transgender Health. I am an author of the WPATH Standards of Care, Version 7, and am Chapter Lead for the Mental Health Chapter of SOC 8.

I chaired of the WPATH Public Policy Committee and was a member of the Global Education Initiative, which developed a specialty certification program in transgender health. I helped plan the 2016 WPATH Amsterdam conference, and was on the scientific committee for the last four biennial international conferences. I was on the founding committee of USPATH, the national affiliate of WPATH, and I chaired the inaugural USPATH conference, in Los Angeles in 2017. As a member of the steering committee of the WPATH Global Educational Initiative, I helped train over 2000 health providers in transgender health, and helped develop a board certification program and examination in transgender health.

UNIVERSITY SERVICE UC SYSTEM AND MULTI-CAMPUS SERVICE

1991 - present HIV/AIDS Task Force Member							
1992 - 1993	HIV Research Group Member						
1992 - 1997	Space Committee		Member				
1992 - present Gay, Lesbian and Bisexual Issues Task Force N							
1994 - 1997	SFGH Residency Training Co	mmittee	Member				
1996 - 1997	Domestic Partners Benefits S	ubcommittee.	Chair				
1996 - 2000	Chancellor's Advisory Commit and Transgender Issues.	tee on Gay, Lesbian,	Member Bisexual				
1996 - 2003	HIV/AIDS Task Force		Co-Chair				
1996 - 2003	Cultural Competence and Dive	ersity Program	Member				
2009 - present Medical Advisory Board, UCSF Center of Excellence for Member Transgender Health							
2010 - 2013 Steering Committee, Child Adolescent Gender Center Member							
2011 – 2017 Mental Health Track, National Transgender Health Summit Chair							

DEPARTMENTAL SERVICE

1991 - present San Francisco General Hospital, Department of Psychiatry, Member HIV/AIDS Task Force

- 1992 1993 San Francisco General Hospital, Department of Psychiatry, Member HIV Research Group
- 1992 1997 San Francisco General Hospital, Department of Psychiatry, Member Space Committee
- 1992 2003 San Francisco General Hospital, Department of Psychiatry, Member GLBT Issues Task Force
- 1994 1997 San Francisco General Hospital, Department of Psychiatry, Member Residency Training Committee
- 1996 2003 San Francisco General Hospital, Department of Psychiatry, Member Cultural Competence and Diversity Program
- 1996 2003 San Francisco General Hospital, Department of Psychiatry, Co-Chair HIV/AIDS Task Force
- 2012 2020 San Francisco Department of Public Health Gender Member Competence Trainings Committee
- 2013 2020 San Francisco Department of Public Health Transgender Member Health Implementation Task Force
- 2014 2020San Francisco General Hospital, Department of Psychiatry, Member Transgender Surgery Planning Workgroup

PEER REVIEWED PUBLICATIONS

- 1. Berliner JA, Frank HJL, **Karasic D**, Capdeville M. Lipoprotein-induced insulin resistance in aortic endothelium. Diabetes. 1984; 33:1039-44.
- Bradberry CW, Karasic DH, Deutch AY, Roth RH. Regionally-specific alterations in mesotelencephalic dopamine synthesis in diabetic rats: association with precursor tyrosine. Journal of Neural Transmission. General Section, 1989; 78:221-9.
- 3. Targ EF, **Karasic DH**, Bystritsky A, Diefenbach PN, Anderson DA, Fawzy FI. Structured group therapy and fluoxetine to treat depression in HIV-positive persons. Psychosomatics. 1994; 35:132-7.
- Karasic DH. Homophobia and self-destructive behaviors. The Northern California Psychiatric Physician. 1996; 37 Nov.-Dec. Reprinted by the Washington State Psychiatric Society and the Southern California Psychiatric Society newsletters.
- 5. Karasic D. Anxiety and anxiety disorders. Focus. 1996 Nov; 11(12):5-6. PMID: 12206111
- Polansky JS, Karasic DH, Speier PL, Hastik KL, Haller E. Homophobia: Therapeutic and training considerations for psychiatry. Journal of the Gay and Lesbian Medical Association. 1997 1(1) 41-47.
- 7. Karasic DH. Progress in health care for transgendered people. Editorial. Journal of the Gay and Lesbian Medical Association, 4(4) 2000 157-8.
- 8. Perry S, **Karasic D**. Depression, adherence to HAART, and survival. Focus: A Guide to AIDS Research and Counseling. 2002 17(9) 5-6.

- 9. Fraser L, **Karasic DH**, Meyer WJ, Wylie, K. Recommendations for Revision of the DSM Diagnosis of Gender Identity Disorder in Adults. International Journal of Transgenderism. Volume 12, Issue 2. 2010, Pages 80-85.
- Coleman, E., Bockting, W., Botzer, M., Cohen-Kettenis, P., DeCuypere, G., Feldman, J., Fraser, L., Green, J., Knudson, G., Meyer, W., Monstrey, S., **Karasic D** and 22 others. (2011). Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version. International Journal of Transgenderism, 13:165-232, 2011
- Tsai AC, Karasic DH, et al. Directly Observed Antidepressant Medication Treatment and HIV Outcomes Among Homeless and Marginally Housed HIV-Positive Adults: A Randomized Controlled Trial. American Journal of Public Health. February 2013, Vol. 103, No. 2, pp. 308-315.
- 12. Tsai AC, Mimmiaga MJ, Dilley JW, Hammer GP, **Karasic DH**, Charlebois ED, Sorenson JL, Safren SA, Bangsberg DR. Does Effective Depression Treatment Alone Reduce Secondary HIV Transmission Risk? Equivocal Findings from a Randomized Controlled Trial. AIDS and Behavior, October 2013, Volume 17, Issue 8, pp 2765-2772.
- 13. **Karasic DH**. Protecting Transgender Rights Promotes Transgender Health. LGBT Health. 2016 Aug; 3(4):245-7. PMID: 27458863
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- 16. Strang JF, Meagher H, Kenworthy L, de Vries AL, 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.

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18. William Byne, Dan H. Karasic, Eli Coleman, A. Evan Eyler, Jeremy D. Kidd, Heino F.L. Meyer-Bahlburg, Richard R. Pleak, and Jack Pula.Gender Dysphoria in Adults: An Overview and Primer for Psychiatrists.Transgender Health.Dec 2018.57-A3.<u>http://doi.org/10.1089/trgh.2017.0053</u>

19. Identity recognition statement of the world professional association for transgender health (WPATH). International Journal of Transgenderism. 2018 Jul 3; 19(3):1-2. Knudson KG, Green GJ, Tangpricha TV, Ettner ER, Bouman BW, Adrian AT, Allen AL, De Cuypere DG, Fraser

FL, Hansen HT, **Karasic KD**, Kreukels KB, Rachlin RK, Schechter SL, Winter WS, Committee and Board of Direct

- 20. Karasic, DH & Fraser, L Multidisciplinary Care and the Standards of Care for Transgender and Gender Non-conforming Individuals. Schechter, L & Safa, B. (Eds.) Gender Confirmation Surgery, Clinics in Plastic Surgery Special Issue, Vol 45, Issue 3, pp 295-299. 2018 Elsevier, Philadelphia. <u>https://doi.org/10.1016/j.cps.2018.03.016</u>
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- 2. **Karasic DH**, Dilley JW. Human immunodeficiency-associated psychiatric disorders. In: The AIDS Knowledge Base, Third Edition. Cohen PT, Sande MA, Volberding PA, eds. Lippincott-Williams & Wilkens, Philadelphia, 1999, pp. 577-584.
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- 5. **Karasic DH**. Mental Health Care of the Transgender Patient. In: Comprehensive Care of the Transgender Patient, Ferrando CA ed. pp. 8-11. Elsevier, 2019.
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- 3. **Karasic DH**. A primer on transgender care. In: Gender and sexuality. The Carlat Report Psychiatry. April 2012. Vol 10, Issue 4.
- 4. **Karasic D and Ehrensaft D.** We must put an end to gender conversion therapy for kids. Wired. 7/6/15.

EXPERT WITNESS AND CONSULTATION ON TRANSGENDER CARE AND RIGHTS

2008 Consultant, California Department of State Hospitals

2012 Dugan v. Lake, Logan UT

2012 XY v. Ontario http://www.canlii.org/en/on/onhrt/doc/2012/2012hrto726/2012hrto726.html

2014 Cabading v California Baptist University

2014 CF v. Alberta http://www.canlii.org/en/ab/abqb/doc/2014/2014abqb237/2014abqb237.html

2017 United Nations Development Programme consultant, transgender health care and legal rights in the Republic of Vietnam; Hanoi.

2017- Forsberg v Saskatchewan; Saskatchewan Human Rights v Saskatchewan 2018 <u>https://canliiconnects.org/en/summaries/54130</u> <u>https://canliiconnects.org/en/cases/2018skqb159</u>

- 2018 United Nations Development Programme consultant, transgender legal rights in Southeast Asia; Bangkok.
- 2018 Consultant, California Department of State Hospitals

2019, 2021 Consultant/Expert, Disability Rights Washington

2019, 2021 Consultant/Expert, ACLU Washington

2021 Consultant, California Department of Corrections and Rehabilitation

2021 Expert, Kadel v. Folwell, 1:19-cv-00272 (M.D.N.C.).

2021 Expert, Drew Glass v. City of Forest Park - Case No. 1:20-cv-914 (Southern District Ohio)

2021-2022 Expert, Brandt et al v. Rutledge et al. 4:21-cv-00450 (E.D. Ark.)

2021-2022 Expert, Fain v. Crouch, 3:20-cv-00740 (S.D.W. Va.)

2022 Expert, C.P. v. Blue Cross Blue Shield of Illinois, No. 3:20-cv-06145-RJB (W.D. Wash.)

<u>Exhibit B</u> *Bibliography*

EXPERT REPORT OF DR. DAN H. KARASIC Case No. 4:22-cv-00325-RH-MAF

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

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

EXPERT DECLARATION OF LOREN S. SCHECHTER, M.D.

Preliminary Statement

1. I am a board-certified plastic surgeon. I specialize in performing gender confirming surgeries¹ (including chest reconstruction surgeries, genital reconstruction surgeries, and other procedures to feminize or masculinize the face

¹ I refer to the family of procedures discussed in this report as "gender confirmation," "gender confirming surgeries," or "gender affirming surgeries" because they are one of the therapeutic tools used to enable people to be comfortable living in accordance with their gender identities. Out of the myriad of labels I've heard for these procedures—"sex reassignment surgery," "gender reassignment surgery," and "sex change operation," to name but a few—none is as accurate when it comes to describing what is actually taking place as "gender confirmation" or "gender affirmation surgery." Most, if not all, of the other names used for these procedures suggest that a person is making a choice to switch genders, or that there is a single "surgery" involved. From the hundreds of discussions I have had with patients over the years, nothing could be further from the truth. This is not about choice; it is about using one or more surgical procedures as therapeutic tools to enable people to live authentically.

and body, as described in more detail below), and I am a recognized expert in this field.

I have been retained by counsel for Plaintiffs in the above-captioned 2. lawsuit to provide an expert opinion on the standards of care for treating individuals diagnosed with gender dysphoria. In particular, I have been asked: 1) whether gender confirming surgeries are safe and effective medical treatment for gender dysphoria experienced by transgender people, including adults age 21 and over and adolescents up to age 21; 2) whether gender confirming surgeries are experimental or investigational; and 3) whether a categorical exclusion on Medicaid coverage for gender confirming surgeries violates the prevailing standards of care for treating transgender people, including for adults age 21 and over and for adolescents up to age 21, who have been diagnosed with gender dysphoria. Additionally, I submit this declaration to respond to points raised in the Florida Agency for Health Care Administration's "Florida Medicaid Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria" report ("GAPMS Report") and the assessment drafted by Patrick W. Lappert, M.D. that was attached to the GAPMS Report ("Lappert Assessment").

Qualifications and Experience

3. The information provided regarding my professional background, experiences, publications, and presentations are detailed in my curriculum vitae ("CV"). A true and correct copy of my most up-to-date CV is attached as **Exhibit A**.

4. I received my medical degree from the University of Chicago, Pritzker School of Medicine. I completed my residency and chief residency in plastic and reconstructive surgery and a fellowship in reconstructive microsurgery at the University of Chicago Hospitals.

5. I previously served as a Clinical Professor of Surgery at the University of Illinois at Chicago. I resigned that position to become the Director of Gender Affirmation Surgery at Rush University Medical Center in April 2022. I am also a Professor of Surgery and Urology at Rush University Medical Center. In addition, I maintain a clinical practice in plastic surgery in Illinois where I treat patients from around the country, as well as from around the world.

6. I have been performing gender confirming surgeries for more than 28 years. For at least the past five years, I have been performing approximately 150 gender confirmation procedures every year. I have performed over 1,500 gender confirmation surgeries during my medical career. Currently,

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approximately 90 percent of the patients in my clinical practice are transgender people seeking gender confirmation surgeries.

7. I was a contributing author to the World Professional Association for Transgender Health's ("WPATH") Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version Seven, which were published in 2012. In particular, I wrote the section focused on the relationship of the surgeon with the treating mental health professional and the physician prescribing hormone therapy. In September 2022, WPATH published the Standards of Care for the Health of Transgender and Gender Diverse People, Version Eight ("Standards of Care") in the International Journal of Transgender Health.² I was the co-lead author of the surgical and postoperative care chapter of Version Eight.

8. The Standards of Care provide clinical guidance for health professionals based on the best available science and expert professional consensus. The purpose of the Standards of Care is to assist health providers in delivering medical care to transgender people in order to provide them with safe

² Coleman, E. et al. (2022). Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int'l J. of Transgender Health, 23: S1-S259, doi: 10.1080/26895269.2022.2100644 [hereinafter "Standards of Care"].

and effective treatment for gender dysphoria, in order to maximize their overall health, psychological well-being, and self-fulfillment.

9. In addition, I have written a number of peer-reviewed journal articles and chapters in professional textbooks about gender confirmation surgeries. In 2016, I published Surgical Management of the Transgender Patient, the first surgical atlas (a reference guide for surgeons on how to perform surgical procedures using safe, well-established techniques) dedicated to gender confirming surgeries. In 2020, I published a guide for surgeons entitled Gender Confirmation Surgery: Principles and Techniques for an Emerging Field. I am also a co-investigator on a study regarding uterine transplantation for transgender women. A full and complete list of my publications is included in my CV.

10. I am a guest reviewer for several peer-reviewed medical journals, including the Journal of Plastic and Reconstructive Surgery, the Journal of Reconstructive Microsurgery, the Journal of the American College of Plastic Surgeons, the Journal of Plastic and Aesthetic Research, and the Journal of Sexual Medicine. I also serve on the editorial board of both Transgender Health and the International Journal of Transgender Health. Each of these publications is a peer-reviewed medical journal. A full and complete list of my reviewerships and editorial roles is included in my CV.

11. I am actively involved in training other surgeons to perform gender confirmation surgeries. In 2017, I started the surgical fellowship in gender surgery, now placed at Rush University Medical Center in Chicago. I am currently the Director of that fellowship.

12. I have given dozens of public addresses, seminars, and lectures on gender confirming surgery, including many through the American Society of Plastic Surgeons. I have also taught a number of courses through WPATH's Gender Education Institute, which provides training courses toward a member certification program in transgender health for practitioners around the world. In addition, in 2018, I co-directed the first live surgery course in gender confirming procedures at Mount Sinai Hospital in New York City, and I am the Director for this upcoming live surgery course in 2023. In 2019, I directed the inaugural Gender Affirming Breast, Chest, and Body Master Class for the American Society of Plastic Surgeons.

13. I am also a founding member and president of the Society for Gender Surgeons; a current member of the Executive Committee of the Board of Directors of WPATH, where I serve as treasurer; and a former member of the Board of Governors of the American College of Surgeons. I am a guest examiner for the American Board of Plastic Surgery, which involves administering the plastic surgery oral board exam to surgeons who have completed their plastic surgery training and seek board certification.

14. I am the former Chair of the Patient Safety Committee for the American Society of Plastic Surgeons, and current Patient Safety Officer for the Division of Plastic Surgery at Rush University Medical Center. In 2017, I was an invited discussant at the Pentagon regarding transgender service members. I recently delivered the Bevan 2023 Lecture at the Chicago Surgical Society, which is a lecture that began in 1928 and was established by Arthur Bevan, a former President of the American Medical Association and Founder of the American Board of Surgery.

Previous Testimony

15. In the past four years, I have provided expert testimony in the following matters: *Kadel v. Folwell*, M.D.N.C. (deposition); *Toomey v. State of Arizona*, D. Ariz. (deposition); and *Fain v. Crouch*, S.D.W.V. (deposition).

Compensation

16. I am being compensated at an hourly rate of \$400/hour plus expenses for my time spent preparing this declaration and for providing any local testimony (including deposition or hearing testimony by telephone or videoteleconference). I will be compensated a flat daily rate of \$7,500 for any out-of-

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town deposition or hearing testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

Basis for Opinions

17. My opinions contained in this report are based on all of the following: (1) my clinical experience of over 28 years of caring for transgender patients, including my experience teaching other surgeons and medical students to care for this population; (2) my review and familiarity with relevant peer-reviewed literature,³ including my own, regarding gender confirming surgeries, which reflects the clinical advancements in these procedures and the corresponding growth in research related to the safety and effectiveness of these procedures in treating gender dysphoria; and (3) discussions with colleagues and other experts in the field, including attendance and participation in various educational conferences both nationally and internationally. The research and

³ I regularly and routinely perform literature searches as an educator, including in my roles as a Professor of Surgery at Rush University Medical Center and an attending surgeon at Rush University, where I participate in fellow, resident, and student education; Director of Gender Affirmation Surgery at Rush University Medical Center; lecturer for the Global Education Initiative for WPATH; invited lecturer at national and international conferences; co-lead author of the surgery and post-operative care chapter of the WPATH Standards of Care Version 8; an editor and reviewer for peer-reviewed publications; and a course director for various educational opportunities for WPATH, American Society of Plastic Surgeons, and other organizations.

materials I relied on in preparing this declaration are cited in the footnotes and detailed in the reference list attached as **Exhibit B** to this declaration.

18. Additionally, in preparing this declaration, I reviewed the GAPMS Report and the Lappert Assessment, as well as the coverage exclusion challenged in this case (Fla. Admin. Code R. 59G-1.050(7)).

DISCUSSION

Background on Gender Identity and Gender Dysphoria

19. The term "transgender" is used to describe a diverse group of individuals whose gender identity, or internal sense of gender, differs from the sex they were assigned at birth.

20. Many transgender people experience gender dysphoria at some point in their lives. Gender dysphoria is a serious medical condition, defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-5TR) published by the American Psychiatric Association as clinically significant distress or impairment related to gender incongruence, which may include desire to change primary and/or secondary sex characteristics. Gender dysphoria is also recognized by the International Classification of Diseases-11 (ICD-11), under the label of gender incongruence, and the International Classification of Diseases-10 (ICD-10). 21. Individuals diagnosed with gender dysphoria have an intense and persistent discomfort with the primary and/or secondary sex characteristics of the sex they were assigned at birth. Gender dysphoria can lead to debilitating anxiety and depression, as well as serious incidents of self-harm, including self-mutilation, suicide attempts, and suicide.

22. Appropriate medical care, including mental health services, hormone therapy, and gender confirmation surgeries can help alleviate gender dysphoria. Gender confirmation surgeries, which bring a person's body into better alignment with their gender identity, have been shown to be a safe and effective treatment for gender dysphoria.

<u>Gender Confirming Surgeries are Standard, Medically Accepted, and</u> <u>Medically Necessary Treatments for Gender Dysphoria for Transgender</u> <u>People</u>

23. It is my professional opinion, supported by the prevailing consensus of the medical community, that surgical procedures used to treat gender dysphoria are medically necessary treatments for many transgender people. Decades of clinical practice and peer-reviewed research have demonstrated that these procedures are safe and effective treatments for gender dysphoria.

Applicable Standards of Care for Treating Gender Dysphoria

WPATH is a non-profit professional and educational organization 24. devoted to transgender health. WPATH's mission is "to promote evidence-based care, education, research, advocacy, public policy, and respect in transgender health."⁴ As described above, WPATH publishes the Standards of Care, which are based on the best available scientific evidence and expert professional consensus.⁵ WPATH published the first version of the Standards of Care in 1979. Since that time, the guidelines have been updated through eight versions, reflecting the significant advances made in the understanding, management, and care of transgender individuals. The Standards of Care are widely recognized guidelines for the clinical management of transgender people with gender dysphoria. Most surgeons who are actively involved in academic training and research in the field and regularly treat people experiencing gender dysphoria, including myself, practice in accordance with the Standards of Care.

25. As indicated in the Standards of Care, medically necessary gender affirming treatments include mental health care, puberty suppression, hormone therapy, and various surgical procedures to align a person's primary and/or

⁴ WPATH, Mission and Vision, <u>https://www.wpath.org/about/mission-and-vision</u>.

⁵ See Standards of Care at S247-251 (describing the methodology used to develop the Standards of Care).

secondary sex characteristics with the person's gender identity.⁶ Surgery is often the last and most considered of the treatment options for gender dysphoria in transgender people. Not every transgender person may undergo every available surgical procedure. As highlighted in the seventh version of the Standards of Care, and as now well-accepted, "[t]he number and sequence of surgical procedures may vary from patient to patient, according to their clinical needs."⁷ Evidence shows that while some transgender people do not require surgery, "for many others surgery is essential and medically necessary to alleviate their gender dysphoria. For the latter group, relief from gender dysphoria cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity."⁸

26. The Endocrine Society—the leading professional organization devoted to research on hormones and the clinical practice of endocrinology—has also issued clinical guidelines for the treatment of transgender people.⁹ The

⁶ Standards of Care at S18, S128.

⁷ Coleman, E. et al. (2012). Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People. Version 7, Int'l J. of Transgenderism, 13(4): 165-232, 201 doi: 10.1080/15532739.2011.70087358.

⁸ *Id.* at 199. *See also* Standards of Care at S18.

⁹ Hembree, W.C. et al. (2017). Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, J. Clin. Endocrinology & Metabolism, 102(11): 3869-3903, doi: 10.1210/jc.2017-01658.

guidelines indicate, that for transgender people, gender confirming surgeries often are necessary and effective treatments.¹⁰

27. The broader medical community, including the American Medical Association, American Academy of Pediatrics, American Psychological Association, American Psychiatric Association, American College of Obstetricians and Gynecologists, American Academy of Family Physicians, and World Health Organization, recognizes that gender confirming surgeries are standard, appropriate, and often necessary treatments for adults and adolescents with gender dysphoria.

Surgical Treatments for Gender Dysphoria

28. Surgical treatment options that are generally accepted in the medical community and are consistent with the Standards of Care include, but are not limited to:

- Breast/chest surgery: augmentation (breast implants) and mastectomy/liposuction (chest masculinizing);
- Genital surgeries: phalloplasty and/or metoidioplasty (creation of the penis and/or scrotum), vaginoplasty, and/or vulvoplasty (creation of the vulva and/or vagina, including the labia minora and majora);

 $^{^{10}}$ *Id*.

- Gonadectomy: hysterectomy (removal of the uterus), orchiectomy (removal of the testes);
- Other surgical interventions: gender affirming facial surgery, body contouring, voice surgery, thyroid cartilage reduction, and hair reconstruction, among others.

29. The Standards of Care set forth criteria for initiation of any gender affirming medical treatment, including surgery. For adults, the criteria for surgery are:

- The patient's experience with gender incongruence is marked and sustained.
- In regions where a diagnosis is necessary to access health care (as it is in the United States), the patient fulfills the diagnostic criteria for gender incongruence.
- Other possible causes of apparent gender incongruences have been identified and excluded prior to the initiation of treatment.
- Any physical or mental health conditions "that could negatively impact the outcome" of treatment were assessed, "with risks and benefits discussed, before a decision was made regarding treatment."

- The patient has the capacity to consent for the specific gender affirming treatment.
- The patient understands "the effect of the treatment on reproduction" and has explored reproductive options.
- "[P]rofessionals who have competencies in the assessment of transgender and gender diverse people wishing gender-related medical treatment consider[ed] the role of social transition" with the patient.
- The patient has a recommendation for the initiation of the treatment "from a professional who has competencies in the assessment of transgender and gender diverse people wishing gender-related medical and surgical treatment."
- Prior to genital reconstruction surgery, the patient has received a minimum of 6 months of hormone therapy as appropriate to their gender goals prior to undergoing the surgery.¹¹

30. The Standards of Care recognize that chest masculinization surgery "can be considered in minors when clinically and developmentally appropriate

¹¹ Standards of Care at S32; see also id. at S256.

as determined by a multidisciplinary team experienced in adolescent and gender development^{"12} They also indicate that breast augmentation may be needed by adolescents. In addition, while it is rare to perform genital surgeries on adolescents, the Standards of Care recognize that studies suggest that some adolescents may benefit from vaginoplasty procedures.¹³ They recommend that clinicians undertake a "comprehensive biopsychosocial assessment of adolescents" seeking gender-affirming treatment "to guide treatment decisions and optimize outcomes."¹⁴ As they do for adults, the Standards of Care set forth criteria for initiation of surgery in adolescents.¹⁵

Gender Confirmation Surgeries Are Medically Necessary

31. The medical community and insurance providers recognize a distinction between surgery which is medically necessary, and cosmetic surgery, which generally is not. No particular procedure is inherently cosmetic or inherently medically necessary; rather, the underlying diagnosis determines whether the procedure is considered cosmetic or medically necessary.

¹² *Id*.at S66.

¹³ Id.

¹⁴ *Id*. at S50.

¹⁵ *Id.* at S48, S256.

32. With respect to surgical treatments for gender dysphoria, the medical community generally considers those surgeries to be medically necessary. This is true even though the same surgical procedures might be considered cosmetic when performed on someone without gender dysphoria (e.g., a cisgender woman obtaining a breast augmentation for aesthetic reasons). Gender confirming surgeries are not cosmetic because, when performed in accordance with the Standards of Care, they are clinically indicated to treat the underlying medical condition of gender dysphoria. Because these medically necessary procedures help transgender people live and present in a manner more consistent with their gender identity and therefore reduce and/or treat their gender dysphoria, the professional medical consensus is that these are appropriately categorized as medically necessary.

33. Dr. Lappert asserts that distinguishing "cosmetic breast surgery from 'medically necessary' surgery is based upon the diagnosis of the underlying pathology."¹⁶ I agree. What Dr. Lappert fails to acknowledge, however, is that

¹⁶ Lappert Assessment at 13.

breast augmentation or mastectomy may be medically indicated for the treatment of gender dysphoria, in addition to other pathologies.¹⁷

34. Dr. Lappert misunderstands that gender dysphoria is a medical condition for which there are effective medical and surgical treatments. While plastic surgeons may encounter individuals with mental health conditions, such as body dysmorphic disorder, surgery for this condition is highly ineffective. This is in contrast to surgery as treatment for gender dysphoria; where medically indicated, surgical procedures for gender dysphoria are both safe and medically effective.

35. Dr. Lappert also wrongly suggests that a mastectomy performed to treat gender dysphoria is cosmetic because it results in a "complete loss of function" that is "two fold (breast feeding and erotic sensibility)."¹⁸ Here, he makes several incorrect assumptions. First, he fails to recognize that for many transgender people (especially transgender men), nipple sensation is rarely a source of erotic sensibility, and the presence of breasts may interfere with romantic relationships. In fact, my research, as well as my clinical experience,

¹⁷ Dr. Lappert incorrectly refers to breast growth in transgender women as "gynecomastia." Gynecomastia refers to enlargement of the male breast, not to breast growth in transgender women.

¹⁸ Lappert Assessment at 10.

shows that gender-affirming mastectomy is associated with an increase in sexual satisfaction.¹⁹ What is more, Dr. Lappert ignores that a mastectomy performed to treat breast cancer or a breast reduction performed in a cisgender woman to relieve symptoms of breast hypertrophy or macromastia may also result in the loss of nipple sensation. A mastectomy performed to treat breast cancer will likewise result in the loss of the ability to breast feed. So, his assertion that any procedure that causes a loss of function is cosmetic cannot be correct. As another example, a prostatectomy performed to treat prostate cancer in a cisgender man may result in the loss of erectile function and impotence.

Gender Confirming Surgeries Are Safe and Effective

36. The prevailing peer-reviewed clinical research, as well as my own clinical expertise as a plastic surgeon specializing in gender confirmation surgeries for nearly three decades, shows that surgical procedures for gender dysphoria are safe, effective, and medically accepted. Indeed, many of these procedures are analogous to surgical procedures used to treat other medical conditions.

¹⁹ See, e.g., Agarwal, C.A. et al. (2018). Quality of Life Improvement After Chest Wall Masculinization in Female-To-Male Transgender Patients: A Prospective Study Using the BREAST-Q and Body Uneasiness Test, J. Plastic, Reconstructive & Aesthetic Surgery, 71(5): 651-657, doi: 10.1016/j.bjps.2018.01.003.
Safety

37. It is my professional opinion that gender confirmation surgeries are safe. My opinion is informed in part by my experience as the former Chair of the Patient Safety Committee for the American Society of Plastic Surgeons and the current Patient Safety Officer for the Division of Plastic Surgery at Rush University Medical Center. Notably, when performing gender confirmation surgeries, surgeons use many of the same procedures that they use to treat other medical conditions. The fact that the medical community deems these analogous procedures sufficiently safe to treat conditions other than gender dysphoria is by itself more than sufficient to support the safety of those surgeries to treat gender dysphoria. There is no medical basis to conclude that the same surgical procedures are more or less safe simply because they are used to treat gender dysphoria, versus other underlying medical conditions.

38. For example, surgeons regularly perform mastectomies and chest/breast reconstruction, hysterectomies/salpingo-oophorectomies (which includes removal of the fallopian tubes and ovaries), and orchiectomies to treat individuals with cancer, or a genetic predisposition to cancer (BRCA 1, 2 genes in the case of prophylactic mastectomy or oophorectomy). Similarly, surgeons perform procedures to reconstruct external genitalia for individuals who have

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certain medical conditions (e.g., cancer) or who have suffered traumatic injuries or disabling infections to their genitalia. This would include procedures to correct conditions such as hypospadias (a disorder in which the urinary opening is not in the typical location on the glans penis), epispadias (a condition where the urethra is not properly developed), exstrophy (where the bladder develops outside the fetus), fournier's gangrene (where tissue dies because of an infection), penile webbing, or buried penis (which can occur as a result of obesity, diabetes, or recurrent infections). This would also include procedures to correct conditions such as congenital absence of the vagina or reconstruction of the vagina/vulva following oncologic resection, traumatic injury, or infection.

Notably, Dr. Lappert concedes that chest reconstructive surgery in the form of a mastectomy is "very safe, and typically performed in the outpatient setting."²⁰ Dr. Lappert also concedes that "[s]urgical enhancement procedures are exactly the same in both men and women."²¹

²⁰ Lappert Assessment at 13.

 $^{^{21}}$ *Id*.

Efficacy

39. It is my professional opinion that standard surgical treatments for gender dysphoria are effective when performed in accordance with the Standards of Care.

40. Peer-reviewed studies find that transgender women who undergo one or more gender confirmation surgeries report positive health outcomes.²² For example, a peer-reviewed study of transgender women found that those who underwent breast reconstruction surgeries experienced statistically significant improvements in their psychosocial well-being.²³ In a study published in 2019 by Miller, et al., 100% of transgender women who underwent breast augmentation reported improvement in their gender dysphoria and "would undergo the operation again."²⁴ Another peer-reviewed study of transgender women who had vaginoplasty found that study participants' mean improvement in quality of life

 $^{^{22}}$ See Standards of Care at S128-129 (gathering studies on breast augmentation and vaginoplasty).

²³ Weigert, R. et al. (2013). Patient Satisfaction with Breasts and Psychosocial, Sexual, and Physical Well-Being after Breast Augmentation in Male-to-Female Transsexuals. Plastic and Reconstructive Surgery, 132(6): 1421-1429. doi: 10.1097/01.prs.0000434415.70711.49.

²⁴ Miller. T.J. et al. (2019). Breast Augmentation in Male-to-Female Transgender Patients: Technical Considerations and Outcomes. JPRAS Open, 21: 63-74, doi: 10.1016/j.jpra.2019.03.003.

after surgery was 7.9 on a scale from one to ten.²⁵ Another study of transgender women found that surgical interventions were highly correlated with alleviating gender dysphoria.²⁶ A recent literature review concluded that in appropriately selected individuals, gender confirmation surgery is effective at improving quality of life, overall happiness, and sexual functioning in transgender women who are diagnosed with gender dysphoria.²⁷ Another recent post-operative and six-month follow-up survey of transgender female patients found improvements in quality of life in a significant majority of patients.²⁸

41. The available peer-reviewed literature likewise concludes that when performed in accordance with the prevailing standards of care, male chest reconstruction surgery is safe and effective in alleviating gender dysphoria.²⁹ For example, one study found that transgender men who received chest reconstruction experienced few clinical complications and were overwhelmingly

²⁵ Horbach, S. E. R. et al. (2015). Outcome of Vaginoplasty in Male-to-Female Transgenders: A Systematic Review of Surgical Techniques. J. Sexual Medicine, 12(6): 1499-1512, doi: 10.1111/jsm.12868.

²⁶ Hess, J. et al. (2014). Satisfaction with Male-to-Female Gender Reassignment Surgery. Deutsches Arzteblatt Int'l, 111: 795-801, doi: 10.3238/arztebl.2014.0795 (Among survey respondents, the majority (90.2%) said that their expectations for life as a woman were fulfilled after surgery. A similarly high percentage (85.4%) saw themselves as women.)

²⁷ Hadj-Moussa, M., et al. (2018). Feminizing Genital Gender-Confirmation Surgery. Sexual Medicine Reviews, 6(3): 457-468.e2, doi: 10.1016/j.sxmr.2017.11.005.

²⁸ Papadopulos, N.A., et al. (2017). Male-to-Female Sex Reassignment Surgery Using the Combined Technique Leads to Increased Quality of Life in a Prospective Study. Plastic and Reconstructive Surgery, 140(2): 286-294. doi: 10.1097/PRS.00000000003529.

²⁹ See Standards of Care at 128 (gathering studies).

satisfied with their surgical outcomes.³⁰ Another peer-reviewed study of transgender men who received chest reconstruction found that the procedure improved psychosocial well-being and physical well-being among participants.³¹

A 2021 study using a validated quality of life assessment tool demonstrated significant improvements in quality of life among transgender men up to one year following chest surgery.³² The authors indicated that "the effect sizes were large and...exhibited excellent internal validity." The authors report that "every patient surveyed at 1 year reported that gender-affirming surgery changed their life for the better" and that, "every patient surveyed after surgery said they would choose it [surgery] again knowing what they know." Numerous other studies have reached similar conclusions.³³

³⁰ Frederick, M. et al. (2017). Chest Surgery in Female to Male Transgender Individuals. Annals of Plastic Surgery, 78(3): 249-253, doi: 10.1097/SAP.0000000000882.

³¹ Agarwal, C.A. et al. (2018). Quality of Life Improvement After Chest Wall Masculinization in Female-To-Male Transgender Patients: A Prospective Study Using the BREAST-Q and Body Uneasiness Test, J. Plastic, Reconstructive & Aesthetic Surgery, 71(5): 651-657, doi: 10.1016/j.bjps.2018.01.003.

³² Alcon, A. et al. (2012). Quantifying the Psychosocial Benefits of Masculinizing Mastectomy in Trans Male Patients with Patient-Reported Outcomes: The University of California, San Francisco, Gender Quality of Life Survey. Plastic and Reconstructive Surgery, 147(5): 731e-740e, doi: 10.1097/PRS.000000000007883. *See also* Schechter, L.S. (2012). Discussion: Quantifying the Psychosocial Benefits of Masculinizing Mastectomy in Trans Male Patients with Patient-Reported Outcomes: The University of California, San Francisco, Gender Quality of Life Survey. Plastic and Reconstructive Surgery, 147(5): 741e-742e. doi: 10.1097/PRS.000000000007902.

³³ See, e.g., Olson-Kennedy, J. et al. (2018). Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults. JAMA Pediatrics, 172(5): 431-436, doi: doi:10.1001/jamapediatrics.2017.5440; Van de Grift, T., et al. (2017). Surgical Indications and

42. These findings extend to adolescents; for example, a recent study in JAMA Pediatrics concluded that: "Chest dysphoria was high among presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults."³⁴ In addition, a 2022 study in JAMA Pediatrics found that in transgender and nonbinary adolescents and young adults, top surgery is associated with low complication rates and improved chest dysphoria, gender congruence, and body image satisfaction.³⁵

43. In my clinical experience, the overwhelming majority of patients who obtain gender confirmation surgery in a manner consistent with the Standards of Care are both satisfied and experience a reduction of gender dysphoria. For the vast majority of transgender people who seek such surgery, the surgery is successful at treating gender dysphoria and alleviating a lifelong struggle to find peace of mind and comfort with their bodies.

Outcomes of Mastectomy in Transmen: A Prospective Study of Technical and Self-Reported Measures. Plastic and Reconstructive Surgery, 140(3): 415e-424e. doi:10.1097/PRS.00000000003607; Berry, M.G. et al. (2012). Female-to-male transgender chest reconstruction: A large consecutive, single-surgeon experience. J. Plastic, Reconstructive & Aesthetic Surgery, 65: 711-719, doi: 10.1016/j.bjps.2011.11.053; Newfield, E. et al. (2006). Female-to-Male Transgender Quality of Life Quality of Life Research, 15(9): 1447-1457. doi: 0.1007/s11136-006-0002-3.

³⁴ Olson-Kennedy, J. supra note 33. Additionally, Frederick et al., *supra* note 30, included adolescents aged 15-17, as well as adults.

³⁵ Ascha, M. et al. (2022). Top Surgery and Chest Dysphoria Among Transmasculine and Nonbinary Adolescents and Young Adults. JAMA Pediatrics, 176(11): 1115-1122, doi:10.1001/jamapediatrics.2022.3424.

Gender Confirmation Surgeries Are Not Experimental

44. It is my professional medical opinion that Dr. Lappert's contention that gender-confirming surgeries are experimental is unsupported by the professional medical consensus and prevailing standards of care for treating gender dysphoria. To the contrary, the prevailing consensus of the medical community recognizes that procedures used to treat gender dysphoria are medically necessary and not experimental or investigational.

45. Surgical care is not considered experimental when it uses accepted techniques and has demonstrative benefits. The techniques used in gender affirming care are employed in other surgeries and are well-established. For example, urethroplasties, orchiectomies, skin grafts, and mastectomies are all accepted techniques for congenital, oncological, and traumatic conditions. They are not experimental simply because they are applied to the well-established diagnosis of gender dysphoria.

46. Gender affirming surgery has been performed for almost 100 years, utilizes accepted surgical techniques, and yields demonstrated benefits for patients. Sir Harold Gilles, the 'father' of plastic surgery performed a phalloplasty on a transgender man in 1946. Sir Harold Gilles also performed a vaginoplasty on a patient in the 1950s. Subsequent to that, the gynecologist

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Georges Borou in Casablanca, developed the pedicled flap for vaginoplasty. This technique remains the mainstay of modern procedures. In fact, pioneering work in gender affirming surgery was performed at Eastern Virginia Medical School in Norfolk, Virginia, where Dr. Lappert was noted to have a faculty appointment. The Center for Gender Reassignment was established in 1984 at Eastern Virginia Medical School. The founder of the program, Dr. David Gilbert, indicated that by 1992, he and his colleagues had performed more than 50 microsurgical phalloplasty procedures. Many of the techniques used in gender affirming surgery were developed in Norfolk, including the 'Norfolk Glansplasty' used in gender affirming phalloplasty.

47. In addition, gender affirming surgeries are: 1) part of the core curriculum in plastic surgery resident education; and 2) a component of both the written and oral board exams in plastic surgery. I have given presentations at multiple professional societies—including, the American Society of Plastic Surgeons, American Association of Plastic Surgeons, American Society for Reconstructive Microsurgery, American College of Surgeons—and none of those societies consider gender affirming surgery experimental. In the disclosures required to give presentations of this kind there is no requirement that they be called experimental. It is widely accepted by professional surgical societies that gender affirming surgeries are not experimental. Indeed, gender affirming surgery is part of the standard resident education in plastic surgery and is included in both the written and oral exams (in order to obtain board certification).

<u>The Opinions of Dr. Lappert Are Inconsistent With the Mainstream</u> <u>Medical Consensus and Scientific Literature and Are Fatally Flawed</u>

Qualifications of Dr. Lappert

48. Based on the disclosures in Dr. Lappert's Assessment, he appears to lack the requisite qualifications to offer his opinions. Dr. Lappert's board certification with the American Board of Plastic Surgery is expired. Dr. Lappert is neither board-certified in plastic surgery, nor does he appear to hold any boardcertification from a member board of the American Board of Medical Specialties.

49. Dr. Lappert is not a member of the American Society of Plastic Surgeons (ASPS), despite its role as the largest plastic surgery specialty organization in the world. ASPS represents 92% of all board-certified plastic surgeons in the United States, and more than 11,000 plastic surgeons worldwide.³⁶ Dr. Lappert does not appear to be a member of any other major or relevant surgical organization, such as the American College of Surgeons.

³⁶ See American Society of Plastic Surgeons, About ASPS, <u>plasticsurgery.org/about-asps</u> (2023).

50. Dr. Lappert lists no current hospital affiliations, nor does he appear to perform surgical procedures any longer. Dr. Lappert has no recent or relevant scientific publications pertaining to the field of gender-affirming surgery. Dr. Lappert references having performed an unspecified number of surgeries for patients who previously identified as transgender, however, he does not disclose any experience in treating individuals in a manner consistent with the Standards of Care.

51. Additionally, Dr. Lappert is not a member of WPATH, which is recognized by the mainstream medical community as the authoritative entity that has established comprehensive Standards of Care in this field.

Quality of Evidence

52. Dr. Lappert repeatedly contends that the body of evidence supporting gender affirming surgery is low-quality, and as a result, the treatment is considered experimental. But that is incorrect. The quality of the evidence supporting gender affirming surgeries is comparable to that supporting many surgeries and clinical procedures. Prospective, randomized, double-blind, placebo-controlled studies cannot be used to evaluate many clinical procedures, especially surgical procedures. For example, there are simply inherent limitations to our ability to conduct such studies in clinical medicine. First, it is unethical to

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withhold medically necessary care. As such, in many situations, clinicians cannot conduct a study that uses a control group who is deprived of the treatment being studied. Practice guidelines published in 2013 by the Royal College of Psychiatrists indicated that a randomized controlled study to evaluate feminizing vaginoplasty would be "impossible to carry out."³⁷ The withholding of medically necessary care that would be required for such a comparison would be considered unethical.

53. Second, it is not possible to perform a double-blind study of surgeries that modify body parts, nor is there a placebo that can mimic such a surgery – unlike studies that use placebo drug regimens, for example, people will know if they have had an operation or not. Third, for relatively uncommon conditions like gender dysphoria, sample sizes of individuals with the condition who are available to participate in a clinical study tend to be small. This is especially true where treatment for a condition has not been covered by insurance programs and plans, and where additional barriers (such as ongoing stigmatization) prevent patients from accessing care. That very lack of access to

³⁷ Good Practice Guidelines for the Assessment and Treatment of Adults with Gender Dysphoria, Royal College of Psychiatrists, at 50 (2013).

the procedure results in there being fewer people who have received treatment and who can participate in a prospective study of that treatment's effect.

54. Put simply, the scientific literature pertaining to gender affirming surgical interventions is similar to that of other accepted plastic surgery procedures. For example, Dr. Lappert points to his experience performing surgery to treat cleft palate and craniofacial differences.³⁸ However, there are only a small number of Level 1 (randomized controlled trials) for that treatment.³⁹ Scientific ratings of evidence generally employ extremely high standards that are not satisfied for many commonly-prescribed treatments and procedures.⁴⁰ Such ratings do not mean that the treatment is unsupported in the literature and clinical practice, or that it is not medically necessary.

55. The recommendation for ongoing research is a standard recommendation in many, if not most or all clinical scenarios. This recommendation for ongoing study in a particular clinical area does not mean that surgical care is withheld.

³⁸ See Lappert Assessment as 15.

³⁹ See, e.g., Bekisz, J.M. (2018). A Review of Randomized Controlled Trials in Cleft and Craniofacial Surgery. J. Craniofacial Surgery, 29(2): 293-301, doi: 10.1097/SCS.00000000004100.

⁴⁰ See, e.g., Lee, B.T., et al. (2017). Evidence-Based Clinical Practice Guideline: Autologous Breast Reconstruction with DIEP or Pedicled TRAM Abdominal Flaps, Plastic and Reconstructive Surgery. 140(5): 651e-664e, doi: 10.1097/PRS.00000000003768.

56. In addition, Dr. Lappert is wrong to suggest that studies are the only way for surgeons to determine the appropriate course of treatment for a particular condition. Critical review of the scientific literature is certainly an important component as to how surgeons evaluate whether a particular procedure is generally safe and effective and whether it is appropriate or recommended for an individual patient. But in addition to considering the literature en masse, we must also account for our own clinical experience and that of our colleagues, as well as our patients' experiences and input. Here, the existing literature, taken as a whole, combined with my own experience and that of many colleagues, indicates that gender affirming surgery is a safe and effective treatment for individuals with gender dysphoria.

57. In fact, in his effort to discredit the research on gender affirming surgery, Dr. Lappert reveals that his lack of experience in the area of gender affirming care is coloring his ability to properly interpret the results of the relevant studies. For example, he suggests that flaws in the methodology of one study could be masking significant numbers of patients who had poor outcomes or regretted having surgery.⁴¹ If significant numbers of patients were having poor outcomes or experiencing regret, those of us who regularly perform gender

⁴¹ See Lappert Assessment at 7-8.

affirming procedures, consult with our colleagues in the field, and attend lectures and conferences on gender affirming care would know about it. We would see many transgender patients requesting revision surgery. That is simply not happening. In contrast, I am aware that some cisgender women who undergo implant-based breast reconstruction subsequently request implant removal.

58. Finally, while criticizing the existing body of research on gender affirming surgical procedures, neither the GAPMS Report nor Dr. Lappert point to any research demonstrating a safe and effective alternative to gender affirming treatment for gender dysphoria.

Informed Consent

59. Dr. Lappert appears to assert that patients cannot provide informed consent for surgical procedures to treat gender dysphoria because of the purported insufficiency of the evidence supporting this care.⁴² Dr. Lappert misunderstands informed consent, both generally and in the context of gender-affirming surgery. And, his view directly contradicts that of the American Society of Plastic Surgeons, which offers documents for surgeons to use to memorialize the process of obtaining informed consent for gender affirming care.

⁴² Lappert Assessment at 4.

60. Gender affirming surgeries are not experimental, as discussed above. Gender affirming surgical procedures have been shown beneficial by multiple surgeons, in multiple countries, over many decades. The risks of gender affirming surgical procedures are well-known and well-described in the literature.⁴³

61. The Standards of Care specifically discuss the importance of a shared decision-making approach (between the patient and the surgeon) that is multidisciplinary and includes a discussion of the patient's goals and expectations, the surgical options and associated risks and benefits, and a plan for care after surgery.⁴⁴ For adolescents, these discussions include the caregiver or parents who must consent as well.⁴⁵

62. The process of securing informed consent is done in a multidisciplinary way. The health care team, which could consistent of a mental health professional, a primary care provider, an endocrinologist, and a surgeon, must assess the ability of the patient to provide informed consent.⁴⁶ And, as noted

⁴³ See, e.g., Schechter, L.S. (2009). The Surgeon's Relationship with the Physician Prescribing Hormones and the Mental Health Professional: Review for Version 7 of the World Professional Association for Transgender Health's Standards of Care. Int'l J. of Transgenderism, 11(4): 222-225, doi: 10.1080/15532730903439468.

⁴⁴ See Standards of Care at S130-132.

⁴⁵ *See id.* at S57-58.

⁴⁶ *See id.* at S38-39, S61-62.

above, a competent health care professional must assess a patient seeking gender affirming surgery prior to the initiation of the treatment. This represents a clinical standard which exceeds the threshold to perform many surgical interventions to treat conditions other than gender dysphoria, including those that are sterilizing. However, this kind of multidisciplinary approach is not unique to gender affirming care. A psychosocial assessment is often performed in other areas of surgery, including transplantation and bariatrics, and has been shown to improve patient outcomes.

Few Patients Experience Regret When Gender Confirming Surgery is Provided in Accordance with the Standards of Care

63. Dr. Lappert suggests that gender confirming surgery is not safe and effective because some patients could later regret their transition and the procedure.⁴⁷ All available research—as well as my own clinical experience—indicates that very few patients experience regret when gender confirming surgery is provided in accordance with the Standards of Care and by a qualified surgeon. Regret of any kind is rare (0.6% in transgender women and 0.3% in transgender men),⁴⁸ but "true regrets," as opposed to regrets due to lack of social

⁴⁷ See, e.g., Lappert Assessment at 7-8, 10-11.

⁴⁸ Wiepjes, C.M. et. al. (2018). The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, And Regrets. J. of Sexual Medicine, 15(4): 582-590. doi: 10.1016/j.jsxm.2018.01.016.

or familial acceptance, comprise an even smaller percentage (approximately half this group, roughly 0.3% in transgender women and 0.15% in transgender men).⁴⁹ Having performed gender confirming surgeries for over 20 years, I have only seen two individuals who have requested a reversal of gender affirming surgery.

64. In a recent study I co-authored regarding regret following gender affirming surgery, Narayan, et al. queried 154 surgeons surgically treating between 18,125 to 27,325 individuals.⁵⁰ The rate of regret was found to be between 0.2-0.3%, consistent with previous literature.

65. Moreover, issues pertaining to regret following surgical procedures are not limited to gender-affirming surgical interventions.⁵¹ Some cisgender women experience regret following breast reconstruction (40%)⁵², prophylactic

⁴⁹ *Id.* at 585, 587 (Researchers classified transgender women as having "social regrets" when they still identified as women, but reported feeling "ignored by surroundings" or they regretted loss of relatives. Researchers classified "true regrets" as those experienced by individuals who "thought gender affirming treatment would be a 'solution' for, for example, homosexuality or [lack of] personal acceptance, but, in retrospect, regretted the diagnosis and treatment.").

⁵⁰ Narayan, S.K. et al. (2021). Guiding the Conversation—Types of Regret After Gender-Affirming Surgery and Their Associated Etiologies. Annals of Translational Medicine, 9(7): 605-616, doi: 10.21037/atm-20-6204.

⁵¹ See, e.g., Christie, D.R.H. et al. (2015). Why do patients regret their prostate cancer treatment? A systematic review of regret after treatment for localized prostate cancer. Psycho-Oncology 24(9): 1002-1011. doi: 10.1002/pon.3776.

⁵² Zhong, T. et al. (2013). Decision regret following breast reconstruction: the role of selfefficacy and satisfaction with information in the preoperative period. Plastic and Reconstructive Surgery, 132(5): 724e-734e, doi: 10.1097/PRS.0b013e3182a3bf5d.

mastectomy (6%),⁵³ and prophylactic oophorectomy (7%).⁵⁴ A study of breast cancer survivors found that five years after diagnosis, 24% expressed regret about primary surgery, and nearly 18% expressed regret about reconstruction.⁵⁵

66. Even if we were to assume that some small percentage of patients who undergo gender-affirming surgery will experience regret, that does not mean that the surgery should never be performed. For example, some patients who undergo an appendectomy are found to have a normal appendix. No one would suggest that surgeons stop performing this procedure altogether. Rather, the appropriate response is to further refine our ability to accurately determine who is most likely to benefit from the procedure.

67. Finally, Dr. Lappert fails to consider that regret can be bidirectional. In other words, a patient may regret not having surgery. In my practice, it is far more common to see a patient who regretted not having access to surgery due to lack of insurance coverage than a patient who regretted having gender affirming surgery.

 ⁵³ Montgomery, L.L. et al. (1999). Issues of regret in women with contralateral prophylactic mastectomies. Annals of Surgical Oncology, 6(6): 546-552, doi: 10.1007/s10434-999-0542-1.
⁵⁴ Swisher, E.M. et al. (2001). Prophylactic oophorectomy and ovarian cancer surveillance. J.

of Reproductive Medicine, 46(2): 87-94 (2001).

⁵⁵ Fernandes-Taylor, S. & Bloom, J.R. (2011). Post-treatment regret among young breast cancer survivors. Psycho-Oncology 20(5): 506-516, doi: 10.1002/pon.1749.

Patient Self-Reporting

68. Dr. Lappert claims that gender confirming surgeries are based on "the patient's subjective report of dysphoria."⁵⁶ Dr. Lappert misrepresents the preoperative process and multidisciplinary assessment that occurs prior to gender affirming surgical interventions.⁵⁷ He demonstrates a lack of familiarity with both the assessment process done before the transgender patient is eligible for surgery and the role and responsibility of the surgeon in providing this care.

69. When a person is referred to a surgeon to receive gender confirming surgery, the surgeon receives in writing one or more assessments from one or more health professionals outlining the patient's diagnosis and the medical necessity of the care, as required under the Standards of Care.⁵⁸ But that is only one step in the assessment for surgical interventions. Contrary to Dr. Lappert's suggestions, the surgeon remains ultimately responsible for deciding whether a particular surgical intervention is medically indicated. The surgeon evaluates the patient and makes the final decision about whether it is safe and medically indicated to proceed. This includes an evaluation of the patient's understanding

⁵⁶ Lappert Assessment at 13.

⁵⁷ See Standards of Care at S133; Schechter, L.S., *supra* note 43.

⁵⁸ The Standards of Care recommend that health care professionals assessing patients for gender-affirming surgical care have specific qualifications. *See* Standards of Care at S33-35.

of the condition, their self-awareness, and their goals and expectations for the intervention. The surgeon also evaluates other factors that would affect the patient's fitness for the surgery, such as obesity or smoking, and determines whether additional information might be required, such as x-rays or laboratory work. The surgeon also typically obtains an assessment from the person's primary care physician about their overall health. In my own clinical practice, I have declined to perform a requested intervention based on my exercise of professional judgment.

70. What is more, his reliance on "objective" tests is misplaced. What he considers to be objective tests – an x-ray, pathology report or lab value – are open to interpretation. It is not uncommon to have conflicting opinions regarding an x-ray or a pathology report. In addition, while various tests may be considered in regards to establishing a diagnosis, the tests are usually interpreted within the clinical context. For example, x-ray reports typically include the phrase "clinical correlation is recommended."

71. Finally, Dr. Lappert ignores that once a diagnosis is established, treatment then depends on a discussion with the patient. That discussion includes information from the literature, but also includes other clinical considerations,

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such as the patient's values, preferences, choices, and autonomy, which Dr. Lappert disregards.

72. Finally, Dr. Lappert also suggests that the difference between reconstructive surgery (which he states that insurance will cover) and cosmetic surgery (which he states that insurance will not) turns on pathology reports, using surgery to treat gynecomastia as an example.⁵⁹ Similarly, he alleges that the need for breast reduction surgery is determined by objective tests, including the weight of the specimen which is removed.⁶⁰ But, for both of those procedures, the American Society of Plastic Surgeons states that symptomatology – not pathology reports or the weight of the specimen which is removed – is the important determinant for insurance coverage.⁶¹

<u>The GAPMS Report Misrepresents the Literature in Medical Necessity,</u> <u>Safety, and Effectiveness</u>

73. The overwhelming weight of the scientific and medical literature supports the benefits of gender affirming surgical interventions. Gender

⁵⁹ See Lappert Assessment at 9.

⁶⁰ *Id*. at 10.

⁶¹ See American Society of Plastic Surgeons, ASPS Recommended Insurance Coverage Third-Party Reduction Mammaplasty Criteria for Payers, (2021),https://www.plasticsurgery.org/documents/Health-Policy/Reimbursement/insurance-2021reduction-mammaplasty.pdf; American Society of Plastic Surgeons, ASPS Recommended Criteria Insurance Coverage for Third-Party Payers, Gynecomastia, https://www.plasticsurgery.org/documents/Health-Policy/Positions/Gynecomastia ICC.pdf.

affirming interventions have been performed for decades, and the safety and efficacy of these procedures have been reported by multiple surgeons practicing at different institutions in different countries and continents.

The GAPMS Report cites a study by Dhejne, et al. to imply that 74. because individuals who received gender confirming surgeries had higher morbidity and mortality rates compared to the general population, the surgeries are not effective.⁶² The Agency misunderstands that study. First, while the study itself clearly states that it is not intended to evaluate whether gender affirming surgeries are "an effective treatment or not," it did conclude that surgeries alleviate gender dysphoria. Second, the study found that those who receive medically necessary surgery generally have reduced morbidity and mortality compared to those with the same condition who do not, even if morbidity and mortality for both groups is higher than average. Third, the study includes patients who had surgery prior to the development of the current standards of care. Finally, the fact that gender confirming surgeries do not entirely resolve all possible causes of morbidity and mortality among transgender individuals is completely unsurprising. While surgery can treat gender dysphoria by aligning transgender people's bodies with their gender identity, surgery alone cannot fully

⁶² GAPMS Report at 24-25.

eliminate the stigma and discrimination that transgender people face. Surgery does not occur in a vacuum. The Standards of Care specifically recognize the need for patients to receive continued social and medical support after surgery.⁶³

75. Moreover, it is rare for any surgery to eliminate morbidity and mortality. For example, people who have surgery to remove a cancerous tumor may still experience higher rates of morbidity and mortality than the general population, but that does not mean that they should not undergo the surgery. In addition, individuals suffering from other medical conditions (including chronic conditions and traumatic injuries such as burns) are also at elevated risk of suicide. The increased risk of suicide does not preclude treatment of burn patients.⁶⁴

76. The fact that surgery does not always reduce morbidity for everyone who receives it does not mean that the surgery is not safe or effective, particularly given the number of potential confounding factors that can impact

⁶³ See Standards of Care at S131 (recommending that prior to surgery, surgeons inform patients about aftercare requirements, travel and accommodations, and the importance of postoperative follow-up care), S133 (recommending that surgeons encourage life-long urological follow-up for patients who have undergone metoidioplasty/phalloplasty), S134 (recommending surgeons encourage patients who have undergone vaginoplasty follow-up with their primary surgeon, primary care physician, or gynecologist).

⁶⁴ Lerman, S.F. et al. (2021). Suicidality After Burn Injuries: A Systematic Review. J. of Burn Care & Research, 42(3): 357-364, doi: 10.1093/jbcr/irab014.

morbidity. Similarly, the continued existence of elevated morbidity and mortality rates, compared to the population at large, say nothing about whether a treatment is a safe and effective way to treat a particular condition. Moreover, while suicide is not necessarily the correct marker for efficacy of treatment, in the Dhejne study, suicide attempts in the years 1989-2003 were reduced (and death by suicide during that time is listed as NA). Additionally, the number of mental health visits following surgical care is not a marker for treatment efficacy. For example, people receiving care for cancer will continue to see their oncologist this does not imply that care received for the treatment of cancer was not successful. We continue to provide care to patients with cancer even though treatments may be "temporary" (i.e., some forms of care may extend the lifespan of a patient with cancer for several years). This does not suggest that withholding medically necessary care is appropriate for patients with cancer, any more than it is for transgender people.

77. The GAPMS Report also misunderstands Medicare policy on coverage of gender-affirming surgery. In 2014, an impartial adjudicative board in the Department of Health & Human Services concluded, based on decades of studies, that surgical care to treat gender dysphoria is safe, effective, and

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medically necessary.⁶⁵ As a result, the Centers for Medicare & Medicaid Services (CMS) within HHS started covering surgical care for gender dysphoria and continues to provide that coverage, including for patients in my practice.

78. In 2016, CMS decided not to issue national standards (called a National Coverage Determination or "NCD") for determining under what circumstances Medicare will cover gender confirming surgical care because "the clinical evidence . . . was inconclusive *for the Medicare population*."⁶⁶ The result of CMS's review of the evidence is not applicable to other population groups. For the most part, the Medicare population consists of individuals over the age of 65. While the number of older adults who have gender affirming surgery is increasing, most individuals who undergo gender affirming surgery are under age 65, meaning that fewer older adults have been included in studies assessing the effectiveness of the treatment. That was a significant factor in CMS's decision. As CMS articulated, "older adults may respond to health care treatments

⁶⁵ See Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Div., Decision No. 2676 (May 30, 2014), <u>hhs.gov/sites/default/files/static/dab/decisions/board-decisions/2014/dab2576.pdf</u>. That decision also discussed the quality of data demonstrating the efficacy of surgical care to treat gender dysphoria, noting regardless of whether the studies were randomized double-blind trials, there was sufficient evidence to prove "a consensus among researchers and mainstream medical organizations that transsexual surgery is an effective, safe and medically necessary treatment for [gender dysphoria]." *Id.* at 20.

⁶⁶ Ctrs. for Medicare & Medicaid Servs., *Decision Memo for Gender Dysphoria and Gender Reassignment Surgery* (Aug. 30, 2016) (emphasis added) [hereinafter "CMS Decision Memo"].

differently than younger adults. These differences can be due to, for example, multiple health conditions or co-morbidities, longer duration needed for healing, metabolic variances, and impact of reduced mobility."⁶⁷

79. What is more, CMS acknowledged that gender confirming surgery may be necessary for certain Medicare beneficiaries and concluded that the appropriateness of surgical care for this population should continue to be determined on a case-by-case basis, as is already required by the Standards of Care. Many widely accepted surgical procedures and surgical conditions do not have NCDs under Medicare. The fact that gender confirming surgery does not have an NCD is not unusual.

80. Notably, I have performed gender confirming surgeries on a number of Medicare beneficiaries in recent years, and Medicare has covered the cost of that care. Indeed, most medical and surgical care provided to patients should be individualized, taking into account each patient's unique clinical circumstances. In contrast, the exclusion challenged in this case does not evaluate the medical necessity of surgical care for gender dysphoria on a case-by-case basis. It categorically excludes all coverage regardless of an individualized showing of medical necessity.

⁶⁷ *Id.* at 57.

Summary of Opinions and Conclusions

81. Based on over 28 years of clinical experience performing gender confirmation procedures and caring for transgender people, my knowledge of the Standards of Care and relevant peer-reviewed literature, and my discussions and interactions with experts throughout the world, it is my professional opinion that gender confirmation surgeries are safe, effective, and medically necessary treatments for gender dysphoria in transgender people. Gender affirming surgeries are not experimental or investigational. In my experience, the overwhelming number of individuals who undergo gender confirmation procedures describe relief and/or reduction of their gender dysphoria and improvement in their quality of life and overall functioning.

82. Furthermore, based on my clinical and professional experience and my ongoing review of the literature, it is my professional opinion that the denial of necessary medical care is likely to perpetuate gender dysphoria and create or exacerbate other medical issues, such as depression and anxiety, leading to an increased possibility of self-harm, negative health outcomes, and even suicide.

83. In conclusion, it is my professional opinion that the categorical exclusion of transition-related surgical care in Florida's Medicaid program is: 1) inconsistent with the Standards of Care for treating transgender individuals

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diagnosed with gender dysphoria; 2) inconsistent with the peer-reviewed scientific and medical research demonstrating that gender confirmation surgeries are safe and effective; and 3) inconsistent with expert medical and surgical consensus. To the extent the exclusion is premised on the conclusion in the GAPMS Report that gender confirming surgical care is experimental and not medically necessary, that conclusion is wrong. The Standards of Care confirm, based on clinical evidence, that gender confirmation surgeries are medically necessary to help people alleviate the often serious and life-threatening symptoms of gender dysphoria.

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

Executed this <u>day of February</u>, 2023.

Loren S. Schechter, M.D.

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

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Curriculum Vitae

NAME: LOREN SLONE SCHECHTER, MD, FACS

- OFFICE: Rush University Medical Center 1725 W. Harrison St Suite 758 Chicago, Il 60712 312.942.3640
- **E-MAIL:** loren_schechter@rush.edu lorenschechter1@gmail.com
- MARITAL STATUS: Married (Rebecca Brown Schechter, MD)
- **CERTIFICATION:**The American Board of Plastic Surgery 2001
Certificate Number 6271
Date Issued: September 2001
Maintenance of Certification: 2011
Maintenance of Certification: 2021

EDUCATION:

1986-1990	he University	of Michigan	BS,	1990
1990-1994	he University	of Chicago	MD,	1994
	ritzker School	of Medicine		

POSTGRADUATE TRAINING:

Residency:	The University of Chicago Hospitals	1994-1999
	Coordinated Training Program in	
	Plastic and Reconstructive Surgery	
Chief Resident:	The University of Chicago Hospitals	1998-1999
	Section of Plastic and Reconstructive	
	Surgery	
Fellowship:	Reconstructive Microsurgery	1999-2000
	The University of Chicago Hospitals	
	Section of Plastic and Reconstructive	
	Surgery	

TEACHING APPOINTMENT and CURRENT PRACTICE LOCATION:

Professor of Surgery (Department of Surgery, Division of Plastic Surgery with joint appointment in the Department of Urology), Chief Section of Gender-Affirmation Surgery, Rush University Medical Center Director, Gender Affirmation Surgery-Rush University Medical Center

LICENSURE: Illinois Illinois Controlled Substance DEA Georgia

STAFF APPOINTMENTS:

Rush University Medical Center Advocate Lutheran General Hospital Louis A. Weiss Memorial Hospital

HONORS AND AWARDS:	
2022	WPATH award for Courage and Bravery
2022	Chicago Magazine Top Doctor
2021	Chicago Magazine Top Doctor-Surgery
2020	The University of Minnesota Program in Human
	Sexuality, recipient of 50 Distinguished Sexual and
	Gender Health Revolutionaries
2017-2020	Castle Connolly Top Doctor (Chicago)
2017	Chicago Consumer Checkbook Top Doctor
2015	University of Minnesota Program in Human Sexuality
2010	Leadership Council
2014-2015	Rosalind Franklin University of Medicine and Science
	Chicago Medical School Honors and recognizes for
	dedication and commitment to teaching
2014	National Center for Lesbian Rights bonored quest
2013	Illippis State Par Association Award for
2013	Community Londorship
2010	Advocate Lutheran Coneral 2000 Dhuqiqiana
2010	Auvocate Lucheran General 2009 Physicians
	Inside relief Leadership Committee-Outstanding
2000	LeaderShip
2009	Advocate Lutheran General Hospital Value Leader
1004	(received for compassion)
1994	Doctor of Medicine with Honors
1994	University of Chicago Department of
	Surgery Award for Outstanding
1004	Performance in the Field of Surgery
1994	Catherine Dobson Prize for the Best Oral Presentation
	Given at the 48 th
	Annual Senior Scientific Session in
	The Area of Clinical Investigation
1993	Alpha Omega Alpha
1991	University of Chicago National Institutes
	Of Health Summer Research Award
1990	Bachelor of Science with High Distinction
	And Honors in Economics
1990	James B. Angell Award for Academic Distinction
1989	Omicron Delta Epsilon-National Economic Honor
	Society
1988	College Honors Program Sophomore Honors Award
	For Academic Distinction
1988	Class Honors (Dean's List)
MEMBERSHIPS:	
2023-	Society of Gender Surgeons
2018-	The American Association of Plastic Surgeons
2016-	The American Society for Gender Surgeons
	(founding member and president-elect)

World Society for Reconstructive Microsurgery

2010-

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2005-	The University of Chicago Plastic Surgery Alumni
	Association
2005-	The Chicago Surgical Society
2004-	The American Society for Reconstructive Microsurgery
2003-	The American College of Surgeons
2002-	The American Society of Plastic Surgeons
2001-	Illinois Society of Plastic Surgeons (formerly Chicago
	Society of Plastic Surgeons)
2001-	The American Society of Maxillofacial Surgeons
2001-	American Burn Association
2001-	Midwest Association of Plastic Surgeons
2001-	WPATH
1994-	The University of Chicago Surgical Society
1994-	The University of Chicago Alumni Association
1992-	American Medical Association
1992-	Illinois State Medical Society
1992-	Chicago Medical Society
1990-	The University of Michigan Alumni Association

CURRENT HOSPITAL COMMITTEES:

Patient Safety and Quality Officer, Division of Plastic Surgery, Rush University Medical Center

PROFESSIONAL SOCIETY COMMITTEES:

WPATH Executive Committee

Treasurer, The World Professional Association for Transgender Health

Chair, Finance and Investment Committee, The American Society of Plastic Surgeons

WPATH 2020 Biennial Meeting Steering Committee

American Society of Breast Surgeons Research Committee, ASPS representative

American Board of Plastic Surgery, Guest Oral Board Examiner

WPATH Ethics Committee

American College of Radiology Committee on Appropriateness Criteria Transgender Breast Imaging Topic, Expert Panel on Breast Imaging: Transgender Breast Cancer Screening Expert Panel on Breast Imaging

American Society of Plastic Surgeons, Finance and Investment Committee

Board of Directors, at-large, The World Professional Association for Transgender Health

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PlastyPac, Board of Governors Medicare Carrier Advisory Committee

OTHER:

American Board of Plastic Surgery-Oral Board Guest Examiner (2020, 2021) Guest Reviewer, Pain Management Guest Reviewer, Plastic and Aesthetic Research Guest Reviewer, European Medical Journal Guest Reviewer, Open Forum Infectious Diseases Reviewer, The Journal of American Guest The College of Surgeons Plastic and Guest Book Reviewer, Reconstructive Surgery Editorial Board, Transgender Health Editorial Board (Associate Editor), International Journal of Transgenderism Fellow of the Maliniac Circle Guest Reviewer, Journal of Reconstructive Microsurgery Guest Reviewer, Journal of Plastic and Reconstructive Surgery Guest Reviewer, Journal of Sexual Medicine Guest Editor, Clinics in Plastic Surgery, Transgender Surgery (Elsevier Publishing) The Journal of Plastic Guest Reviewer, and Reconstructive Surgery PREVIOUS EDITORIAL ROLE: Guest Reviewer, EPlasty, online Journal Module Editor for Patient Safety, Plastic Surgery Hyperguide Editorial Advisory Board, Plastic Surgery Practice Reviewer, International Journal of Guest Transgenderism

Guest Reviewer, Pediatrics

PREVIOUS ACADEMIC APPOINTMENT:

Clinical Professor of Surgery, The University of Illinois at Chicago

Visiting Clinical Professor in Surgery, The University of Illinois at Chicago

Chief, Division of Plastic and Reconstructive Surgery, Chicago Medical School, Rosalind Franklin University of Medicine and Science

Associate Professor, Physician Assistant Program, College of Health Professionals, Rosalind Franklin University

Associate Professor of Surgery, The College of Health Professionals, Rosalind Franklin University

Clinical Associate in Surgery, The University of Chicago

PREVIOUS HOSPITAL COMMITTEES:

Director, Center for Gender Confirmation Surgery, Louis A. Weiss Memorial Hospital

Division Director, Plastic Surgery, Lutheran General Hospital

Division Director, Plastic Surgery, St. Francis Hospital

Medical Staff Executive Committee, Secretary, Advocate Lutheran General Hospital

Credentials Committee, Lutheran General Hospital

Pharmacy and Therapeutics Committee Lutheran General Hospital

Operating Room Committee, St. Francis Hospital

Cancer Committee, Lutheran General Hospital -Director of Quality Control

Risk and Safety Assessment Committee, Lutheran General Hospital

Nominating Committee, Rush North Shore Medical Center

Surgical Advisory Committee, Rush North Shore Medical Center

Section Director, Plastic Surgery, Rush North Shore Medical Center

PREVIOUS SOCIETY COMMITTEES:

PlastyPac, Chair, Board of Governors

Chair of the Metro Chicago District #2 Committee on Applicants, American College of Surgeons

American Society of Plastic Surgery, Health Policy Committee

American Society of Plastic Surgery, Patient Safety Committee

American Society of Plastic Surgeons, Coding and Payment Policy Committee

American Society of Plastic Surgeons, Practice Management Education Committee

Board of Governors, Governor-at-large, The American College of Surgeons

American College of Surgeons, International Relations Committee

Chair, Government Affairs Committee, American Society of Plastic Surgeons

President, The Metropolitan Chicago Chapter of The American College of Surgeons

2012 Nominating Committee, American Society of Plastic Surgeons

Program Committee, The World Society for Reconstructive Microsurgery, 2013 Bi-Annual Meeting

President, Illinois Society of Plastic Surgeons

Vice-President, The Illinois Society of Plastic Surgeons (formerly the Chicago Society of Plastic Surgery)

Vice-President, The Metropolitan Chapter of the American College of Surgeons

American Society of Plastic Surgery, Chairman, Patient Safety Committee

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2006-2007 Pathways to Leadership, The American Society of Plastic Surgery

2005 & 2006 President, The University of Chicago Plastic Surgery Alumni Association

2003 Leadership Tomorrow Program, The American Society of Plastic Surgery

Senior Residents Mentoring Program, The American Society of Plastic Surgery

American Society of Maxillofacial Surgery, Education Committee

Alternate Councilor, Chicago Medical Society

American Society of Aesthetic Plastic Surgery, Electronic Communications Committee

American Society of Aesthetic Plastic Surgery, Intranet Steering Committee

American Society of Aesthetic Plastic Surgery, International Committee

Membership Coordinator, The Chicago Society of Plastic Surgeons The Illinois State Medical Society, Governmental Affairs Council

The Illinois State Medical Society, Council on Economics

Chicago Medical Society, Physician Review Committee -Subcomittee on Fee Mediation

Chairman, Chicago Medical Society, Healthcare Economics Committee

Secretary/Treasurer, The Metropolitan Chicago Chapter of the American College of Surgeons

Scientific Committee, 2007 XX Biennial Symposium WPATH

Local Organizing Committee 2007 WPATH

Secretary, The Chicago Society of Plastic Surgeons

Treasurer, The Chicago Society of Plastic Surgeons

Council Member, The Metropolitan Chicago Chapter of the American College of Surgeons
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INTERNATIONAL MEDICAL SERVICE:

Northwest Medical Teams Manos de Ayuda (Oaxaca, Mexico)

Hospital de Los Ninos (San Juan, Puerto Rico)

COMMUNITY SERVICE:

Alumni Council, The University of Chicago Medical and Biological Sciences Alumni Association

The University of Minnesota Presidents Club Chancellors Society

Board of Directors, Chicago Plastic Surgery Research Foundation

National Center for Gender Spectrum Health Advisory Council

PREVIOUS COMMUNITY SERVICE:

Board of Directors, Committee on Jewish Genetic Diseases, Jewish United Fund, Chicago, Illinois

Governing Council, Lutheran General Hospital, Park Ridge, Il

Lutheran General Hospital Development Council, Park Ridge, Il

Lutheran General Hospital Men's Association, Park Ridge, Il

Advisory Board, Committee on Jewish Genetic Diseases, Cancer Genetics Subcommittee, Jewish United Fund, Chicago, Illinois

Health Care Advisory Board, Congressman Mark Kirk, 10th Congressional District, Illinois

Major Gifts Committee, Saint Francis Hospital Development Council, Evanston, Il

Visiting Professor:

- 1. University of Utah, Division of Plastic Surgery, November 6-8, 2014.
- Northwestern University, Division of Plastic Surgery, April 21-22, 2016.
- The University of North Carolina, Division of Plastic Surgery, March 28-29, 2017
- 4. Georgetown University, Department of Plastic Surgery, May 17-18, 2017

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- The University of Basel, Basel, Switzerland, August 31-September 1, 2018
- The Ochsner Health System, New Orleans, LA January 28-January 30, 2019
- 7. The University of Toronto, Toronto, Ontario, Canada, February 21-22, 2019
- 8. The University of Michigan, October3-4, 2019, Ann Arbor, MI
- 9. Georgetown University, Department of Plastic Surgery, July 21, 2022

Invited Discussant:

1. Department of Defense, Military service by people who are transgender, Invitation from Terry Adirim, M.D., M.P.H.Deputy Assistant Secretary of Defense for Health Services Policy & Oversight, The Pentagon, November 9, 2017

2. Aesthetic Surgery Journal, Invited Discussant May 7, 2019, Journal Club. "What is "Nonbinary" and What Do I need to Know? A Primer for Surgeons Providing Chest Surgery for Transgender Patients."

Honorary Lecture:

1. 2023 Arthur D. Bevan Lectureship, The Chicago Surgical Society, February 2, 2023, Chicago, Il

Research Interests:

1. Role of Omental Stem Cells in Wound Healing (Grant: Tawani Foundation)

2. Robotic-Assisted Bilateral Prophylatic Nipple Sparing Mastectomy with Immediate Tissue Expander/Implant Reconstruction (Pending submission to the FDA for Investigational Device Exemption in association with Intuitive Surgical)

3. Transgender Health and Medicine Research Conference, National Institutes of Health, Bethesda, MD May 7-8, 2015

4. Uterine Transplantation, Rush University Medical Center (IRB pending)

5. Gender Affirmation Surgery Prospective Surveys (Rush University-IRB approved)

6. National Network for Gender Affirming Surgeries: Canadian Institute of Health Research, Training Grant - LGBQT 2S Stigma Reduction & Life Course Mental Wellness (application in process)

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2. David C. Cronin, II, **Loren Schechter**, Somchi Limrichramren, Charles G. Winans, Robert Lohman, and J. Michael Millis, Advances in Pediatric Liver Transplantation: Continuous Monitoring of Portal Venous and Hepatic Artery Flow with an Implantable Doppler Probe. *Transplantation* 74(6):887-889, 2002.

3. Robert F. Lohman, Loren S. Schechter, Lawrence S. Zachary, Solomon Aronson: Evaluation of Changes in Skeletal Muscle Blood Flow in the Dog with Contrast Ultrasonography Revisited: Has the Technique Been Useful, and Where are We Headed Now? *The Journal of Plastic and Reconstructive Surgery* 111(4):1477-1480, 2003.

4. Alvin B. Cohn, Eric Odessey, Francis Casper, **Loren S. Schechter**: Hereditary Gingival Fibromatosis: Aggressive Two-Stage Surgical Resection in Lieu of Traditional Therapy, *The Annals of Plastic Surgery Vol 57*, *Number 5*, *November 2006*.

5. Eric Odessey, Al Cohn, Kenneth Beaman, and **Loren Schechter**: Mucormycosis of the Maxillary Sinus: Extensive Destruction with an Indolent Presentation, *Surgical Infections*, Vol. 9, Number 1, 2008

6. Iris A. Seitz, MD, David Tojo, MD, **Loren S. Schechter**, MD Anatomy of a Medication Error: Inadvertent Intranasal Injection of Neosynephrine During Nasal Surgery - A Case Report and Review of The Literature Plast Reconstr Surg. 2010 Mar;125(3):113e-4e. doi: 10.1097/PRS.0b013e3181cb68f9

7. Iris Seitz, MD Craig Williams, MD, Thomas Weidrich, MD, John Seiler, MD, Ginard Henry, MD, and Loren S. Schechter, MD: Omental Free Tissue Transfer for Coverage of Complex Upper Extremity Defects: The Forgotten Flap (N Y). 2009 Dec;4(4):397-405. doi: 10.1007/s11552-009-9187-6. Epub 2009 Mar 25.

8. Michael Salvino and **Loren S. Schechter**: Microvascular Reconstruction of Iatrogenic Femoral Artery Thrombus in an Infant: A Case Report and Review of the Literature ePlasty Volume 9 ISSN: 19357-5719, E-location ID: e20

9. Phillip C. Haeck, MD, Jennifer A. Swanson, BS, Med, Ronald E. Iverson, MD., Loren S. Schechter, MD, Robert Singer, MD, Bob Basu, MD, MPH, Lynn A. Damitz, MD, Scott Bradley Bradley Glasberg, MD, Lawrence S. Glasman, MD, Michael F. McGuire, MD, and the ASPS Patient Safety Committee: Evidence-Based Patient Safety Advisory: Patient Selection and Procedures in Ambulatory Surgery, Supplement to Plastic and Reconstructive Surgery, Volume 124, Number 4s, October Supplement 2009.

10. Philip C. Haeck, MD, Jennifer A. Swanson, BS, Med, Loren S. Schechter, MD, Elizabeth J. Hall-Findlay, MD, Noel B. McDevitt, MD, Gary Smotrich, MD, Neal R. Reisman, MD, JD, Scot Bradley Glasberg, MD, and the ASPS Patient Safety Committee: Evidence-Based Patient Safety Advisory: Blood Dyscrasias, Patient Selection and Procedures in Ambulatory Surgery, Supplement to Plastic and Reconstructive Surgery, Volume 124, Number 4s, October Supplement 2009.

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11. Loren S. Schechter, MD, The Surgeon's Relationship with The Physician Prescribing Hormones and the Mental Health Professional: Review for Version 7 of the World Professional Association of Transgender Health's Standards of Care International Journal of Transgenderism 11 (4), p.222-225 Oct-Dec 2009

12. Iris A Seitz, MD, PhD, Craig Williams, MD, Loren S. Schechter, MD, Facilitating Harvest of the Serratus Fascial Flap With Ultrasonic Dissection, *Eplasty 2010 Feb 23;10:e18*

13. Seitz, I, Friedewald SM, Rimler, J, **Schechter**, **LS**, Breast MRI helps define the blood supply to the nipple-areolar complex, Plastische Chirurgie, Supplement 1, 10. Jahrgang, September 2010, p. 75

14. Iris A. Seitz, Sally Friedwald, MD; Jonathon Rimler, Loren S. Schechter, Breast MRI to Define The Blood Supply to The Nipple-Areolar Complex. *Plast Recon Surg Suppl 126 (26) p. 27 Oct 2010*

15. Kalliainen LK; ASPS Health Policy Committee Evidence-Based Clinical Practice Guidelines: Reduction Mammaplasty, The American Society of Plastic Surgeons Plast Reconstr Surg. 2012 Oct;130(4):785-9 Loren S. Schechter (member and contributor, ASPS Health Policy Committee)

16. Eli Coleman, Walter Bockting, Marsha Botzer, Peggy Cohen-Kettenis, Griet DeCuypere, Jamie Feldman, Lin Fraser, Jamison Green, Gail Knudson, Walter J. Meyer, Stan Monstrey, Richard K. Adler, George R. Brown, Aaron H. Devor, Randall Ehrbar, Randi Ettner, Evan Eyler, Rob Garofalo, Dan H. Karasic, Arlene Istar Lev, Gal Mayer, Heino Meyer-Bahlburg, Blaine Paxton Hall, Friedmann Pfäfflin, Katherine Rachlin, Bean Robinson, Loren S. Schechter, Vin Tangpricha, Mick van Trotsenburg, Anne Vitale, Sam Winter, Stephen Whittle, Kevan R. Wylie & Ken Zucker, Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7, International Journal of Transgenderism, 13 (4) p. 165-232, August 2012.

17. Jonathan Bank, M.D., Lucio A. Pavone, M.D., Iris A. Seitz, M.D., Ph.D., Michelle C. Roughton M.D., Loren S. Schechter M.D. Case Report and Review of the Literature - Deep Inferior Epigastric Perforator Flap for Breast Reconstruction after Abdominal Recontouring, eplasty Ref.: Ms. No. EPLASTY-D-12-00050R1

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22. Loren S. Schechter, Mimis N. Cohn, Gender Confirmation Surgery: A New Frontier in Plastic Surgery Education, Journal of Plastic and Reconstructive Surgery, October 2016, 138 (4): 784 e

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25. Loren S. Schechter, Salvatore D'Arpa, Mimis Cohen, Ervin Kocjancic, Karel Claes, Stan Monstrey, Gender Confirmation Surgery: Guiding Principles J Sex Med. 2017 Jun;14(6):852-856. doi: 10.1016/j.jsxm.2017.04.001. Epub 2017 May 3

26. Response to Letter to the Editor: "Gender Confirmation Surgery: Guiding Principles". Schechter LS. J Sex Med. 2017 Aug;14(8):1067. doi: 10.1016/j.jsxm.2017.06.002. PMID: 28760249

27. Iris A. Seitz, Loren S. Schechter, "Successful Tongue Replantation Following Segmental Auto-Amputation Using Supermicrosurgical Technique," J Reconstr Microsurg Open 2017; 02(02): e132-e135 DOI: 10.1055/s-0037-1606584

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Flap (GAT Flap) for Single Stage Reconstruction of Combined Soft Tissue and Extensor Mechanism Defects of the Knee: An Eighteen Year Experience"

16. The 6th Annual Chicago Trauma Sympsoium, August 12-15, 2004, Chicago, Il "Complex Wound Management"

17. The American Society of Plastic Surgery, October 9-13, 2004, Philadelphia, Pennsylvania: "The Gastrocnemius-Achilles Tendon Myocutaneous Flap (GAT Flap) for Single Stage Reconstruction of Combined Soft Tissue and Extensor Mechanism Defects of the Knee: An Eighteen Year Experience"

18. The American Society for Reconstructive Microsurgery, January 15-18, 2005, Fajardo, Puerto Rico: "Surviving as a Plastic Surgeon"

19. American Hernia Society, Poster Presentation, February 9-12, 2005, San Diego, California: "When Component Separation Isn't Enough"

20. The Midwestern Association of Plastic Surgeons, April 23-24, Chicago, Il: "Hereditary Gingival Fibromatosis in Monozygotic Twins: First Reported Case"

21. The Midwestern Association of Plastic Surgeons, April 23-24, Chicago, Il: "Modified Components Separation Technique for Two Massive Ventral Hernias"

22. The Midwestern Association of Plastic Surgeons, April 23-24, Chicago, Il: "Mucormycosis of the Head and Neck: A Fatal Disease?"

23. The 7th Annual Chicago Trauma Symposium, August 11-14, 2005, Chicago, Il "Management of Complex Injuries"

24. Current Concepts in Advanced Wound Healing: A Practical Overview, Rush North Shore Medical Center, Skokie, Il September 18, 2005 "From Flaps to Grafts"

25. Taizoon Baxamusa, M and Loren S.Schechter, MD, Abdominoplasty: Use in Reconstruction of the Mangled Upper Extremity, The American Association For Hand Surgery Annual Scientific Meeting, January 11-14, 2006, Tucson, Arizona.

26. The American Academy of Orthopedic Surgeons 2006 Annual Meeting, March 22-26, 2006, Chicago, Il "Methods of Patella-Femoral and Extensor Mechanism Reconstruction for Fracture and Disruption After Total Knee Arthroplasty"

27. Midwestern Association of Plastic Surgeons 44th Annual Meeting, April 29-30, 2006, Oak Brook, Illinois "Elective Abdominal Plastic Surgery Procedures Combined with Concomitant Intra-abdominal Operations: A Single Surgeon's Four Year Experience"

28. Midwestern Association of Plastic Surgeons 44th Annual Meeting, April 29-30, 2006, Oak Brook, Illinois "Hereditary Gingival Fibromatosis: Aggressive Two-Stage Surgical Resection Versus Traditional Therapy"

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29. Midwestern Association of Plastic Surgeons 44th Annual Meeting, April 29-30, 2006, Oak Brook, Illinois "Abdominoplasty Graft & VAC Therapy: Two Useful Adjuncts in Full-Thickness Grafting of the Mangled Upper Extremity"

30. The American Association of Plastic Surgeons 85th Annual Meeting, May 6-9, 2006 Hilton Head, South Carolina "Excision of Giant Neurofibromas"

31. The 8th Annual Chicago Trauma Symposium, July 27-30, 2006, Chicago, Il "Management of Complex Injuries"

32. The American Society of Plastic Surgeons Annual Meeting, October 6-12, 2006, San Francisco, California "Excision of Giant Neurofibromas"

33. The American College of Surgeons Poster Presentation, October, 2006, Chicago, Il "Abdominoplasty: Use in Reconstruction of the Mangled Upper Extremity"

34. American Medical Association-RFS 3rd Annual Poster Symposium, November 10, Las Vegas, NV, 2006 "Abdominal Wall Reconstruction With Alloderm"

35. Advocate Injury Institute: "Trauma 2006: The Spectrum of Care), November 30-December 2, 2006, Lisle, Il, "Pit Bull Mauling: A Case Study"

36. The 9th Annual Chicago Trauma Symposium, August 10-12, 2007, Chicago, Il "Management of Complex Injuries"

37. The World Professional Association for Transgender Health (WPATH) 2007 XX Biennial Symposium, September 5-8. 2007, Chicago, Il Revision Vaginoplasty With Sigmoid Interposition: "A Reliable Solution for a Difficult Problem"

38. Metropolitan Chicago Chapter of the American College of Surgeons, 2008 Annual Meeting, March 15, 2008 "ER Call: Who's Job is it Anyway"

39. The 10th Annual Chicago Trauma Symposium, August 7-10, 2008, Chicago, Il "Management of Complex Injuries"

40. 23nd Annual Clinical Symposium on Advances in Skin & Wound Care: The Conference for Prevention and Healing October 26-30, 2008, Las Vegas, Nevada, poster presentation "Use of Dual Therapies Consisting of Negative Pressure Wound Therapy (NPWT) and Small Intestine Mucosa (SIS) on a Complex Degloving Injury With an Expose Achilles Tendon: A Case Report."

41. The American Society of Plastic Surgeons Annual Meeting, October 31-November 3, 2008, Chicago, Il "Panel: Fresh Faces, Real Cases"

42. The American Association for Hand Surgery Annual Meeting, January 7-13, 2009, Maui, Hawaii, poster session: "Omental Free Tissue Transfer for Coverage of Complex Upper Extremity and Hand Defects-The Forgotten Flap."

43. Plastic Surgery At The Red Sea Symposium, March 24-28, 2009 Eilat, Israel, "Omental Free Tissue Transfer for Coverage of Complex Upper Extremity and Hand Defects-The Forgotten Flap."

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44. ASPS/IQUAM Transatlantic Innovations Meeting, April 4-7, 2009 Miason de la Chimie, Paris, France, "Advertising in Plastic Surgery?"

45. ASPS/IQUAM Transatlantic Innovations Meeting, April 4-7, 2009 Miason de la Chimie, Paris, France, "Cost-Effectiveness of Physician Extenders in Plastic Surgery"

46. Midwestern Association of Plastic Surgeons, 47th Annual Meeting, April 18-19, 2009, Chicago, Il, "Microvascular Reconstruction of Iatrogenic Femoral Artery Injury in a Neonate"

47. Midwestern Association of Plastic Surgeons, 47th Annual Meeting, April 18-19, 2009, Chicago, Il,"Two Birds, One Stone: Combining Abdominoplasty with Intra-Abdominal Procedures"

48. The 11th Annual Chicago Trauma Symposium, August 1, 2009, Chicago, Il "Management of Complex Injuries"

49. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, "Omental Free Tissue Transfer for Coverage of Complex Extremity Defects: The Forgotten Flap."

50. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, "Challenging Cases."

51. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, "President's Panel: The Future of the Solo Practice-Can We, Should We Survive?"

52. The 12th Annual Chicago Trauma Symposium, August 5-8, 2010, Chicago, Il "Management of Complex Injuries"

53. Breast MRI to Define The Blood Supply to the Nipple-Areolar Complex. German Society of Plastic, Reconstructive and Aesthetic Surgery (DGPRAEC), Dresden, Germany, September 2010

54. Roundtable Discussion: Electronic Health Records-Implications for Plastic Surgeons, The American Society of Plastic Surgeons Annual Meeting, October 3, 2010, Toronto, CA

55. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, The American Society of Plastic Surgeons Annual Meeting, October 3, 2010, Toronto, CA.

56. ASPS/ASPSN Joint Patient Safety Panel: Patient Selection and Managing Patient Expectations, The American Society of Plastic Surgeons Annual Meeting, October 4, 2010, Toronto, CA

57. Lunch and Learn: Prevention of VTE in Plastic Surgery Patients, The American Society of Plastic Surgeons Annual Meeting, October 5, 2010, Toronto, CA

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58. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, 16th Congress of The International Confederation for Plastic Reconstructive and Aesthetic Surgery, May 22-27, 2011, Vancouver, Canada

59. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, The 6th Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland

60. Applications of the Omentum for Limb Salvage: The Largest Reported Series, The 6th Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland

61. Successful Tongue Replantation Following Auto-Amputation Using Supermicrosurgical Technique, Poster Session, The 6th Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland

62. The 13th Annual Chicago Trauma Symposium, August 25-28, 2011, Chicago, Il "Soft Tissue Defects-Getting Coverage"

63. WPATH: Pre-conference Symposium, September 24, 2011, Atlanta, GA "Surgical Options and Decision-Making"

64. American Society of Plastic Surgeons Annual Meeting, September 27, 2011, Denver, CO Closing Session Lunch and Learn: Pathways to Prevention-Avoiding Adverse Events, Part I: Patient Selection and Preventing Adverse Events in the Ambulatory Surgical Setting

65. American Society of Plastic Surgeons Annual Meeting, September 27, 2011, Denver, CO Closing Session Lunch and Learn: Pathways to Prevention-Avoiding Adverse Events, Part III: Preventing VTE

66. XXIV Congresso Nazionale della Societa Italiana di Microchirugia congiunto con la American Society for Reconstructive Microsurgery, October 20-22, 2011, Palermo, Sicily: 3 Step Approach to Lower Extremity Trauma

67. XXIV Congresso Nazionale della Societa Italiana Microchirugia congiunto con la American Society for Reconstructive Microsurgery, October 20-22, 2011, Palermo, Sicily: Applications of the Omentum for Limb Salvage: The Largest Reported Series

68. American Society for Reconstructive Microsurgery, Poster Presentation, January 14-17, 2012, Las Vegas, NV: Neonatal Limb Salvage: When Conservative Management is Surgical Intervention

69. The 14th Annual Chicago Trauma Symposium, August 2-5, 2012, Chicago, Il "Soft Tissue Defects-Getting Coverage"

70. The Annual Meeting of The American Society of Plastic Surgeons, October 25th-30, 2012, New Orleans, LA "Reimbursement in Breast Reconstruction"

71. The Annual Meeting of The American Society of Plastic Surgeons, October 25th-30, 2012, New Orleans, LA "Thriving in a New Economic Reality: Business Relationships and Integration in the Marketplace"

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72. The 15th Annual Chicago Trauma Symposium, August 2-5, 2013, Chicago, Il "Soft Tissue Defects-Getting Coverage"

73. 2014 WPATH Symposium, Tansgender Health from Global Perspectives, February 14-18, 2014, "Short Scar Chest Surgery."

74. 2014 WPATH Symposium, Transgender Health from Global Perspectives, February 14-18, 2014, "Intestinal Vaginoplasty with Right and Left Colon."

75. 24th Annual Southern Comfort Conference, September 3-7, 2014, Atlanta, Georgia, "Gender Confirmation Surgery: State of the Art."

76. The 15th Annual Chicago Trauma Symposium, September 4-7, 2014, Chicago, Il "Soft Tissue Defects-Getting Coverage"

77. The Midwest Association of Plastic Surgeons, May 30, 2015, Chicago, Il "Gender Confirmation Surgery: A Single-Surgeon's Experience"

78. The Midwest Association of Plastic Surgeons, May 30, 2015, Chicago, Il, Moderator, Gender Reassignment.

79. the American Society of Plastic Surgeons 2015 Professional Liability Insurance and Patient Safety Committee Meeting, July 17, 2015, "Gender Confirmation Surgery."

80. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. From Fee-for-Service to Bundled Payments

81. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Moderator, Transgender Surgery

82. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Efficient Use of Physician Assistants in Plastic Surgery.

83. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Patient Safety: Prevention of VTE

84. The World Professional Association for Transgender Health, Objective Quality Parameters for Gender Confirmation Surgery, June 18-22, 2016, Amsterdam, Netherlands

85. The World Professional Association for Transgender Health, Resident Education Curriculum for Gender Confirmation Surgery, June 18-22, 2016, Amsterdam, Netherlands

86. The World Professional Association for Transgender Health, Urologic Management of a Reconstructed Urethra(Poster session #195), June 18-22, 2016, Amsterdam, Netherlands

87. The World Professional Association for Transgender Health, Construction of a neovagina for male-to-female gender reassignment surgery using a modified intestinal vaginoplasty technique, poster session (Poster session #198), June 18-22, 2016, Amsterdam, Netherlands

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88. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Genital Aesthetics: What are we trying to achieve?, Washington, DC June 23-25, 2016

89. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Female to Male Gender Reassignment, Washington, DC June 23-25, 2016

90. Aesthetica Super Symposium, The American Society of Plastic Surgeons, The journal of retractions, what I no longer do, Washington, DC June 23-25, 2016

91. Aesthetica Super Symposium, The American Society of Plastic Surgeons, The three minute drill, tips and tricks, Washington, DC June 23-25, 2016

92. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Moderator, Mini master class: Male genital plastic surgery, Washington, DC June 23-25, 2016

93. The 16th Annual Chicago Trauma Symposium, August 18-21, 2016, Chicago, Il "Soft Tissue Defects-Getting Coverage"

94. USPATH Poster Session, Feb 2-5, 2017, Los Angeles, CA, Partial Flap Failure Five Weeks Following Radial Forearm Phalloplasty: Case Report and Review of the Literature

95. USPATH Poster Session, Feb 2-5, 2017, Los Angeles, CA, Urethroplasty for Stricture after Phalloplasty in Transmen Surgery for Urethral Stricture Disease after Radial Forearm Flap Phalloplasty-Management Options in Gender Confirmation Surgery

96. USPATH, Feb 2-5, 2017, Los Angeles, CA, Patient Evaluation and Chest Surgery in Transmen: A Pre-operative Classification

97. USPATH, Feb 2-5, 2017, Los Angeles, CA Single Stage Urethral Reconstruction in Flap Phalloplasty: Modification of Technique for Construction of Proximal Urethra

98. USPATH, Feb 2-5, 2017, Los Angeles, CA, Use of Bilayer Wound Matrix on Forearm Donor Site Following Phalloplasty

99. USPATH, Feb 2-5, 2017, Los Angeles, CA, Vaginoplasty: Surgical Techniques

100. USPATH, Feb 2-5, 2017, Los Angeles, CA, Positioning of a Penile Prosthesis with an Acellular Dermal Matrix Wrap following Radial Forearm Phalloplasty

101. USPATH, Feb 2-5, 2017, Los Angeles, CA, Principles for a Gender Surgery Program

102. USPATH, Feb 2-5, 2017, Los Angeles, CA, Construction of a Neovagina Using a Modified Intestinal Vaginoplasty Technique

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103. The 18th Annual Chicago Orthopedic Symposium, July 6-9, 2017, Chicago, Il "Soft Tissue Defects-Getting Coverage"

104. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Moderator: Genital Surgery Trends for Women

105. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Adding Transgender Surgery to Your Practice, Moderator and Speaker

106. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Transbottom Surgery

107. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018 A Novel Approach to IPP Implantation Post Phalloplasty: The Chicago Experience

108. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018, A Novel Approach for Neovagina Configuration During Vaginoplasty for Gender Confirmation Surgery

109. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018 DevelopIment of a Pelvic Floor Physical Therapy Protocol for Patients Undergoing Vaginoplasty for Gender Confirmation

110. 14th Congress of The European Federation of Societies for Microsurgery, Belgrade, May 5-8, 2018 Establishing Guidelines for Gender Confirmation Surgery: The Perioperative Risk of Asymptomatic Deep Venous Thrombosis for Vaginoplasty

111. The 19th Annual Chicago Trauma Symposium, August 16-19, 2018, Chicago, Il "Soft Tissue Defects-Getting Coverage"

112. Midwest LGBTQ Health Symposium, September 14-15, 2018, Chicago, Il "Quality Parameters in Gender Confirmation Surgery"

113. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Poster Session, Proposed Guidelines for Medical Tattoo Following Phalloplasty; An Interdisciplinary Approach

114. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Establishment of the First Gender Confirmation Surgery Fellowship

115. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, ISSM Lecture, The Importance of Surgical Training

116. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Tracking Patient-Reported Outcomes in Gender Confirmation Surgery

117. "Theorizing the Phantom Penis," The Psychotherapy Center for Gender and Sexuality's 6th Biannual Conference, Transformations, March 29-March 30, 2019, NY, NY 118. "Uterine Transplantation and Donation in Transgender Individuals; Proof of Concept," World Professional Association for Transgender Health 27th Scientific Symposium, September 16-20, 2022, Montreal, Canada

119. Differences and Similarities of Vaginoplasty Techniques Throughout the World: Is There a Consensus?, World Professional Association for Transgender Health 27th Scientific Symposium, September 16-20, 2022, Montreal, Canada

INSTRUCTIONAL COURSES:

1. Emory University and WPATH: Contemporary Management of Transgender Patients: Surgical Options and Decision-Making, September 5, 2007 Chicago, Il

2. Craniomaxillofacial Trauma Surgery: An Interdisciplinary Approach, February 16-17, 2008, Burr Ridge, Il

3. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, Moderator: Free Papers, Lower Extremity

4. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Moderator: ASPS/ASPSN Patient Panel: Effective Communication-A Key to Patient Safety and Prevention of Malpractice Claims

5. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Instructional Course: Strategies to Identify and Prevent Errors and Near Misses in Your Practice

6. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Roundtable Discussion: Electronic Health Records-Implications for Plastic Surgeons

7. 10th Congress of The European Federation of Societies for Microsurgery, May 2-22, 2010, Genoa, Italy, "The Mangled Lower Extremities: An Algorithm for Soft Tissue Reconstruction."

8. Mulitspecialty Course for Operating Room Personnel-Craniomaxillofacial, Orthopaedics, and Spine, A Team Approach, AO North American, June 26-27, 2010, The Westin Lombard Yorktown Center.

9. Management of Emergency Cases in the Operating Room, The American Society of Plastic Surgeons Annual Meeting, October 4, 2010, Toronto, CA.

10. Surgical Approaches and Techniques in Craniomaxillofacial Trauma, November 6, 2010, Burr Ridge, Il.

11. The Business of Reconstructive Microsurgery: Maximizing Economic value (Chair)The American Society for Reconstructive Microsurgery, January 14-17, 2012, Las Vegas, Nevada.

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12. Strategies to Identify and Prevent Errors and Near Misses in Your Practice, The Annual Meeting of The American Society of Plastic Surgeons, October $25^{th}-30^{th}$, 2012, New Orleans, LA

13. Strategies to Identify and Prevent Errors and Near Misses in Your Practice, The Annual Meeting of The American Society of Plastic Surgeons, October 11th-15th, 2013, San Diego, CA

14. Mythbusters: Microsurgical Breast Reconstruction in Private Practice, The Annual Meeting of The American Society of Plastic Surgeons, October 11th-15th, 2013, San Diego, CA

15. Minimizing Complications in Perioperative Care, The American Society for Reconstructive Microsurgery, January 11-14, 2014, Kauai, Hawaii

16. Genitourinary and Perineal Reconstruction, The American Society for Reconstructive Microsurgery, January 11-14, 2014, Kauai, Hawaii

17. Transgender Breast Surgery, The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA

18. Gender Confirmation Surgery, The School of the Art Institute (recipient of American College Health Fund's Gallagher Koster Innovative Practices in College Health Award), October 27, 2015, Chicago, Il

19. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Overview of Surgical Treatment Options

20. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015 Chicago, Il Surgical Procedures

21. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Surgical Complications

22. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Postoperative Care

23. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Case Discussions: The Multidisciplinary Team

24. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, January 20-23,2016, Atlanta, GA Overview of Surgical Treatment Options

25. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, January 20-23, 2016, Atlanta, GA Surgical Treatment Options Case 4:22-cv-00325-RH-MAF Document 120-26 Filed 04/07/23 Page 80 of 111

26. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, March 30-April 1, 2016, Springfield, MO, Surgical Treatment Options.

27. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, March 30-April 1, 2016, Springfield, MO, Multi-disciplinary Case Discussion.

28. Introduction to Transgender Surgery, ASPS Breast Surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

29. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course, September 28, 2016, Ft. Lauderdale, FL.

30. Cirugias de Confirmacion de Sexo Paso a Paso, XXXV Congreso Confederacion Americana de Urologia (CAU), Panama City, Panama, October 4-8, 2016.

31. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course, December 3, 2016, Arlington, VA.

32. PSEN (sponsored by ASPS and endorsed by WPATH), Transgender 101 for Surgeons, January 2017-March 2017

33. Surgical Anatomy and Surgical Approaches to M-to-F Genital Gender Affirming Surgery and the Management of the Patient Before, During and After Surgery: A Human Cadaver Based Course, Orange County, CA, Feb. 1, 2017

34. Gender Confirmation Surgery, ALAPP, 2 Congreso Internacional de la Asociacion Latinoamericana de Piso Pelvico, Sao Paulo, Brasil, 9-11 de marzo de 2017

35. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course, Overview of Surgical Treatment, March 31-April 2, 2017, Minneapolois Minnesota.

36. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course, The Multi-Disciplinary Team Case Discussions, March 31-April 2, 2017, Minneapolois Minnesota.

37. Transfeminine Cadaver Course, WPATH, May 19-20, 2017, Chicago, Il

38. Transgender/Penile Reconstruction-Penile Reconstruction: Radial Forearm Flap Vs. Anterolateral Thigh Flap, Moderator and Presenter, The World Society for Reconstructive Microsurgery, June 14-17, 2017, Seoul, Korea

39. Primer of Transgender Breast Surgery, ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017

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40. Confirmation Surgery in Gender Dysphoria: current state and future developments, International Continence Society, Florence, Italy, September 12-15, 2017

41. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, ASPS/WPATH Joint Session, Session Planner and Moderator

42.Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course: Overview of Surgical Treatment, Columbus, OH, October 20-21, 2017

43. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course: Medical Care in the Perioperative Period, Aftercare: Identifying Potential Complications, Columbus, OH, October 20-21, 2017

44. Webinar: Gender Affirming Surgeries 101: Explore The Latest Topics in Gender Affirmation Surgery, PSEN, April 18, 2018

45. Course Director: MT. Sinai/WPATH Live Surgery Training Course for Gender Affirmation Procedures, April 26-28, 2018, New York, NY

46. Philadelphia Trans Wellness Conference, Perioperative Care of the Transgender Woman Undergoing Vaginoplasty (Workshop), Philadelphia, PA, August 3, 2018

47. Philadelphia Trans Wellness Conference, Gender Confirmation Surgery (Workshop), Philadelphia, PA, August 3, 2018

48. Gender Confirmation Surgery, 2018 Oral and Written Board Preparation Course, The American Society of Plastic Surgeons, August 16-18, 2018, Rosemont, Il

49. Confirmation Surgery in Gender Dysphoria: Current State and Future Developments, The International Continence Society, Philadelphia, PA August 28, 2018

50. WPATH Global Education Initiative, Foundations Training Course, "Overview of Surgical Treatment," Cincinnati, OH, September 14-15, 2018

51. WPATH Global Education Initiative, Foundations Training Course, "The Multi-Disciplinary Team: Case Discussions," Cincinnati, OH, September 14-15, 2018

52. WPATH Global Education Initiative, Advanced Training Course, "Medical Care in the Perioperative Period After Care: Identifying Potential Complications," Cincinnati, OH, September 14-15, 2018

53. 25th WPATH Symposium, Surgeons Conference, November 1, 2018, Buenos Aires, Argentina, Moderator

54. 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Global Education Initiative (GEI): Surgery and Ethics

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55. WPATH GEI: Best Practices in Medical and Mental Health Care, Foundations in Surgery, New Orleans, March 22, 2019

56. WPATH GEI: Best Practices in Medical and Mental Health Care, Advanced Surgery, New Orleans, March 22, 2019

57. Program Chair: ASPS/WPATH GEI Inaugural Gender-Affirming Breast, Chest, and Body Master Class, Miami, Fl, July 20, 2019

58. Overview of Surgical Management and The Standards of Care (WPATH, v. 7) ASPS/WPATH GEI Inaugural Gender-Affirming Breast, Chest, and Body Master Class, Miami, Fl, July 20, 2019

59. Program Director, Gender Affirming Breast, Chest, and Body Master Class, The American Society of Plastic Surgeons, Miami, Fl, July 20, 2019

60. Gender Confirmation Surgery, The American Society of Plastic Surgeons Oral and Written Board Preparation Course, August 15, 2019, Rosemont, Il

61. Upper Surgeries (chest surgery & breast augmentation), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

62. Preparing for Upper Surgeries-Case Based (chest surgery & breast augmentation), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

63. Preparing for Feminizing Lower Surgeries-Case Based (vaginoplasty), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

64. Lower Surgeries-Masculinizing (phalloplasty & metoidioplasty), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

65. Preparing for Masculinizing Lower Surgeries-Case Based (phalloplasty & metoidioplasty), WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

66. Panel Discussion about Ethics in Surgery and Interdisciplinary Care, WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

67. Discussion about Ethics and Tensions in Child and Adolescent Care, WPATH, Global Education Initiative, September 4-5, 2019, Washington, DC

68. Transgender Health: Best Practices in Medical and Mental Health Care Foundation Training Courses, Hanoi, Viet Nam, Jan 14-17, 2020 (Foundations in Surgery, Advanced Medical-surgery and complicated case studies), Planning & Documentation (upper surgeries-chest surgery and breast augmentation, preparing for upper surgeries-case based (chest surgery and breast augmentation), lower surgeries (feminizing-vaginoplasty), preparing for feminizing lower surgeries-case based, lower surgeries-masculinizing (phalloplasty and metoidioplasty), preparing for masculinizing lower surgeries-case-based (phalloplasty and metoidioplasty), Ethics-panel discussion about ethics in surgery and interdisciplinary care)

69. WPATH GEI Panel Cases Discussion, via Webinar, May 29, 30, 31, 2020

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70. WPATH GEI: Illinois Dept. of Corrections, Foundations in Surgery, November 20, 2020

71. WPATH GEI: Illinois Dept. of Corrections, Ethical Considerations in Transgender Healthcare, November 20, 2020

72. WPATH GEI: Illinois Dept. of Corrections, Foundations in Surgery, February 26, 2021

73. WPATH GEI: Illinois Dept. of Corrections, Ethical Considerations in Transgender Healthcare, February 26, 2021.

74. Current Concepts in Gender Affirming Surgery for Women in Transition, March 11-12, 2021 (online event), Moderator, Transgender Health.

75. GEI Foundations Course, Live Q&A, March 21, 2021

76. GEI Foundations Course, Live Case Panel Discussion, March 23, 2021

77. GEI Advanced Ethics Workshop; Surgical and Interdisciplinary care ethics panel, May 1, 2021 (virtual)

78. Wpath GEI Foundations course for the Illinois Dept of Corrections, Foundations in Surgery, May 21, 2021

79. Wpath GEI, Foundations course for the Illinois Dept of Corrections, Ethical considerations in Transgender Healthcare, May 21, 2021

80. WPATH GEI, Online GEI Foundations Course, Moderator, August 31, 2021.

81. WPATH Health Plan Provider (HPP) Training, Q&A Panel, September 13, 14, 21 2021, via Zoom

82. WPATH, GEI Advanced Medical Course, Upper and Lower Surgery (via zoom), December 9, 2021

83. I want to be a gender surgeon: where do I even start, American Society for Reconstructive Microsurgery, Annual Meeting, January 17, 2022, Carlsbad, CA

84. Faculty Instructor, Upper Extremity Flaps and Lower Extremity Trauma, 1st Annual Rush University - University of Chicago Cadaver Lab, June 11, 2022

85. WPATH Health Plan Provider (HPP) Training, Q&A Panel, July 12, 2022, via Zoom

86. Nonbinary Workshop, WPATH GEI, July 23, 2022, via Zoom

87. WPATH GEI Advanced Ethics workshop (2022-2023), September 17-18, 2022, Montreal, Canada

SYMPOSIA:

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1. Program Director, 2011 Chicago Breast Symposium, October 15, 2011, The Chicago Plastic Surgery Research Foundation and The Chicago Medical School at Rosalind Franklin University, North Chicago, IL,

2. Fundamentals of Evidence-Based Medicine & How to Incorporate it Into Your Practice, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

3. Understanding Outcome Measures in Breast & Body Contouring Surgery, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

4. Benchmarking Complications: What We Know About Body Contouring Complication Rates from Established Databases, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

5. Special Lecture: VTE Prophylaxis for Plastic Surgery in 2011, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

6. Nipple Sparing Mastectomy: Unexpected Outcomes, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

7. Program Director, 2011 Chicago Breast Symposium, October 13-14, 2012, The Chicago Plastic Surgery Research Foundation and The Chicago Medical School at Rosalind Franklin University, North Chicago, Il

8. Practice Strategies in a Changing Healthcare Environment, Moderator, Midwestern Association of Plastic Surgeons, April 27-28, 2013, Chicago, Il

9. Moderator: Breast Scientific Paper Session, The Annual Meeting of The American Society of Plastic Surgery, October 12, 2014, Chicago, Il.

10. Moderator: The World Professional Association for Transgender Health, Tuesday, June 21, Surgical Session (0945-1045), June 18-22, 2016, Amsterdam, Netherlands

11. Course Director: Transmale Genital Surgery: WPATH Gender Education Initiative, October 21-22, 2016 Chicago, Il

12. Co-Chair and Moderator: Surgeon's Only Session, USPATH, Los Angeles, CA, Feb. 2, 2017

13. Vascular Anastomosis: Options for Lengthening Vascular Pedicle, Surgeon's Only Session, USPATH, Los Angeles, CA, Feb. 2, 2017

14. Transgender Healthcare Mini-Symposium, Chicago Medical School of Rosalind Franklin University, North Chicago, Il March 10, 2017.

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15. Moderator: Penile Transplant: Genito-urinary trauma/penile cancer, The European Association of Urologists, Meeting of the EAU Section of Genito-Urinary Reconstructive Surgeons (ESGURS), London, United Kingdom, March 23-26, 2017

16: 25th WPATH Symposium, November 2-6, 2018, Buenos Aires, Argentina, Mini-Symposium: A Comprehensive Approach to Gender Confirming Surgery

17. Program Director, 2nd Annual Live Surgery Conference for Gender Affirmation Procedures, Ichan School of Medicine at Mt. Sinai, NY, NY February 28, 2019-March 2, 2019.

18. Moderator, "Genital Reassignment for Adolescents: Considerations and Conundrums," Discussions on gender affirmation: surgery and beyond, Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

19. Moderator, "Reconstructive Urology and Genitourinary Options in Gender Affirming Surgery," Discussions on gender affirmation: surgery and beyond, Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

20. Moderator, "Complications in Masculinizing Genital Reconstruction Surgery," Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

21. Moderator, "Preparing for Surgery and Recovery," Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

22. Discussant, "WPATH Standards of Care Version 8 Preview," Dignity Health Saint Francis Memorial Hospital and WPATH GEI, San Francisco, CA, May 30-June 1, 2019

23. Program Coordinator, Surgeon's Only Course, USPATH, September 5, 2019, Washington, DC

24. Master Series in Transgender Surgery 2020: Vaginoplasty and Top Surgery, course co-director, Mayo Clinic, Rochester, MN, August 7-8, 2020

25. WPATH 2020 Surgeons' Program, Co-Chair, November 6-7, 2020, Virtual Symposium (due to covid-19 cancellation of Hong Kong meeting)

26. WPATH Journal Club #3, Uterine Transplantation and Donation in Transgender Individuals; Proof of Concept, December 13, 2021 (Zoom)

27. Program Coordinator and Moderator, Surgeon's Only Course, WPATH 27th Scientific Symposium, September 16-17, 2022, Montreal, Canada

FACULTY SPONSORED RESEARCH:

1. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery

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Conference, Modena, Italy, October 1-3, 2009, "Free Tissue Transfer in the Treatment of Zygomycosis." Presented by Michelle Roughton, MD

2. Hines/North Chicago VA Research Day, Edward Hines, Jr., VA Hospital, Maywood, Il, April 29, 2010, "Breast MRI Helps to Define the Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.

3. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Breast MRI Helps to Define the Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.

4. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Achieving Soft Tissue Coverage of Complex Upper and Lower Extremity Defects with Omental Free Tissue Transfer." Presented by Iris A. Seitz, MD, PhD.

5. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Facilitating Harvest of the Serratus Fascial Flap with Ultrasonic Dissection." Presented by Iris A. Seitz, MD, PhD.

6. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010,"Patient Safety: Abdominoplasty and Intra-Abdominal Procedures." Presented by Michelle Roughton, MD

7. The Midwestern Association of Plastic Surgeons, 49th Annual Scientific Meeting, May 15th, 2010, "Breast MRI Helps Define The Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.

8. Jonathan M. Hagedorn, BA, Loren S. Schechter, MD, FACS, Dr. Manoj R. Shah, MD, FACS, Matthew L. Jimenez, MD, Justine Lee, MD, PhD, Varun Shah. Re-examining the Indications for Limb Salvage, 2011 All School Research Consortium at Rosalind Franklin University. Chicago Medical School of Rosalind Franklin University, 3/16/11.

9. Jonathan Bank, MD, Lucio A. Pavone, MD, Iris A. Seitz, Michelle C. Roughton, MD, Loren S. Schechter, MD Deep Inferior Epigastric Perforator Flap for Breast Reconstruction after Abdominoplasty The Midwestern Association of Plastic Surgeons, 51st Annual Educational Meeting, April 21-22, 2012, Northwestern Memorial Hospital, Chicago, Illinois

10. Samuel Lake, Iris A. Seitz, MD, Phd, Loren S. Schechter, MD, Daniel Peterson, Phd Omentum and Subcutaneous Fat Derived Cell Populations Contain hMSCs Comparable to Bone Marrow-Derived hMSCsFirst Place, Rosalind Franklin University Summer Research Poster Session

11. J. Siwinski, MS II, Iris A. Seitz, MD PhD, Dana Rioux Forker, MD, Lucio A. Pavone, MD, Loren S Schechter, MD FACS. Upper and Lower Limb Salvage With Omental Free Flaps: A Long-Term Functional Outcome Analysis. Annual Dr. Kenneth A. Suarez Research Day, Midwestern University, Downers Grove, IL, May 2014

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12. Whitehead DM, Kocjancic E, Iacovelli V, Morgantini LA, Schechter LS. A Case Report: Penile Prosthesis With an Alloderm Wrap Positioned After Radial Forearm Phalloplasty. Poster session presented at: American Society for Reconstructive Microsurgery Annual Meeting, 2018 Jan 13-16; Phoenix, AZ.

13. Whitehead DM, Kocjancic E, Iacovelli V, Morgantini LA, **Schechter LS**. An Innovative Technique: Single Stage Urethral Reconstruction in Female-to-Male Patients. Poster session presented at: American Society for Reconstructive Microsurgery Annual Meeting, 2018 Jan 13-16; Phoenix, AZ.

14. Whitehead, DM Inflatable Penile Prosthesis Implantation Post Phalloplasty: Surgical Technique, Challenges, and Outcomes, MAPS 2018 Annual Scientific Meeting, April 14, 2018, Chicago, Il

15. Whitehead, DM, Inverted Penile Skin With Scrotal Graft And Omission of Sacrospinal Fixation: Our Novel Vaginoplasty Technique MAPS 2018 Annual Scientific Meeting, April 14, 2018, Chicago, Il

16. S. Marecik, J. Singh. L. Schechter, M. Abdulhai, K. Kochar, J. Park, Robotic Repair of a Recto-Neovaginal Fistula in a Transgender Patient Utilizing Intestinal Vaginoplasty, The American College of Surgeons Clinical Congress 2020, October 7, 2020

17. Natalia Whitney, Randi Ettner, **Loren Schechter**, Sexual Function Expectations, Outcomes, and Discussions for Patients Undergoing Gender-Affirming Surgery, 2022 Trainee Research Day, Rush University Medical Center, The Irwin Press Patient Experience Research Poster Award

18. Natalia Whitney, Randi Ettner, **Loren Schechter**, Sexual Function Expectations, Outcomes, and Discussions for Patients Undergoing Gender-Affirming Surgery, 2022 Trainee Research Day, Rush University Medical Center, Peoples Choice-Third Place Poster Presentation

19. Adam Steur, Christy Ciesla, Clarion Mendes, Loren Schechter, The Need for a Comprehensive Interprofessional Postsurgical Rehabilitation Pathway: Initial Recommendations and Future Visions, The World Professional Association for Transgender Health, 27th Scientific Symposium, Surgeon's Only Program September 16-17, 2022, Montreal Canada

Keynote Address:

1. University of Utah, Gender Confirmation Surgery, Transgender Provider Summit, November 8, 2014

INVITED LECTURES:

1. Management of Soft Tissue Injuries of the Face, Grand Rounds, Emergency Medicine, The University of Chicago, August, 1999

2. Case Report: Excision of a Giant Neurofibroma, Operating Room Staff Lecture Series, Continuing Education Series, St. Francis Hospital, Evanston, Il March 2000

3. Wounds, Lincolnwood Family Practice, Lincolnwood, Il April 2000

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4. The Junior Attending, Grand Rounds, Plastic and Reconstructive Surgery, The University of Chicago, June 2000

5. Case Report: Excision of a Giant Neurofibroma, Department of Medicine Grand Rounds, St. Francis Hospital, Evanston, Il June 2000

6. Facial Trauma, Resurrection Medical Center Emergency Medicine Residency, September 2000

7. Plastic Surgery of the Breast and Abdomen, Grand Rounds, Dept. of Obstetrics and Gynecology, Evanston Hospital, September, 2000

8. Change of Face; Is Cosmetic Surgery for You?, Adult Education Series, Rush North Shore Medical Center, October, 2000

9. Reconstructive Surgery of the Breast, Professional Lecture Series on Breast Cancer, St. Francis Hospital, October, 2000

10. Plastic Surgery of the Breast and Abdomen, Grand Rounds, Dept. of Obstetrics and Gynecology, Lutheran General Hospital, December, 2000

11. Change of Face; Is Cosmetic Surgery for You?, Adult Education Series, Lutheran General Hospital and The Arlington Heights Public Library, December, 2000

12. Updates in Breast Reconstruction, The Breast Center, Lutheran General Hospital, January 2001

13. Abdominal Wall Reconstruction, Trauma Conference, Lutheran General Hospital, February 2001

14. Wound Care, Rush North Shore Medical Center, March 2001

15. Breast Reconstruction, Diagnosis and Treatment Updates on Breast Cancer, Lutheran General Hospital, April 2001

16. Wound Care and V.A.C. Therapy, Double Tree Hotel, Skokie, Il October 2001

17. The Role of the V.A.C. in Reconstructive Surgery, LaCrosse, WI November 2001

18. Dressing for Success: The Role of the V.A.C. in Reconstructive Surgery, Grand Rounds, The University of Minnesota Section of Plastic and Reconstructive, Minneapolis, MN January, 2002

19. The Vacuum Assisted Closure Device in the Management of Complex Soft Tissue Defects, Eau Claire, WI February, 2002

20. The Vacuum Assisted Closure Device in Acute & Traumatic Soft Tissue Injuries, Orland Park, Il March, 2002

21. Body Contouring After Weight Loss, The Gurnee Weight Loss Support Group, Gurnee, Il April, 2002

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22. An Algorithm to Complex Soft Tissue Reconstruction With Negative Pressure Therapy, Owensboro Mercy Medical Center, Owensboro, Ky, April, 2002

23. Breast and Body Contouring, St. Francis Hospital Weight Loss Support Group, Evanston, Il April, 2002

24. The Wound Closure Ladder vs. The Reconstructive Elevator, Surgical Grand Rounds, Lutheran General Hospital, Park Ridge, Il, May, 2002.

25. An Algorithm for Complex Soft Tissue Reconstruction with the Vacuum Assisted Closure Device, The Field Museum, Chicago, Il, May, 2002

26. The Role of Negative Pressure Wound Therapy in Reconstructive Surgery, Kinetic Concepts, Inc. San Antonio, Texas, July 31, 2002

27. Management of Complex Soft Tissue Injuries of the Lower Extremity, Chicago Trauma Symposium, August 2-5, 2002, Chicago, Illinois:

28. Wound Bed Preparation, Smith Nephew, Oak Brook, Il, August 6, 2002

29. Getting Under Your Skin...Is Cosmetic Surgery for You?, Rush North Shore Adult Continuing Education Series, Skokie, Il August 28, 2002.

30. The Role of Negative Pressure Therapy in Complex Soft Tissue Wounds, Columbia/St. Mary's Wound, Ostomy, and Continence Nurse Program, Milwaukee, Wi, September 17, 2002

31. A Systematic Approach to Functional Restoration, Grand Rounds, Dept. of Physical Therapy and Rehabilitation Medicine, Lutheran General Hospital, September 19, 2002

32. The Role of Negative Pressure Wound Therapy in Reconstructive Surgery, Ann Arbor, Mi September 26, 2002

33. Dressing for Success: The Role of the Vaccuum Assisted Closure Device in Plastic Surgery, Indianopolis, In November 11, 2002

34. The Wound Closure Ladder Versus the Reconstructive Elevator, Crystal Lake, Il November 21, 2002

35. A Systematic Approach to Functional Restoration, Grand Rounds, Dept. of Physical Therapy, Evanston Northwestern Healthcare, Evanston, Il February 13, 2003

36. Case Studies in Traumatic Wound Reconstruction, American Association of Critical Care Nurses, Northwest Chicago Area Chapter, Park Ridge, Il February 19, 2003

37. Reconstruction of Complex Soft Tissue Injuries of the Lower Extremity, Podiatry Lecture Series, Rush North Shore Medical Center, Skokie, Il March 5, 2003 Case 4:22-cv-00325-RH-MAF Document 120-26 Filed 04/07/23 Page 90 of 111

38. The Use of Negative Pressure Wound Therapy in Reconstructive Surgery, Kalamazoo, Mi March 19, 2003

39. Updates in Breast Reconstruction, The Midwest Clinical Conference, The Chicago Medical Society, Chicago, Il March 21, 2003

40. Updates of Vacuum Assisted Closure, Grand Rounds, The Medical College of Wisconsin, Department of Plastic Surgery, Milwaukee, Wi March 26, 2003

41. Breast Reconstruction, Surgical Grand Rounds, Lutheran General Hospital, Park Ridge, Il March 27, 2003

42. Decision-Making in Breast Reconstruction: Plastic Surgeons as Members of a Multi-Disciplinary Team, 1st Annual Advocate Lutheran General Hospital Breast Cancer Symposium, Rosemont, Il, April 11, 2003

43. The Wound Closure Ladder Versus The Reconstructive Elevator, Duluth, Mn, April 24, 2003

44. Dressing For Successs: The Role of The Wound VAC in Reconstructive Surgery, Detroit, Mi, May 9, 2003

45. Plastic Surgery Pearls, Grand Rounds Orthopedic Surgery Physician Assistants Lutheran General Hospital and Finch University of Health Sciences, Park Ridge, Il, June 5, 2003

46. A Systematic Approach to Complex Reconstruction, 12th Annual Vendor Fair "Surgical Innovations," October 18, 2003, Lutheran General Hospital, Park Ridge, Il 2003

47. Dressing For Success: The Role of the Wound VAC in Reconstructive Surgery, American Society of Plastic Surgery, October 26, 2003, San Diego, CA

48. Beautiful You: From Botox to Weekend Surgeries, 21st Century Cosmetic Considerations, March 21, 2004 Hadassah Women's Health Symposium, Skokie, Il

49. Updates in Breast Reconstruction, The 2nd Annual Breast Cancer Symposium, Advocate Lutheran General, Hyatt Rosemont, April 2, 2004

50. Head and Neck Reconstruction, Grand Rounds, The University of Illinois Metropolitan Group Hospitals Residency in General Surgery, Advocate Lutheran General Hospital, May 6, 2004

51. Abdominal Wall Reconstruction, Surgeons Forum, LifeCell Corporation, May 15, 2004, Chicago, Il

52. 4th Annual Chicagoland Day of Sharing for Breast Cancer Awareness, Saturday, October 2, 2004, Hoffman Estates, Il

53. Abdominal Wall Reconstruction, University of Illinois Metropolitan Group Hospitals Residency in General Surgery, November 19, 2004, Skokie, Il Case 4:22-cv-00325-RH-MAF Document 120-26 Filed 04/07/23 Page 91 of 111

54. Advances in Wound Care, Wound and Skin Care Survival Skills, Advocate Good Samaritan Hospital, Tuesday, February 8, 2005, Downer's Grove, Il

55. Plastic Surgery: A Five Year Perspective in Practice, Grand Rounds, The University of Chicago, May 18, 2005, Chicago, Il

56. New Techniques in Breast Reconstruction, The Cancer Wellness Center, October 11, 2005 Northbrook, Il

57. Principles of Plastic Surgery; Soft Tissue Reconstruction of the Hand, Rehab Connections, Inc., Hand, Wrist, and Elbow Forum, October 28, 2005, Homer Glen, Il

58. Principles of Plastic Surgery, Lutheran General Hospital Quarterly Trauma Conference, November 9, 2005, Park Ridge, Il

59. Principles of Plastic Surgery, Continuing Medical Education, St. Francis Hospital, November 15, 2005, Evanston, Il

60. Dressing for Success: A Seven Year Experience with Negative Pressure Wound Therapy, Kinetic Concepts Inc, November 30, 2005, Glenview, Il.

61. Breast Reconstruction: The Next Generation, Breast Tumor Conference, Lutheran General Hospital, May 9, 2006.

62. Complex Wound Care: Skin Grafts, Flaps, and Reconstruction, The Elizabeth D. Wick Symposium on Wound Care, *Current Concepts in Advanced Healing: An Update*, Rush North Shore Medical Center, November 4, 2006.

63. An Approach to Maxillofacial Trauma: Grand Rounds, Lutheran General Hospital/Univ. of Illinois Metropolitan Group Hospital Residency in General Surgery, November 9, 2006.

64. "From Paris to Park Ridge", Northern Trust and Advocate Lutheran General Hospital, Northern Trust Bank, June 7, 2007.

65. "Private Practice Plastic Surgery: A Seven Year Perspective," Grand Rounds, The University of Chicago, Section of Plastic Surgery.

66. "Meet the Experts on Breast Cancer," 7th Annual Chicagoland Day of Sharing, Sunday, April 13th, 2008

67. Gender Confirmation Surgey: Surgical Options and Decision-Making, The University of Minnesota, Division of Human Sexuality, May 10, 2008, Minneapolis, Minnesota.

68. "Private Practice Plastic Surgery: A Seven Year Perspective," Grand Rounds, Loyola University, 2008 Section of Plastic Surgery.

69. "Management of Lower Extremity Trauma," Grand Rounds, The University of Chicago, Section of Plastic Surgery, October, 8, 2008.

70. "Concepts in Plastic Surgery: A Multi-Disciplinary Approach," Frontline Surgical Advancements, Lutheran General Hospital, November 1, 2008

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71. "Surgical Techniques-New Surgical Techniques/Plastic Surgery/Prosthetics," Caldwell Breast Center CME Series, Advocate Lutheran General Hospital, November 12, 2008

72. "Genetics: A Family Affair" Panel Discussion: Predictive Genetic Testing, 23rd Annual Illinois Department of Public Health Conference, Oak Brook Hills Marriott Resort, Oak Brook, Il, March 18, 2009

73. "Gender Confirmation Surgery" Minnesota TransHealth and Wellness Conference, May 15, 2009, Metropolitan State University, Saint Paul, MN.

74. "The Role of Plastic Surgery in Wound Care, " Practical Wound Care A Multidisciplinary Approach, Advocate Lutheran General Hospital, October 9-10, 2009, Park Ridge, Il.

75. "In The Family," Panel, General Session III, 2009 Illinois Women's Health Conference, Illinois Dept. of Health, Office of Women's Health October 28-29, 2009, Oak Brook, Il.

76. "Patient Safety in Plastic Surgery," The University of Chicago, Section of Plastic Surgery, Grand Rounds, November 18, 2009.

77. "Compartment Syndrome," 6th Annual Advocate Injury Institute Symposium, Trauma 2009: Yes We Can!, November 19-20, 2009.

78. "Maxillofacial Trauma," 6th Annual Advocate Injury Institute Symposium, Trauma 2009: Yes We Can!, November 19-20, 2009.

79. "Management of Complex Lower Extremity Injuries," Grand Rounds, The Section of Plastic Surgery, The University of Chicago, December 16, 2009, Chicago, Il.

80. "Gender-Confirming MTF Surgery: Indications and Techniques," Working Group on Gender, New York State Psychiatric Institute, March 12, 2010

81. "Gender-Confirmation Surgery," Minnesota Trans Health and Wellness Conference, Metropolitan State University, St. Paul Campus, May 14th, 2010

82. "Physical Injuries and Impairments," Heroes Welcome Home The Chicago Association of Realtors, Rosemont, Illinois, May 25th, 2010.

83. "Genetics and Your Health," Hadassah Heals: Healing Mind, Body, & Soul, Wellness Fair, 2010, August 29, 2010, Wilmette, Illinois.

84. "GCS," Southern Comfort Conference 2010, September 6-11, 2010, Atlanta, GA.

85. "Gender Confirming Surgery," The Center, The LGBT Community Center, October 22, 2010 New York, NY.

86. "Gender Confirming Surgery," the Center, The LGBT Community Center, May 20, 2011, New York, NY.

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87. "Gender Confirming Surgery," Roosevelt-St. Lukes Hospital, May 20, 2011, New York, NY

88. "Principles of Plastic Surgery," Learn about Ortho, Lutheran General Hospital, May 25, 2011, Park Ridge, Il.

89. "Forging Multidisciplinary Relationships in Private Practice," Chicago Breast Reconstruction Symposium 2011, September 9, 2011, Chicago, Il

90. "Gender Confirming Surgery," Minnesota TransHealth and Wellness Conference, Diverse Families: Health Through Community, September 10, 2011, Minneapolis, Minnesota

91. "Gender Confirming Surgery," University of Chicago, Pritzker School of Medicine, Anatomy Class, September 16, 2011, Chicago, Il

92. "Facial Trauma," 8th Annual Advocate Injury Institute Symposium, Trauma 2011: 40 years in the Making, Wyndham Lisle-Chicago, November 9-10, 2011

93. "Establishing a Community-Based Microsurgical Practice," QMP Reconstructive Symposium, November 18-20, 2011, Chicago, Il

94. "Surgery for Gender Identity Disorder," Grand Rounds, Dept. of Obstetrics and Gynecology, Northshore University Health System, December 7, 2011

95. "Managing Facial Fractures," Trauma Grand Rounds, Lutheran General Hospital, Park Ridge, Il July 17, 2012

96. "Principles of Transgender Medicine," The University of Chicago Pritzker School of Medicine, Chicago, Il, September 7, 2012

97. "State of the art breast reconstruction," Advocate Health Care, 11th Breast Imaging Symposium, January 26, 2013, Park Ridge, Il.

98. "State of the art breast reconstruction," Grand Rounds, Dept. of Surgery, Mount Sinai Hospital, April 25, 2013, Chicago, Il.

99. "Getting under your skin: is cosmetic surgery right for you?" Lutheran General Hospital community lecture series, May 7, 2013, Park Ridge, Il.

100. "Gender Confirming Surgery," University of Chicago, Pritzker School of Medicine, Anatomy Class, September 27, 2013, Chicago, Il

101. "State of the Art Breast Reconstruction," Edward Cancer Center, Edward Hospital, October 22, 2013, Naperville, Il

102. "Transgender Medicine and Ministry," Pastoral Voice, Advocate Lutheran General Hospital, October 23, 2013, Park Ridge, Il

103. "Principles of Transgender Medicine and Surgery," The University of Illinois at Chicago College of Medicine, January 28, 2014, Chicago, Il

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104. "Principles of Transgender Medicine and Surgery," Latest Surgical Innovations and Considerations, 22nd Annual Educational Workshop, Advocate Lutheran General Hospital, March 1, 2014, Park Ridge, Il.

105. "Principles of Transgender Medicine: Gender Confirming Surgery," Loyola University Medical Center, March 12, 2014.

106. "Principles of Plastic Surgery," Grand Rounds, Dept. of Obstetrics and Gynecology, Lutheran General Hospital, September 12, 2014.

107. "Gender Confirmation Surgery," The University of Chicago, Pritzker School of Medicine, October 3, 2014

108. "Private Practice: Is There a Future?" The Annual Meeting of The American Society of Plastic Surgical Administrators/The American Society of Plastic Surgery Assistants, Chicago, Il, October 11, 2014.

109. "Private Practice: Is There a Future?" The Annual Meeting of The American Society of Plastic Surgery Nurses, Chicago, Il, October 12, 2014.

110. "Gender Confirmation Surgery" Grand Rounds, The University of Minnesota, Dept. of Plastic Surgery, Minneapolis, MN, October 29, 2014.

111. "Body Contour After Massive Weight Loss," The Bariatric Support Group, Advocate Lutheran General Hospital, February 5, 2015, Lutheran General Hospital, Park Ridge, Il.

112. "Gender Confirmation Surgery," The School of the Art Institute of Chicago, February 1, 2015, Chicago, Il.

113. "Gender Confirmation Surgery," The Community Kinship Life/Bronx Lebanon Department of Family Medicine, Bronx, NY, March 6, 2015

114. "Gender Confirmation Surgery," Educational Inservice, Lutheran General Hospital, Park Ridge, Il, April 20, 2015

115. "Principles of Plastic Surgery, " Surgical Trends, Lutheran General Hospital, Park Ridge, Il, May 16, 2015

116. "Updates on Gender Confirmation Surgery, " Surgical Trends, Lutheran General Hospital, Park Ridge, Il, May 16, 2015

117. "Gender Confirmation Surgery," Lurie Childrens' Hospital, Chicago, Il, May 18, 2015, Chicago, Il 2015.

118. "Gender Confirmation Surgery," TransClinical Care and Management Track Philadelphia Trans-Health Conference, June 5, 2015, Philadelphia, Pa.

119. "Gender Confirmation Surgery: A Fifteen Year Experience," Grand Rounds, The University of Minnesota, Plastic and Reconstructive Surgery and the Program in Human Sexuality, July 30, 2015, Minneapolis, Mn

120. "Gender Confirmation Surgery," Grand Rounds, Tel Aviv Medical Center, Tel Aviv, Israel, August 13, 2015

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121. "Gender Confirmation Surgery," Grand Rounds, University of Illinois, Dept of Family Medicine, September 2, 2015

122. "Principles of Plastic Surgery," Grand Rounds, St. Francis Hospital, Evanston, Il September 18, 2015

123. "Gender Confirmation Surgery," Midwest LGBTQ Health Symposium, Chicago, Il, October 2, 2015

124. "Gender Confirmation Surgery," Southern Comfort Conference, Weston, Fl, October 3, 2015

125. "Surgical Transitions for Transgender Patients," Transgender Health Training Institute, Rush University Medical Center, Chicago, Il, October 8, 2015

126. "Gender Confirmation Surgery," The Transgender Health Education Peach State Conference, Atlanta, GA, October 30, 2015

127. "Gender Confirmation Surgery," Weiss Memorial Medical Center, November 4, 2015, Chicago, Il

128. "Gender Confirmation Surgery," University of Illinois at Chicago, Operating Room Staff Inservice, November 18, 2015, Chicago, Il

129. "Gender Confirmation Surgery," University of Illinois at Chicago, Plastic Surgery and Urology Inservice, November 18, 2015, Chicago, Il

130. "Gender Confirmation Surgery," Weiss Memorial Medical Center, November 19, 2015, Chicago, Il

131. "Gender Confirmation Surgery," Section of Plastic Surgery, The University of Illinois at Chicago, January 13, 2016, Chicago, Il

132. "Gender Confirmation Surgery," Dept. of Medicine, Louis A. Weiss Memorial Hospital, February 18, 2016, Chicago, Il

133. "Gender Confirmation Surgery," BCBSIL Managed Care Roundtable March 2, 2016 Chicago, Il

134. "Gender Confirmation Surgery-MtF," Keystone Conference, March 10, 2016, Harrisburg, PA

135. "Gender Confirmation Surgery-FtM," Keystone Conference, March 10, 2016, Harrisburg, PA

136. "Gender Confirmation Surgery," Grand Rounds, Dept. of Ob-Gyn, March 25, 2016, Lutheran General Hospital, Park Ridge, Il 60068

137. "Surgical Management of the Transgender Patient," Spring Meeting, The New York Regional Society of Plastic Surgeons, April 16, 2016, New York, NY

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138. "A Three Step Approach to Complex Lower Extremity Trauma," University of Illinois at Chicago, April 27, 2016, Chicago, Il.

139. "Gender Confirmation Surgery," Howard Brown Health Center, July 12, 2016, Chicago, Il

140. "Creating the Transgender Breast M-F; F-M", ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

141. "Overview of Transgender Breast Surgery," ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

142. "VTE Chemoprophylaxis in Cosmetic Breast and Body Surgery: Science or Myth", ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

143. "Gender Confirmation Surgery," Gender Program, Lurie Childrens', Parent Group, September 20, 201, 467 W. Deming, Chicago, Il

144. "Gender Confirmation Surgery," The American Society of Plastic Surgeons Expo, September 24, 2016, Los Angeles, CA

145. Transgender Surgery, Management of the Transgender Patient, Female to Male Surgery, Overview and Phalloplasty, The American College of Surgeons, Clinical Congress 2016 October 16-20,2016 Washington, DC

146. "Gender Confirmation Surgery," The Department of Anesthesia, The University of Illinois at Chicago, November 9, 2016

147. "Gender Confirmation Surgery," The Division of Plastic Surgery, The University of Illinois at Chicago, December 14, 2016

148. "Gender Confirmation Surgery," Nursing Education, The University of Illinois at Chicago, January 10, 2017

149. "F2M-Radial Forearm Total Phalloplasty: Plastic Surgeon's Point of View," The European Association of Urologists, Meeting of the EAU Section of Genito-Urinary Reconstructive Surgeons (ESGURS), London, United Kingdom, March 23-26, 2017

150. "Gender Confirmation Surgery," Grand Rounds, The Department of Surgery, The University of North Carolina, March 29, 2017.

151. "Transgender Facial Surgery," The Aesthetic Meeting 2017 - 50 Years of Aesthetics - in San Diego, California April 27- May 2, 2017.

152. "Gender Confirmation Surgery: A New Surgical Frontier," 15th Annual Morristown Surgical Symposium Gender and Surgery, Morristown, NJ, May 5, 2017.

153. "Gender Confirmation Surgery: A New Surgical Frontier," Dept. of Obstetrics and Gynecology, The Medical College of Wisconsin, May 24, 2017 Case 4:22-cv-00325-RH-MAF Document 120-26 Filed 04/07/23 Page 97 of 111

154. "Gender Confirmation Surgery: A New Surgical Frontier," Dept. of Obstetrics and Gynecology, Howard Brown Health Center, August 8, 2017

155. "Current State of the Art: Gynecomastia," ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017

156. "Gender Confirmation Surgery-An Overview," ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017

157. "Gender Confirmation Surgery," Grand Rounds, Dept. of Obstetrics and Gynecology, The University of Chicago, August 25, 2017

158. "Gender Confirmation Surgery," Wake Forest School of Medicine, Transgender Health Conference, Winston-Salem, NC, September 28-29, 2017

159. "Phalloplasty," Brazilian Professional Association for Transgender Health, Teatro Marcos Lindenberg, Universidade Federal de São Paulo (Unifesp), November 1-4, 2017

160. "Gender Confirmation Surgery," Brazlian Professional Association for Transgender Health/WPATH Session, Teatro Marcos Lindenberg, Universidade Federal de São Paulo (Unifesp), November 1-4, 2017

161. "Gender Confirmation Surgery," The Division of Plastic Surgery, The University of Illinois at Chicago, December 13, 2017, Chicago, Il

162. "Gender Confirmation Surgery," Gender and Sex Development Program, Ann and Robert H. Lurie Children's Hospital of Chicago, December 18, 2017, Chicago, Il

163. "Transgender Breast Augmentation," 34th Annual Atlanta Breast Surgery Symposium, January 19-21, 2018, Atlanta, GA

164. "Top Surgery: Transmasculine Chest Contouring," 34th Annual Atlanta Breast Surgery Symposium, January 19-21, 2018, Atlanta, GA

165. "Gender Confirmation Surgery," The 17th International Congress of Plastic and Reconstructive Surgery in Shanghai, March 18-25, 2018, Shanghai, China

166. "Gender Confirmation Surgery: Facial Feminization and Metoidioplasty," 97th Meeting of the American Association of Plastic Surgeons, Reconstructive Symposium, April 7-10, 2018, Seattle, WA

167. Moderator: "Gender Confirmation Surgery: Top Surgery", The Annual Meeting of The American Society of Aesthetic Plastic Surgery, April 26-May 1, 2018, New York, NY

168. "Gender Confirmation Surgery," Econsult monthly meeting, Dept. of Veterans' Affaris, May 24, 2018

169. "Gender Confirmation Surgery," Transgender Care Conference: Improving Care Across the Lifespan, Moses Cone Hospital, Greensboro, NC, June 8, 2018

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170. "WPATH State of the Art," 1st Swiss Consensus Meeting on the Standardization of Sex Reassignment Surgery, The University of Basel, August 31, 2018-September 1, 2018

171. "Facial Feminiztion Surgery: The New Frontier?" 1st Swiss Consensus Meeting on the Standardization of Sex Reassignment Surgery, The University of Basel, August 31, 2018-September 1, 2018

172. "Current Techniques and Results in Mastectomies," 1st Swiss Consensus Meeting on the Standardization of Sex Reassignment Surgery, The University of Basel, August 31, 2018-September 1, 2018

173. "Gender Confirmation Surgery," The University of Chicago, Pritzker School of Medicine, September 7, 2018, Chicago, Il.

174. The Business End: Incorporating Gender Confirmation Surgery, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, September 29, 2018, Chicago, Il

175. Body Contouring in Men, Gynecomastia, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, September 30, 2018, Chicago, Il

176. Moderator: Breast Augmentation and Chest Surgery in Gender Diverse Individuals, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, October 1, 2018, Chicago, Il

177. Moderator: Aesthetic Surgery of The Male Genitalia, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, October 1, 2018, Chicago, Il

178. Moderator: Gender Confirmation Surgeries: The Standards of Care and Development of Gender Identity, Plastic Surgery The Meeting, Annual Meeting of The American Society of Plastic Surgeons, October 1, 2018, Chicago, Il

179. The Center for Gender Confirmation Surgery Lecture Series, "Introduction to Gender Confirmation Surgery," Weiss Memorial Hospital, October 17, 2018, Chicago, Il

180. Institute 3: Gender Dysphoria Across Development: Multidisciplinary Perspectives on the Evidence, Ethics, and Efficacy of Gender Transition, Gender Confirming Care in Adolescence: Evidence, Timing, Options, and Outcomes, The American Academy of Child and Adolescent Psychiatry, 65th Annual Meeting, October 22-27, 2018, Seattle, WA

181. Gender Confirmation Surgery, Combined Endocrine Grand Rounds, The University of Illinois at Chicago, Rush University, Cook County Hospital, January 8, 2019

182. Gender Confirmation Surgery: An Update, Division of Plastic Surgery, The University of Illinois at Chicago, January 23, 2019

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183. Gender Confirmation Surgery from Top to Bottom: A 20 Year Experience, Grand Rounds, The Department of Surgery, Ochsner Health System, January 30, 2019, New Orleans, LA

184. Master Series of Microsurgery: Battle of the Masters One Reconstructive Problem - Two Masters with Two Different Approaches, Gender Affirmation, Male-to-Female Vaginoplasty: Intestinal Vaginoplasty, The American Society for Reconstructive Microsurgery, Palm Desert, California, February 2, 2019

185. Gender Confirmation Surgery: From Top to Bottom, The University of Toronto, Toronto, Canada, February 21, 2019

186. Gender Confirmation Surgery: Where are We, The University of Toronto, Toronto, Canada, February 21, 2019

187. Professors' Rounds: Gender Confirmation Surgery: A Twenty Year Experience, Princess Margaret Hospital, Toronto, Canada, February 22, 2019

188. A 3 Step Approach to Lower Extremity Trauma, Plastic Surgery at The Red Sea, Eilat, Israel, March 6-9, 2019.

189. Gender Surgery: Where are We Now?, Plastic Surgery at The Red Sea, Eilat, Israel, March 6-9, 2019.

190. Gender Confirmation Surgery, A Single Surgeon's 20 Year Experience, Plastic Surgery at The Red Sea, Eilat, Israel, March 6-9, 2019.

191. Gender Confirmation Surgery: Where We Have Been and Where We Are Going, Grand Rounds, The University of Chicago, Section of Plastic Surgery, March 13, 2019

192. Gender Confirmation Surgery: From Top To Bottom, Resident Core Curriculum Conference, The University of Chicago, Section of Plastic Surgery, March 13, 2019.

193. "Gender Confirmation Surgery," WPATH/AMSA Medical School Trans Health Elective, Webinar, March 13, 2019

194. Robotic Vaginoplasty: An Alternative to Penile Inversion Vaginoplasty in Cases of Insufficient Skin, Vaginal Stenosis, and Rectovaginal Fistula. The European Professional Association for Transgender Health, April 9-13, Rome, Italy

195. Current State of Gender-Affirming Surgery in the US and Beyond, Gender-affirming genital surgery presented by the American Urologic Association in collaboration with the Society for Genitourinary Reconstructive Surgeons (GURS), May 2, 2019, Chicago, Il

196. Surgical Training-How Can I get it, The Aesthetic Meeting 2019, New Orleans, LA, May 20, 2019

197. What is the Standard of Care in This New Frontier, The Aesthetic Meeting 2019, New Orleans, LA, May 20, 2019

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198. The 20th Annual Chicago Orthopedic Symposium, August 15-18, 2019, Chicago, Il "Soft Tissue Defects-Getting Coverage"

199. Gender Confirmation Sugery, The Potocsnak Family Division of Adolescent and Young Adult Medicine, Ann & Robert H. Lurie Children's Hospital of Chicago, August 19, 2019

200. Anatomy, Embryology, and Surgery, The University of Chicago, First Year Medical Student Anatomy Lecture, September 9, 2019, The University of Chicago, Chicago, Il.

201. Gender Confirmation Surgery, Howard Brown Health Center Gender Affirming Learning Series, September 13, 2019, Chicago, Il.

202. Moderator, Patient Selection in Gender Affirming Survey Surgery, 88th Annual Meeting of The American Society of Plastic Surgeons, September 20-23, 2019, San Diego, CA

203. Breast Augmentation in Transwomen: Optimizing Aesthetics and Avoiding Revisions, 88th Annual Meeting of The American Society of Plastic Surgeons, September 20-23, 2019, San Diego, CA

204. Breast Reconstruction, State of the Art, NYU-Langone Health, NYU School of Medicine, Standards of Care and Insurance Coverage, Saturday, November 23, 2019, New York, NY.

205. ASRM Masters Series in Microsurgery: Think Big, Act Small: The Building Blocks for Success, "Building a Microsurgery Private Practice from the Ground Up", 2020 ASRM Annual Meeting, Ft. Lauderdale, Florida, January 10-14, 2020

206. ASPS/ASRM Combined Panel II: Gender Affirmation Surgery: Reconstruction Challenges of Function and Sensation, 2020 ASRM Annual Meeting, Ft. Lauderdale, Florida, January 10-14, 2020

207. Rush University Medical Center, Division of Urology, Grand Rounds, "Gender Confirmation Surgery: A Single Surgeon's Experience," January 22, 2020

208. Rush University Medical Center, Department of General Surgery, Grand Rounds, "Gender Confirmation Surgery: A Single Surgeon's Experience," February 5, 2020.

209. WPATH/AMSA (American Medical Association) Gender Scholar Course, Webinar, March 11, 2020

210. Rush University Medical Center, Division of Plastic Surgery, Weekly Presentation, Gender Confirmation Surgery: Can a Surgeon Provide Informed Consent?, April 29, 2020

211. Legal Issues Faced by the Transgender Community, ISBA Standing Committee on Women and The Law and the ISBA Standing Committee on Sexual

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Orientation and Gender Identity, Co-Sponsored by the National Association of Women Judges District 8, Live Webinar, May 28, 2020

212. Principles of Transgender Surgery, National Association of Women's Judges, District 8, Webinar, June 4, 2020

213. Gender-Affirming Surgery, National Association of Women's Judges, District 8, Webinar, July 8, 2020

214. Gender-Affirming Surgery, The University of Chicago, Pritzker School of Medicine, 1st year Anatomy, September 15, 2020

215. Gender-Affirming Surgery, Rush University Medical School, 2nd year Genitourinary Anatomy, September 16, 2020.

216. Surgical Management of the Transgender Patient, Rosalind Franklin University, The Chicago Medical School, Plastic Surgery Interest Group, October 7, 2020

217. Breast Augmentation in Transgender Individuals, The American Society of Plastic Surgeons Spring Meeting, March 20, 2021

218. International Continence Society Institute of Physiotherapy Podcast 5-Pelvic Floor Most Common Disorders and Transgender Patients (recorded April 30, 2021)

219. The American Association of Plastic Surgeons Annual Meeting, Reconstructive Symposium, Gender Affirmation Panel, Complications of GCS, Miami, FL, May 15, 2021 (presented virtually)

220. Gender Confirmation Surgery, Grand Rounds, Rush University, Section of Urology, June 8, 2021.

221. Genitourinary introduction lecture, M2, Rush University School of Medicine, September 2, 2021 (by Zoom)

222. Demystifing Gender: Fostering Gender Friendly Healthcare, Gender Affirmative Care in Adults, Querencia (lady hardinge medical college, WHO Collaborating Center for Adolescent Health, Dept of Paediatrics, JSCH & LHMC, New Delhi, WPATH September 5, 2021 (by zoom)

223. Gender Confirmation Surgery, The University of Chicago Pritzker School of Medicine, MS-1, Anatomy lecture, September, 14, 2021, Chicago Il.

224. Gender Confirmation Surgery, A Single Surgeon's 22 Year Experience: Where are We Now?, Research Seminar, Section of Endocrinology, The University of Chicago, Chicago, Il, October 4, 2021 (by Zoom) 225. Chest Surgery, The Illinois Dept. of Corrections (by zoom), October 13, 2021.

226. Vaginoplasty, The Illinois Dept. of Corrections (by zoom), October 15, 2021.

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227. International Continence Society, 20th Physioforum, Pelvic Floor Physical Therapy and Gender-Affirming Surgery, October 16, 2021, Melbourne, Australia (by Zoom)

228. Rush University Division of Plastic Surgery, Gender Affirmation Surgery: Where Are We Now?, educational conference, November 23, 2021, Chicago, Il

229. 51 Congreso Argentino de Cirugia Plastica, Microsurgery Symposium, SACPER-FILACP, 3 Step Approach to Lower Extremity Trauma, November 29, 2021, Mar del Plata, Argentina

230. 51 Congreso Argentino de Cirugia Plastica, Genital Aesthetics and Gender Confirmation Surgery I, "Gestión Quirúrgica de la Disforia de Género: Descripción general del manejo quirúrgico y los estándares de atención," December 1, 2021, Mar del Plata, Argentina

231. 51 Congreso Argentino de Cirugia Plastica, Genital Aesthetics and Gender Confirmation Surgery II, Cirugía Genital Masculinizante (Metoidioplastia y Faloplastia), December 2, 2021, Mar del Plata, Argentina

232. 51 Congreso Argentino de Cirugia Plastica, Genital Aesthetics and Gender Confirmation Surgery III, Faloplastia: optimización de resultados y reducción de complicaciones, December 2, 2021, Mar del Plata, Argentina

233. Government of India, Ministry of Health and Welfare, National AIDS Control Organization, Meeting with AIIMS on Gender Affirmation Care (GAC) Clinic Pilot Intervention, December 21,2021, New Delhi (virtual)

234. Affirming Care for Gender Diverse Patients, Rosalind Franklin University, January 5, 2022, North Chicago, Il (Virtual by Zoom)

235. Sub-Unit Transplantation, Penile Transplant, WSRM/ASRT Mini-Symposium VCA Transplant, World Society for Reconstructive Microsurgery/American Society for Reconstructive Transplantation/American Society for Reconstructive Microsurgery Annual Meeting, January 14, 2022, Carlsbad, CA

236. Strategies for Penile Transplantation, American Society for Reconstructive Microsurgery, Annual Meeting, January 16, 2022, Carlsbad, CA

237. ASRM/WSRM/ASRT Battle of the Frontiers: To Transplant or Not? Conventional Reconstruction (Phalloplasty), American Society for Reconstructive Microsurgery, Annual Meeting, January 16, 2022, Carlsbad, CA

238. Strategies for Penile Innervation, American Society for Gender Surgeons, Annual Meeting, January 18, 2022, Carlsbad, CA

239. Pathway To Informed Consent: Vaginoplasty, Illinois Dept. of Corrections (virtual), February 10, 2022

240. Gender Confirmation Surgery From Top to Bottom: A Single Surgeon's 22 Year Experience, Where are We Now, Grand Rounds (virtual), Department of Plastic Surgery, University of South Florida, February 14, 2022 Case 4:22-cv-00325-RH-MAF Document 120-26 Filed 04/07/23 Page 103 of 111

241. Vaginoplasty: Dissection of the vaginal canal and selection of technique, International Confederation of Plastic Surgery Societies (ICOPLAST), First World Congress, Lima Peru May 19-21, 2022 (President of the session: Genital/Transgender Session 1)

242. Phalloplasty: Strategies to reduce complications and optimize outcomes, International Confederation of Plastic Surgery Societies (ICOPLAST), First World Congress, Lima Peru May 19-21, 2022

243. Chest Surgery in Transgender Men, International Confederation of Plastic Surgery Societies (ICOPLAST), First World Congress, Lima Peru May 19-21, 2022

244. Gender-Affirming Surgery: A 23 Year Experience Where are we now, 65th Annual Scientific Meeting, Southeastern Society of Plastic and Reconstructive Surgeons (Finding The Solutions Now and The Future), Orlando, F1, June 11-15, 2022

245. Top Tips for Safety: The Culture of Safety, 65th Annual Scientific Meeting, Southeastern Society of Plastic and Reconstructive Surgeons (Finding The Solutions Now and The Future), Orlando, Fl, June 11-15, 2022

246. Uterine Transplantation, GAPS (Ghent Academy of Plastic Surgery) 2022: Bridging the Gap Between Reconstructive and Aesthetic Surgery, June 17-18, 2022, Ghent, Belgium

247. In Honor of Professor Stan Monstrey, GAPS (Ghent Academy of Plastic Surgery) 2022: Bridging the Gap Between Reconstructive and Aesthetic Surgery, June 17-18, 2022 Ghent, Belgium

248. "TRANS" Grand Rounds Panel Discussion (panel discussants: Loren S. Schechter, MD, Michaela West, MD, PhD, Courtney Cripps, MD, Ervin Kocjancic, MD), University of Chicago, Department of Surgery, July 6, 2022, Chicago, Il

249. Gender Affirming Surgery, Grand Rounds, July 12, 2022, Department of Urology, Rush University Medical Center, Chicago, Il

250. Gender Affirming Surgery, Gender Affirmation Lecture Series, Rush University Medical Center, July 15, 2022, Chicago, Il

251. Anatomy of A Lawsuit, Rush PRS Weekly Didactic Conference, Rush University Medical Center, Plastic and Reconstructive Surgery, July 20, 2022, Chicago, Il

252. Gender Affirmation Surgery: Where are We Now? The University of Chicago, Section of Plastic Surgery, Grand Rounds, August 10, 2022, Chicago, Il

253. Thriving in Sexual & Gender Diversity, The Transgender Patient, August 10, Virtual CME Event (broadcast from Dr. Shino Bay Aguilera's office in Miami, Fl)

254. Gender Affirming Medical and Surgical Therapies, Illinois College of Emergency Physicians Webinar, August 17, 2022

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255. Gender Affirming Surgery Panel, Liebert Publishing, Webinar, August 26, 2022, Moderator: Jeffrey Spiegel, MD

256. Gender Confirmation Surgery, The University of Chicago Pritzker School of Medicine, MS-1, Anatomy lecture, September, 14, 2022, Chicago Il

257. Gender Affirmation Surgery: Where We Have Been and Where We are Going: GURS-WPATH Invited Lecture, Society of Genitourinary Reconstructive Surgeons, Academic Congress, Montreal, Canada, September 15, 2022

258. Phalloplasty: Optimizing Outcomes and Reducing Complications, North Carolina Society of Plastic Surgeons 2022 Annual Scientific Meeting, Pinehurst, North Carolina, October 7-9, 2022

259. Special Guest Lecture: Gender Affirmation Surgery: Where We've Been and Where We're Going, North Carolina Society of Plastic Surgeons 2022 Annual Scientific Meeting, Pinehurst, North Carolina, October 7-9, 2022

260. Diversity in Practice, North Carolina Society of Plastic Surgeons 2022 Annual Scientific Meeting, Pinehurst, North Carolina, October 7-9, 2022 261. Gender Affirming Surgery, Fenway/HMS Advances in Transgender Care, October 15, 2022

262. Genitourinary introduction lecture, M2, Rush University School of Medicine, October 26, 2022, Chicago, Il

263. Optimizing Aesthetics and Sensation in Vaginoplasty and Phalloplasty, The American Society of Plastic Surgeons $91^{\rm st}$ Annual Meeting (PSTM), Boston, MA, October 30, 2022

264. Gender-Affirming Surgery: From Top to Bottom, The Rush University Medical Center Departments of Emergency Medicine and Internal Medicine for the Emergency Medicine Grand Rounds Lecture, Chicago, Il, November 16, 2022

265. Dueling Perspectives in Transgender Surgery, New York Regional Society of Plastic Surgeons, New York, New York, November 19, 2022

266. Gender-Affirming Surgery: From Top to Bottom, Rush University Medical Center Department of Anesthesia Grand Rounds, November 30, 2022, Chicago, Il.

267. Gender-Affirming Surgery: Where We Have Been and Where We are Going, Mass General Brigham Center For Transgender Health, Grand Rounds, December 13, 2022 Boston, MA (lecture delivered virtually)

268. An Intro to Providing Gender Affirming Care to Gender Diverse Patients, Rosalind Franklin University, Chicago Medical School, December 21, 2022, North Chicago, Il (virtual by Zoom)

269. Surgical Techniques and Outcomes in Penile Reconstruction, WSRM/ ASRT Symposium on VCA in the Transgender Patient, Annual Meeting of The American Society for Reconstructive Microsurgery, January 20, 2023, Aventura, Fl

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270. Argument for Transgender Transplantation, WSRM/ ASRT Symposium on VCA in the Transgender Patient, Annual Meeting of The American Society for Reconstructive Microsurgery, January 20, 2023, Aventura, Fl

271. Moderator: Gender Surgery Symposium, Society of Gender Surgeons, January 24, 2023, Aventura, Fl

272. Trans female top surgery, $38^{\rm th}$ Annual Atlanta Breast Surgery Symposium, January 27-29-2023, Atlanta, GA

273. Trans male top surgery, 38th Annual Atlanta Breast Surgery Symposium, January 27-29-2023, Atlanta, GA

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<u>Exhibit B</u> *Bibliography*

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- 5. American Society of Plastic Surgeons, ASPS Recommended Insurance Coverage Criteria for Third-Party Payers, Reduction Mammaplasty (2021), <u>https://www.plasticsurgery.org/documents/Health-</u> <u>Policy/Reimbursement/insurance-2021-reduction-mammaplasty.pdf</u>.
- 6. American Society of Plastic Surgeons, ASPS Recommended Insurance Coverage Criteria for Third-Party Payers, Gynecomastia, <u>https://www.plasticsurgery.org/documents/Health-</u> <u>Policy/Positions/Gynecomastia_ICC.pdf</u>.
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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA Tallahassee Division

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

CORRECTED EXPERT REBUTTAL REPORT OF E. KALE EDMISTON, PH.D.

I, E. Kale Edmiston, Ph.D., hereby declare and state as follows:

1. I am over the age of eighteen and submit this expert rebuttal report based on my expert opinion.

2. I have been retained by counsel for plaintiffs as an expert in connection with the above referenced litigation. The opinions expressed herein are my own and do not express the views or opinions of my employer.

3. I have actual knowledge of the matters stated herein. If called to testify,

I would testify truthfully based on my expert opinion.

Background and Qualifications

4. I am an Associate Professor of Psychiatry at the University of Massachusetts Chan Medical School. Prior to this appointment, I was an Assistant

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Professor of Psychiatry at the University of Pittsburgh from 2019 to 2022. I have more than 15 years of experience conducting psychiatric neuroimaging research, with a focus on adolescence and young adulthood, mood and anxiety disorders, and impulsivity and emotional regulation. My methodological expertise lies in neuropsychological assessment, multimodal neuroimaging, psychophysiological measures such as heart rate variability, and measures of neuroendocrine function across adolescent development.

5. I completed a bachelor's degree from Hampshire College in 2007, where I studied cognitive science. I received postbaccalaureate training in psychiatric neuroimaging at the Yale School of Medicine. I earned a PhD in neuroscience from Vanderbilt University in 2015, as well as a graduate certificate in medical humanities, with a focus on bioethics and medical decision-making. I then completed post-doctoral training at China Medical University and the University of Pittsburgh.

6. In 2014, I co-founded the Trans Buddy Program at Vanderbilt University Medical Center, a peer navigator and support program for transgender people seeking healthcare. As a part of this program, my work primarily focused on supporting transgender adolescents experiencing mental health crisis. At this time, I also served as the Co-Director for the Vanderbilt University Program for LGBTI Health. I later replicated the Trans Buddy Program at the University of Pittsburgh Department of Adolescent Medicine.

7. From 2018-2022, I served as a chapter author for the Assessment chapter of the World Professional Association for Transgender Health's *Standards* of Care for the Health of Transgender and Gender Diverse People, Version 8.

8. I have authored over 100 peer-reviewed manuscripts, book chapters, and conference proceedings in psychiatric neuroscience and transgender health.

9. Further information about my professional background and experience is outlined in my curriculum vitae, a true and accurate copy of which is attached as **Exhibit A** to this report.

Prior Testimony

10. I have not testified as an expert at trial or by deposition within the last four years.

Compensation

11. I am being compensated for my time at a rate of \$175/hour. My compensation is in no way contingent on the conclusions reached as a part of my testimony or on the outcome of this case.

Basis for Opinions

12. In preparing this report, I have reviewed: the Complaint in this case; Florida Administrative Code 59G-1.050(7) (the "Challenged Exclusion"); the document titled "Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria," published by the Florida Agency for Health Care Administration in June 2022, and its attachments; the expert reports of Drs. Armand Antommaria, Dan Karasic, Johanna Olson-Kennedy, Loren Schechter, and Dr. Daniel Shumer, submitted by plaintiffs; and the expert reports Drs. Michael Biggs, G. Kevin Donovan, Paul Hruz, Kristopher Kaliebe Michael Laidlaw, Patrick Lappert, Stephen Levine, Sophie Scott, and Joseph Zanga, submitted by defendants.

13. My opinions are based on my years of research and academic experience, as well as my professional knowledge, as set out in my curriculum vitae (**Exhibit A**) and the materials listed therein; my knowledge of the peer-reviewed literature relating to neuropsychological assessment and brain development; my knowledge of the clinical practice guidelines for the treatment of gender dysphoria, including my work as a contributing author of WPATH SOC 8; and my review of any of the materials cited herein.

14. I have also reviewed the materials listed in the bibliography attached asExhibit B. I may rely on those documents as additional support for my opinions.

15. 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 the subject. I may wish to supplement these opinions or the bases for them as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

Adolescent Brain Development

16. Dr. Scott's report stating that adolescents are more likely to engage in risky behaviors relative to adults fails to include the specific context in which this is true. That is, the literature indicates that there are *highly specific circumstances* in which adolescents are more likely to engage in risky or impulsive behavior. Indeed, Dr. Scott lists some of these circumstances in her testimony: driving, drinking alcohol, getting a tattoo. However, none of these examples are relevant to the issue at hand: protracted medical decision-making made in the context of adult guidance and consultation with a medical professional.

17. Dr. Scott fails to cite the large body of evidence indicating that adolescents are capable of deliberative decision making in the presence of adults (i.e., healthcare providers and caregivers) and when decision making occurs over a protracted period. This is the exact context in question: decisions about accessing gender-affirming medical care, such as gonadotropin releasing hormone agonists (GnRHa) and hormone treatment, are made jointly among the adolescent patient, their caregiver(s), and medical professionals. These decisions are also made over time; data show that the typical time between an adolescent realizing they are transgender and coming out to an adult is three years (Bauer et al., 2022). Furthermore, once an adolescent discloses their identity to a supportive adult, they will then have to schedule a healthcare appointment and undergo assessment prior to accessing treatment. This process typically takes months and for some, even years.

18. Dr. Scott misrepresents the literature on adolescent decision making by generalizing findings made in "hot" contexts to those made in "cold" contexts. Indeed, the Blakemore and Robbins review from 2012 that she cites explicitly states that the literature concludes that adolescents demonstrate adult-typical decision-making abilities in cold contexts. It is not that adolescence is associated with a failure to engage cognitive control networks, but rather, that cognitive control networks are engaged with greater variability during this time than during adulthood. Decision-making is a multifactorial process that includes valuation of both risk and reward. While adolescents are more likely to overvalue reward and underestimate risk when peers are present or when decisions must be made quickly, they demonstrate deliberative and appropriate consideration of reward and risk valuation in the absence of peers, in the presence of adults, and when decisions are made over time.

This important difference in the contextual nature of decision-making in adolescence is an established finding that has been replicated across multiple studies (Chein et al., 2011; O'Brien et al., 2011; Simons-Morton et al., 2011; Smith et al., 2014; Weigard et al., 2014; Hartley & Somerville, 2015; Guassi Moreira & Telzer, 2018). Indeed, deliberative decision making in contexts without pressure to decide quickly has been repeatedly shown in adolescents (Byrnes, 2002; Figner et al., 2009; Wolff & Crockett, 2011; Icenogle & Cauffman, 2021).

19. Dr. Scott also states that "at 18yrs old, the connections to the frontal lobes are not myelinated¹ like a mature adult brain, and this is likely to affect frontal lobe functions." This is an oversimplification of an extremely complex literature. A study of over 10,000 participants has shown quite the opposite: that by the age of 18, adult-level cognition is established (Tervo-Clemmens et al., 2022), while other studies have shown mature integration of functional networks by late adolescence (Marek et al., 2015) and fractional anisotropy of prefrontal white matter (Lebel & Beaulieu, 2011, fractional anisotropy is an indirect measure of myelination). Even though, on average, there are developmental differences in prefrontal myelination,

¹ Myelin is a protein sheath that covers the axons of neurons. The axons comprise white matter in the brain, and bundles of these fibers transmit signals from region to region in the brain. When an axon is myelinated, the signal can travel faster down the axon.

there is not strong evidence that these differences are associated with an inability to make deliberative decisions with the support of caregivers and expert clinical guidance.

20. Furthermore, there is a great deal of variation in the timing of development between different prefrontal white matter tracts, as well as a great deal of variation between individuals. Indeed, in Lebel & Beaulieu's longitudinal study of over 100 individuals from childhood to young adulthood, many individuals showed decreases or no changes in fractional anisotropy (FA) during adolescence, and these differences also varied by prefrontal white matter tract (2011). This literature represents differences in group averages and should not be used to predict the behavior or development of an individual adolescent; we cannot draw conclusions about all 18-year-olds from these studies. This is why the WPATH SOC 8 recommends an individualized approach to joint decision-making regarding healthcare.

There is Little Evidence to Support Defendants' Designated Experts' Speculation about Negative Effects of GnRHas on Cognition

21. Dr. Scott cites a 2016 study by Wojniusz and colleagues as evidence of the negative effects of GnRHas on emotional reactivity in a sample of girls with central precocious puberty. This is puzzling because the authors of this paper explicitly state the opposite interpretation: "Overall, our findings do not provide firm conclusions with regard to differences in emotional processing between the GnRHa treated CPP girls and age-matched controls." (pp13).

Perhaps Dr. Scott has misinterpreted the nature of the emotional flanker 22. task. This task asks participants to determine if two simultaneously presented houses are the same or different. The houses are presented at the center of a screen, and emotional or neutral face distractors flank them. The outcome of interest is the reaction time for the determination of whether the houses are the same or different. The idea here is that people with poor emotional regulation will be more distracted during the emotional face condition and therefore take longer to respond. This interpretation can only be made when reaction times are increased in both the emotional face conditions. In this study, the CPP girls showed longer reaction time than controls during the emotional face condition only when the houses were different, but not when the houses were the same. Thus, the findings do not indicate an issue with emotional regulation. More likely, the results are incidental and due to statistical issues regarding false discovery rate correction, an argument that the authors of the paper themselves make.

23. The authors do find reduced heart rate and elevated heart rate variability (HRV) during the emotional task. HRV is distinct from heart rate and is a measure of cardiac vagal tone. HRV is a proxy for parasympathetic system or "rest and

digest" function. Thus, elevated HRV is associated with increased regulatory capacity and is a marker of health. Thus, these findings are a sign of *optimal* emotional regulation. Indeed, the authors state, "...the lower HR and higher HRV could suggest that treated CPP girls have better emotion regulation capacity and higher adaptability to changing contexts than controls" (pp13).

24. Dr. Scott then points out that, in a separate commentary on the article, Dr. Hayes states that there were "notably" lower scores on IQ measures in the CPP group relative to controls. However, Dr. Hayes's comment, and Dr. Scott's reliance on it, is not supported by the findings of the study. Specifically, none of the differences in IQ were statistically significant, and the mean IQ scores for both groups were within the normal range. Furthermore, the mean difference between groups in this study is within the realm of variation that may occur from repeated administration of the WISC-III, i.e., although scores for an individual tend to remain relatively stable over time, there is fluctuation that occurs even within an individual and small differences in IQ (Watkins & Smith, 2013), as reported in this study, are not only not statistically significant, they are not clinically significant. Dr. Scott has, again, offered a misrepresentation of the literature.

25. Dr. Levine cites a single case study as evidence for an effect of GnRHa treatment on IQ. Case studies are the lowest quality of evidence. Case studies can

provide important evidence for future areas of study or to provide an illustrative example of a common clinical phenomenon, but they should not be used to make general conclusions or policy positions. Putting aside the low quality of evidence typical of case studies in general, this case study does not even provide sufficient support for Dr. Levine's opinion as it describes a transgender girl who, prior to initiation of treatment, already had below average IQ. While Dr. Levine highlights the lack of change in fractional anisotropy values over the course of the study in this case, this could be due to developmental delays that are independent of treatment and are instead related to her low IQ. Therefore, the findings of this case study are simply not generalizable to the broader population.

26. Dr. Michael Biggs, a sociologist, also offers speculation regarding cognitive effects of GnRHa treatment as well, describing it as "...stopping normal sexual and cognitive development..." This statement regarding cognitive development appears to be pure speculation as he offers no citation regarding evidence for deleterious effects of GnRHa treatment on cognition. In reviewing the literature, including through specific searches, I have been unable to find compelling evidence of this. I was able to identify two studies that showed no effect of GnRHa treatment on executive function (Soleman et al., 2016; Staphorsius et al., 2015). The

lack of evidence for these effects is itself compelling, given that these medications have been used in adolescents with central precocious puberty for decades.

Evidence for Effects of GnRHa treatment on the Brain

27. Both Dr. Levine and Dr. Laidlaw state that the effects of GnRHa treatment on the brain are both "unknown" and "likely negative." They do not cite any original research that supports this conclusion and thus it is unclear to me how they concluded that the effects are likely negative in the absence of evidence. Dr. Laidlaw even goes so far as to speculate on the individual brain maturation of three specific transgender individuals. Both Levine and Laidlaw admit that there is no evidence from the neuroimaging literature on negative effects of these treatments on brain development, but even if there was, any neuroimaging study that compares group averages would not support an inference about the brains of individual people. There is a great deal of variation between and within individuals in many commonly used neuroimaging measures. For this reason, neuroimaging methods commonly used in research, such as fMRI, cannot be used diagnostically for individual people in the absence of organic brain disease (Schleim & Roise, 2019).

28. Dr. Hruz also speculates in his testimony that there are negative effects of GnRHa treatment on the brain: "A possible effect of blocking normally timed puberty is alteration of normal adolescent brain maturation". Dr. Hruz then cites a

2013 review paper that describes typical adolescent brain maturation but does not mention or describe any effects of blocking or delaying puberty on the brain (Arain et al., 2013). Dr. Hruz therefore has not cited any support for his conclusion, and I have not identified any studies relating to the evidence of negative longitudinal effects on brain development related to GnRHa treatment in central precocious puberty or in transgender adolescents, even after targeted searches for it.

There is not a large literature on the effects of GnRHa treatment on the 29. brain in humans, but this does not render such care experimental. GnRHa treatments have been in used for decades, including for the treatment of gender dysphoria. That said, there are a few cross-sectional studies on this issue, and it is significant that none of the experts (nor the GAPMS memo) cited this literature in their testimonies. In a study that compared transgender adolescent boys and girls taking GnRH agonists to cisgender boys and girls, there were differences in brain function in some brain regions that would indicate congruence with gender identity and other differences that would indicate congruence with sex assigned at birth. However, there were no between-group differences in network function on the basis of GnRHa treatment. Furthermore, the authors searched for relationships between duration of GnRHa treatment in the transgender adolescents and brain function and were unable to find any effects. In a diffusion tensor imaging study of fractional anisotropy

values, an index of white matter myelination, again there was no significant association between fractional anisotropy values and GnRHa treatment (van Heesewijk et al., 2022). Similarly, in an fMRI study comparing cisgender boys and girls to transgender boys and girls, there were no significant differences in brain activity between transgender and cisgender adolescents during a verbal fluency task, and no deficits in verbal ability in transgender youth (Soleman et al., 2013). In a study of transgender individuals receiving GnRHa treatment and cisgender people, there were differences in brain activity between groups, but these differences were not associated with hormone levels, leading the authors to conclude that these differences are associated with group differences that predate GnRHa treatment (Soleman et al., 2016). In summary, to my knowledge, there have been three studies of brain structure and function of transgender adolescents receiving GnRHa treatment, and none of them have found any significant effects of treatment on the brain.

30. A recent primate study provides evidence for some regional neuroprotective effects of GnRHa treatment, although the results are complex (Godfrey et al., 2023). In this study, the authors compared dominant and subordinate adolescent rhesus monkeys. These monkeys form social hierarchies much like human adolescents, and subordinate monkeys are subjected to aggression from the

more dominant monkeys. Both dominant and subordinate monkeys were randomly assigned to a GnRHa treatment or control group and then followed longitudinally. In the primates exposed to chronic social subordination stress, GnRHa treatment rescued the negative effect of stress on regional brain volume over time. These differences were seen in brain regions such as the amygdala that are well-established in the pathophysiology of depression and anxiety. There were also effects of GnRHa treatment in general; treatment in both social groups was associated with smaller hippocampal volume than control animals. Regarding the prefrontal cortex, a critical region during adolescent development, GnRHa treatment was associated with greater prefrontal grey matter volume prepubertally but this difference decreased by adolescence. There was an effect of GnRHa treatment early in puberty on prefrontal white matter volume; however, this difference was no longer present by the end of the study. Importantly, there are species-specific differences in prefrontal volume changes across puberty; the generalizability of the prefrontal findings to humans should be made with caution. Finally, the authors also assessed social behavior in both submissive and dominant primates over time and were able to determine that, at prepuberty, submissive primates were more socially isolated, but that GnRHatreated subordinate animals had normalized social behavior (reduced time spent alone) and normalized cortisol response to threat (cortisol is a stress hormone

associated with the hypothalamic pituitary adrenal axis). The authors conclude that "...delayed puberty and estrogen suppression may be protective against the impact of social stress" (pp12). This study provides strong evidence that GnRHa treatment normalizes brain structure, physiological stress reactivity, and social behavior in adolescent primates subjected to social subordination, an ecologically valid non-human primate model of the psychosocial environment for transgender youth.

31. There is a small body of literature on the effects of gender affirming hormone care on the brain in transgender adolescents. In a study comparing transgender boys receiving testosterone therapy and those who were not, testosterone treatment was associated with reductions in mood and anxiety symptoms, as well as reductions in body image dissatisfaction. Gender affirming hormone care was associated with an increase of functional coupling between the amygdala and prefrontal cortex while research participants viewed threatening emotional faces, likely indicating improved emotional regulation of the amygdala in the boys who were treated with testosterone. Indeed, in the boys who were treated with lower anxiety symptom severity (Grannis et al., 2021). Another study of transgender boys receiving testosterone found that testosterone caused a shift in amygdala
activation, such that it became more typical of cisgender boys than cisgender girls (Beking et al., 2020).

Both Dr. Scott and Dr. Biggs cite studies from the animal 32. 17. literature regarding the "side effects" of GnRHa treatment on the brain and behavior. However, they misinterpret or misrepresent the meaning of the term "side effect" in this context. Pharmacological agents have effects. The determination of what is a side effect and what is a desired effect is contextual. For example, Scott cites a 2021 rodent study of GnRHa treatment as an example of the "side effects" associated with GnRHa treatment (Anacker, et al., 2021). If one were to read the abstract of the study and not the full text, it may lead some to come to such a conclusion. However, what the study shows is that, prior to GnRHa treatment, there are sex differences in rodent behavior. Following GnRHa treatment, those sex differences are no longer present. This is the expected and desired outcome of GnRHa treatment, not a side effect. For example, female mice show greater locomotion behavior than male mice. Following GnRHa treatment, male mice show greater locomotion behavior than untreated male mice. Similarly, in a test of social interaction, GnRHa-treated males showed differences in the time spent with male versus female mice relative to untreated male mice, but not relative to untreated female mice. In both force-swim tests and a test of feeding behavior, female GnRHa-treated mice differed from control female mice,

but not from male mice. This is a consistent pattern across behavioral assays performed in the study, and this pattern was present in biological assays as well. GnRHa-treated male mice showed greater corticosterone stress response to novelty than control male mice but did not differ from female mice. GnRHa treatment increased neural activity in the hippocampus of female mice, but this activity increase did not differ from male mice. This is not a compelling study of the side effects of GnRHa treatment, but rather, a study that shows us exactly what we would expect: that blocking sex hormones decreases sex differences, the intended outcome for transgender youth.

33. Dr. Scott and Dr. Biggs cite a series of studies of GnRHa effects on sheep from a specific laboratory. One study from this group did show sex-specific changes in feeding behavior and HRV following GnRHa treatment. While Dr. Biggs opts to highlight changes in behavior in the female sheep that could be interpreted as an increase in anxiety-like behavior, he fails to mention that GnRHa treatment was associated with *improvements* in these behaviors in the treated male sheep (Wojniusz et al., 2011). They also fail to mention that other studies from this group show no effects of GnRHa treatment on cognition (Nuruddin et al., 2013; Wojniusz et al., 2013), and, like the Anacker study, brain differences are best explained by an expected reduction of sex differences following treatment (Nuruddin et al., 2013).

This issue of inappropriate reference group is a common problem in the GnRHa animal literature and its extrapolation to transgender youth (Edmiston & Juster, 2022). While the literature regarding the effects of GnRHa treatment on sheep behavior from this research group is complex, it by no means offers compelling evidence of negative effects of GnRHa treatment. Furthermore, Dr. Biggs highlights a negative effect from one study- an increase in anxiety-like behavior in female sheep only. However, we know from studies of transgender youth and young adults that anxiety and depression symptoms decrease with treatment (de Vries et al., 2014; Dhejne et al., 2016; Aldridge et al., 2021; Chen et al., 2023). This is more compelling evidence than a single animal study, as sheep do not have the complex psychosocial identities that humans do.

Evidence for Negative Consequences of Depression and Anxiety on the Developing Brain

34. The brain is more plastic during adolescence than during adulthood. This means that adolescents are particularly vulnerable and at increased risk for the onset of mood and anxiety disorders, and, if untreated, that the onset of mood and anxiety symptoms can permanently alter the developmental trajectory of the brain into adulthood (Holder & Blaustein, 2014). Termed the "kindling effect", the concept here is that, as the efficiency of neural circuits is reinforced over time (i.e., "neurons that fire together wire together"), each depressive episode or

environmental stressor increases the risk for later depressive episodes. This effect may be amplified during adolescence because of the greater plasticity of the brain.

35. There are well-documented disparities in mental health outcomes in transgender youth that are caused by minority stress (for review, see White Hughto et al., 2015). This includes evidence that transgender people who live in areas with more accepting political climates show reduced biological stress markers and fewer mental health symptoms than transgender people who live in less accepting areas (DuBois & Juster, 2022). Others have shown an association between decreased social support and biological markers of stress in transgender adolescents (McQuillan et al., 2021). Given that transgender adolescents report high chronic stress and high rates of depression, anxiety, and suicidality, transgender adolescents are particularly vulnerable to the effects of stress on brain development, stress system regulation, and long-term mental health outcomes (DuBois et al., 2021; Potter et al., 2021; Randall et al., 2022).

36. In Dr. Levine's testimony, he quotes the Hippocratic Oath, "Above All Do No Harm". He makes this argument on the assumption that GnRHa treatment must necessarily cause harm because it is an intervention. This assumes that the psychosocial environment and biology of transgender youth is like that of cisgender youth. There is a great deal of evidence that this is not the case. Instead, in my opinion not offering an intervention to transgender individuals that require treatment actually does harm.

37. In this case, puberty blockers have demonstrated efficacy in reducing symptoms of depression in transgender adolescents (de Vries et al., 2011), and therefore may in fact be neuroprotective to the cumulative effects of stress caused by gender dysphoria.

Conclusion

38. There is little to support the Defendants' designated experts' speculation about the negative effects of GnRHa treatment on the brain. In contrast, there is a great deal of evidence supporting the mental health benefits of GnRHa treatment for transgender adolescents. Furthermore, it is well-known that transgender adolescents face higher rates of psychosocial stress than their cisgender peers, and there is clear evidence for the negative effects of gnRHa treatment on the brain are an important area for future research, this does not render such care experimental. To the contrary, this is treatment that has existed for decades and arguments that a purported lack of evidence is equivalent to known harm are spurious, particularly when there is a large literature indicating benefits of treatment and harm of withholding treatment.

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

Executed this $\underline{22}$ day of March 2023.

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E. Kale Edmiston, Ph.D.

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

EXPERT REPORT OF E. KALE EDMISTON, Ph.D. Case No. 4:22-cv-00325-RH-MAF

E. Kale Edmiston, PhD

Associate Professor Department of Psychiatry University of Massachusetts Chan Medical School kale.edmiston@umassmed.edu

ACADEMIC APPOINTMENTS

Associate Professor of Psychiatry University of Massachusetts Chan Medical School	2022-present Worcester, MA
Assistant Professor of Psychiatry University of Pittsburgh School of Medicine	2019-2022 Pittsburgh, PA
Postdoctoral Scholar University of Pittsburgh Medical Center PI: Mary L. Phillips, MD, MD (CANTAB)	2016-2019 Pittsburgh, PA
Postdoctoral Fellow China Medical University PI: Fei Wang, MD, PhD	2016 Shenyang, China
Research Assistant Yale University School of Medicine PI: Hilary P. Blumberg, MD	2007-2010 New Haven, CT
<u>EDUCATION</u> PhD, Neuroscience Vanderbilt University	2010-2015 Nashville, TN
Graduate Certificate Medicine, Health and Society Vanderbilt University	2015 Nashville, TN

2005-2007 Amherst, MA

RESEARCH **CITATION METRICS (03/23):** H-Index: 25

Citations: 2087

RESEARCH INTERESTS:

social and affective neuroscience, visual processing, anxiety disorders, multimodal MRI, neuromodulation

i10 Index: 34

AWARDED GRANTS:

BA, Cognitive Science

Hampshire College

American Foundation for Suicide Prevention Award

2022

Title: Real-time study of psychotherapy, suicide risk, and resilience in transgender and nonbinary adults PI: Sarah Victor Co-I: E. Kale Edmiston Award amount: \$90,000.00 K01 MH117290 Mentored Scientist Career Development Award 2019-2024 Title: Feed forward visual system function in high trait anxiety PI: E. Kale Edmiston Award amount: \$868,978.00 Brain and Behavior Research Foundation Early Career Award 2019-2021 Title: Neuromodulation of visual cortex BOLD in high trait anxiety PI: E. Kale Edmiston Award amount: \$69,401.00 2019 The Opportunity Fund Title: Trans Buddy PGH: Peer healthcare support program PI: Gerald Montano Co-I: E. Kale Edmiston Award amount: \$15,000 Center for Interventional Psychiatry 2018 Title: Neuromodulation of visual cortex and threat sensitivity in high anxiety PI: E. Kale Edmiston Award amount: \$9,900.00 Campaign for Southern Equality 2017 Title: The Trans Buddy Program: Mental health advocacy for trans communities PI: E. Kale Edmiston Award amount: \$1,000.00 University of Pittsburgh Office of Diversity and Inclusion Mini-Grant 2017 Title: Developing health promotion materials for the transgender community PI: E. Kale Edmiston Award amount: \$1,000.00 2017 Trans Justice Funding Project Title: The Trans Buddy Program: Peer advocacy solutions for mental health care access PI: E. Kale Edmiston Award amount: \$2,500.00 The Pollination Project 2016 Title: The Trans Buddy Program: An innovative solution to transgender mental health disparity PI: E. Kale Edmiston Award Amount: \$1,500.00 2006

Culture, Brain, and Development Grant

Title: *Brain sex differences in mood disorders* PI: **E. Kale Edmiston** Award amount: \$3,000.00

PEER-REVIEWED PUBLICATIONS (<u>https://orcid.org/0000-0002-3548-6026</u>): 2023:

48. Hoelscher EC, Victor SE, **Edmiston EK**. Gender minority resilience and suicidal ideation: a longitudinal and daily examination of transgender and non-binary adults. Behavior Therapist. (In Press).

47. Schroth-Erickson L, Levin R, Mak K, **Edmiston EK**. A review of the neurobiobehavioral literature of transgender identity. J Gay and Lesbian Mental Health. (In Press). **2022:**

46. Coleman E, Radix AE, Bouman WP...**Edmiston EK**...Arcelus J. Standards of care for the health of transgender and gender diverse people, version 8. International Journal of Transgender Health. 2022; 23:1-258.

45. Juster RP, **Edmiston EK**. Refining research and representation of sexual and gender diversity in neuroscience. Biological Psychiatry: CNNI. 2022; 7(21):1251-7.

44. Colic L, Clark A, Sankar A, Rathi D, Goldman D, Kim JA, Villa LM, **Edmiston EK**, Lippard ETC, Mazure CM, Blumberg HP. Gender-related associations among childhood maltreatment on brain circuitry and clinical features of bipolar disorder. European Neuropsychopharmacology. 2022; 63:35-46.

43. **Edmiston EK**, Fournier JC, Chase HW, Aslam H, Lockovich J, Graur S, Bebko G, Bertocci M, Rozovsky R, Mak K, Forbes EE, Stiffler R, Phillips ML. Left ventrolateral prefrontal cortical activity during reward expectancy predicts mania risk up to one year post scan. J Affective Disorders. 2022; 319:325-8.

2021:

42. Bertocci MA, Chase HW, Graur S, Stiffler R, **Edmiston EK**, Coffman B, Greenberg T, Phillips ML. Reward circuitry-targeted cathodal transcranial direct current stimulation impacts reward circuitry and affect in bipolar disorder. Molecular Psychiatry. 2021; 26(8):4137-45. **2020:**

41. Feng R, Womer FY, **Edmiston EK**, Chen Y, Wang Y, Chang M, Yin Z, Wei Y, Duan J, Ren S, Li C, Liu Z, Jiang X, Wei S, Li S, Zhang X, Nuo X, Tang Y, Wang F. Antipsychotic effects on cortical morphology in schizophrenia and bipolar disorders. Frontiers Neuroscience. 2020; 14:579139.

40. Wang L, Zhao Y, **Edmiston EK**, Womer FY, Zhang R, Zhao P, Jiang X, Wu F, Kong L, Zhou Y, Tang Y, Wei S, Wang F. Structural and functional abnormalities of amygdala and prefrontal cortex in major depressive disorder with suicide attempts. Frontiers Psychiatry. 2020; 10:923.

39. Wang Y, Wei Y, **Edmiston EK**, Womer FY, Zhang X, Duan J, Zhu Y, Zhang R, Zhang Y, Jiang X, Wei S, Liu Z, Zhang Y, Tang Y, Wang F. Altered structural connectivity and cytokines levels in schizophrenia and genetically high-risk individuals: associations with disease state and vulnerability. Schizophrenia Research. 2020; 223:158-165.

38. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam HA, Lockovich JC, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Assessing relationships

among impulsive sensation-seeking, reward circuitry activity, and risk for psychopathology: an fMRI replication and extension study. Biological Psychiatry: CNNI. 2020; 5(7):660-68.

37. Sha Z, Versace A, **Edmiston EK**, Fournier JC, Graur S, Greenberg T, Lima Santos JP, Chase HW, Stiffler R, Bonar L, Hudak R, Yendiki A, Greenberg BD, Rasmussen S, Liu H, Quirk G, Haber S, Phillips ML. Functional disruption in prefrontal-striatal network in obsessive compulsive disorder. Psychiatry Research: Neuroimaging. 2020; 300:111081.

36. **Edmiston EK,** Song Y, Chang M, Yin Z, Zhou Q, Zhou Y, Jiang X, Wei S, Xu K, Tang Y, Wang F. Hippocampal functional connectivity in patients with schizophrenia and unaffected family members. Frontiers in Psychiatry. 2020; 11:278.

35. Wei S, Womer F, **Edmiston EK**, Zhang R, Jiang X, Wu F, Kong L, Zhou Y, Tang Y. Structural alterations associated with suicide attempts in major depressive disorder and bipolar disorder: a diffusion tensor imaging study. Progress in Neuropsychopharmacology & Biological Psychiatry. 2020; 98.

34. Beach L, Eckstrand K, Ehrenfeld J, **Edmiston EK**, Ding J. A model for improving transgender healthcare quality. The Joint Commission Journal on Quality and Patient Safety. 2020; 46:37-43.

2019:

33. Sha Z*, **Edmiston EK***, Versace A, Fournier JC, Graur S, Greenberg T, Lima Santos JP, Chase HW, Stiffler RS, Bonar L, Hudak R, Yendiki A, Greenberg BD, Rasmussen S, Liu H, Buckner R, Quick G, Haber S, Phillips ML. Multimodal disruption of cerbello-thalamo-motor circuit in obsessive compulsive disorder. Biological Psychiatry: CNNI. 2019; 5(4):438-47. *co-first authors

32. Wang L, Zhao Y, **Edmiston EK**, Womer FY, Zhang R, Zhao P, Jiang X, Wu F, Kong L, Zhou Y, Tang Y, Wei S. Structural and functional abnormalities of amygdala and prefrontal cortex in major depressive disorder with suicide attempts. Frontiers Psychiatry. 2019; 10:923.

 Chang M, Edmiston EK, Womer F, Zhou Q, Shengnan W, Jiang X, Zhou Y, Ye Y, Huang H, Zui X, Xu K, Tang Y, Wang F. Spontaneous low-frequency fluctuations in the neural system for emotional perception in major psychiatric disorders: amplitude similarities and differences across frequency bands. Journal of Psychiatry and Neuroscience. 2019; 44:132-41.
Xia M, Womer FY, Chang M, Zhu Y, Edmiston EK, Jiang X, Wei S, Duan J, Xu K, Tang Y, He Y, Wang F. Shared and distinct functional architecture of brain networks across psychiatric disorders. Schizophr Bulletin. 2019; 47:450-63.

2018:

28. Li J, **Edmiston EK**, Tang Y, Fan G, Xu K, Wang F, Xu J. Shared facial emotion processing in medication-naive major depressive disorder and healthy individuals: detection by sICA. BMC Psychiatry, 2018; 18:96.

27. Chang M, Womer FY, **Edmiston EK**, Bai C, Zhou Q, Jiang X, Wei S, Wei Y, Ye Y, Huang H, He Y, Xu K, Tang Y, Wang F. Neurobiological commonalities among three major psychiatric diagnostic categories: a structural MRI study. Schizophrenia Bulletin. 2018; 44:65-74.

2017:

26. Wang N, **Edmiston EK**, Luo X, Yang H, Chang M, Wang F, Fan G. Comparing amplitude of low-frequency fluctuations in multiple system atrophy and idiopathic Parkinson's disease. Psychiatry Research Neuroimaging, 2017; 269:73-81.

25. Jiang X, **Edmiston EK**, Zhou Q, Xu K, Zhou Y, Wu F, Kong L, Wei S, Zhou Y, Chang M, Geng H, Wang D, Wang Y, Cui W, Tang Y, Wang F. Alteration of a cortico-striatal-limbic neural system in major depressive disorder and bipolar disorder. Journal of Affective Disorders, 2017; 221:297-303.

24. Corbett BA, Blain S, **Edmiston EK**. The role of context in psychosocial stress among adolescents with Autism Spectrum Disorder: piloting a semi-structured, video game-based paradigm. Journal of Intellectual & Developmental Disability. 2017; 43:20-8.

23. **Edmiston EK**, Muscatello RA, Corbett BA. Altered pre-ejection period response to social evaluative threat in adolescents with autism spectrum disorder. Research in Autism Spectrum Disorders. 2017; 36:57-65.

2016:

22. **Edmiston EK**, Donald CA, Sattler AR, Peebles JK, Ehrenfeld JM, Eckstrand KL. Opportunities and gaps in transgender primary healthcare: a systematic review. Transgender Health. 2016; 1(1):216-30.

21. **Edmiston EK**, Jones RM, Corbett BA. Physiological response to social evaluative threat in adolescents with autism spectrum disorder. Journal of Autism Developmental Disorders. 2016; 46(9):2992-3005.

20. **Edmiston EK**, Blain S, Corbett BA. Salivary cortisol and behavioral response to social evaluative threat in adolescents with autism spectrum disorder. Autism Research. 2016; Epub ahead of print.

2015:

19. Tang Y, Chen K, Zhou Y, Wang Y, Driesen N, **Edmiston EK**, Chen X, Jiang X, Kong L, Zhou Q, Li H, Wu F, Xu K, Wang Z, Tang Y, Wang F. Neural activity changes in unaffected children of patients with schizophrenia: a resting-state fMRI study. Schizophrenia Research. 2015; 168(1-2):360-5.

18. **Edmiston EK**, Merkle K, Corbett BA. Neural and cortisol responses during play with human and computer partners in children with autism. Social Cognitive Affective Neuroscience. 2015; 10(8):1074-83.

2014:

17. Corbett BA, Newsom C, Key AP, Qualls L, **Edmiston EK**. Examining the relationship between face processing and social interaction behavior in children with and without autism spectrum disorder. J Neurodevelopmental Disorders, 2014; 6(1):35.

16. Li J*, **Edmiston EK**,* Chen B, Tang Y, Ouyang X, Jiang Y, Fan G, Ren L, Liu J, Zhou Y, Jiang W, Liu Z, Xu K, Wang F. A comparative diffusion tensor imaging study of corpus callosum subregion integrity in bipolar disorder and schizophrenia. Psychiatry Res. 2014; 221(1):58-62.*co-first authors

2013:

15. **Edmiston EK***, McHugo M*, Dukic MS, Smith SD, Abou-Khalil B, Zald DH. Enhanced visual cortical activation for emotional stimuli is preserved in patients with unilateral amygdala resection. J Neuroscience, 2013; 33(27):11023-11031. *co-first authors

14. Liu H, **Edmiston EK**, Fan G, Ku X, Zhao B, Shang X, Wang F. Altered resting-state functional connectivity of the dentate nucleus in Parkinson's disease. Psychiatry Research: Neuroimaging. 2013; 211(1):64-71.

13. **Edmiston EK**, Blackford JU. Childhood maltreatment and response to novel face stimuli presented during functional magnetic resonance imaging in adults. Psychiatry Research: Neuroimaging. 2013; 212(1):36-42.

2012:

12. Fengrong O, Kai L, Qian G, Dan L, Jinghai L, Liwen H, Xian W, **Edmiston EK**; Yang L. An urban neo-poverty population-based quality of life and related social characteristics investigation from northeast china. PLoS One. 2012; 7(6):e38861.

11. Chepenik LG, Wang F, Spencer L, Spann MN, Kalmar JH, Womer F, **Edmiston EK**, Pittman B, Blumberg HP. Structure-function associations in hippocampus in bipolar disorder. Biological Psychiatry. 2012; 90(1):18-22.

2011:

10. Wang F, Kalmar JH, Womer FY, **Edmiston EK**, Chepenik LG, Chen R, Spencer L, Blumberg HP. Olfactocentric paralimbic cortex morphology in adolescents with bipolar disorder. Brain. 2011; 134(7):2005-12.

9. **Edmiston E**, Wang F, Mazure CM, Sinha R, Mayes LC, Blumberg HP. Cortico-striatal limbic gray matter morphology in adolescents reporting exposure to childhood maltreatment. Archives of Pediatric and Adolescent Med. 2011; 165(12):1069-77.

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2009:

7. Womer FY, Wang F, Chepenik LG, Kalmar JH, Spencer L, **Edmiston E**, Constable RT, Papademetris X, Blumberg HP. Sexually dimorphic features of vermis morphology in bipolar disorder. Bipolar Disord 2009; 11(7):753-8.

6. Jiang Y, **Edmiston E**, Wang F, Blumberg HP, Papademetris X, Staib, LH. Improving the reliability of shape comparison by perturbation. IEEE Biomedical Imaging 2009; 1:686-9.

5. Jiang Y, **Edmiston E**, Wang F, Blumberg HP, Staib LH and Papademetris X. Shape comparison using perturbing shape registration. IEEE Computer Vision Pattern Recognition 2009;683-90.

4. Wang F, Kalmar JH, He Y, Jackowski M, Chepenik LG, **Edmiston E**, Tie K, Gong G, Shah MP, Jones M, Uderman J, Constable RT, Blumberg HP. Functional and structural connectivity between the perigenual anterior cingulate and amygdala in bipolar disorder. Biological Psychiatry 2009; 66(5):516-21.

3. Kalmar JH, Wang F, Spencer L, **Edmiston E**, Lacadie CM, Martin A, Constable RT, Duncan JS, Staib LH, Papademetris X, Blumberg HP. Preliminary evidence for progressive prefrontal abnormalities in adolescents and young adults with bipolar disorder. J Int Neuropsychol Soc. 2009; 15(3):476-81.

2008:

2. Blumberg HP, Wang F, Chepenik LG, Kalmar JH, **Edmiston E**, Duman RS, Gelernter J. Influence of vascular endothelial growth factor variation on human hippocampus morphology. Biological Psychiatry 2008; 64(10):901-3.

1. Wang F, Kalmar JH, **Edmiston E**, Chepenik LG, Bhagwagar Z, Spencer L, Pittman B, Jackowski M, Papademetris X, Constable RT, Blumberg HP. Abnormal corpus callosum

integrity in bipolar disorder: A diffusion tensor imaging study. Biological Psychiatry 2008; 64(8):730-3.

MANUSCRIPTS (IN PROGRESS):

Ravindranath O, Perica MI, Parr AC, Pjha A, McKeon SD, Montano G, Ullendorf N, Luna B, **Edmiston EK**. Adolescent neurocognitive development and decision-making regarding gender affirming care. (Submitted).

Soehner AM, **Edmiston EK**, Wallace M, Chase HW, Lockovich J, Aslam H, Stiffler R, Graur S, Skeba A, Bebko G, Benjamin OE, Wang Y, Phillips ML. Neurobehavioral reward and sleepcircadian phenotypes predict present and next-year mania/hypomania risk. (Submitted).

Sequiera S, Tervo-Clemmens B, Carmel T, **Edmiston EK.** Towards a biopsychosocial model for neurodevelopment in transgender and gender diverse adolescents: understanding risk and resilience for mood disorders. (Submitted).

POSTERS, ABSTRACTS, AND CONFERENCE PROCEEDINGS:

53. Victor SE, **Edmiston EK**. Ecological momentary assessment of gender-relevant versus other interpersonal stressors predicting self-injurious thoughts and behaviors among transgender and non-binary adults. *Association for Behavioral and Cognitive Therapy Annual Convention. Submitted.*

52. **Edmiston EK**, Fournier JC, Chase HW, Phillips ML. Ventral visual stream functional coupling during implicit emotional face perception is associated with internalizing symptoms: a double dissociation by face valence at baseline and six months post-scan. *American College of Neuropsychopharmacology.* 2023.

51. Victor SE, Hoelscher E, Sandel D, Trieu T, **Edmiston EK.** Interpersonal and intrapersonal gender minority stressors as contribution to suicidal ideation among transgender and non-binary adults. *Suicide Research Symposium.* 2022.

50. Aslam MA, Mak K, **Edmiston EK.** Piloting transcranial direct current stimulation to reduce threat sensitivity in high trait anxiety. *University of Pittsburgh Department of Psychology Undergraduate Directed Experiences in Research Poster Day.* 2022.

49. **Edmiston EK** & Strakowski S. Understanding diagnosis and assessment disparities in transgender populations. *Society of Biological Psychiatry Annual Meeting.* 2022. Discussant, Lunchtime "Fireside Chat" Series.

48. Bertocci M, Afriyie-Agyemang Y, Rosovsky R, Aslam H, Graur S, **Edmiston EK**, Chase HW, Bebko G, Stiffler R, Phillips ML. Network interference during emotion regulation in distressed adults consistently predicts depression symptoms. *Society of Biological Psychiatry Annual Meeting.* 2022.

47. Afriyie-Agyemang Y, Bertocci M, Rozovsky R, Aslam H, Graur S, **Edmiston EK**, Chase HW, Bebko G, Stiffler R, Phillips ML. Overcompensation of the central executive network during working memory may be a neural marker for youth at risk for bipolar disorder. *Society of Biological Psychiatry Annual Meeting*. 2022.

46. Schumer MC, Bertocci MA, Bebko G, Stiffler RS, Lockovich JC, Aslam HA, Graur S, **Edmiston EK**, Chase HW, Johnson SL, Phillips ML. Trait urgency mediates associations between neural emotion-processing markers of emotion-triggered impulsivity and mania in young adults at-risk for bipolar disorder. *Society of Biological Psychiatry Annual Meeting*. 2022.

45. Young J, Roepke T, Anacker C, Ehrensaft D, **Edmiston EK**, Guthman EM, Eshel N, Marrocco J. Challenges and opportunities for translational research and clinical strategies within the LGBTQIA2S+ community. *American College of Neuropsychopharmacology Annual Meeting.* 2021. Discussant, Study Group.

44. Phillips ML, Bertocci M, Chase HW, Graur S, Stiffler R, **Edmiston EK**, Coffman BA. Targeted non-invasive neuromodulation impacts reward expectancy-related reward circuitry activity and affect in bipolar disorder and healthy adults. *Society of Biological Psychiatry Annual Meeting.* 2021.

43. **Edmiston EK,** Fournier JC, Rozovsky R, Chase HW, Bertocci MA, Aslam HA, Lockovich J, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Left ventrolateral prefrontal cortex structure and reward-expectancy related activity predict manic symptom changes one year later. *American College of Neuropsychopharmacology Annual Meeting.* 2021.

42. **Edmiston EK**, Phillips ML, Mak K, Chase HW, Fournier JC. Visual cortex coupling and childhood maltreatment: associations with major depression and a compensatory mechanism. *Society of Biological Psychiatry Annual Meeting.* 2021.

41. Marrocco J, **Edmiston EK**, Anacker C, Bangasser D. The study of sex differences and gender bias, and trans inclusive research practices. *American College of Neuropsychopharmacology Annual Meeting.* 2020. Panelist, Networking Session.

40. Chase HW, Fournier JC, Bertocci MA, **Edmiston EK**, Lockovich JC, Aslam H, Stiffler RS, Graur S, Bebko G, Phillips ML. Decision-making variability in mood disorders: new insights for a replication attempt. *Society of Biological Psychiatry Annual Meeting.* 2020 (Submitted, meeting canceled due to COVID-19).

39. **Edmiston EK**, Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. A double dissociation between anxiety and depression symptom improvement and fusiform coupling and positive and negative emotional face processing. *Society of Biological Psychiatry Annual Meeting.* 2020 (Submitted, meeting canceled due to COVID-19).

38. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam HA, Lockovich JC, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Assessing relationships among impulsive sensation-seeking, reward circuitry activity, and predisposition to bipolar disorder: an fMRI replication and extension study. *American College of Neuropsychopharmacology Annual Meeting. 2019.*

37. Paglisotti T, Montano G, Simpson A, **Edmiston EK**. Preliminary implementation of Trans Buddy PGH: establishing trust among transgender patients and healthcare providers. *University of Pittsburgh Medical Center Department of Psychiatry 19th Annual Research Day.* 2019. 36. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Phillips ML. Left ventrolateral prefrontal cortical BOLD signal during reward expectancy and impulsive sensation seeking: a replication study. *University of Pittsburgh Medical Center Department of Psychiatry 19th Annual Research Day. 2019.*

35. Chase HW, **Edmiston EK**, Bertocci M, Fournier JC, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Forbes EE, Phillips ML. Similar neural representation of appetitive and loss avoidance prediction errors across distressed and healthy individuals. *Society of Biological Psychiatry Annual Meeting.* 2019.

34. **Edmiston EK**, Simpson A. Progress report: Quality improvement programming for transgender mental health. Symposium. *TransPride PGH Professional Conference*. 2018.

33. Schroth-Erickson L, Levin R, **Edmiston EK**. Talking to your patients about the biological basis of transgender identity. *Philadelphia Trans Wellness Conference Professional Track. 2018*.

32. **Edmiston EK**, Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Fusiform gyrus-salience network coupling during emotion processing predicts anxiety and depression symptom change. *University of Pittsburgh Medical Center Department of Psychiatry 18th Annual Research Day.* 2018.

31. **Edmiston EK**, Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Salience network BOLD response to emotional faces predicts anxiety and depression symptom outcomes. *Society of Biological Psychiatry Annual Meeting.* 2018.

30. Chase HW, Qiu H, Kerestes R, Shah N, Alkhar H, **Edmiston EK**, Soehner A, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Pan L, Eickhoff SB, Phillips ML. Implication of the visual cortex in resting state fMRI studies of mood and anxiety disorders may relate to the propensity for within-scanner sleep. *Society of Biological Psychiatry Annual Meeting.* 2018.

29. Ding J, Ehrenfeld J, Raynor L, **Edmiston EK**, Eckstrand K, Beach L. A proposed systems level quality improvement model for transgender healthcare delivery. *The National Transgender Health Summit.* 2017.

28. **Edmiston EK.** Setting the agenda for transgender neuroimaging: a critical review and future directions. Symposium. *The National Transgender Health Summit.* 2017.

27. **Edmiston EK,** Fournier J, Greenberg T, Bertocci M, Stiffler R, Aslam H, Lockovich J, Phillips ML. Trait anxiety predicts visual system response to emotional faces. *Developmental Affective Neuroscience Symposium*. 2017.

26. **Edmiston EK.** The Trans Buddy Program: an innovative intervention for increasing health care utilization. Symposium. *TransPride PGH Professional Conference*. 2017.

25. Buchanan K, Richmond M, Sattler AR, **Edmiston EK**. Red state solutions for transgender health care access: provision in low resource areas. Symposium. *Philadelphia Transgender Health Conference*. 2017.

24. **Edmiston EK**, Chase H, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Predicting quality of life in distressed youth: Cortico-thalamic BOLD signal and reward processing. *University of Pittsburgh Medical Center Department of Psychiatry 17th Annual Research Day.* 2017.

23. **Edmiston EK**, Chase H, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Cortico-thalamic BOLD signal during reward processing predicts quality of life at follow up in distressed young adults. *Society of Biological Psychiatry Annual Meeting.* 2017.

22. Eckstrand KL, Mitchell L, **Edmiston EK.** The Trans Buddy Program: Transgender Leadership and peer advocacy for reducing health disparities. *University of Pittsburgh Health Sciences Health Disparity Poster Competition.* 2017.

21. **Edmiston EK.** Reframing the search for transgender neuroimaging biomarkers. *New Materialisms Annual Meeting* Warsaw, Poland. 2016.

20. Corbett BA, Muscatello R, **Edmiston EK**, Muse I. Examining the Diurnal Profile of Children and Adolescents with Autism Spectrum Disorder (ASD) and Typical Development between 8 to 17 years of age. *International Society for Psychoneuroendocrinology.* 2016.

19. Corbett BA, Muse I, **Edmiston EK**, Muscatello R. Diurnal and Stress Hormonal Profiles of Testosterone and Cortisol in Adolescents with Autism Spectrum Disorder (ASD) and Typical Development (TD). *International Society for Psychoneuroendocrinology.* 2016.

18. **Edmiston EK**. Psychophysiological characterization of adolescents with Autism Spectrum Disorder. Presentation, *Chinese Psychiatric Association Annual Meeting.* 2016.

17. **Edmiston EK**, Jones RM, Blain S, Corbett BA. Neuroendocrine and physiological responsivity during social stress in adolescents with and without autism spectrum disorder. *Vanderbilt Kennedy Center Science Day.* 2015.

16. **Edmiston EK**, Valencia B, Corbett BA. Autonomic nervous system function in response to social judgment in adolescents with and without autism spectrum disorder. *International Meeting for Autism Research.* 2015.

15. Corbett BA, Newsom C, Key S, Qualls L, **Edmiston EK**. A randomized wait-list control trial of a peer-mediated, theatre-based intervention to improve social ability in children with autism spectrum disorder. *International Meeting for Autism Research*. 2015.

14. Singer B, Eckstrand K, Ehrenfeld J, **Edmiston EK**. Transgender health and advocacy in academic medicine: an empowerment model. Workshop; *Gay and Lesbian Medical Association Annual Meeting.* 2014.

13. **Edmiston EK**, Corbett BA. Behavioral and endocrine alterations in adolescents with autism spectrum disorder. Selected presentation; *Vanderbilt Kennedy Center Science Day*. 2014.

12. **Edmiston EK.** Effects of a neurobiological explanation of sexual orientation on student attitudes towards lesbian, gay and transgender people. *Society for Neuroscience*. 2013.

11. Corbett BA, **Edmiston EK**, Zald DH. Neural and physiological responses during play with human and computer partners in children with autism. *Society for Neuroscience*. 2013.

10. **Edmiston EK**, McHugo M, Dukic MS, Eggers E, Zald DH. Visuocortical BOLD response to emotional stimuli in the absence of a functional amygdala. *Society for Neuroscience*. 2012.

9. **Edmiston EK.** Pelvic and chest exams in transgender men. Workshop; *Philadelphia Trans Health.* 2011.

8. **Edmiston EK**, Blackford JU. Childhood maltreatment affects face processing. *Biology of Prosocial Behavior.* 2011.

7. **Edmiston E,** Wang F, Mazure CM, Sinha R, Mayes LC, Blumberg HP. Cortico-striatal limbic gray matter morphology in adolescents reporting exposure to childhood maltreatment. *Vanderbilt Kennedy Center Science Day.* 2011.

6. Wang F, **Edmiston E**, Hur E, Kalmar JH, Womer FY, Chepenik LG, Blumberg HP. An Altered Developmental Trajectory of Frontotemporal Connectivity in Bipolar Disorder. *Biological Psychiatry* 2010; 67 (Supplement 9): 107.

5. Wang F, Chepenik LG, Shah MP, Kalmar JH, **Edmiston E**, Spencer L, Duman R, Gelernter J, Blumberg HP. Genes Regulating Neurotrophic Factors that Influence the Corticolimbic Connectivity in Mood Disorders: Treatment Implications. *Biological Psychiatry* 2009; 65 (Supplement 1): 174.

4. Kalmar JH, Wang F, Chepenik LG, Shah MP, McDonough A, **Edmiston E**, Blumberg HP. Amygdala functioning during emotional processing in adolescents with bipolar disorder or ADHD. *Biological Psychiatry* 2008; 63 (Supplement 1): 184.

3. Womer F, Wang F, Chepenik LG, Kalmar JH, **Edmiston E**, Spencer L, Constable RT, Papademetris X, Blumberg HP. Structural abnormalities of the cerebellar vermis in bipolar disorder. *Biological Psychiatry* 2008; 63 (Supplement 1): 141.

2. Wang F, Kalmar JK, Womer F, He Y, Chepenik L, **Edmiston E**, Blumberg HP. Abnormal morphological correlations within a cortico-limbic neural system in adolescents with bipolar disorder. *American Academy of Childhood and Adolescent Psychiatry.*

1. Wang F, Kalmar JH, **Edmiston E**, Chepenik LG, Tie K, Spencer L, Jackowski M, Papademetris X, Constable RT & Blumberg HP. Abnormal callosal integrity in bipolar disorder determined from diffusion tensor imaging. *Biological Psychiatry* 2008; 63 (Supplement 1): 43.

BOOK CHAPTERS:

Edmiston EK, Bertocci M, Phillips ML. Neuroimaging and Circuit Mechanisms of Bipolar Disorder. In *Neurobiology of Mental Illness*. 6th Ed. Eds: Eric Nestler & Alexander Charney. Oxford University Press. (In Press).

Tomson A & **Edmiston EK**. Understanding the basis of gender identity development: biological and psychosocial models. In *Trans Bodies, Trans Selves*. 2nd Ed. Ed: Sand Chang. Oxford University Press. 2022.

Edmiston EK. Community-led peer advocacy for transgender health care access in the southeastern United States: The Trans Buddy Program. In *Healthcare in Motion: Mobility forms in health service delivery and accessibility.* Berghahn Books. 2017.

Robles RJ & Edmiston EK. Community Responses to Trauma. In *Trauma, Resilience, and Health Promotion for LGBT Patients.* Springer Press. 2017.

Edmiston EK & Mitchell L. Trans Buddy: Innovation Profile. In *The Remedy: Queer and Trans Voices on Health and Health Care.** Arsenal Press. 2016. *Lambda Literary Award Winner, Non-Fiction Anthology

Eckstrand KL, **Edmiston EK**, Potter J. Obstetric and Gynecologic Care to LGBT Individuals. In *Lesbian, Gay, Bisexual, Transgender, and Intersex Healthcare: A Clinical Guide to Preventative, Primary, and Specialist Care*. Springer Press. 2015.

ADDITIONAL SCHOLARSHIP:

Edmiston EK. Letter to the Editor: The legacy of transgender surgery access is complex. *Annals of Plastic Surgery.* 2019.

Edmiston EK. Invited Commentary: Transgender health research must serve transgender people. *BJOG.* 2018.

Edmiston EK. Feminist bioethics and intersex medical interventions: A review of *Making Sense* of Intersex. Catalyst: Feminism, Theory, Technoscience. 2016; 2(1).

Jann JT, **Edmiston EK**, Ehrenfeld J. Letter to the Editor: Important considerations for addressing LGBT health care competency. *American J of Public Health* 2015; e1.

HONORS, AWARDS, AND FELLOWSHIPS:

American College of Neuropsychopharmacology Travel Award	2021
Society of Biological Psychiatry Early Career Investigator Travel Award	2019
NYC tDCS Fellowship City University of New York, New York, NY	2018
Trainee, T32 MH018951 Child and Adolescent Mental Health Research University of Plttsburgh, Pittsburgh, PA	2018-2019
Research Day Department of Psychiatry Outstanding Poster Award	2018
PLOS One Travel Award	2017
Fellow, Winter School in the Neuroscience of Consciousness Canadian Institute For Advanced Research	2017
Trainee, T32 MH16804 Transformative Discovery in Psychiatry	2016-2018

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University of Pittsburgh, Pittsburgh, PA

2015
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2014-2015 tudents
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2003-2005

TEACHING AND MENTORSHIP

SELECTED TALKS:	
Invited Speaker: <i>Neuroscience in Service of Our Community:</i> <i>How Research Rooted in Empathy and Humility Makes Us Better Scientis</i> Neuroscience Diversity Seminar University of Maryland School of Medicine	2023 ts
Invited Speaker: <i>Visual Cortex Distinguishes Anxiety and Depression</i> Fournier Group Lab Meeting The Ohio State Medical School	2023
Presenter: Assessing Visual Perception in Depression and Anxiety Department of Psychiatry Faculty Meeting UMass Chan Medical School	2023
Invited Speaker: <i>Neuroimaging Studies of Transgender People</i> The Friedman Brain Institute and oSTEM The Icahn School of Medicine at Mount Sinai	2022
Invited Speaker: <i>Impulsivity and Reward-related Activity:</i> A Stable Marker for Bipolar Disorder risk STEP Seminar Truman State University	2022

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Invited Speaker: Assessing Relationships Among impulsivity, Reward Circuitry, and Risk for Psychopathology Magnetic Resonance Research Center Forum Yale School of Medicine	2019
Presenter: Fusiform Gyrus Alterations During Emotion Processing: Predicting the Future in Anxiety Disorders Center for the Neural Basis of Cognition Seminar University of Pittsburgh and Carnegie Mellon University	2018
Panelist: <i>Setting the Research Agenda in Transgender Health</i> 27 th Annual Issues in Medical Ethics Conference The Icahn School of Medicine at Mount Sinai	2017
Panelist: <i>Neuroimaging in Child and Adolescent Mental Disorders</i> Chinese Society of Psychiatry 14 th Annual Meeting	2016
<i>The Trans Buddy Program: An Innovative Model for Healthcare Access</i> Medicine Health and Society Colloquium Series Vanderbilt University	2015
Panel Organizer: <i>Intra-community Stigma in LGBT Populations</i> 615Thrive Conference Tennessee Department of Health	2015
<i>Transgender Health: Provider Considerations</i> Department of Hearing and Speech Sciences Grand Rounds Vanderbilt University	2014
<i>Sexual and Reproductive Health in LGBT Populations</i> Sarah Fogel, PhD Department of Nurse Midwifery Vanderbilt University School of Nursing	2014, 2015
Panelist: <i>(Im)Possible Politics: Intersectional Trans Organizing</i> Ben Singer, PhD; Dean Spade, JD; Lisa Guenther PhD Department of Women and Gender Studies Vanderbilt University	2014
Plenary Speaker: <i>Creating Change for LGBTI Health</i> Gay and Lesbian Medical Association Annual Meeting	2013
Invited Speaker: <i>Threat Detection, Visual Cortex, and Anxiety</i> Department of Radiology Beijing Normal University	2013
Invited Speaker: <i>Threat Detection, Visual Cortex, and Anxiety</i> Department of Psychiatry China Medical University	2013

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MEDICAL STUDENT TEACHING EXPERIENCE:

Guest Lecturer: <i>Neuromodulatory Interventions in Mood Disorders</i> Neuroscience Area of Concentration Seminar Series University of Pittsburgh School of Medicine	2022
Guest Lecturer: <i>Building Trust with your Transgender Patients</i> Texas Christian University School of Medicine	2021,2022
Instructor of Record: <i>Introduction to Scientific Writing</i> China Medical University	2016
Guest Lecturer: <i>Clinical and Biobehavioral Features of Autism</i> Clinical Medicine 400 China Medical University	2016
Guest Lecturer: <i>Building an Inclusive Practice for LGB and T Patients</i> First Year Seminar Meharry Medical College	2015
Guest Lecturer: <i>Community Models for Improving Trans Healthcare</i> Intercession Course Meharry Medical College	2015
Guest Lecturer: <i>Providing Excellent Care for LGBT People</i> Capstone Series Meharry Medical College	2015
GRADUATE AND UNDERGRADUATE TEACHING EXPERIENCE: Guest Lecturer: <i>Neuromodulation interventions for threat sensitivity</i> Biomedical Sciences First Year Seminar Graduate School of Biomedical Sciences UMass Chan Medical School	2022
Guest Lecturer: <i>Impulsivity and reward-related activity: Predicting mania</i> Undergraduate Research Methods Department of Psychology University of California San Diego	2021
Guest Lecturer: <i>Transgender people and neuroimaging: a critical review</i> Department of Psychology Mount Holyoke College	2021
Instructor of Record: PSY0205 Psychopathology Department of Psychology University of Pittsburgh	2021
Guest Lecturer: <i>Transgender People and Healthcare Systems</i> MHS 2110: American Medicine and the World	2015

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Laura Stark, PhD, Vanderbilt University

Guest Lecturer: <i>Transgender People and Healthcare Systems</i> MHS 3890: Documenting the Body Odie Lindsey, PhD, Vanderbilt University	2015
Guest Lecturer: <i>Introduction to Social Neuroscience</i> PSY3609: Educational Cognitive Neuroscience Sasha Key, PhD, Vanderbilt University	2014
Guest Lecturer: <i>Imagining Transgender Bodies in Healthcare</i> WGS 290: Theories of the Body Aimi Hamraie, PhD, Vanderbilt University	2013
<i>Introduction to Cognitive Neuroscience</i> Vanderbilt Neuroscience Graduate Program Boot Camp	2013-2014
The Center for Teaching, Vanderbilt University Scholarship of Teaching and Learning Certificate	2013
Teaching Assistant: NSC201 Introduction to Neuroscience Department of Neuroscience, Vanderbilt University	2011
TRAINEE MENTORSHIP, CERTIFICATION, AND SUPERVISION: Culturally Aware Mentorship Workshop University of Wisconsin Madison School of Medicine	2022
Tiffany Nhan (post bac lab assistant)	2022-present
M. Ali Aslam (undergraduate lab assistant)	2022
Paloma Rueda (undergraduate lab assistant)	2020-2021
Shelby Gardner (undergraduate lab assistant)	2020
Kristie Mak (undergraduate lab assistant)	2019-2020
Taylor Pagliosotti, BA (graduate student, Department of Public Health)	2018-2019
Zhiqiang Sha, PhD (post doc, Mood and Brain Laboratory, PI: Phillips)	2019
Alicyn Simpson, BA (research assistant, Adolescent Medicine)	2018-2019
Hana Choi, BA (intern, The Trans Buddy Program)	2016
William Horn, BA (intern, The Trans Buddy Program)	2015
RJ Robles, BA (student worker, Program for LGBTI Health)	2015-2016
Keanan Gottlieb, BA (summer intern, The Trans Buddy Program)	2014
Cameron Donald, BA (summer intern, Program for LGBTI Health)	2014

E. KALE EDMISTON Case 4:22-cv-00325-RH-MAF Document 120-27 Filed 04/07/23 Page 40 of 48

Jamieson Jann, BA (summer intern, Program for LGBTI Health)	2014
SERVICE CURRENT MEMBERSHIPS: Society of Biological Psychiatry	
DEPARTMENTAL, INSTITUTIONAL, AND DISCIPLINARY SERVICE: Editorial Board, <i>Journal of Mood and Anxiety Disorders</i>	2023-present
Member, Grand Rounds Committee Department of Psychiatry, UMass Chan Medical School	2023-present
Interviewer, Graduate School of Biomedical Sciences UMass Chan Medical School	2023-present
Co-Director, NeuroNexus Institute UMass Chan Medical School	2022-present
Co-chair, Diversity, Equity and Inclusion Committee Society of Biological Psychiatry	2021-present
Member, LGBTQIA+ Task Force American College of Neuropsychopharmacology	2021-present
Editorial Board, Bulletin of Applied Transgender Studies	2021-present
Grant Reviewer, Lesbian Health Fund, GLMA	2021
Member, Diversity, Equity, and Inclusion Committee Department of Psychiatry University of Pittsburgh School of Medicine	2019-2021
Chapter Author, Assessment of Adults with Gender Dysphoria WPATH Standards of Care 8 Committee	2018-2022
Member, Diversity and Inclusion Committee Society of Biological Psychiatry	2018-2021
<i>Ad Hoc</i> Member, Diversity and Inclusion Task Force American College of Neuropsychopharmacology	2020-2021
Member, Cross-Network Transgender Working Group, NIH Office of HIV/AIDS Network Coordination	2017-2019
Co-Founder, Trans Buddy Pittsburgh	2016-2018
Student Representative, Vanderbilt Brain Institute Diversity Committee	2015-2016
Founding Director, The Trans Buddy Program Nashville	2014-2016
Co-Director, Vanderbilt School of Medicine Program for LGBTI Health	2014-2015
Assoc. Director, Vanderbilt School of Medicine Program for LGBTI Health	n 2013-2014

Associate Editor, Vanderbilt Reviews Neuroscience	2013-2014
President, Vanderbilt Neuroscience Student Organization	2013-2014
Member, Vanderbilt Neuroscience Organization Academic Committee	2012-2013
Board Member, Vanderbilt School of Medicine Program for LGBTI Health	2012-2013
Affiliate, Vanderbilt Kennedy Center	2011-2016

AD HOC PEER REVIEW:

Acta Psychologica; American Journal of Psychiatry; American Journal of Sexuality Education; Annals of Internal Medicine; Biological Psychiatry: Cognitive Neuroscience Neuroimaging; BJOG: An International Journal of Obstetrics and Gynaecology; Bipolar Disorder; Brain and Behavior; Child Abuse & Neglect; Development and Psychopathology; Developmental Cognitive Neuroscience; Frontiers in Neuroscience; Frontiers in Sociology; Human Brain Mapping; Journal of Affective Disorders; Journal of Autism and Developmental Disorders; Journal of Homosexuality; Journal of Medical Systems; Journal of Neuroscience Research; Journal of Psychiatry, Depression, and Anxiety; LGBT Health; Molecular Autism; NeuroImage; Neuropsychologia; Neuropsychopharmacology; Neuroscience Letters; Psychiatry Research: Neuroimaging; PLOS One; Psychological Medicine; Psychology of Violence; Psychoneuroendocrinology; Scientific Reports; Schizophrenia Research; Transgender Health

REFERENCES

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Jay C. Fournier, PhD, Associate Professor, Department of Psychiatry & Behavioral Health, The Ohio State University. email: jay.fournier@osumc.edu

Hilary P. Blumberg, MD, John and Hope Furth Professor of Psychiatric Neuroscience, Professor Departments of Psychiatry and Radiology and Biomedical Imaging, Yale School of Medicine. email: hilary.blumberg@yale.edu

<u>Exhibit B</u> *Bibliography*

EXPERT REBUTTAL REPORT OF E. KALE EDMISTON, Ph.D. Case No. 4:22-cv-00325-RH-MAF

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

AUGUST DEKKER, et al.,

Plaintiffs,

v.

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

JASON WEIDA, et al.,

Defendants.

EXPERT REBUTTAL REPORT OF ARON JANSSEN, M.D.

I, Aron Janssen, M.D., hereby declare and state as follows:

1. I am over 18 years of age, of sound mind, and in all respects competent to testify.

2. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation. The opinions expressed herein are my own and do not express the views or opinions of my employer.

3. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

BACKGROUND AND QUALIFICATIONS

A. Qualifications

4. I am the Vice Chair of the Pritzker Department of Psychiatry and Behavioral Health at the Ann and Robert H. Lurie Children's Hospital of Chicago ("Children's Hospital"), where I also serve as Clinical Associate Professor of Child and Adolescent Psychiatry. I maintain a clinical practice in Illinois where I treat patients from Illinois and the surrounding states.

5. I received my medical degree from the University of Colorado School of Medicine and completed by residency in psychiatry and fellowship in child and adolescent psychiatry at New York University Langone Medical Center.

6. In 2011, I founded the Gender and Sexuality Service at New York University, for which I served as Clinical Director. I also previously served as Co-Director of the New York University Pediatric Consultation Liaison Service for the New York University Department of Child and Adolescent Psychiatry.

7. I am board certified in Child and Adolescent Psychiatry and Adult Psychiatry.

8. I have been treating children and adolescents with gender dysphoria for over 12 years. I have seen and treated over 500 children and adolescents with gender dysphoria during my medical career. Currently, approximately 90 percent of the patients in my clinical practice are transgender children and adolescents.

9. As part of my practice, I stay current on medical research and literature relating to the care of transgender persons and patients with gender dysphoria. I am an Associate Editor of the peer-reviewed publication *Transgender Health* and a

reviewer for LGBT Health and Journal of the American Academy of Child and Adolescent Psychiatry, both of which are peer-reviewed journals.

10. I am the author or co-author of 16 articles on care for transgender patients and am the co-editor of *Affirmative Mental Health Care for Transgender and Gender Diverse Youth: A Clinical Casebook* (Springer Publishing, 2018), which is the first published clinical casebook on the mental health treatment for children and adolescents with gender dysphoria. I have also authored or co-authored numerous book chapters on treatment for transgender adults and youth.

11. I have been a member of the World Professional Association for Transgender Health ("WPATH") since 2011. I was actively involved in the revision of WPATH's *Standards of Care for the Health of Transgender and Gender Diverse People* ("Standards of Care"), serving as a member of revision committees for both the child and adult mental health chapters of version 8 of WPATH's Standards of Care (SOC 8), published in 2022.

12. In addition to the above, I am involved in training other medical and mental health providers in the treatment of children and adolescents with gender dysphoria. I have conducted trainings for over 1,000 medical and mental health providers and have given dozens of public addresses, seminars, and lectures on the treatment of gender dysphoria in children and adolescents.

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13. I am also involved in a number of international, national, and regional committees that contribute to the scholarship and provision of care to transgender people. I am the Chair of the American Academy of Child and Adolescent Psychiatry's Sexual Orientation and Gender Identity Committee. I serve as a member of the Transgender Health Committee for the Association of Gay and Lesbian Psychiatrists. I was the Founder of the Gender Variant Youth and Family Network.

14. Further information about my professional background and experience is outlined in my curriculum vitae, a true and accurate copy of which is attached as **Exhibit A** to this report.

B. Prior Testimony

15. Within the last four years, I testified as an expert at trial or by deposition in: *B.P.J. v. W. Va. Bd. of Educ.*, Case No. 2:21-cv-00316 (S.D. W.Va.); and *L.E. v. Lee*, Case No. 3:21-CV-00835 (M.D. Tenn.).

C. Compensation

16.I am being compensated for my work on this matter at a rate of \$400 per hour for preparation of this report and for time spent preparing for and giving local deposition or trial testimony. In addition, I would be compensated \$2,500 per day for deposition or trial testimony requiring travel and \$300 per hour for time spent
travelling, plus reasonable expenses. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

D. Bases for Opinions

17. In preparing this report, I reviewed: the Complaint in this case; Florida Administrative Code 59G-1.050(7) (the "Challenged Exclusion"); the document titled "Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria," published by the Florida Agency for Health Care Administration in June 2022, and its attachments; the expert reports of Drs. Armand Antommaria, Dan Karasic, Johanna Olson-Kennedy, Loren Schechter, Daniel Shumer, and Kellan Baker, submitted by plaintiffs; and the expert reports Drs. Michael Biggs, G. Kevin Donovan, Paul Hruz, Kristopher Kaliebe Michael Laidlaw, Patrick Lappert, Stephen Levine, Sophie Scott, and Joseph Zanga, submitted by defendants.

18. My opinions are based on: (1) my clinical experience as a psychiatrist treating patients with gender dysphoria, including transgender children, adolescents, and adults; (2) my knowledge of the peer-reviewed research, including my own, regarding the treatment of gender dysphoria, which reflects advancements in the field of transgender health; my knowledge of the clinical practice guidelines for the treatment of gender dysphoria, including my work as a contributing author of WPATH SOC 8; and (4) my review of any of the materials cited herein.

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19. I have also reviewed the materials listed in the bibliography attached asExhibit B. I may rely on those documents as additional support for my opinions.

20. In addition, I have relied on my years of research and clinical experience in child, adolescent, and adult psychiatry, as well as my professional knowledge, as set out in **Exhibit A** and the materials listed therein.

21. 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 the subject. I may wish to supplement these opinions or the bases for them as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

22. I have not met or spoken with the Plaintiffs in this case.

SUMMARY OF OPINIONS

23. As with all of medicine, transgender medicine is a continuously evolving field. But this does not make medical treatment for gender dysphoria experimental or investigational. To the contrary, such treatment is well-established and large body of evidence (more so than exists for other non-experimental medical interventions) documents that safety and efficacy of these medical interventions.

24. Transgender people have always existed and the provision of medical care to address transgender people's gender incongruence/gender dysphoria goes back decades. In fact, the field of transgender medicine was built to increase

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oversight around patient care, and often requires consent processes that go above and beyond what is expected for other medical decisions.

25. There is robust evidence demonstrating the value of social, medical and surgical interventions for children, adolescents, and adults when in the context of an appropriate psychosocial evaluation. And to be clear, no medical or surgical interventions are recommended or provided to anyone until after the onset of puberty, meaning such care is only available to adolescents and adults.

26. The Defendants and their designated experts spent much time arguing about hypothetical concerns, for which there is no proof, and the limitations of particular studies. But Defendants and their designated experts completely ignore that the evidence-base for the safety and efficacy for gender-affirming care is not based on any one particular study. Rather, as is the norm in all of science and medicine, we look at the entire body of research surrounding gender-affirming care. When one does so, the conclusion that gender-affirming medical care for the treatment of gender dysphoria in transgender adolescents and adults is safe and effective becomes inescapable. Decades on clinical experience further support this conclusion.

27. Defendants and their designated experts further ignore the robust evidence for the potential harm faced by transgender individuals when barred access to medically necessary gender-affirming care.

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28. Defendants and their designated experts also ignore every transgender adult was once a child. The Defendants' designated experts focus on children and adolescents, but the Challenged Exclusion bans coverage for all care for an already vulnerable population, including adults. None of them explain why this case is experimental for transgender adults.

29. While there can be debate about the techniques and modalities of care to support transgender youth, it is important to keep in mind that the opposite of substandard care is excellent care, not no care. To be clear, however, genderaffirming care is safe and effective, it is not substandard or experimental.

30. Understanding patients' experience of distress around gender is a vital component of being an expert in this field. Without understanding the distress transgender patients face – as well as the joy and resilience they experience when they get the care they need – one is only spouting unmoored and unfounded opinions. Medicine and science demand more than just personal opinions, it demands study and experience in the field. For the most part, Defendants' designated experts lack both.

EXPERT OPINIONS

A. Defendants' experts lack the experience and/or training to opine on the diagnosis, assessment, and treatment of gender dysphoria of transgender children and adolescents.

<u>Dr. Levine</u>

31. Because Dr. Levine does not appear to be board certified in child and adolescent psychiatry, he lacks the related experience and training in specific developmental considerations for children and adolescents that is critical for working with transgender youth and their families.

32. Moreover, Dr. Levine repeatedly acknowledges in his report that he has no firsthand knowledge of how gender-affirming mental health care is actually provided to children and adolescents. His descriptions are based on second-hand conversations and often sensationalized media reports. (*See, e.g.*, Levine Report, at ¶49 (offering opinions based on anecdotal reports from the internet)). He speaks in his report with authority on developmental and family factors that shape identity development in youth despite lacking the requisite training and experience and even ascribes reasons for why boys and girls may pursue social transition despite no clinical experience in the relevant population.

<u>Dr. Kaliebe</u>

33. Similarly, Dr. Kaliebe is not qualified to opine as an expert on the care of transgender children and adolescents. There is a difference between having an

interest in a topic and having expertise in a clinical or research domain. Dr. Kaliebe's report of the number of transgender patients he has seen is consistent with what many of our child psychiatry trainees are exposed to in their residency, and is not consistent with the volume of patients necessary to demonstrate expertise on the clinical nuance of the field. In addition to a lack of clinical expertise, Dr. Kaliebe's report calls into question his expertise in research methods or ethics. As an example, throughout his report Dr. Kaliebe makes claims about the quality of the evidence for gender affirming care while describing unscientific survey questions asked outside of the IRB process as having the same weight as data published in a peer-reviewed journal. Furthermore, nowhere in his CV does it describe a history of expertise in evolutionary biology or early human behavior, but this doesn't stop him from making unsubstantiated and uncited assertions about adaptive behaviors in "ancient evolutionary environments."

Defendants' other experts

34. Expertise in mental health care requires specialized training and ongoing work in the field with appropriate certification and licensure. To my knowledge, and based on a review of their respective CV's, Drs. Hruz, Laidlaw, Lappert, Biggs, Donovan, and Zanga have neither had the training nor the certification and licensure to weigh in as experts on the appropriateness of a mental health assessment or treatment plan. This lack of expertise, however, has not stopped them from making broad generalizations about mental health care that bear little resemblance to the care as typically delivered. As such, their characterizations of the practice of mental health care should be seen as a lay opinion based on secondhand knowledge at best. Furthermore, expertise in the treatment of transgender individuals requires experience in the care of transgender individuals, a characteristic in short supply with the aforementioned experts.

B. Gender Identity

35. At birth, infants are assigned a sex, either male or female, based on the appearance of their external genitalia. For most people, their sex assigned at birth, or assigned sex, matches that person's gender identity. For transgender people, their assigned sex does not align with their gender identity.

36. Gender identity is a person's core sense of belonging to a particular gender, such as male or female.

37. Gender identity is one of a person's multiple sex-related characteristics, which also include, among others, internal reproductive organs, external genitalia, chromosomes, hormones, and secondary sex characteristics.

38. In their reports, Defendants' designated experts state repeatedly that sex is binary and conditions of sexual differentiation are not a "third sex." This simplistic view, however, ignores that there is great variance among the multiple sex-related characteristics that a person possesses, including gender identity, and that such variance is a natural phenomenon with biological underpinnings. While conditions of sexual differentiation (i.e., intersex conditions) are not a "third sex," they are indicative of the natural variance regarding certain sex-related characteristics. These are rare conditions with an estimated aggregate incidence of 0.1- 0.5% of live births (Arboleda, et al., 2013). What is more, many people cannot make either eggs or sperm, yet are recognized as female or male based on other sex-related characteristics.

39. Every person has a gender identity and it is not a personal decision, preference, or belief. A transgender boy cannot simply turn off his gender identity like a switch, any more than a nontransgender boy or anyone else could.

40. Living in a manner consistent with one's gender identity is critical to the health and wellbeing of any person, including transgender people.

41. The lack of evidence demonstrating that gender identity can be altered, either for transgender or for nontransgender individuals, further underscores the innate nature and immutability of gender identity. Past attempts to "cure" transgender individuals by using talk therapy, and even aversive therapy, to change their gender identity to match their birth-assigned sex were ineffective and caused extreme psychological damage.

42. A recent study found that experiencing those conversion efforts was associated with greater odds of attempting suicide, especially for those had those

experiences in childhood (Turban, et al., 2020b). That conclusion is further supported by the extensive evidence that rejection of a young person's gender identity from family and peers are the strongest predictors for adverse mental health outcomes. Every leading medical and mental health organization has issued clear statements that those practices are discredited, harmful, and ineffective, including the American Medical Association (2022), the American Psychiatric Association (2018), the American Academy of Child & Adolescent Psychiatry (2018), the American Psychological Association (2021), and the American Academy of Pediatrics (Rafferty, et al., 2018), among others.

43. Dr. Levine notes in his report "it is widely agreed that the therapist should not directly challenge a claimed transgender identity in a child." (Levine Report, at ¶50). This characterization mischaracterizes gender affirming therapy and calls into question his understanding of conversion efforts in the context of prepubertal youth. Within the model of gender affirming care, challenging assumptions based on stereotypes of gender and encouraging a child to build nuance around identity is inherent to the process of care. However, what Dr. Levine seems to be arguing for is not to encourage a psychotherapeutic process that helps a child come to a clear and nuanced sense of self, whatever the gender identity may be, but instead recommending a psychotherapeutic intervention that privileges a non-transgender identity as inherently preferred. While Dr. Levine focuses much of his report on children who desist during puberty, inherent in the literature on desistance includes the substantial portion of prepubertal youth who persist in a transgender identity through puberty and into adulthood. By foreclosing the possibility of a healthy transgender identity and instead encouraging these transgender youth who will persist into transgender adults to strive towards a cisgender outcome, as Defendants and their experts argue, one is, by definition, practicing conversion therapy.

44. There is no one way by which people experience their gender identity development from early questioning to consolidation and affirmation. Though it is common for transgender youth to come out at puberty, for other transgender persons this is not true, and it may take them longer to come to recognize and acknowledge their gender identity. For the latter group, this is not due to some "late onset" of dysphoric feelings or sudden understanding themselves as transgender, it is the result of a long and difficult process toward accepting and understanding themselves in a social context where being transgender is still a difficult reality due to external stigma, fears of family and social rejection, and even internalized transphobia (Pullen Sansfaçon, et al., 2020).

45. Dr. Levine, Dr. Kaliebe, and Defendants' other designated experts devote a great deal of space to discussing a theory that an increasing number of people who are assigned female at birth are suddenly identifying as males in mid-to-late adolescence as a result of peer pressure and social contagion. (*See, e.g.*, Levine

Report, at ¶¶ 38, 96; Kaliebe Report, at ¶¶30-31, 40-43; Laidlaw Report, at ¶29; Hruz Report, at ¶¶ 117, 131). The theory that some adolescents experience "rapidonset gender dysphoria" as a result of social influences is based almost exclusively on one highly controversial study (Littman, 2018). Although purporting to provide a basis for Dr. Levine's speculations, the study was based on an anonymous survey, allegedly of parents, about the etiology of their child's gender dysphoria. Participants were recruited from websites promoting this social contagion theory, and the children were not surveyed or assessed by a clinician. Those serious methodological flaws render the study meaningless. The only conclusion that can be drawn from that study is that a self-selected sample of anonymous people recruited through websites that predisposed participants to believe transgender identity can be influenced by social factors do, in fact, believe those social factors influence children to identify as transgender.¹

46. Dr. Kaliebe seems to argue that the fact that transgender adolescents find other transgender adolescents online is proof of a "social contagion." He cites to no scientific study to support this speculation, other than Littman study discussed above. But Dr. Kaliebe ignores that online spaces often provide a safe place for transgender youth to come out and be themselves, allowing them to explore their

¹ Aside from these serious methodological flaws, Littman's hypothesis of "rapid onset gender dysphoria" focuses specifically on gender dysphoria in boys who are transgender and were assigned a female sex at birth.

identity. This is no different from a host of other affinity-type groupings one can find on social media. Just like many other minoritized youth, adolescents often search out groups that share core characteristics. Dr. Kaliebe's assertion that social media is a leading cause of the increased prevalence of transgender identifying youth is not demonstrated in the extant literature, and it is also beside the point. Part of an assessment of gender dysphoria includes an inquiry into the social context of the patient – this includes online spaces and potential positive and negative reinforcing factors, including social group status online. This also includes assessing for the concerns Dr. Kaliebe describes that assigned females at birth often face at puberty.

47. Notwithstanding the above, Dr. Kaliebe goes on to assert that "psychiatrists believe social media has significantly contributed to the rise in gender dysphoria." In support thereof, Dr. Kaliebe references conversations as his evidence and further asserts that "most child psychiatrists admit to me they will not speak publicly on this subject due to how sensitive the topic is." But such anecdotal evidence is not the type of evidence one would look to in answering scientific question nor whether a particular form of care is experimental or investigative. (Kaliebe Report, at ¶41). Dr. Kaliebe then cites not one but two unscientific polls of attendees to a particular session at a conference as support for the bold assertion that such data "confirm[] that the vast majority of a group of child and adolescent psychiatrists acknowledge social contagion is a major contributor to the rise in

gender dysphoria." But this is not how scientific study is conducted in medicine. There is no plausible basis for Dr. Kaliebe to extrapolate the poll results of an unscientific survey of attendees to a panel as proof that a "majority of a group of child and adolescent psychiatrists acknowledge social contagion is a major contributor to the rise in gender dysphoria." To the contrary, what Dr. Kaliebe is doing can hardly be considered science and illustrates how D. Kaliebe does not understand what selection bias is nor what a study is.

C. Gender Dysphoria and Its Diagnostic Criteria

48. The term "gender dysphoria" is the distress related to the incongruence between one's gender identity and one's sex assigned at birth.

49. Gender dysphoria is the clinical diagnosis for the significant distress that results from the incongruity between one's gender identity and sex assigned at birth. It is a serious medical condition, and it is codified in the American Psychiatric Association's in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision* (DSM-5-TR) (DSM-5 released in 2013 and DSM-5-TR released in 2022).

50. The DSM-5 defines gender dysphoria as a: "marked difference between the individual's expressed/experienced gender and the gender others would assign him or her, and it must continue for at least six months. In children, the desire to be of the other gender must be present and verbalized. This condition causes clinically significant distress or impairment in social, occupational, or other important areas of functioning."

51. The DSM-5 also states that: "gender dysphoria is manifested in a variety of ways, including strong desires to be treated as the other gender or to be rid of one's sex characteristics, or a strong conviction that one has feelings and reactions typical of the other gender."

52. "Gender Dysphoria in Children" is a diagnosis applied only to prepubertal children in the DSM-5. The DSM-5 has a separate diagnosis of "Gender Dysphoria in Adolescents and Adults." The diagnostic criteria for these diagnoses are distinct. Understanding that children have less capacity to articulate abstract concepts about the sense of self as well as a reflection of what can be a lack of specificity of gender nonconforming behaviors in childhood, there are more nuanced criteria to make the diagnosis for children. Furthermore, prepubertal youth are not eligible for medical or surgical intervention while the diagnosis of gender dysphoria in adolescents/adults is required for medical and/or surgical treatments,

53. Simply being transgender or gender diverse is not a medical condition or pathology to be treated. As the DSM-5 recognizes, diagnosis and treatment are "focus[ed] on dysphoria as the clinical problem, not identity per se." (DSM-5, at 451). The DSM-5 unequivocally repudiated the outdated view that being transgender is a pathology by revising the diagnostic criteria (and name) of gender

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dysphoria to recognize the clinical distress as the focus of the treatment, not the patient's transgender status.

54. When untreated, gender dysphoria can cause significant distress including increased risk of depression, anxiety, and suicidality. This is noted both in adolescents and adults. However, these risks decline when transgender individuals are supported and live according to their gender identity. Not only is this documented in scientific literature and published data, but I witness this each time I see my patients being supported by their community, family, school, and medical providers.

D. The Guidelines for the Treatment of Gender Dysphoria Are Evidence-Based.

55. The World Professional Association of Transgender Health (WPATH) has issued Standards of Care for the Health of Transgender and Gender Diverse People ("WPATH Standards of Care") since 1979. The current version is SOC 8, published in 2022. The WPATH Standards of Care provide guidelines for multidisciplinary care of transgender individuals, including children and adolescents, and describes criteria for medical interventions to treat gender dysphoria, including hormone treatment and surgery when medically indicated, for adolescents and adults.

56. The SOC 8 is based upon a rigorous and methodological evidencebased approach. (Coleman, et al., 2022). Its recommendations are evidence-based, informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options, as well as expert consensus via a Delphi procedure. The process for development of SOC 8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization. Its recommendations were graded using a modified GRADE methodology (Guyatt, et al., 2011), considering the available evidence supporting interventions, risks and harms, and feasibility and acceptability.

57. A clinical practice guideline from the Endocrine Society (the Endocrine Society Guidelines) provides similar protocols for the medically necessary treatment of gender dysphoria. (Hembree, et al., 2017).

58. Each of these guidelines are evidence-based and supported by scientific research and literature, as well as extensive clinical experience.

59. Each of these guidelines also provides distinct guidance for ageappropriate care for children, adolescents, and adults with gender dysphoria. And none of these guidelines recommend medical treatment for prepubertal children, meaning no medical treatment is recommended until after the onset of puberty.

60. The protocols and policies set forth by the WPATH Standards of Care and the Endocrine Society Guidelines are endorsed and cited as authoritative by the major professional medical and mental health associations in the United States, including the American Medical Association, the American Academy of Pediatrics,

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the American Psychiatric Association, the American Psychological Association, the American College of Obstetrics and Gynecology, the American College of Physicians, and the World Medical Association, among others.

E. Assessment and Treatment of Gender Dysphoria in Children

61. Defendants' experts spend substantial portions of their expert reports to criticizing gender-affirming care for prepubertal transgender children. For example, according to Dr. Levine, studies have indicated that gender dysphoria in prepubertal gender diverse children may desist by the time the children reach puberty, and thus medical professionals should adopt a "watchful waiting" approach and avoid affirming a prepubertal child's gender identity.

62. However, with regards to prepubertal gender diverse children, the Standards of Care state that prepubertal gender diverse children "are not eligible to access medical intervention," and therefore focuses on developmentally appropriate psychosocial practices. However, this case concerns coverage of medical treatment, namely, puberty delaying medications, hormones, and surgery, and none of those treatments are recommended for transgender youth until *after* the onset of puberty (i.e., until adolescence), and even then it is only a subset of those, when it is medically necessary, age appropriate, and the legal caregivers consent.

63. As such, many of Dr. Levine's and Defendants' other designated experts' litany of criticisms is largely irrelevant to the population of people affected

by the Challenged Exclusion. For example, a significant number of Dr. Levine's and Defendants' other designated experts' arguments relate to prepubertal children who "desist" from expressing a transgender identity once they reach puberty. While the statements being made about this population are erroneous, they are also largely irrelevant.

64. That said, to avoid any confusion, I address some of Dr. Levine's and Defendants' other designated experts' arguments pertaining to transgender youth prepubertal here.

65. As with all health care, treatment of prepubertal gender diverse children is individualized based on the needs of the child and the family and other psychosocial considerations and is decided upon only after a discussion of possible benefits and risks (Hidalgo, et al., 2013). As part of those discussions, the child and their family are advised that prepubertal gender diverse children do not always go on to identify as transgender when they reach adolescence, and that children are encouraged to continue developing an understanding of their gender identity without expectation of a specific outcome even after social transition takes place (American Psychological Association, 2015; Edwards-Leeper and Spack, 2012).

66. The term "gender diverse" includes transgender children as well as children who will ultimately not identify as transgender later in life (Coleman, et al., 2022).

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67. Dr. Levine and Defendants' other designated experts present a caricatured description of prevailing standards of care that reflects a profound misunderstanding of the subject with respect to prepubertal gender diverse children. Mental health providers cannot change a prepubertal child's gender identity or prevent them from being transgender, just as mental health providers cannot change a cisgender child's gender identity. Furthermore, it is far from the standard of care for clinicians to blindly support a child's potential social transition without careful assessment and a thorough discussion of the risks, benefits and alternatives of this intervention.

68. Prepubertal children who "desist" are children with nonconforming gender expression who realize with the onset of puberty that their gender identity is consistent with their sex assigned at birth. Their understanding of their gender identity changes with the onset of puberty, but their gender identity does not. We cannot definitively determine which prepubertal children will go on to identify as transgender when they reach adolescence, but we know that children with gender dysphoria who persist into puberty are more likely to have expressed a consistent, persistent, and insistent understanding of their gender identity from a young age (Steensma, et al., 2013).

69. The focus of gender-affirming care and SOC 8 is thus in supporting the overall health and wellbeing of the child. In this manner, the primary goal of

gender-affirming care is to help a child understand their own gender identity and build resilience and mental wellness in a child and family, without privileging any one outcome over another.

70. Important considerations in deciding whether social transition is in a child's best interest include: whether there is a consistent, stable articulation of a gender different from the child's sex assigned at birth, which should be distinguished from merely dressing or acting in a gender non-conforming manner; whether the child is expressing a strong desire or need to transition; the degree of distress the child is experiencing as a result of the gender dysphoria; and whether the child will be emotionally and physically safe during and following transition (Coleman, et al., 2022; American Psychological Association, 2015).

71. A treatment plan is informed by a psychosocial assessment, which may vary greatly depending on the patient's presentation and the complexity of the issues the patient is navigating. Further, in conducting that assessment, the mental health provider is drawing from their professional training and experience in working with transgender young people, exercising professional judgment, and tailoring the assessment to each individual patient.

72. There is also no requirement that prepubertal children who socially transition receive mental health therapy. Many prepubertal children who express a gender identity different from their sex assigned at birth do not experience any co-

occurring conditions or other psychological distress requiring treatment (Coleman, et al., 2022; de Vries, et al., 2011a). Mental health therapy may be useful for some prepubertal children but is not necessary or appropriate for everyone. Forcing children to undergo therapy when it is not medically indicated is both harmful and unethical.

73. What makes gender-affirming care "gender affirming" is that it does not presume that being transgender is incompatible with a young person's short- and long-term health and wellbeing. It is also important to note that clinicians utilizing gender affirming care do not assume that all children asserting a gender identity incongruent with their sex assigned at birth are inherently transgender. A clinician doing a careful assessment and recommending a child not socially transition or an adolescent not pursue medical care is fully aligned with this treatment paradigm.

74. Dr. Levine and Defendants' additional designated experts seem to think social transition is a single decision that irrevocably alters a child's trajectory over time. This belief belies their lack of clinical experience in working with gender diverse pre-pubertal youth. Clinically, social transition is often a series of steps taken gradually with feedback from the child, the family, and the clinician elicited over time. It is false that allowing prepubertal transgender children to socially transition puts these children on a path to becoming transgender adolescents and adults. Rather, the evidence shows that the same prepubertal children who are likely to have a stable transgender identity into adolescence are the children who are most likely to articulate a strong and consistent need to socially transition (Steensma, et al., 2013). For example, a recent study found that a group of transgender children who transitioned before puberty and a group of transgender children who waited to transition until after puberty both showed the same intensity of cross-gender identification. In other words, socially transitioning before puberty did not increase children's cross-gender identification, and deferring transition did not decrease cross-gender identification (Rae, et al., 2019).

75. Intense cross-gender identification and a strong, persistent desire to transition is simply an indicator that a child is more likely to be transgender and not merely gender nonconforming.

F. Assessment and Treatment of Gender Dysphoria in Adolescents

76. WPATH SOC 8 recommends that health care professionals working with transgender and nonbinary adolescents be licensed, hold a postgraduate degree in relevant clinical field, have received training and developed expertise in working with children and adolescents, and have received training and developed expertise in gender identity and diversity in youth and in the ability of youth to assent/consent to care (Coleman, et al., 2022).

77. The Standards of Care also recommend a "comprehensive biopsychosocial assessment" for adolescents "prior to any medically necessary

medical or surgical intervention" for gender dysphoria. The assessment should include gender identity development, social development and support, diagnostic assessment of co-occurring mental health or developmental concerns, and capacity for decision-making (Coleman, et al., 2022). So do the Endocrine Society Guidelines (Hembree, et al., 2017).

78. Defendants' experts point to the rates of co-occurring psychiatric diagnoses among youth presenting with gender identity concerns. But not only are some of these co-occurring diagnoses, like anxiety and depression, often associated with dysphoria, but because youth experiencing gender identity concerns present for care before mental health providers more often, it is easier to diagnose other co-occurring diagnoses that would otherwise often go undiagnosed. In any event, it is precisely because of these co-occurring mental health diagnoses that specialized training is required to do a comprehensive biopsychosocial assessment that takes into account the possibility of diagnoses that may lead a child to experience confusion around gender identity that is inconsistent with a diagnosis of gender dysphoria. However, once properly assessed and the other conditions are properly managed, the presence of these diagnoses is not a contraindication to provide medical care to adolescents with gender dysphoria.

79. For transgender adolescents, the onset of puberty is often a painful and sometimes traumatic experience that brings increased dysphoria and the

potential development of a host of comorbidities including depression, anxiety, substance abuse, self-harming behaviors, social isolation, high-risk sexual behaviors, and increased suicidality. It is notable that Dr. Levine acknowledges that many transgender adults have derived significant benefit from gender affirming medical and surgical care but fails to recognize that all transgender adults were once adolescents and that much of the stigma faced by transgender adults that he recognizes as a source of distress and dysfunction would be avoided had they had access to this care during adolescence.

80. Some transgender people who do not come forward until adolescence may have experienced symptoms of gender dysphoria for long periods of time but have been uncomfortable disclosing those feelings to parents. Other transgender people do not experience distress until they experience the physical changes accompanying puberty. In either case, gender-affirming care requires a comprehensive assessment and evidence of persistent, sustained gender dysphoria before medical treatment is recommended.

81. Gender-affirming treatment also requires a careful and thorough assessment of a patient's mental health, including co-occurring conditions, history of trauma, and substance use, among many other factors (Olson-Kennedy, et al., 2019; Edwards-Leeper and Spack, 2012). As a result, I have had patients who presented with some symptoms of gender dysphoria, but who ultimately did not meet the diagnostic criteria for a variety of reasons, and therefore I recommended treatments other than transition to alleviate their psychological distress. I have also seen patients that did meet the diagnostic criteria for gender dysphoria but had mental health impairments that precluded proceeding with gender affirming hormonal and surgical care.

82. Studies on transgender young people have long reported data on cooccurring conditions, including some of my own (e.g., Janssen, et al., 2019; Olson, et al., 2015; Reisner, et al., 2015; Spack, et al., 2012; Mustanski, et al., 2010).

83. The existence—and prevalence—of co-occurring conditions among transgender young people is unsurprising. Transgender young people must cope with many stressors, from the fear of rejection by family and peers to pervasive societal discrimination. Not to mention, their underlying gender dysphoria can cause significant psychological distress which, if left untreated, can result in or exacerbate the co-occurring conditions identified in studies on transgender young people (van der Miesen, et al., 2020; Turban, et al., 2021). And, given that transgender young people typically delay disclosing their transgender status or initially experience family rejection following disclosure, it is not uncommon for transgender young people to engage with psychological or psychiatric care for other reasons prior to being diagnosed with gender dysphoria.

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84. Transgender young people, however, are not outliers in this regard. Research and clinical experience show that most psychiatric conditions are highly correlated with other co-occurring psychiatric conditions. For example, young people with depression are very likely to have at least one other diagnosable condition, most often anxiety (Costello, et al., 2003). Likewise, a study on children diagnosed with Attention-Deficit/Hyperactivity Disorder found between 74-79% participants had additional co-occurring psychiatric conditions (Wilens, et al., 2002).

85. Requiring that a transgender patient resolve all co-occurring conditions, many of which are chronic with no reasonable expectation that they be "resolved," prior to receiving gender-affirming care is not possible, nor is it ethical. No relevant organizations cite the need for co-occurring mental health conditions to be resolved before a patient may receive gender-affirming care. Rather, such conditions should be reasonably well-controlled and not impair the ability of the patient to make an informed decision or interfere with the accuracy of the diagnosis of gender dysphoria. Indeed, some co-occurring conditions (for example, Attention Deficit Hyperactivity Disorder and Autism Spectrum Disorder, to name a few) could be chronic disorders where complete resolution is impossible and the goal of treatment is mitigating harm and improving functioning.

86. WPATH SOC 8 recommends that "mental health professionals address mental health symptoms that interfere with a person's capacity to consent to gender-

affirming treatment before gender-affirming treatment is initiated," but note that "mental health symptoms such as anxiety or depressive symptoms that do not affect the capacity to give consent should not be a barrier for gender-affirming medical treatment, particularly as this treatment has been found to reduce mental health symptomatology" (Coleman, et al., 2022). Indeed, SOC 8's chapter on adolescents specifically notes that "while addressing mental health concerns is important during the course of treatment, it does not mean all mental health challenges can or should be resolved completely" (Coleman, et al., 2022).

87. The Endocrine Society Guidelines similarly provide that because gender dysphoria "may be accompanied with psychological or psychiatric problems," "in cases in which severe psychopathology" "interfere[s] with diagnostic work or make[s] satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues" (Hembree, et al., 2017). The Guidelines thus require that these issues be managed, not resolved.

88. Gender dysphoria, by definition, is accompanied by clinically significant psychological distress. That distress can take on many different forms (e.g., anxiety, mood disorders, and depression) and vary greatly in severity, resulting in co-occurring conditions. Because psychological distress is not easily compartmentalized, the distress associated with gender dysphoria can also amplify co-occurring conditions that developed independently of the gender dysphoria. In either situation, gender dysphoria limits the effectiveness of treatment of any cooccurring mental health conditions. Thus, treating the underlying gender dysphoria is essential to alleviating the psychological distress associated with co-occurring conditions.

G. Efficacy of Gender-Affirming Treatment for Gender Dysphoria in Adolescents

89. "For some youth, obtaining gender-affirming medical care is important while for others these steps might not be necessary." (Coleman, et al., 2022). In my clinical experience, some adolescent patients have a critical need for medical interventions at or at some point after the onset of puberty and others do not. As with all medical interventions, it is highly individualized and responsive to the particular medical and mental health needs of each patient as well as the understanding and preferences of the legal guardians who ultimately make these healthcare decisions.

90. The criticisms of gender-affirming care for adolescents by Dr. Levine and Defendants' other designated experts reflect a distorted interpretation of the relevant scientific literature and what gender-affirming care is. Despite Dr. Levine's and Defendants' other designated experts' suggestion to the contrary, there is no "watchful waiting" approach for transgender adolescents. Even practitioners who oppose social transition in childhood provide gender-affirming care for transgender adolescents, including puberty-delaying medication and gender-affirming hormone treatments for gender dysphoria (Turban, et al., 2018; Ehrensaft, 2017).

91. Dr. Levine and Defendants' other designated experts criticize the methodology of studies supporting gender-affirming care while proposing a "therapy only" treatment without any empirical or scientific support whatsoever. They also fail to understand that not all patients in a gender-affirming model of care will initiate medical or surgical care. The difference is that in the affirming care model, those decisions are made in concert with the young person and their family.

92. Adolescents with gender dysphoria who have entered puberty 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. Puberty-delaying medications allow the adolescent time to better understand their gender identity, while delaying distress from the progression of the development of secondary sex characteristics such as breasts or facial hair.

93. Prior to initiation of puberty-delaying medications, providers counsel patients and their families extensively on potential benefits and risks. The intended benefit of treatment is to reduce the risk of worsening gender dysphoria and mental health deterioration. More specifically, use of puberty-delaying medications in transmasculine adolescents allows for decreased chest development, reducing the need for breast binding and surgical intervention in adulthood. For transfeminine adolescents, puberty-delaying medications limit facial and body hair growth, voice deepening, and masculine bone structure development, which greatly reduce distress both at the time of treatment and later in life and reduce the need for later interventions such as voice therapy, hair removal, and facial feminization surgery. The goal in using puberty-delaying medications is to minimize the patient's dysphoria related to progression of puberty and allow for later initiation of puberty consistent with gender identity. The pubertal stage and individual needs of the patient direct conversations regarding care options.

94. A growing body of evidence, including peer-reviewed cross-sectional and longitudinal studies, demonstrates the positive impact of pubertal suppression in adolescents with gender dysphoria on psychological functioning and quality of life, including a decrease in behavioral and emotional problems, a decrease in depressive symptoms, and improvement in general functioning (e.g., Achille, et al., 2020; Turban, et al., 2020a; van der Miesen, et al., 2020; Costa, et al., 2015; de Vries, et al., 2011b). Furthermore, studies show improvements in body satisfaction with gender-affirming treatment, and the extant literature recognizes that the body satisfaction is a mediator for improved quality of life and mental health outcomes. (Chen, et al., 2023).

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95. In my own practice, I have had patients describe pubertal suppression as life saving and a vast majority have experienced a great deal of relief when the treatment is initiated. In contrast to Dr. Levine's assertion that starting pubertal suppression is a one-way road to hormones, I have also had patients who, through gender affirming psychotherapy, came to understand their gender identity to be congruent with their sex assigned at birth and discontinued this treatment with a resumption of puberty. While each patient and each family is unique, a thorough assessment and a clear discussion of the risks, benefits and alternatives of this interventions is consistent among all of my patients.

96. After ongoing work with mental health professionals and when the adolescent has lived in accordance with their gender identity for a significant period of time, they may start treatment with hormones (testosterone for transgender boys, estrogen and testosterone suppressants for transgender girls), if and when medically indicated.

97. There is no credible basis for Dr. Levine's assertion that an adolescent's decision to begin puberty-blocking medication "act[s] as a psychosocial 'switch,' decisively shifting many children to a persistent transgender identity." (Levine Report, ¶133). Studies showing that a high percentage of transgender adolescents who receive puberty blockers ultimately decide to move forward with gender-affirming hormone therapy more likely reflect the fact that participants were

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rigorously screened and had demonstrated sustained, persistent gender dysphoria before receiving medical treatment.

98. Eligibility and medical necessity are determined case-by-case, based on an assessment of the adolescent's unique cognitive and emotional maturation and ability to provide a knowing and informed assent in addition to the informed consent of the legal medical decision maker, most often the parent or guardian. The decision would be made only after a careful review with the youth and parents/guardians of the potential risks and benefits of hormone therapy.

99. Under SOC 8 and the Endocrine Society Clinical Guidelines, 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, and 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).

100. As with puberty-delaying medications, the risks and benefits of hormone treatment are discussed with the patient and their families, prior to initiation of gender affirming hormone therapy. 101. And, as with the use of puberty-delaying medications, 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).

102. In my own practice, I have seen youth with severe gender dysphoria who avoided all social contacts who were able to thrive with the initiation of gender affirming hormones and feel confident with the changes seen as they developed secondary sex characteristics aligned with their gender identity. I have seen my patients start hormones and find themselves more able to build social and romantic relationships, and begin to address underlying co-occurring psychiatric disorders.

103. For some older transgender adolescents, surgery may be provided prior to age 18 if medically indicated (typically, chest surgery for transgender male adolescents). Peer-reviewed research has also shown improvements in mental health following gender-affirming chest surgery for transgender males with gender dysphoria where medically indicated (Mehringer, et al., 2021; Olson-Kennedy, et al., 2018).

104. As part of the treatment process for gender dysphoria, adolescent patients provide assent to their care, while their parents or guardians provide informed consent. In addition, a treating doctor will not offer gender-affirming medical treatments unless they have concluded after weighing the risks and benefits of care for the specific patient that treatment is appropriate. The risks and benefits of care are discussed with the adolescent patient and their family. This process is no different than the informed consent process for other medical treatments. However, for gender-affirming medical care, there is the additional safeguard of the recommended assessments by a mental health care professional, who must not only be experienced in the assessment of gender dysphoria, but also in the assessment of a patient's capacity to consent/assent to treatment and ability to understand the risks and benefits of treatment. Indeed, SOC 8 notes that mental health professionals are the best positioned practitioners to conduct these assessments for adolescents and also recommends that a mental health professional address any mental health issues that may interfere with a patient's ability to consent prior to the initiation of genderaffirming care.

105. Dr. Levine and Dr Kaliebe fail to discuss many of the studies documenting the benefits of puberty-delaying medication and gender-affirming hormone therapy (Chen, et al., 2023; de Vries, 2023). When viewed as a comprehensive body of research, the weight of the evidence and the experience of

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clinicians as well as from the experience of patients has demonstrated that pubertydelaying medication and hormones have been associated with a variety of mental health benefits across different contexts (Chen, et al., 2023).

106. Dr. Levine and Dr. Kaliebe also criticize the quality of evidence supporting treatment of gender dysphoria. (*See, e.g.*, Levine Report, at ¶136-141; Kaliebe Report, at 45-70). But treatments for gender dysphoria have the same or similar level of evidentiary support as many other well-established treatment protocols in psychiatry—and other disciplines of medicine. The evidentiary basis for those treatment protocols is developed, and regularly updated, using a combination of peer-reviewed research and the extensive clinical experience of providers who regularly treat patients with that condition. Those treatment protocols are considered the standard of care and are safe and effective for the conditions they are intended to treat.

107. Dr. Levine also suggests that the lack of FDA approval of genderaffirming medical treatments for these specific uses indicates that the treatments are not supported by evidence of safety. (*See, e.g.*, Levine Repport, ¶179). But off-label use of medication is common in medicine, especially treatments for children and adolescents. For example, in children, Zoloft is FDA approved to treat Obsessive-Compulsive Disorder, but is also regularly used to treat depression and anxiety, such that the use of Zoloft is considered the standard of care for children who require medication to treat those conditions despite the lack of FDA approval for those indications.

108. In their reports, Dr. Levine and Dr. Kaliebe present a distorted picture of the gender affirming model of care where they imply that gender-affirming care requires the unquestioned and automatic affirmation of an adolescent's desires. But gender-affirming medical care such as GAH is only provided to an adolescent after working with the adolescent and their parents/guardians, who are the ones who provide the informed consent. Indeed, in my practice, I have had patients with unrealistic expectations of the impact of testosterone or estrogen including on a belief that initiation of gender affirming medical care would eradicate any cooccurring psychiatric disorders despite many of these being chronic and predating any symptoms of gender dysphoria. But in accordance with SOC 8 and Endocrine Society Guidelines, the gender-affirming model of care requires that these patients be provided with additional psychotherapy and psychoeducation to determine the appropriateness of moving forward, and for some of these youth a delay in initiation of hormones, or even potentially a recommendation to not pursue hormones, is aligned with the gender affirming model of care.
H. Assessment and Treatment of Gender Dysphoria in Adults

109. In the DSM-5, the diagnostic criteria for Gender Dysphoria are shared by adolescents and adults. The assessment and treatment of a gender dysphoric adolescent is very similar to the assessment of the gender dysphoric adult.

110. As with any condition that typically presents with symptoms in childhood or adolescence, collateral information from caregivers, partners, employers, etc. is often useful in informing the initial diagnostic assessment. For children and adolescents, the legal structures of consent and assent as well as best practice and ethics of care require parental involvement in ongoing mental health care, and standard practice is to gather history of the child from the parent and guardian. For adults, the individual patient can make decisions about whom they want involved in their care. That said, the assessment process of gathering a detailed history and developing a biopsychosocial assessment takes the same factors into account as one does with adolescents. And similar to adolescents, the risks, benefits and alternatives to social transition, hormonal care and surgical options are weighed in collaboration with the patient prior to making any recommendations. The evidence supporting this process of assessment and care is documented in the plaintiffs' experts' reports.

111. Despite that the Challenged Exclusion impacts the ability of both adolescent and adult Medicaid beneficiaries to get coverage, and therefore get access, to medical treatment for gender dysphoria, neither Drs. Levine nor Kaliebe address the impact of losing access to medical care for transgender adults in the state of Florida. This same flaw characterizes all of the defendants' designated experts' reports, as well as the GAPMS Memo itself.

112. Their reports focus primarily on pre-pubertal youth, which are not subject to this ban, and seek to call into question practices in assessing and treating transgender adolescents. This report seeks to rebut their mischaracterization of the current standard of care for transgender adolescents as well as the mischaracterization of the current standard of care for transgender adults. However, neither expert in their report sought to undermine the evidence base for the treatment of transgender adults and Dr. Levine even acknowledges the benefit of hormonal and surgical care for some adults.

I. Additional Responses to Defendants' Designated Experts

113. In his report, Dr. Kaliebe states that the Chen et al. study did not address the suicides in the study population and that "the most research shows a much higher than expected rate of suicide in the condition of affirmative hormone treatment." (Kaliebe Repport, at ¶70). This is not true. For one, the Chen et al. study looked at the study population at baseline (pre-intervention), which shows that 66% endorsed lifetime suicidal ideation; 29% endorsed lifetime suicidal ideation with a plan, and a full 25% had reported having already had at least one suicide attempt prior to engaging in care. This is not much different from the suicide completion rate in the Ghent clinic (5/235) compared to the NIH 4 site (2/315). For another, Dr. Kaliebe compares the study population in Chen et al. to apparent suicides of transgender youth purportedly associated with the Gender Identity Development Service (GIDS) in the United Kingdom. For these numbers, Dr. Kaliebe cites to a letter to the editor from a sociologist, not a peer-reviewed study or a letter from someone experienced in this care. But two of the GIDS youth never saw a doctor for gender-affirming care, and there is no evidence the two others were receiving care. What is more, even the letter to the editor Dr. Kaliebe cites states: "One final caveat is that these data shed no light on the question of whether counseling or endocrinological interventions—gonadotropin-releasing hormone agonist or cross-sex hormones—affect the risk of suicide." (Biggs, 2022).

114. Defendants' designated experts, including several who are not mental health professionals, continue to misconstrue the practice of psychiatry and misunderstand what occurs in a mental health assessment. They indicate that mental health clinicians believe without scrutiny what a patient is telling them on face value. In fact, mental health professionals are trained to assess not just the words being said, but also to recognize behaviors, gather collateral data from other informants, and assess the meaning of the inherent disparities between these various data points to help understand the patient's experience. These assessments require training and

skill which the non-mental health providers lack. As an example, it is not uncommon for a patient to deny suicidal intent despite having clear risk factors – this denial occurs even after some have been discovered post-suicide attempt. To argue that highly trained clinicians simply believe everything a patient says is a farce. Furthermore, many of the defendants' experts attempt to invalidate Gender Dysphoria, as well as nearly all psychiatric diagnoses because these diagnoses rely on a patient's description of their symptoms to make the diagnosis. Every mental condition, and many physical conditions, rely on the patient's self-expressed disclosure of phenomenology. Do migraines not exist because they require patient self-report? Is depression not a cause of disability unless there is a blood test to diagnose it? Did auto-immune encephalitis not exist as a phenomenon until the antibody test was developed? Mental health providers, as well as all physicians rely on patient reports of symptoms and an exercise of independent judgment based on training and experience to make a diagnosis.

115. Dr. Kaliebe criticizes AACAP for purportedly being inconsistent about the capacity of minors, suggesting there is a discrepancy between their arguments protecting adjudicated youth vis-à-vis the ability of transgender youth to obtain care. But this criticism has no basis and is more indicative of Dr. Kaliebe's lack of experience and familiarity with this field. In its amicus brief, AACAP argued the U.S. Supreme Court should have taken adolescents' mental capacity into account when evaluating the question of whether adjudicated youth should be sentenced to life without the possibility of parole. Not only is the context of gender-affirming medical care entirely inapposite, but in such context, adolescents do not make decisions on their own. In order to access gender-affirming medical care, the adolescents work in conjunction with their parents/legal guardians and their doctors. And while adolescents provide assent to care, it is their parents/legal guardians who provide consent.

116. There appears to be a consistent lack of understanding of the consent process for pediatric medical care among the defendants' designated experts. This is most starkly demonstrated in Dr. Hruz's report. In his report, he highlights many potential reasons why adolescents may be unable to provide consent to gender affirming care. However, he neglects to understand that minors do not consent to gender affirming care. Parents/legal caregivers and at time the state maintain the capacity to consent on behalf of the adolescent, who depending on their age may provide assent. While his arguments are spurious, they are also irrelevant to the matter at hand.

117. Furthermore, there are also misstatements about the impact of psychiatric diagnoses on the capacity to consent. In Dr. Hruz's report, he notes "individuals with transgender identity who also have clinical depression or other serious psychiatric comorbidity may have limited capacity to objectively weigh

proposed clinical interventions with potentially irreversible consequences and would therefore fail to meet psychological abilities criteria." (Hruz Report, at ¶ 103). His reference justifying this sentence is an ethics analysis of participation in clinical research not in clinical care, and makes no reference to "psychological abilities criteria," which may sound official but has no bearing on evidence-based assessments of capacity to consent. Dr. Hruz further mischaracterizes Helmchen's paper which speaks specifically about excluding patients with "suicidal intentions" which is a separate phenomenology than clinical depression.

118. Similarly, Dr. Lappert reports "as is known by all surgeons, it is considered imprudent to obtain informed consent from patients suffering from psychological conditions that provoke the patient to acts of self-harm, or to suicidal ideation." (Lappert Report, at ¶69). This uncited assertion is drawn from ignorance about the capacity to consent to care for psychiatric patients. First, capacity to consent is specific to the intervention at hand. While a patient with suicidal ideation may lack capacity to end life-saving medical care, they may still retain capacity to consent to an appendectomy. To assume that all patients with psychiatric illness lack capacity to consent across all contexts is both unfounded and unethical.

119. Even in the context of clinical research, when the question of retention of capacity is actually studied as opposed to assumed it is of concern, individuals with both severe depression and schizophrenia demonstrate relatively high-decision making capacity as measured by the MacArthur Competence Assessment Tool-Clinical Research (Cohen, et al., 2004).

120. Dr. Kaliebe makes an assertion that medical academies are delegitimizing and politicizing care by convening expert committees to advise the organization on a topic. But this is well within the norms of academic medicine and speaks to a wish to be informed by experts in the field; it is not evidence of malfeasance. Speaking from personal experience as a member of several committees on transgender health, professional disagreements and debates about approaches, practices and priorities for care and research are commonplace, and dissenting opinions are welcomed, particularly when informed by their own expertise and a fair review of the literature.

121. Dr. Laidlaw makes many of the same mistakes about consent as the other experts, namely mistaking that children consent to gender affirming medical and surgical care. But he goes further and notes that in his opinion, even parents are unable to provide consent because the full accounting of the potential risks is, according to him, unknown. If Dr. Laidlaw's rubric were to be applied to the rest of medicine, medicine would never evolve. There are inherent unknown risks to every intervention, and it is the role of the provider to incorporate what is known and what is not known about these risks into a discussion about informed assent and informed consent. Moreover, the fact that we do not know *everything* about an intervention

does not make that intervention experimental. In medicine and in science, every day we discover something and with the advent of new techniques or investigative tools we are able to learn new information about the effects of well-established and longstanding medical interventions. None of this renders a medical intervention to be experimental.

122. Additionally, Dr. Laidlaw spends much of his report opining on the appropriateness of the psychiatric care of the patients involved in this case. However, Dr. Laidlaw is not a psychiatrist and has no authority to comment on the psychiatric care of either patient. It is unethical for him to do so.

J. Prohibiting Access to Gender-Affirming Care Harms Transgender People

123. Defendants' experts completely ignore the harms associated with prohibiting access to gender-affirming care to adolescents and adults with gender dysphoria for whom it is necessary and appropriate. They also ignore the harmful effects of governmental like the Challenged Exclusion adopted by Defendants.

124. The overarching goal of treatment for gender dysphoria is to eliminate clinically significant distress. For some, this is achieved by aligning an individual patient's body and presentation with their internal sense of self. The denial of medically indicated care to transgender adolescents and adults not only frustrates this goal and results in the prolonging of their gender dysphoria, but also causes

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additional distress and poses other health risks, such as depression, trauma, selfharm, and suicidality.

125. Defendants and their designated experts not only ignore the volumes of data showing the efficacy of gender-affirming medical care, but they also cannot deny that there are transgender adolescents that persist into transgender adults and who benefit from this care. But notwithstanding this latter undeniable fact neither Defendants nor their designated experts are interested in a nuanced discussion about prevalence, process, or technique, instead they advocate for a complete bar to the coverage of this safe, efficacious, and medically necessary care for *all* transgender adolescents and adults.

126. Lack of access to gender-affirming care therefore directly contributes to poorer mental health outcomes for transgender people (Owen-Smith, et al., 2018).

127. It is also well documented that experiencing discrimination has negative impacts on people's mental health and wellbeing. For example, a 2019 study found that experiencing discrimination in health care settings posed a unique risk factor for heightened suicidality among transgender individuals, a population already at heightened risk compared with the general population (Herman, et al., 2019). And of note, the 2022 National Survey on LGBTQ Youth Mental Health found that LGBTQ youth who had experienced discrimination based on sexual orientation or gender identity had attempted suicide in the past year at nearly three times the rate as those who had not (19% vs. 7%) (The Trevor Project, 2022).

128. In addition, the 2022 National Survey on LGBTQ Youth Mental Health found that 93% of transgender and nonbinary youth said that they have worried about transgender people being denied access to gender-affirming medical care due to state or local laws (The Trevor Project, 2022).

129. Research has shown that the mere introduction, debate, and adoption of discriminatory laws and policies like the Challenged Exclusion negatively affects the mental health of transgender youth. A prospective study with sexual minority populations found that living in states with discriminatory policies was associated with a statistically significant increase in the number of psychiatric disorder diagnoses (Hatzenbuehler, et al., 2010). Other studies "shown that restrictive laws and policies are related to destructive health behaviors on the part of transgender individuals" (Cunningham, et al., 2022; Du Bois, et al., 2018).

130. Recent studies show the negative toll that anti-LGBTQ measures, like the Challenged Exclusion, and debates surrounding them have had on the mental health of transgender youth. For example, in a survey of youth in November 2022, 86% of transgender and nonbinary youth said that the debates about anti-transgender bills had negatively impacted their mental health (Movement Advancement Project, 2023; The Trevor Project and Morning Consult, 2023). And a study from 2022, though with limitations, showed that the passage of anti-transgender bills is linked with Internet searches related to depression and suicide (Cunningham, et al., 2022).

131. Perhaps, more poignantly, those of us with clinical experience hear from our patients about how it feels to be targeted with this kind of legislation. As two of my transgender patients expressed to me within the past few weeks, "why does everyone hate me just for existing?" and "it's a hard time to be transgender right now."

CONCLUSION

132. By denying coverage and therefore access to necessary, safe, and effective medical care as treatment for gender dysphoria, the Challenged Exclusion endangers the mental health and well-being of transgender Medicaid beneficiaries in Florida.

133. Defendants and their designated experts, who for the most part have no experience in transgender health, not only ignore the robust evidence for the potential harm faced by transgender individuals when barred access to medically necessary gender-affirming care, but they also mischaracterize, misapprehend, and even ignore the robust body of evidence showing that gender-affirming medical care is safe, effective, and not experimental or investigational.

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

Executed this <u>9th</u> day of March 2023.

Aron Janssen, M.D.

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

EXPERT REPORT OF ARON C. JANSSEN, M.D. Case No. 4:22-cv-00325-RH-MAF

Curriculum Vitae

Aron Janssen, M.D. 312-227-7783 aronjans@gmail.com

Personal Data

Born	Papillion, Nebraska
Citizenship	USA

Academic Appointments

2011-2017	Clinical Assistant Professor of Child and Adolescent Psychiatry
2011-2019	Founder & Clinical Director, NYU Gender and Sexuality Service
	Director, LGBT Mental Health Elective, NYULMC
2015-2019	Co-Director, NYU Pediatric Consultation Liaison Service
	New York University Department of Child and Adolescent Psychiatry
2017-present	Clinical Associate Professor of Child and Adolescent Psychiatry
2019-present	Vice Chair, Pritzker Department of Psychiatry and Behavioral Health
	Ann and Robert H. Lurie Children's Hospital of Chicago
2020-present	Medical Director, Outpatient Psychiatric Services
	Ann and Robert H. Lurie Children's Hospital of Chicago

Education

Year	Degree	Field	Institution
6/97	Diploma		Liberty High School
5/01	B.A.	Biochemistry	University of Colorado
5/06	M.D.	Medicine	University of Colorado

Postdoctoral Training

2006-2009	Psychiatry Residency	Ze'ev Levin, M.D.	NYU Department of Psychiatry
2009-2011	Child and Adolescent	Psychiatry Fellowship -	- Fellow and Clinical Instructor
		Jess Shatkin, M.D.	NYU Dept of Child/Adolescent Psychiatry

Licensure and Certification

2007-2018	New York State Medical License
2017-present	Illinois Medical License
2011-present	Certification in Adult Psychiatry, American Board of Psychiatry and Neurology
2013-present	Certification in Child and Adolescent Psychiatry, ABPN

Academic Appointments

2009-2011	Clinical Instructor, NYU Department of Child and Adolescent Psychiatry
2011-2017	Clinical Asst Professor, NYU Dept of Child and Adolescent Psychiatry
2017-2019	Clinical Assoc Professor, NYU Dept of Child and Adolescent Psychiatry
2011-2019	Clinical Director, NYU Gender and Sexuality Service
2015-2019	Co-Director, NYU Pediatric Consultation-Liaison Service
2019-present	Associate Professor of Child and Adolescent Psychiatry, Northwestern University
2019-present	Vice Chair of Clinical Affairs, Pritzker Department of Psychiatry and Behavioral
•	Health, Lurie Children's Hospital of Chicago

Major Committee Assignments

International, National and Regional

international, reational and	a Regional
2021-present	Sexual Orientation and Gender Identity Committee, Chair, AACAP
2019-present	WPATH Standards of Care Revision Committee, Children
2019-present	WPATH Standards of Care Revision Committee, Adult Mental Health
2015-2019	Department of Child Psychiatry Diversity Ambassador
2013-2021	Sexual Orientation and Gender Identity Committee Member, AACAP
2012-2019	Founder and Director, Gender Variant Youth and Family Network
2012-present	Association of Gay and Lesbian Psychiatrists, Transgender Health
	Committee
2012-2019	NYULMC, Chair LGBTQ Advisory Council
2012-2019	NYULMC, Child Abuse and Protection Committee
2013-2015	NYULMC, Pediatric Palliative Care Team
2003-2004	American Association of Medical Colleges (AAMC), Medical Education
	Delegate
2004-2006	AAMC, Western Regional Chair
Psychiatry Residency	-
2006-2009	Resident Member, Education Committee
2007-2008	Resident Member, Veterans Affairs (VA) Committee
Medical School	
2002-2006	Chair, Diversity Curriculum Development Committee
2002-2006	AAMC, Student Representative
2003-2004	American Medical Student Assoc. (AMSA) World AIDS Day Coordinator
2003-2004	AMSA, Primary Care Week Coordinator
2004-2006	Chair, Humanism in Medicine Committee
Memberships, Offices, and	nd Committee Assignments in Professional Societies
2006-present	American Psychiatric Association (APA)
2009-present	American Academy of Child and Adolescent Psychiatry (AACAP)
2011-present	World Professional Association for Transgender Health (WPATH)
2011-2019	Director, Gender Variant Youth and Family Network, NYC
2013-2019	Chair, NYU Langone Medical Center LGBTQ Council
Editorial Positions	
2016-2018	Clinical Assistant Editor, Transgender Health
2014-present	Ad Hoc Reviewer, LGBT Health.
2016-present	Ad Hoc Reviewer, JAACAP
2018-present	Associate Editor, Transgender Health
2020-present	Ad Hoc Reviewer, Pediatrics
Principal Clinical and H	Ospital Service Responsibilities
2011-2019	Stall Psychiatrist, Pediatric Consultation Liaison Service
2011-2019	Faculty Physician, NYU Child Study Center
2011-2019	Founder and Clinical Director, NYU Gender & Sexuality Service
2015-2019	U-Director, Pediatric Consultation Liaison Service
2019-present	vice Unair, Pritzker Dept of Psychiatry and Behavioral Health
2019-present	Unier Psychiatrist, Gender Development Program

2020-present Medical Director, Outpatient Psychiatry Services

Relevant Program Development

Gender and Sexuality Service

- -founded by Aron Janssen in 2011, who continues to direct the service
- -first mental health service dedicated to transgender youth in NYC
- -served over 200 families in consultation, with 2-3 referrals to the gender clinic per week

-trained over 500 mental health practitioners in transgender mental health – 1 or 2 full day trainings in partnership with the Ackerman Institute's Gender and Family Project (GFP) and with WPATH Global Educational Initiative (GEI)

- -New hires in Adolescent Medicine, Psychology, Plastic Surgery, Urology, Gynecology, Endocrinology, Social Work, Department of Population Health with focus on transgender care has led to expansion of available services for transgender youth at NYULMC in partnership with the Gender and Sexuality Service
- -development of partnerships with Ackerman Institute, Callen-Lorde Health Center both institutions have been granted access to our IRB and have agreed to develop shared research and clinical priorities with the Gender and Sexuality Service.
- -multiple IRB research projects underway, including in partnership with national and international clinics

-model has been internationally recognized

Clinical Specialties/Interests

Gender and Sexual Identity Development

Co-Occurring Mental Health Disorders in Transgender children, adolescents and adults Pediatric Consultation/Liaison Psychiatry

Psychotherapy

-Gender Affirmative Therapy, Supportive Psychotherapy, CBT, MI

Teaching Experience

- 2002-2006 Course Developer and Instructor, LGBT Health (University of Colorado School of Medicine
- 2011-2019 Instructor, Cultural Competency in Child Psychiatry (NYU Department of Child and Adolescent Psychiatry) 4 hours per year
- 2011-2019 Course Director, Instructor "Sex Matters: Identity, Behavior and Development" 100 hours per year
- 2011-2019 Course Director, LGBT Mental Health Elective (NYU Department of Psychiatry) - 50 hours of direct supervision/instruction per year
- 2011-2019 Course Director, Transgender Mental Health (NYU Department of Child and Adolescent Psychiatry course to begin in Spring 2018.
- 2015-2019 Instructor, Gender & Health Selective (NYU School of Medicine) 4 hours per year.

Academic Assignments/Course Development

New York University Department of Child and Adolescent Mental Health Studies

-Teacher and Course Director: "Sex Matters: Identity, Behavior and Development."

A full semester 4 credit course, taught to approximately 50 student per year since 2011, with several students now in graduate school studying sexual and gender

identity development as a result of my mentorship.

NYU Department of Child and Adolescent Psychiatry

-Instructor: Cultural Competency in Child and Adolescent Psychiatry

-Director: LGBTQ Mental Health Elective

World Professional Association of Transgender Health

-Official Trainer: Global Education Initiative – one of two child psychiatrists charged with training providers in care of transgender youth and adults.

Peer Reviewed Publications

- 1. Janssen, A., Erickson-Schroth, L., "A New Generation of Gender: Learning Patience from our Gender Non-Conforming Patients," Journal of the American Academy of Child and Adolescent Psychiatry, Volume 52, Issue 10, pp. 995-997, October, 2013.
- 2. Janssen, A., et. al. "Theory of Mind and the Intolerance of Ambiguity: Two Case Studies of Transgender Individuals with High-Functioning Autism Spectrum
- Janssen A, Huang H, and Duncan C., Transgender Health. February 2016, "Gender Variance Among Youth with Autism: A Retrospective Chart Review." 1(1): 63-68. doi:10.1089/trgh.2015.0007.
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- 5. Janssen A., et. al., "Gender Variance Among Youth with ADHD: A Retrospective Chart Review," in review
- 6. Janssen A., et. al., "Initial Clinical Guidelines for Co-Occurring Autism Spectrum Disorder and Gender Dysphoria or Incongruence in Adolescents," Journal of Child & Adolescent Psychology, 105-115, January 2018.
- Janssen A., et. al., "A Review of Evidence Based Treatments for Transgender Youth Diagnosed with Social Anxiety Disorder," Transgender Health, 3:1, 27–33, DOI: 10.1089/ trgh.2017.0037.
- 8. Janssen A., et. al., "'The Complexities of Treatment Planning for Transgender Youth with Co-Occurring Severe Mental Illness: A Literature Review and Case Study," Archives of Sexual Behavior, 2019. # 3563492
- 9. Kimberly LL, Folkers KM, Friesen P, Sultan D, Quinn GP, Bateman-House A, Parent B, Konnoth C, Janssen A, Shah LD, Bluebond-Langner R, Salas-Humara C., "Ethical Issues in Gender-Affirming Care for Youth," Pediatrics, 2018 Dec;142(6).
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- 12. Madora, M., Janssen, A., Junewicz, A., "Seizure-like episodes, but is it really epilepsy?" Current Psychiatry. 2019 Aug; 18(8): 42-47.

- Janssen, A., Busa, S., Wernick, J., "The Complexities of Treatment Planning for Transgender Youth with Co-Occurring Severe Mental Illness: A Literature Review and Case Study," Archives of Sexual Behavior. 2019 Oct; 48(7): 2003-2009.
- Wernick Jeremy A, Busa Samantha, Matouk Kareen, Nicholson Joey, Janssen Aron, "A Systematic Review of the Psychological Benefits of Gender-Affirming Surgery," Urol Clin North Am. 2019 Nov; 46(4): 475-486.
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- 16. Coyne, C. A., Poquiz, J. L., Janssen, A., & Chen, D. Evidence-based psychological practice for transgender and non-binary youth: Defining the need, framework for treatment adaptation, and future directions. Evidence-based Practice in Child and Adolescent Mental Health.
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- Dubin, S., Cook, T., Liss, A., Doty, G., Moore, K., Janssen, A. (In press 2020). Comparing Electronic Health Records Domains' Utility to Identify Transgender Patients. Transgender Health, DOI 10.1089/trgh.2020.0069
- 19. Busa, S., Wernick, J.,...Janssen, A. A Descriptive Case Study of a Cognitive Behavioral Therapy Group Intervention Adaptation for Transgender Youth With Social Anxiety Disorder, Behavioral Therapy, April, 2022
- 20. Ramsden SC, Pergjika A, Janssen AC, Mudahar S, Fawcett A, Walkup JT, Hoffmann JA. A Systematic Review of the Effectiveness and Safety of Droperidol for Pediatric Agitation in Acute Care Settings. Acad Emerg Med. May, 2022.
- 21. Janssen, A., Walkup, J., More is Not Always Better, When Different is Required, J Am Acad Child Adolesc Psychiatry. June, 2022 doi: 10.1016/j.jaac.2022.05.006.
- 22. Wanta, J., Gianakakos, G., Belfort, A., Janssen, A., Considering "Spheres of Influence" in the Care of LGBTQ Youth, CAP Clinics of North America. Volume 31, Issue 4, p649-664, October 2022 doi: 10.1016/j.chc.2022.05.008
- 23. Coleman, E., Radix, A.... Janssen, A., et. al., Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. International Journal of Transgender Health, 23:sup1, S1-2259, September 2022. doiL 10.1080/26895269.2022.2100644
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Published Abstracts

1. Thrun, M., Janssen A., et. al. "Frequency of Patronage and Choice of Sexual Partners may Impact Likelihood of HIV Transmission in Bathhouses," original research poster

presented at the 2007 Conference on Retroviruses and Opportunistic Infections, February, 2007.

- Janssen, A., "Advocating for the mental health of Lesbian, Gay, Bisexual and Transgender (LGBT) population: The Role of Psychiatric Organizations." Workshop for the American Psychiatric Association Institute of Psychiatric Services Annual Meeting, October 2012.
- Janssen, A., "Gender Variance in Childhood and Adolescents: Training the Next Generation of Psychiatrists," 23rd Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, February 2014.
- 4. Janssen, A., "When Gender and Psychiatric Acuity/Comorbidities Overlap: Addressing Complex Issues for Gender Dysphoric and Non-Conforming Youth," AACAP Annual Meeting, October 2014.
- Janssen, A., "Patient Experiences as Drivers of Change: A unique model for reducing transgender health disparities as an academic medical center," Philadelphia Transgender Health Conference, June 2016.
- 6. Janssen, A., "How much is too much? Assessments & the Affirmative Approach to TGNC Youth," 24th Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, June 2016.
- 7. Janssen, A., "Trauma, Complex Cases and the Role of Psychotherapy," 24th Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, June 2016.
- 8. Janssen, A., "Gender Variance Among Youth with Autism: A Retrospective Chart Review," Research Poster, 24th Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, June 2016.
- 9. Janssen, A., "Gender Fluidity and Gender Identity Development," Center for Disease Control STD Prevention Conference, September 2016.
- 10. Janssen, A., "Transgender Identities Emerging During Adolescents' Struggles With Mental Health Problems," AACAP Annual Conference, October 2016.
- 11. Janssen, A., "How Much is Too Much? Assessments and the Affirmative Approach to Transgender and Gender Diverse Youth," US Professional Association for Transgender Health Inaugural Conference, Los Angeles, February 2017.
- 12. Janssen, A., "Trauma, Complex Cases and the Role of Psychotherapy," US Professional Association for Transgender Health Inaugural Conference, Los Angeles, February 2017.
- Sutter ME, Bowman-Curci M, Nahata L, Tishelman AC, Janssen AC, Salas-Humara C, Quinn GP. Sexual and reproductive health among transgender and genderexpansive AYA: Implications for quality of life and cancer prevention. Oral presentation at the Oncofertility Consortium Conference, Chicago, IL. November 14, 2017.
- 14. Janssen, A., Sidhu, S., Gwynette, M., Turban, J., Myint, M., Petersen, D., "It's Complicated: Tackling Gender Dysphoria in Youth with Autism Spectrum Disorders from the Bible Belt to New York City," AACAP Annual Conference, October 2017.
- 15. May 2018: "A Primer in Working with Parents of Transgender Youth," APA Annual Meeting.
- 16. October 2018: "Gender Dysphoria Across Development" Institute for AACAP Annual Conference.

- 17. November 2018: "Gender Variance Among Youth with Autism," World Professional Association for Transgender Health Biannual Conference.
- 18. March 2019: "Gender Trajectories in Child and Adolescent Development and Identity," Austin Riggs Grand Rounds.
- 19. Janssen, A., et. al., "Ethical Principles in Gender Affirming Care," AACAP Annual Conference, October 2019.
- 20. Janssen, A., "Gender Diversity and Gender Dysphoria in Youth," EPATH Conference, April 2019
- 21. Englander, E., Janssen A., et. al., "The Good, The Bad, and The Risky: Sexual Behaviors Online," AACAP Annual Conference, October 2020
- 22. Englander, E., Janssen, A., et. al., "Love in Quarantine," AACAP Annual Conference, October 2021
- 23. Janssen, A., Leibowitz, S., et. al., "The Evidence and Ethics for Transgender Youth Care: Updates on the International Standards of Care, 8th Edition," AACAP Annual Conference, October 2021
- 24. Turban, J., Janssen, A., et. al., "Transgender Youth: Understanding "Detransition," Nonlinear Gender Trajectories, and Dynamic Gender Identities," AACAP Annual Conference, October 2021
- 25. Hoffmann JA, Pergjika, A, Liu X, Janssen AC, Walkup JT, Alpern ER, Johnson EJ, Corboy JB. Standardizing and Optimizing Care for Pediatric Acute Agitation Management in the Emergency Department. Oral Abstract Presentation. Academic Pediatric Association Annual Conference on Advancing Quality Improvement Science for Children's Healthcare. New Orleans. Accepted for presentation on April 22, 2022.
- 26. Janssen, A., Malpas, J., Glaeser, E., "Family-Based Interventions with Transgender and Gender Nonbinary Youth," World Professional Association of Transgender Health 27th Scientific Symposium, September 2022.
- 27. Tishelman, A., Janssen A., et. al., WPATH Standards of Care "Child Chapter," World Professional Association of Transgender Health 27th Scientific Symposium, September 2022
- 28. Janssen, A., Leibowitz, S., et al, "The Evidence and Ethics for Transgender Youth Care: Updates on the New International Standards of Care, Eighth Edition. AACAP Annual Conference, October 2022.
- 29. Turban, J., Janssen, A., et al, "Transgender Youth: Evolving Gender Identities and "Detransition," AACAP Annual Conference, October 2022.

Books

1. Janssen, A., Leibowitz, S (editors), Affirmative Mental Health Care for Transgender and Gender Diverse Youth: A Clinical Casebook, Springer Publishing, 2018.

Book Chapters

- 1. Janssen, A., Shatkin, J., "Atypical and Adjunctive Agents," Pharmacotherapy for Child and Adolescent Psychiatric Disorders, 3rd Edition, Marcel Dekker, Inc, New York, 2012.
- Janssen, A; Liaw, K: "Not by Convention: Working with People on the Sexual & Gender Continuum," book chapter in The Massachusetts General Hospital Textbook on Cultural Sensitivity and Diversity in Mental Health. Humana Press, New York, Editor R. Parekh, January 2014.

- 3. Janssen, A; Glaeser, E., Liaw, K: "Paving their own paths: What kids & teens can teach us about sexual and gender identity," book chapter in Cultural Sensitivity in Child and Adolescent Mental Health, MGH Psychiatry Academy Press, Editor R. Parekh, 2016
- 4. Janssen A., "Gender Identity," Textbook of Mental and Behavioral Disorders in Adolescence, February 2018.
- 5. Busa S., Wernick, J., & Janssen, A. (In Review) Gender Dysphoria in Childhood. Encyclopedia of Child and Adolescent Development. Wiley, 2018.
- 6. Janssen A., Busa S., "Gender Dysphoria in Childhood and Adolescence," Complex Disorders in Pediatric Psychiatry: A Clinician's Guide, Elsevier, Editors Driver D., Thomas, S., 2018.
- Wernick J.A., Busa S.M., Janssen A., Liaw K.RL. "Not by Convention: Working with People on the Sexual and Gender Continuum." Book chapter in The Massachusetts General Hospital Textbook on Diversity and Cultural Sensitivity in Mental Health, editors Parekh R., Trinh NH. August, 2019.
- 8. Weis, R., Janssen, A., & Wernick, J. The implications of trauma for sexual and reproductive health in adolescence. In *Not Just a nightmare: Thinking beyond PTSD to help teens exposed to trauma*. 2019
- 9. Connors J., Irastorza, I., Janssen A., Kelly, B., "Child and Adolescent Medicine," The Equal Curriculum: The Student and Educator Guide to LGBTQ Health, editors Lehman J., et al. November 2019.
- Janssen, A., et. al., "Gender and Sexual Diversity in Childhood and Adolescence," Dulcan's Textbook of Child and Adolescent Psychiatry, 3rd edition, editor Dulcan, M., (in press)
- Busa S., Wernick J, Janssen, A., "Gender Dysphoria," The Encyclopedia of Child and Adolescent Development, DOI: 10.1002/9781119171492. Wiley, December 2020.

Invited Academic Seminars/Lectures

- 1. April 2006: "How to Talk to a Gay Medical Student" presented at the National AAMC Meeting.
- 2. March 2011: "Kindling Inspiration: Two Model Curricula for Expanding the Role of Residents as Educators" workshop presented at National AADPRT Meeting.
- 3. May 2011: Janssen, A., Shuster, A., "Sex Matters: Identity, Behavior and Development," Grand Rounds Presentation, NYU Department of Child and Adolescent Psychiatry.
- 4. March 2012: Janssen, A., Lothringer, L., "Gender Variance in Children and Adolescents," Grand Rounds Presentation, NYU Department of Child and Adolescent Psychiatry.
- 5. June 2012: Janssen, A., "Gender Variance in Childhood and Adolescence," Grand Rounds Presentation, Woodhull Department of Psychiatry
- 6. October 2012: "Advocating for the mental health of Lesbian, Gay, Bisexual and Transgender (LGBT) population: The Role of Psychiatric Organizations." Workshop for the American Psychiatric Association Institute of Psychiatric Services Annual Meeting.
- 7. March 2013: "Gender Variance in Childhood and Adolescence," Sexual Health Across the Lifespan: Practical Applications, Denver, CO.
- 8. October 18th, 2013: "Gender Variance in Childhood and Adolescence," Grand Rounds Presentation, NYU Department of Endocrinology.

- 9. October, 2014: GLMA Annual Conference: "Theory of Mind and Intolerance of Ambiguity: Two Case Studies of Transgender Individuals with High-Functioning ASD," Invited Presentation
- 10. October 2014: New York Transgender Health Conference: "Mental Health Assessment in Gender Variant Children," Invited Presentation.
- 11. November, 2014: Gender Spectrum East: "Affirmative Clinical Work with Gender-Expansive Children and Youth: Complex Situations."
- 12. October 2015: "Gender Dysphoria and Complex Psychiatric Co-Morbidity," LGBT Health Conference, Invited Speaker
- 13. October 2015: "Transgender Health Disparities: Challenges and Opportunities," Grand Rounds, Illinois Masonic Department of Medicine
- 14. November 2015: "Autism and Gender Variance," Gender Conference East, Invited Speaker
- 15. February 2016: "Working with Gender Variant Youth," New York State Office of Mental Health State Wide Grand Rounds, Invited Speaker
- 16. March, 2016: "Working with Gender Variant Youth," National Council for Behavioral Health Annual Meeting, Invited Speaker
- 17. March 2016: "Gender Variance Among Youth with Autism: A Retrospective Chart Review and Case Presentation," Working Group on Gender, Columbia University, Invited Speaker.
- September, 2016: "Best Practices in Transgender Mental Health: Addressing Complex Issues for Gender Dysphoric and Non-Conforming Youth," DeWitt Wallace Institute for the History of Psychiatry, Weill Cornell.
- 19. October, 2016: "LGBTQ Youth Psychiatric Care," Midwest LGBTQ Health Symposim
- 20. October, 2016: "Gender Fluidity and Gender Identity Development," NYU Health Disparities Conference.
- 21. February, 2017: "Best Practices in Transgender Mental Health," Maimonides Grand Rounds
- 22. March, 2017: "Transgender Health: Challenges and Opportunities," Invited speaker, Center for Disease Control STD Prevention Science Series.
- 23. September 2017: "Autism and Gender Dysphoria," Grand Rounds, NYU Department of Neurology.
- 24. November 2017: "Consent and Assent in Transgender Adolescents," Gender Conference East.
- 25. November 2017: "Transgender Mental Health: Challenges and Opportunities," Grand Rounds, Lenox Hill Hospital.
- 26. April 2018: "Gender Trajectories in Childhood and Adolescent Development and Identity," Sex, Sexuality and Gender Conference, Harvard Medical School.
- 27. September 2019: "Social and Psychological Challenges of Gender Diverse Youth," Affirmative Mental Health Care for Gender Diverse Youth, University of Haifa.
- 28. October 2019: "Best Practices in Transgender Mental Health," Grand Rounds, Rush Department of Psychiatry.
- 29. February 2020: "The Overlap of Autism and Gender Dysphoria," Grand Rounds, Northwestern University Feinberg School of Medicine Department of Psychiatry
- 30. February 2020: "Gender Dysphoria and Autism," Grand Rounds, University of Illinois at Chicago Department of Psychiatry
- 31. September 2021: "Gender Diversity and Autism," Grand Rounds, Kaiser Permanente Department of Pediatrics

32. October 2021: Gender Dysphoria and Autism," Grand Rounds, Case Western Reserve University Department of Psychiatry.

Selected Invited Community Seminars/Lectures

- 1. April 2012: "Gender and Sexuality in Childhood and Adolescence," Commission on Race, Gender and Ethnicity, NYU Steinhardt Speakers Series.
- 2. February 2013: "Supporting Transgender Students in School," NYC Independent School LGBT Educators Panel, New York, NY.
- 3. June 2013: "LGBT Health," Presentation for Neuropsychology Department
- 4. August 2013: "Chronic Fatigue Syndrome: Etiology, Diagnosis and Management," invited presentation.
- 5. September 2013: Panelist, "LGBTQ Inclusive Sex Education."
- 6. April 2015: Transgender Children, BBC News, BBCTwo, invited expert
- 7. January 2016: Gender Dysphoria and Autism Ackerman Podcast <u>http://ackerman.podbean.com/e/the-ackerman-podcast-22-gender-dysphoria-autism-with-aron-janssen-md/</u>
- 8. February 2016: "Best Practices in Transgender Mental Health," APA District Branch Meeting, Invited Speaker.
- 9. May 2016: "Best Practices in Transgender Mental Health," Washington D.C., District Branch, APA, Invited Speaker
- 10. July 2016: "Transgender Youth," Union Square West
- 11. November 2017: "Understanding Gender: Raising Open, Accepting and Diverse Children," Heard in Rye, Conversations in Parenting.
- 12. January 2018: "The Emotional Life of Boys," Saint David's School Panel, Invited Speaker
- 13. June 2018: "Supporting Youth Engaged in Gender Affirming Care," NYU Child Study Center Workshop.
- 14. October 2018: "Medicine in Transition: Advances in Transgender Mental Health," NYCPS HIV Psychiatry and LGBT Committee Meeting.
- 15. October 2018: "Understanding Gender Fluidity in Kids," NYU Slope Pediatrics.
- 16. October, 2021: Issues of Ethical Importance: Health Care for Pediatric LGBTQ+ Patients, American Medical Association, Invited Talk

Major Research Interests

Gender and Sexual Identity Development Member, Research Consortium for Gender Identity Development Delirium: Assessment, Treatment and Management Suicide Prevention

Research Studies

<u>Study Title</u> Suicide Attempts Identified in a Children's Hospital Before and During COVID-19	<u>IRB Study#</u> 2021-4428	Dates 2/26/21-present
Lurie Children's Sex & Gender Development Program Clinical Measure Collection	2019-2898	2019-present

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Adolescent Gender Identity Research Study (principal investigator) - unfunded	s15-00431	4/15-5/19
Co-Occurrence of Autism Spectrum Disorders and Gender Variance: Retrospective Chart Review (principal investigator) - unfunded	s14-01930	10/14-5/19
Expert Consensus on Social Transitioning Among Prepubertal Children Presenting with Transgender Identity and/or Gender Variance: A Delphi Procedure Study (principal investigator) - unfunded	s13-00576	3/16-5/19
Co-Occurrence of ADHD/Gender Dysphoria (principal investigator) - unfunded	s16-00001	1/16-5/19
PICU Early Mobility- unfunded	s16-02261	12/16-5/19
Metformin for Overweight and Obese Children and Adolescents with Bipolar Spectrum Disorders Treated with Second-Generation Antipsychotics – Funded by PCORI	s16-01571	8/16-5/19
Other Grant Funding: Zero Suicide Initiative, PI Aron Janssen, M.D. Awarded by Cardinal Health Foundation, 9/202 Total amount: \$100,000 Catalyst Fund, PI Aron Janssen, M.D. Suicide Prevention in Pediatric Primary Care Total amount: \$750,000	0	
 Selected Media Appearances: Guest Expert on Gender Identity on Anderson, ⁶ Date February 8th, 2012 Guest Host, NYU About Our Kids on Sirius XM NYU Doctor Radio: LGBT Health, September 20 NYU Doctor Radio: LGBT Kids, November 20 NYU Doctor Radio: LGBT Health, July 2014 NYU Doctor Radio: Gender Variance in Childh BBC Two: Transgender Youth, April 2015 NYU Doctor Radio: Transgender Youth, June 2 Fox-5 News: Trump's proposed military ban an Healthline.com: Mental Health Experts Call Pre July, 2017 Huffington Post: What the Military Ban Says to Metro: How to talk to your transgender kid about 	"When Your Husban 4, 2011 2013 13 wood, December 2014 2015 d Transgender Youth esident's Tweets 'Dev o Our Transgender Youth o Our Transgender Youth	d Becomes Your Wife," Air h, July, 2017 vastating' for Trans Teens, puth: August, 2017 17

<u>Exhibit B</u> *Bibliography*

EXPERT REBUTTAL REPORT OF ARON C. JANSSEN, M.D. Case No. 4:22-cv-00325-RH-MAF

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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), 302-311.

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https://www.aacap.org/AACAP/Policy Statements/2018/Conversion Therapy.asp <u>x</u>.

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American Medical Association and GLMA. (2019). Issue Brief: Health insurance coverage for gender- affirming care of transgender patients. Available at: <u>https://www.ama-assn.org/system/files/2019-03/transgender-coverage-issue-brief.pdf</u>.

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Biggs M. (2022). Suicide by Clinic-Referred Transgender Adolescents in the United Kingdom. *Archives of sexual behavior*, *51*(2), 685–690.

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Coleman, E., Radix, A. E., Bouman, W. P., Brown, G. R., de Vries, A. L. C., Deutsch, M. B., Ettner, R., Fraser, L., Goodman, M., Green, J., Hancock, A. B., Johnson, T. W., Karasic, D. H., Knudson, G. A., Leibowitz, S. F., Meyer-Bahlburg, H. F. L., Monstrey, S. J., Motmans, J., Nahata, L., Nieder, T. O., ... Arcelus, J. (2022). Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *International journal of transgender health*, *23*(Suppl 1), S1–S259.

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https://www.wpath.org/soc8/Revision-Committee



Establishing the soc8 Revision committee and <u>meet the chairs and lead evidence team</u>



2.1 <u>Establishing SOC Revision</u> <u>Committee Process</u>

The Standards of Care 8 revision started by identifying a multidisciplinary team of clinicians, researchers and stakeholders using a clearly defined process. The following steps were followed to select the members of the SOC8 review

committee:

2.1.1 Establish Guideline Steering Committee

The WPATH Guideline Steering Committee provided oversight of the guideline development process for all chapters of the Standards of Care. Except for the Chair (Dr Eli Coleman) who was selected by WPATH to provide continuity from previous SOC, the two co-chairs were selected by the WPATH Board from WPATH members applying for these positions. The Chairs of the Guideline Steering Committee:

- Appointed the Chapter Leads and Members for each chapter
- Selected topics for the chapters

The Guideline Steering Committee (chairs and Co-chairs) provided general oversight of the guideline development process. The Committee reviewed all chapters of the Standards of Care to confirm adherence to the WPATH guideline methodology and to ensure consistency of statements across the Standards of Care.

2.1.2 Nomination Procedures and selection for Co-Chairs

- A member of WPATH proposed a candidate for co-chair by sending a letter of nomination and the address of the recommended co-chair, to the Executive Director of the Society.
- A Member of WPATH could self-nominate, by sending a letter of self-nomination to the Executive Director of the Society.
- The Executive Director (ED) sent a membership application form, including a request for a curriculum vitae, to the nominated individual.
- The ED distributed copies of the nominating letter, completed application, and curriculum vitae to the Board of Directors.
- The BOD discussed each application and assigns a score in a blinded ballot only seen by the office staff across the application criteria with the three top candidates moving to the next round of voting.
- Any conflict of interest was declared and in the case of a conflict of interest, the conflicted person did not vote.
- The BOD discussed the nominees with the Chair, and best fit for the group was chosen.
- The ED corresponded with the candidate and the nominator regarding the action on each nomination.

2.1.2.1 Key Criteria Used for the Selection of Co-Chair on the SOC8 Revision Committee (2 positions)

- Longstanding WPATH Full Member in good standing
- Well recognized advocate for WPATH and the SOC
- Well known expert in transgender health
- Extensive experience in leading consensus building projects and guideline development
- Accomplished clinician, scholar, and researcher in trans health with a publication record
- Able to assess the evidence-based and peer review literature and peer and contribute specific recommendations from an evidence-based perspective
- Able to select and supervise chapter leads

2.1.2.1 Results

A total of 8 individuals applied for two positions and 2 people were selected, Dr. Asa Radix and Dr. Jon Arcelus.

2.1.3 Nomination and selection procedures for Chapter Leads

- A member of WPATH proposed a candidate for a chapter lead by sending a letter of nomination, including address of the recommended chapter lead (and indicated chapter(s)), to the Executive Director (ED) of the Society.
- A member of WPATH could self-nominate by sending a letter of self-nomination to the ED of the Society.
- The ED sent a membership application form, including a request for a curriculum vitae, to the nominated individual.
- The ED distributes copies of the nominating letter, completed application, and curriculum vitae to the Chair and Co-Chairs.
- The Chair and Co-Chairs discussed the applications and assign a score in a blinded ballot only seen by the office staff across the application criteria with the top 2 candidates moving to the next round of voting. The Chair and Co-Chairs discussed the top 2 candidates with the goal of selecting the best fit for the topic and the other members of the workgroup.
- The Chair and Co-Chairs informed the BOD of their decisions.
- The ED corresponded with the candidate and the nominator regarding the action on each nomination.

2.1.3.1 Key Criteria for Chapter Lead on the SOC Revision Committee

- WPATH Full Member in good standing
- Well recognized advocate for WPATH and the SOC
- Well known expert in transgender health
- Accomplished scholar and researcher in trans health with a publication record related to the chapter
- Accomplished clinician, scholar, and researcher in trans health with a publication record
- Able to assess the evidence-based literature and write chapters based on peer review or contribute

2.1.3.2 Results

A total of 39 applicants and 24 were selected.

2.1.4 Nomination Procedures and selection for Chapter Workgroup Members

- A member of WPATH proposed a candidate for a chapter workgroup member by sending a letter of nomination, including address of the recommended new member, to the Executive Director (ED) of the Society
- A member of WPATH could self-nominate, by sending a letter of self-nomination to the ED of the Society
- The ED sent a membership application form, including a request for a curriculum vitae, to the nominated individual.
- The ED distributed copies of the nominating letter, completed application, and curriculum vitae to the Chapter Leads.
- The Chair and Co-Chairs and Chapter Leads discuss the applications and assign a score in a blinded ballot only seen by the office staff across the application criteria with the top 5-7 candidates (number to be determined prior to voting) within each chapter being chosen.
- The Chair, Co-Chairs and Chapter Lead informed the BOD of their decisions.
- The ED corresponded with the candidate and the nominator regarding the action on each nomination.

2.1.4.1 Key Criteria for Chapter Workgroup Member on the SOC8 Revision Committee (5-7 people per chapter)

- WPATH Full Member in good standing
- Well known expert in transgender health
- Accomplished scholar and researcher in trans health with a publication record related to the chapter
- Able to assess the evidence-based literature and write chapters related to peer review or contribute specific recommendations from an evidence-based perspective
- Able and willing to work collaboratively with chapter leads and other committee members
- Applicants could apply to work on more than one workgroup and rank their chapter interests.

2.1.4.2 Results

A total of 149 applicants for workgroup members applied and 127 were selected (link it to a page with names of the chairs, leads)

2.1.5 Nomination and selection procedures for Chapter Stakeholder Members

- A member of WPATH proposed a candidate for a chapter workgroup member by sending a letter of nomination, including address of the recommended new member, to the Executive Director (ED) of the Society
- A person could self-nominate, by sending a letter of self-nomination to the ED of the Society
- The ED sent a committee membership application form, including a request for a curriculum vitae, to the nominated individual.
- The ED distributed copies of the nominating letter, completed application, and curriculum vitae to the Chapter Leads.
- The Chair and Co-Chairs and Chapter Leads discussed the applications and assign a score in a blinded ballot only seen by the office staff across the application criteria with the top 2 candidates (number to be determined prior to voting) per chapter being chosen.
- The Chair, Co-Chairs and Chapter Leads discussed the top 2 candidates and the best fit within each chapter group were chosen.
- The Chair, Co-Chairs and Chapter Lead informed the BOD of their decisions.
- The ED corresponded with the candidate and the nominator regarding the action on each nomination.

2.1.5.1 Key Criteria for Stakeholder Membership on the SOC8 Revision Committee

Our intent was that by involving experts (with or without lived experience) that work outside of the scientific publishing arena, we will be able to provide input from those working directly in community health or in policy making and in NGOs around the globe.

- Associate Members of WPATH (with or without lived transgender experience) and other individuals (with or without lived transgender experience) with expertise due to accomplishments in trans health advocacy and a history of work in the community, or a member of a family that includes a transgender child, sibling, partner, parent, etc.
- Able to review the drafts of the SOC committee and contribute specific recommendations from a community health perspective

2.1.5.2 Results

A total of 57 and 20 were selected.

2.1.6 Selection of the evidence review team

The WPATH Board released a request for proposals (RFP) for the WPATH Standards of Care 8th Version Evidence Review Team. The Board received four complete proposals in response to the RFP. After careful review and discussions of each submitted proposal, the WPATH Board selected and engaged an Evidence Review Team at Johns Hopkins University. Dr Karen Robinson was the lead of the evidence-based review.

Conflict of Interest

Members of the Guideline Steering Committee, Chapter Leads and Members, and members of the Evidence Review Team are asked to disclose any conflicts of interest. Also reported, in addition to potential financial and competing interests or conflicts, were personal or direct reporting relationships with a chair, co-chair or a WPATH Board Member or the holding of a position on the WPATH Board of Directors.

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