EXHIBIT 1

ACT #2022 - 289

SB184

216600-4

By Senators Shelnutt and Allen

RFD: Healthcare

First Read: 03-FEB-22

SB184

ENROLLED, An Act,

Relating to public health; to prohibit the performance of a medical procedure or the prescription of medication, upon or to a minor child, that is intended to alter the minor child's gender or delay puberty; to provide for exceptions; to provide for disclosure of certain information concerning students to parents by schools; and to establish criminal penalties for violations; and in connection therewith would have as its purpose or effect the requirement of a new or increased expenditure of local funds within the meaning of Amendment 621 of the Constitution of Alabama of 1901, as amended by Amendment 890, now appearing as Section 111.05 of the Official Recompilation of the Constitution of Alabama of 1901, as amended.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. This act shall be known and may be cited as the Alabama Vulnerable Child Compassion and Protection Act (V-CAP).

Section 2. The Legislature finds and declares the following:

(1) The sex of a person is the biological state of being female or male, based on sex organs, chromosomes, and

endogenous hormone profiles, and is genetically encoded into a person at the moment of conception, and it cannot be changed.

(2) Some individuals, including minors, may experience discordance between their sex and their internal sense of identity, and individuals who experience severe psychological distress as a result of this discordance may be diagnosed with gender dysphoria.

(3) The cause of the individual's impression of discordance between sex and identity is unknown, and the diagnosis is based exclusively on the individual's self-report of feelings and beliefs.

(4) This internal sense of discordance is not permanent or fixed, but to the contrary, numerous studies have shown that a substantial majority of children who experience discordance between their sex and identity will outgrow the discordance once they go through puberty and will eventually have an identity that aligns with their sex.

(5) As a result, taking a wait-and-see approach to children who reveal signs of gender nonconformity results in a large majority of those children resolving to an identity congruent with their sex by late adolescence.

(6) Some in the medical community are aggressively pushing for interventions on minors that medically alter the child's hormonal balance and remove healthy external and

internal sex organs when the child expresses a desire to appear as a sex different from his or her own.

(7) This course of treatment for minors commonly begins with encouraging and assisting the child to socially transition to dressing and presenting as the opposite sex. In the case of prepubertal children, as puberty begins, doctors then administer long-acting GnRH agonist (puberty blockers) that suppress the pubertal development of the child. This use of puberty blockers for gender nonconforming children is experimental and not FDA-approved.

(8) After puberty blockade, the child is later administered "cross-sex" hormonal treatments that induce the development of secondary sex characteristics of the other sex, such as causing the development of breasts and wider hips in male children taking estrogen and greater muscle mass, bone density, body hair, and a deeper voice in female children taking testosterone. Some children are administered these hormones independent of any prior pubertal blockade.

(9) The final phase of treatment is for the individual to undergo cosmetic and other surgical procedures, often to create an appearance similar to that of the opposite sex. These surgical procedures may include a mastectomy to remove a female adolescent's breasts and "bottom surgery" that removes a minor's health reproductive organs and creates an

artificial form aiming to approximate the appearance of the genitals of the opposite sex.

(10) For minors who are placed on puberty blockers that inhibit their bodies from experiencing the natural process of sexual development, the overwhelming majority will continue down a path toward cross-sex hormones and cosmetic surgery.

(11) This unproven, poorly studied series of interventions results in numerous harmful effects for minors, as well as risks of effects simply unknown due to the new and experimental nature of these interventions.

(12) Among the known harms from puberty blockers is diminished bone density; the full effect of puberty blockers on brain development and cognition are yet unknown, though reason for concern is now present. There is no research on the long-term risks to minors of persistent exposure to puberty blockers. With the administration of cross-sex hormones comes increased risks of cardiovascular disease, thromboembolic stroke, asthma, COPD, and cancer.

(13) Puberty blockers prevent gonadal maturation and thus render patients taking these drugs infertile. Introducing cross-sex hormones to children with immature gonads as a direct result of pubertal blockade is expected to cause irreversible sterility. Sterilization is also permanent for those who undergo surgery to remove reproductive organs, and

such persons are likely to suffer through a lifetime of complications from the surgery, infections, and other difficulties requiring yet more medical intervention.

(14) Several studies demonstrate that hormonal and surgical interventions often do not resolve the underlying psychological issues affecting the individual. For example, individuals who undergo cross-sex cosmetic surgical procedures have been found to suffer from elevated mortality rates higher than the general population. They experience significantly higher rates of substance abuse, depression, and psychiatric hospitalizations.

(15) Minors, and often their parents, are unable to comprehend and fully appreciate the risk and life implications, including permanent sterility, that result from the use of puberty blockers, cross-sex hormones, and surgical procedures.

(16) For these reasons, the decision to pursue a course of hormonal and surgical interventions to address a discordance between the individual's sex and sense of identity should not be presented to or determined for minors who are incapable of comprehending the negative implications and life-course difficulties attending to these interventions.

Section 3. For the purposes of this act, the following terms shall have the following meanings:

(1) MINOR. The same meaning as in Section 43-8-1, Code of Alabama 1975.

(2) PERSON. Includes any of the following:

a. Any individual.

b. Any agent, employee, official, or contractor of any legal entity.

c. Any agent, employee, official, or contractor of a school district or the state or any of its political subdivisions or agencies.

(3) SEX. The biological state of being male or female, based on the individual's sex organs, chromosomes, and endogenous hormone profiles.

Section 4. (a) Except as provided in subsection (b), no person shall engage in or cause any of the following practices to be performed upon a minor if the practice is performed for the purpose of attempting to alter the appearance of or affirm the minor's perception of his or her gender or sex, if that appearance or perception is inconsistent with the minor's sex as defined in this act:

(1) Prescribing or administering puberty blocking medication to stop or delay normal puberty.

(2) Prescribing or administering supraphysiologic doses of testosterone or other androgens to females.

(3) Prescribing or administering supraphysiologic doses of estrogen to males.

(4) Performing surgeries that sterilize, including castration, vasectomy, hysterectomy, oophorectomy, orchiectomy, and penectomy.

(5) Performing surgeries that artificially construct tissue with the appearance of genitalia that differs from the individual's sex, including metoidioplasty, phalloplasty, and vaginoplasty.

(6) Removing any healthy or non-diseased body part or tissue, except for a male circumcision.

(b) Subsection (a) does not apply to a procedure undertaken to treat a minor born with a medically verifiable disorder of sex development, including either of the following:

(1) An individual born with external biological sex characteristics that are irresolvably ambiguous, including an individual born with 46 XX chromosomes with virilization, 46 XY chromosomes with under virilization, or having both ovarian and testicular tissue.

(2) An individual whom a physician has otherwise diagnosed with a disorder of sexual development, in which the physician has determined through genetic or biochemical testing that the person does not have normal sex chromosome structure, sex steroid hormone production, or sex steroid hormone action for a male or female.

(c) A violation of this section is a Class C felony.

Section 5. No nurse, counselor, teacher, principal, or other administrative official at a public or private school attended by a minor shall do either of the following:

(1) Encourage or coerce a minor to withhold from the minor's parent or legal guardian the fact that the minor's perception of his or her gender or sex is inconsistent with the minor's sex.

(2) Withhold from a minor's parent or legal guardian information related to a minor's perception that his or her gender or sex is inconsistent with his or her sex.

Section 6. Except as provided for in Section 4, nothing in this act shall be construed as limiting or preventing psychologists, psychological technicians, and master's level licensed mental health professionals from rendering the services for which they are qualified by training or experience involving the application of recognized principles, methods, and procedures of the science and profession of psychology and counseling.

Section 7. Nothing in this section shall be construed to establish a new or separate standard of care for hospitals or physicians and their patients or otherwise modify, amend, or supersede any provision of the Alabama Medical Liability Act of 1987 or the Alabama Medical Liability Act of 1996, or any amendment or judicial interpretation of either act.

Section 8. If any part, section, or subsection of this act or the application thereof to any person or circumstances is held invalid, the invalidity shall not affect parts, sections, subsections, or applications of this act that can be given effect without the invalid part, section, subsection, or application.

Section 9. This act does not affect a right or duty afforded to a licensed pharmacist by state law.

Section 10. Although this bill would have as its purpose or effect the requirement of a new or increased expenditure of local funds, the bill is excluded from further requirements and application under Amendment 621, as amended by Amendment 890, now appearing as Section 111.05 of the Official Recompilation of the Constitution of Alabama of 1901, as amended, because the bill defines a new crime or amends the definition of an existing crime.

Section 11. This act shall become effective 30 days following its passage and approval by the Governor, or its otherwise becoming law.

President and Presiding Officer of the Senate

Speaker of the House of Representatives

SB184

Senate 23-FEB-22

I hereby certify that the within Act originated in and passed the Senate, as amended.

Patrick Harris,
Secretary.

House of Representatives
Passed: 07-APR-22

By: Senator Shelnutt

APPROVED 4-8-2022

TIME 2:10 pm

GOVERNOR

Alabama Secretary Of State

Act Num....: 2022-289
Bill Num...: S-184

Recv'd 04/08/22 02:23pmSLF

SPONSOR

1 Shelnutt

CO-SPONSORS

2 Allen

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I hereby certify that the Resolution as required in Section C of Act No. 81-889 was adopted and is attached to the Bill, SB 184.

yeas 24 nays 4 abstain 0

PATRICK HARRIS,
Secretary

I hereby certify that the notice & proof is attached to the Bill, SB _____ as required in the General Acts of Alabama, 1975 Act No. 919.

PATRICK HARRIS,
Secretary

CONFERENCE COMMITTEE

Senate Conferees _____

_____

_____

DATE: 2-24

RD 1 RFD Judy

REPORT OF STANDING COMMITTEE

This bill having been referred by the House to its standing committee on _____ was acted upon by such committee in session, and returned therefrom to the House with the recommendation that it be Passed, w/amend(s) _____ w/sub _____.

This 2 day of March, 2022.

_____, Chairperson

DATE: 3-2

RF **RD 2**

DATE:

RE-REFERRED ☐ RE-COMMITTED ☐

Committee _____

I hereby certify that the Resolution as required in Section C of Act No. 81-889 was adopted and is attached to the Bill, SB _____.

YEAS _____ **NAYS** _____

JEFF WOODARD,
Clerk

FURTHER HOUSE ACTION (OVER)

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

BRIANNA BOE, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
UNITED STATES OF AMERICA,	)	
	)	
Intervenor Plaintiff,	)	
	)	
v.	)	Civil Action No. 2:22-cv-184-LCB
	)	
HON. STEVE MARSHALL, in his Official capacity as Attorney General, of the State of Alabama, *et al.*,	)	
	)	
Defendants.	)	

EXPERT REPORT OF
JAMES CANTOR, PH.D.

Table of Contents

I. Credentials and Qualifications

A. Education and professional background

1. I am a sexual behavior scientist, with an internationally recognized record studying the development of human sexualities, and an expert in research methodology of sexuality. . My curriculum vitae is attached as Appendix 1 to this report. My publication record includes both biological and non-biological influences on sexuality, ranging from pre-natal brain development, through adulthood, to senescence. The primary, but not exclusive, focus of my own research studies has been the development of atypical sexualities. In addition to the studies I myself have conducted, I am regularly consulted to evaluate the research methods, analyses, and proposals from sexual behavior scientists throughout the world. The methodologies I am qualified to assess span the neurochemical and neuroanatomic level, individual behavioral level, and social and interpersonal levels.

2. I am trained as a clinical psychologist and neuroscientist, and I am the author of over 50 peer-reviewed articles in my field, spanning the development of sexual orientation, gender identity, hypersexuality, and atypical sexualities collectively referred to as *paraphilias*. Although I have studied many atypical sexualities, the most impactful of my work has been MRI and other biological studies of the origins of pedophilia. That work has revolutionized several aspects of the sex offender field, both with regard to the treatment of offenders and to the prevention of sexual abuse of children. In 2022, I received the Distinguished Contribution Award from the Association for the Treatment and Prevention of Sexual Abuse in recognition of my research and its integration into public policy. My efforts in this regard have been the subject of several documentary films.

3. Over my academic career, my posts have included Senior Scientist and Psychologist at the Centre for Addiction and Mental Health (CAMH), and Head of Research for CAMH's Sexual

Behaviour Clinic. I was on the Faculty of Medicine of the University of Toronto for 15 years and have served as Editor-in-Chief of the peer reviewed journal, *Sexual Abuse*. That journal is one of the top-impact, peer-reviewed journals in sexual behavior science and is the official journal of the Association for the Treatment and Prevention of Sexual Abuse. In that appointment, I was charged to be the final arbiter for impartially deciding which contributions from other scientists in my field merited publication. I believe that appointment indicates not only my extensive experience evaluating scientific claims and methods, but also the faith put in me by the other scientists in my field. I have also served on the Editorial Boards of *The Journal of Sex Research*, the *Archives of Sexual Behavior*, and *Journal of Sexual Aggression*. I am currently the Director of the Toronto Sexuality Centre in Canada. Thus, although I cannot speak for other scientists, I regularly interact with and am routinely exposed to the views and opinions of most of the scientists active in our field today, within the United States and throughout the world.

4. For my education and training, I received my Bachelor of Science degree from Rensselaer Polytechnic Institute, where I studied mathematics, physics, and computer science. I received my Master of Arts degree in psychology from Boston University, where I studied neuropsychology. I earned my doctoral degree in psychology from McGill University, which included successfully defending my doctoral dissertation studying the effects of psychiatric medication and neurochemical changes on sexual behavior, and included a clinical internship assessing and treating people with a wide range of sexual and gender identity issues.

5. I have a decades-long, international, and award-winning history of advocacy for destigmatizing people with atypical sexualities. While still a trainee in psychology, I founded the American Psychological Association's (APA) Committee for Lesbian, Gay, and Bisexual Graduate Students. Subsequently, I have served as the Chair for the Committee on Science Issues

for APA's Division for the Psychology of Sexual Orientation and Gender Diversity and was appointed to its Task Force on Transgender Issues. Throughout my career, my writings and public statements have consistently supported rights for transgender populations and the application of science to help policy-makers best meet their diverse needs. Because my professional background also includes neurobiological research on the development of other atypical sexualities, I have become recognized as an international leader also in the destigmatizing of the broader range of human sexuality patterns.

6. I am highly experienced in the application of sex research to forensic proceedings: I have served as the Head of Research for the Law and Mental Health Program of the University of Toronto's psychiatric teaching hospital, the Centre for Addiction and Mental Health, where I was appointed to the Faculty of Medicine.

7. I have served as an expert witness in 21 cases in the past four years, as listed on my *curriculum vitae*. These cases included criminal, civil, and custody proceedings, preliminary injunction and Frye hearings, as well as trials. I have testified in courts in Canada and throughout the U.S., including Alabama, Arizona, Florida, Illinois, Indiana, Kansas, Kentucky, Massachusetts, New York, Texas, Utah, and West Virginia. I have provided expert testimony concerning the nature and origins of atypical sexualities, as well as concerning gender dysphoria and gender identity in children.

8. For my work in this case, I am being compensated at the hourly rate of $400 per hour. My compensation does not change based on the conclusions and opinions that I provide here or later in this case or on the outcome of this lawsuit.

B. Clinical expertise vs. scientific expertise

9. In clinical science, there are two kinds of expertise: Clinicians' expertise regards

applying general principles to the care of an individual patient and the unique features of that case. A scientist's expertise is the reverse, accumulating information about many individual cases and identifying the generalizable principles that may be applied to all cases. Thus, different types of decisions may require different kinds of experts, such that questions about whether a specific patient represents an exception to the general rule might be better posed to a physician's expertise, whereas questions about establishing the general rules themselves might be better posed to a scientist's.

10. In legal matters, the most familiar situation pertains to whether a given clinician correctly employed relevant clinical standards. Often, it is other clinicians who practice in that field who will be best equipped to speak to that question. When it is the clinical standards that are themselves in question, however, it is the experts in the assessment of scientific studies who are the relevant experts.

C. The professional standard to evaluate treatment models is to rely on objective assessors, not treatment model users in a conflict of interest with its results.

11. I describe in a later section the well-recognized procedures for conducting reviews of literature in medical and scientific fields to evaluate the strength of evidence for particular procedures or treatments. Importantly, the standard procedure is for such evaluations to be conducted by objective assessors with expertise in the science of assessment, and not by those with an investment in the procedure being assessed. Because the people engaged in providing clinical services are necessarily in a conflict of interest when claiming that their services are effective, formal evaluations of evidence are routinely conducted by those *without* direct professional involvement and thus without financial or other personal interest in whether services are deemed to be safe or effective. This routine practice standard is exemplified by all of the only three

systematic, comprehensive research reviews that have been conducted concerning the safety and efficacy of puberty blockers and cross-sex hormones as treatments for gender dysphoria in children.

12. In 2020, England's National Health Service (NHS) commissioned a major review of the use of puberty blockers and cross-sex hormones in children and young people and appointed prominent pediatrician Dr. Hilary Cass to lead that review, explicating that "Given the increasingly evident polarization among clinical professionals, Dr. Cass was asked to chair the group as a senior clinician with *no prior involvement* or fixed views in this area." (Cass 2022 at 35, italics added.) Dr. Cass's committee in turn commissioned formal systematic reviews of evidence from the England National Institute for Health & Care Excellence (NICE), a government entity of England's Department of Health and Social Care, established to provide guidance to health care policy, such as by conducting systematic reviews of clinical research, but without direct involvement in providing treatment to gender dysphoric individuals. (https://www.nice.org.uk/.) Similarly, the Finnish health care council commissioned its systematic review to an external firm, Summaryx Oy. (Pasternack 2019.) Summaryx Oy is a "social enterprise" (a Finnish organization analogous to a non-profit think-tank) that conducts systematic research reviews and other analyses for supporting that nation's medical and social systems. Its reviews are conducted by assessment professionals, not by clinicians providing services. (www.summaryx.eu/en/.) The systematic review by Sweden's National Board of Health and Welfare (NBHW) included four experts. (SBU Scoping Review 2019.) In addition to their own research fields, they provided clinical services in areas adjacent to but apart from gender dysphoric children, such as physical disorders of sexual development (Dr. Berit Kriström) or gender dysphoria in adults (Dr. Mikael Landén).

13. My own most-cited peer-reviewed paper relating to gender dysphoria in minors

illustrates the expertise in the evaluation of scientific evidence that I have and am recognized for. That is, that paper provided not clinical advice or a clinical study, but rather a review and interpretation of the available evidence concerning desistance in children who suffer from gender dysphoria, as well as of evidence (and lack of evidence) concerning the safety and efficacy of medical transition to treat gender dysphoria in minors. (Cantor 2019.)

14. My extensive background in the assessment of sexuality research and in the development of human sexuality places me in exactly the position of objectivity and freedom from conflict-of-interest required by the universal standards of medical research science.

15. I do not offer opinions about the best public policy. Multiple jurisdictions have attempted multiple different means of implementing that science into various public policies. Although I accept as an axiom that good public policy must be consistent with the scientific evidence, science cannot objectively assess societal values and priorities. Therefore, my opinions summarize and assess the science on which public policy is based, but I can offer no opinion regarding which public policy mechanisms would be best in light of that science.

II. Multiple international health care systems that had initially expanded medicalized transition to include minors have reversed that policy, as research on safety and effectiveness accumulated, in a growing international trend against the medicalized transition of minors.

16. Medicalized interventions for minors originated in European clinics (most prominently in the Netherlands and Sweden), and these precedents (and in particular the so-called "Dutch Protocol") are frequently cited by American clinicians. However, growing concerns about safety together with the continuing absence of reliable evidence of benefit even after more than 20 years of experience have led respected and far-from "conservative" European health care ministries to step back and discourage or even cease providing medicalized transition of minors, other than in exceptional and carefully limited circumstances, such as within registered and approved research trials. Instead, these authorities now endorse psychotherapy as the treatment of choice for minors, with medical interventions representing a method of last resort, if permitted at all. These range from medical advisories to outright bans on the medical transition of minors. I provide details concerning these policy changes below, and provide additional details regarding the underlying systematic reviews in Section II and V below.

A. England

17. The National Health Service (NHS) of the United Kingdom centralized gender counselling and transitioning services into a single clinic, the Gender Identity Development Service (GIDS) of the Tavistock and Portman NHS Foundation Trust. Between 2008 and 2018, the number of referrals to the clinic had increased by a factor of 40, leading to a government inquiry into the causes. (Rayner 2018.) The GIDS was repeatedly accused of approving and endorsing medical transition in minors without adequate justification, including by 35 members of the GIDS own staff, who resigned by 2019. (BBC News 2021; Donnelly 2019). An ex-governor and psychotherapist of the Trust who resigned, Marcus Evans, said staff feared being called

transphobic, which was impacting their objectivity in their work. (Doward 2019a).

18. In 2020, a former patient of the GIDS, Keira Bell, brought a lawsuit alleging that the GIDS practices with respect to prescribing puberty blockers for minors were unproven and potentially harmful in ways that meant that it was impossible for minors to give meaningful informed consent. After taking extensive expert evidence, the trial court concluded that puberty blockers might have "potentially irreversible" and "life-changing" effects on a young person (*Bell v. Tavistock*, [2020] EWHC 3274 (Admin), ¶148, 151), that there was "very limited evidence as to its efficacy" (¶134) such that "it is right to call the treatment experimental" (¶148), and that use of puberty blockers almost always led to use of cross-sex hormones that "may well lead to a loss of fertility" (¶¶ 137-138). While an appeals court later concluded that the trial court had exceeded the proper role of the court in making factual findings on these questions, the appeals court acknowledged that "Medical opinion is far from unanimous about the wisdom of embarking on treatment before adulthood. The question raises not only clinical medical issues but also moral and ethical issues, all of which are the subject of intense professional and public debate." (Bell v. Tavistock 2021 at ¶3.)

19. Perhaps prompted by the Kiera Bell litigation, also in 2020 the English National Health Service ("NHS") commissioned the thorough independent review of the use of puberty blockers and cross-sex hormones to be chaired by Dr. Cass that I have described above. After an extensive process that included obtaining the systematic reviews of all published studies bearing on safety or efficacy of these hormonal interventions in minors as well as "extensive" listening sessions with clinicians, patients, and families, in February 2022 Dr. Cass issued an extensive "Interim Report" summarizing the state of the relevant medical science and in particular highlighting the presence of serious but unstudied risks, and the lack of strong evidence of efficacy. I will quote specific

items from Dr. Cass's Report as relevant to specific topics below. At a high level, Dr. Cass concluded that to date there has been "very limited research on the sexual, cognitive, or broader developmental outcomes" from the use of puberty blockers for gender dysphoria (Cass 2022 at 19), that it is an unanswered question "whether the evidence for the use and safety of [puberty blockers] is strong enough as judged by reasonable clinical standards" (at 37), and that "the available evidence was not strong enough to form the basis of a policy position" with regard to use of both puberty blockers and cross-sex hormones in minors (at 35).

20. Following issuance of Dr. Cass's Interim Report, the English NHS has published a consultation document concerning a proposed revised service specification under which "NHS England will only commission [puberty blockers] in the context of a formal research protocol." (NHS Interim Service Specification at 12.)

B. Finland

21. In Finland, minors were made eligible for medicalized transition in 2011 by that country's health care service, the Council for Choices in Health Care in Finland (COHERE). Assessments of mental health and preparedness were centralized by law into two research clinics, Helsinki University Central Hospital and Tampere University Hospital.

22. In 2019, the Service Selection Council (Palko) of the Finnish Ministry of Social Affairs and Health commissioned a systematic review of the effectiveness and safety of medicalized transition (Pasternack 2019), and in 2020, Finnish researchers published an analysis of the outcomes of adolescents diagnosed with transsexualism and receiving cross-sex hormone treatment in Finland's Tampere University Hospital. (Kaltiala 2020.) Despite the purpose of medical transition being to improve mental health, the study showed:

> Medical gender reassignment is not enough to improve functioning and relieve psychiatric comorbidities among adolescents with gender dysphoria. Appropriate

> interventions are warranted for psychiatric comorbidities and problems in adolescent development. (Kaltiala 2020 at 213.)

They concluded that the youth who were functioning well after transition were those who were already functioning well before transition, and those who were functioning poorly before transition continued to function poorly after transition.

23. Importantly, the results of this study exemplify why correlations reported from surveys cannot be interpreted as evidence of causality. Mental health assessment would exclude the most poorly functioning youth from among those permitted to transition, but transition itself did not improve the functioning of those who were permitted to transition.

24. Consistent with the results of the independent evidence review by Summaryx Oy and analysis of the ethical issues involved, Finland's health care service ended the surgical transition of minors, ruling in 2020 that "Surgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors." (COHERE Summary 2020.) The review of the research concluded that "[N]o conclusions can be drawn on the stability of gender identity during the period of disorder caused by a psychiatric illness with symptoms that hamper development." (COHERE Summary 2020.) COHERE also greatly restricted access to puberty-blocking and cross-sex hormonal treatments, explicating that they may be considered for minors "only if it can be ascertained that their identity as the other sex is of a permanent nature and causes severe dysphoria," and only "if the need for it continues *after* [any] other psychiatric symptoms have *ceased* and adolescent development is progressing normally." (COHERE Summary 2020, italics added.) They restricted the procedures to their centralized research clinics. The council was explicit in noting the lack of research needed for decision-making, "There is also a need for more information on the disadvantages of procedures and on people who regret them." (COHERE Summary 2020.) In light of the special developmental and ethical considerations surrounding

minors, COHERE recommended that "no decisions should be made that can permanently alter a still-maturing minor's mental and physical development." (COHERE Recommendation 2020 at 7.)

C. Sweden

25. Sweden's national health care policy regarding trans issues has developed quite similarly to that of the UK. Already in place 20 years ago, Swedish health care policy permitted otherwise eligible minors to receive puberty-blockers beginning at age 14 and cross-sex hormones at age 16. At that time, only small numbers of minors sought medical transition services. An explosion of referrals ensued in 2013–2014. Sweden's Board of Health and Welfare ("Socialstyrelsen") reported that, in 2018, the number of diagnoses of gender dysphoria was 15 times higher than 2008 among girls ages 13–17. (Swedish Socialstyrelsen Support 2022 at 15.)

26. Sweden has long been very accepting with regard to sexual and gender diversity. In 2018, a law was proposed to lower the age of eligibility for surgical care from age 18 to 15, remove the requirement for parental consent, and lower the legal age for change of gender to age 12. A series of cases of regret and suicide following medical transition were reported in the Swedish media. (Orange 2020.) In 2019, the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) therefore initiated its own systematic review of the research. The SBU released English-language results first as a summary and then published as a peer reviewed article. (Ludvigsson et al. 2023.) Like the UK, the Swedish investigation employed standardized review methods to ensure the encapsulation of the all the relevant evidence and came to the same conclusions: "This systematic review of almost 10 000 screened abstracts suggests that long-term effects of hormone therapy on psychosocial and somatic health are unknown, except that GnRHa treatment seems to delay bone maturation and gain in bone mineral density." (Ludvigsson 2023 at 12). They emphasized, "The absence of long-term studies is worrying because

many individuals start treatment as minors (<18 years) and CSHT is lifelong." (Ludvigsson 2023 at 10.) Regarding the full set of studies, "No randomised controlled trials were found, but we could identify 24 relevant observational studies. However, these were limited by methodological weaknesses, for instance lack of or inappropriate control group, lack of intra-individual analyses, high attrition rates that precluded conclusion to be drawn." (Ludvigsson 2023 at 9–10.)

27. In 2021, the leading Swedish pediatric gender clinic, at the Karolinska Institute, issued a new policy statement in which it stated that the Swedish evidence review "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." (Karolinska 2021.) The Karolinska Institute further stated that "These treatments are potentially fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis." In a dramatic reversal of its policy, the Institute announced that "In light of the above, and based on the precautionary principle, which should always be applied, it has been decided that hormonal treatments (i.e., puberty blocking and cross-sex hormones) will not be initiated in gender dysphoric patients under the age of 16." Further, the Karolinska clinic announced that patients ages 16–18 would receive such treatments *only* within research settings (clinical trials monitored by the appropriate Swedish research ethics board). (Karolinska 2021.)

28. In 2022, the Swedish National Board of Health and Welfare published a major new national policy document concerning "Support, investigation and hormone therapy in gender incongruence in children and youth," including an English-language summary. (Swedish Socialstyrelsen Support 2022.) The National Board of Health noted "the continued lack of reliable scientific evidence concerning the efficacy and the safety of both [puberty blockers and cross-sex hormones]," and concluded (based on the commissioned evidence reviews) that "the evidence on

treatment efficacy and safety is still insufficient and inconclusive for all reported outcomes. Further, it is not possible to determine how common it is for adolescents who undergo gender-affirming treatment to later change their perception of their gender identity or interrupt an ongoing treatment." As a result, the Board of Health concluded that, "[f]or adolescents with gender incongruence, the . . . risks of puberty suppressing treatment with GnRH-analogues and gender-affirming hormonal treatment currently outweigh the possible benefits." (Swedish Socialstyrelsen Support 2022 at 10-12.) Accordingly, the Swedish Board of Health and Welfare "recommends restraint when it comes to hormone treatment." (Swedish Socialstyrelsen Updated Recommendations 2/22/22.)

D. France

29. While medical authorities in France have not issued any actual restriction, in 2022, the Académie Nationale de Médecine of France issued a strongly worded statement, citing the Swedish ban on hormone treatments:

> [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…such as impact on growth, bone fragility, risk of sterility, emotional and intellectual consequences and, for girls, symptoms reminiscent of menopause." (Académie Nationale de Médecine 2022.)

For hormones, the Académie concluded "the greatest reserve is required in their use," and for surgical treatments, "[T]heir irreversible nature must be emphasized." The Académie warned "the risk of over-diagnosis is real, as shown by the increasing number of transgender young adults wishing to 'detransition'." Rather than medical interventions, it advised health care providers "to extend as much as possible the psychological support phase." The Académie reviewed and emphasized the evidence indicating the very large and very sudden increase in youth requesting medical transition. It attributed the change, not to society now being more accepting of sexual

diversity, but to social media, "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." (Académie Nationale de Médecine 2022.)

E. Norway

30. In 2022, Norway's Healthcare Investigation Board (Ukom) began a review of that country's guidelines for the medicalized transition of minors. (Block, Norway's Guidance, 2023.) In 2023, it released its report, which concluded that the evidence for the use of puberty blockers and cross-sex hormone treatments in youth was insufficient, and acknowledged the international recognition of the dearth of evidence of safety and effectiveness. The report deemed medicalized transition to be experimental. (Ukom 2023, Summary and Section 11.) The report faulted the existing Norwegian guidelines, published in 2020, for concentrating on "equality and rights" while "deviating from the requirements for the development of knowledge-based guidelines." (Ukom 2023, Summary.)

31. The Norwegian report concluded that "The knowledge base, especially research-based knowledge for gender-affirming treatment (hormonal and surgical), is insufficient and the long-term effects are little known" and that "This applies particularly to the teenage population, which accounts for a large part of the increase in referrals to the specialist health service in the last decade." (Ukom 2023, Summary and Section 7.)

32. In an interview about the report with the *British Medical Journal,* the Ukom Medical Director, Stine Marit Moen, said, "We're concerned that there may be undertreatment, overtreatment, and the wrong treatment" and added:

> We've seen a marked increase in referrals to specialised healthcare services in Norway for teenagers, as seen in many other western countries, and nobody knows

> the reason. The stability of the gender dysphoria of these teenagers is not known, and the evidence of long term effects of gender affirming treatments for this young population is insufficient. (Block, Norway's Guidance, 2023.)

33. Ukom noted that referrals to its national treatment service increased by a factor of eight between 2007 and 2018, and that this increase was largely from young biological females. Seventy-five percent of the referrals to its National Treatment Service had other co-morbid psychiatric diagnoses, including not only depression and anxiety but also autism spectrum disorders, ADHD, and Tourette's Syndrome. (Ukom 2023, Summary and Section 7.)

F. Assertions by U.S. organizations and officials that there is 'no debate' over medicalized transition are false.

34. The international consensus is clearly demonstrated by the multiple recent analyses, statements, and policy decisions from the health care service systems around the world. These include England's National Health Service, which noted the "Scarce and inconclusive evidence to support clinical decision making [which] has led to a lack of clinical consensus on what the best model of care for children and young people experiencing gender incongruence and dysphoria should be." (NHS 2022 at 5.)

35. As these several recent national policy reviews, statements, and recommendations make very clear, there is a great deal of doubt and debate among the sophisticated international medical and mental health community as to whether the administration of puberty blockers and cross-sex hormones to children and young people is the best clinical practice, and as to whether these treatments have been shown to be safe and effective. Indeed, the lack of scientifically reliable data concerning safety and efficacy highlighted by the systematic evidence reviews commissioned by the English National Health Service, by the Swedish National Board of Health and Welfare, and by the Finnish Council for Choices in Health Care in Finland have caused those national health authorities and others to move sharply away from approving puberty blockers, cross-sex

hormones, or surgery for minors.

36. In this report, I explain the evidence and lack of evidence behind that doubt, that debate, and the emerging international consensus of caution reflected in the several recent European policy statements or changes.

37. I note that the plaintiffs' experts have excluded all mention of the international reversals of policy, falsely suggesting a consensus. In fact, practices at U.S. gender clinics and statements by U.S. advocacy voices increasingly represent an outlier view, failing to update policy despite the mounting evidence.

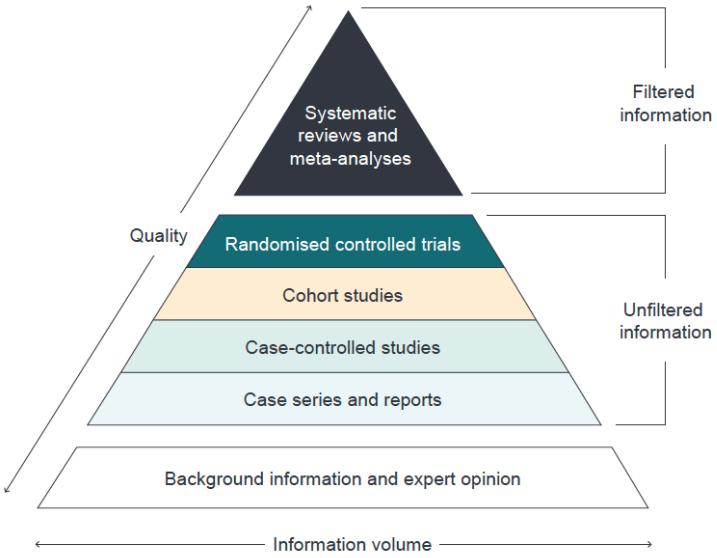
III. Clinical research has a standard *Pyramid of Evidence* that summarizes the relative strength of potential sources of information.

38. The widely accepted starting point in evidence-based medicine is the recognition that clinical experiences and recollections of individual practitioners (often called "expert opinion" or "clinical anecdote") do not and cannot provide a reliable, scientific basis for treatment decisions. Rather, in evidence-based medicine, clinical decision-making is based on objectively demonstrated evidence of outcomes from the treatment options. An essential first step in evidence-based medicine is identifying the relevant findings from among the immense flood of clinical journal articles published each year. Those studies and the evidence they report are then assessed according to the strength offered by the research methods used in each study. The research methods used in a study determine its reliability and generalizability, meaning the confidence one may have that using the same treatment again will have the same result again on other people. In this section, I explain the well-accepted criteria for evaluating the evidentiary value of clinical studies.

A. Clinical research comprises a standard *Pyramid of Evidence*, wherein studies from higher levels of evidence outrank even more numerous studies from lower levels of research.

39. The accepted hierarchy of reliability for assessing clinical outcomes research is routinely represented as a "Pyramid of Evidence" (Figure 1). Scientific questions are not resolved by the number of studies coming to one versus another conclusion. Studies representing higher levels of evidence outrank studies from lower levels. Even large numbers of lower-level studies cannot overcome a study representing a higher level of evidence. Indeed, because lower-level studies are generally faster and less expensive to conduct, it is typical for them to outnumber higher level studies. This is the property meant to be reflected by the pyramid's shape, which is larger at the base and smaller at the apex.

Figure 1: Pyramid of Standards of Evidence



Source: OpenMD. Retrieved from https://openmd.com/guide/levels-of-evidence.

B. The highest level of evidence for safety and effectiveness research is the systematic review of clinical experiments.

40. The most reliable and conclusive method of determining what is actually known or not known with respect to a particular treatment is the *systematic review.* Systematic reviews employ standardized procedures to assess comprehensively all available evidence on an issue, minimizing opportunities for bias in gathering and evaluating research evidence. As described by Dr. Gordon Guyatt, the internationally recognized pioneer in medical research who invented the term *evidence-based medicine,* "A fundamental principle to the hierarchy of evidence [is] that optimal clinical decision making requires systematic summaries of the best available evidence." (Guyatt 2015 at xxvi.)

41. I note that Dr. Antommaria's report for the plaintiffs correctly indicated that "It is best practice to ascertain the studies via systematic reviews of the literature." (Antommaria Report at 6.) Missing from Dr. Antommaria's report is that none of the systematic reviews he cited were systematic reviews of safety and efficacy, both of which are necessary for assessing the risk:benefit

ratio of a treatment. Moreover, I note that none of the plaintiffs' other experts cited any systematic reviews at all, failing to meet the standard Dr. Antommaria and I indicated.

1. Systematic reviews prevent the 'cherry-picking' of studies that favor a particular result.

42. Because systematic reviews are designed to prevent researchers from including only the studies they favor and other biases, systematic reviews are the routine starting point for developing clinical practice guidelines. (Moher 2009.) The methods of a systematic review include:

- Define the scope, including the "PICO": Population/Patient, Intervention, Comparison/Control, and Outcome(s);
- Select and disclose the keywords used to search the (massive) available clinical research database(s) for potentially relevant articles, identify the databases they were applied to, and the date(s) of the searches, including any subsequent updates;
- Select and disclose the inclusion/exclusion criteria to be used to filter the "hits" from the keyword searches to identify research studies to be included in the detailed review;
- Review abstracts to select the final set of studies, using at least two independent reviewers to allow for measuring inter-rater reliability on the criteria;
- Code each study's results impacting the research question(s), disclosing the list of all studies and the results coded from each;
- Evaluate the reliability of the results [risk of bias] of each included study, applying uniform criteria across them all.

43. As detailed in Section V, several systematic reviews have been conducted of the outcomes of medicalized transition of gender in minors. Their conclusions are highly consistent with each other. Much of the expert testimony offered by plaintiffs' experts, however, depends on levels of evidence far lower on the pyramid of evidence (e.g., "expert opinion") or beneath the pyramid entirely (e.g., survey studies) while ignoring the thorough, high-quality systematic reviews available in the research literature. Doing so is in direct conflict with foundational principles of evidence-based medicine.

2. Systematic reviews prevent biased assessment of individual studies by uniformly applying standard criteria to each study reviewed. The most widely used criteria set is "GRADE."

44. In order to produce unbiased assessment of the studies within the systematic review, all the studies must be evaluated using the same evaluation criteria. Without such criteria, assessments can become influenced by researchers who, intentionally or not, hold the evaluative bar higher or lower for studies according to whether the studies' conclusions support or challenge that researcher's perspective. Several such systems have been developed. The most widely used system is the "Grading of Recommendations, Assessment, Development and Evaluations" (GRADE). (Goldet & Howick 2013.) In the GRADE system, studies' findings are downgraded for:

- Risk of bias:[1]
    - Lack of clearly randomized allocation sequence,
    - Lack of blinding,
    - Lack of allocation concealment,
    - Failure to adhere to intention-to-treat analysis,
    - Trial is cut short,
    - Large losses to follow-up;
- Inconsistency;
- Indirectness of evidence;
- Imprecision; and
- Publication bias (when studies with 'negative' findings remain unpublished).

Studies' ratings are upgraded if their findings identify:

- A large effect of the treatment;
- A dose-response relationship (the size of the effect has a systematic association with the dose of the treatment given); or
- That all plausible biases only *reduce* the apparent effect of the treatment (necessarily making the estimated effect sizes conservative estimates).

[1] In science, including in the GRADE system, the term "bias" refers to any external influence leading to a systematic over- or underreporting of the outcome being measured. That is, in this context "bias" is not used in the sociopolitical sense of personal values.

45. GRADE assessments yield a four-point score representing the certainty that a reported treatment effect is true. These certainty scores are (GRADE Handbook, Section 5):

Certainty	Meaning
High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very Low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

C. The highest level experimental study of clinical safety and effectiveness is the Randomized Controlled Trial (RCT). RCTs can demonstrate that a given treatment causes (rather than only correlates with) a given outcome.

46. Randomized Controlled Trials are the gold standard method of assessing the effects caused by an experimental treatment. The great scientific weight of RCTs follows from the randomization: people do not pick which research group they are in—a treatment group or a control group. Without random group assignment, it is not possible to identify which, if any, changes are due to the treatment itself or to the factors that led to who did and did not receive treatment.

47. Levels of evidence lower than RCTs are unable to distinguish when changes are caused by the experimental treatment, or by factors that can mimic treatment effects, such as 'regression to the mean' and the placebo effect.

48. In the absence of evidence that X causes Y, it is a scientific error to use language indicating there is causal relationship. In the absence of evidence of causality, it is scientifically unsupportable to describe a correlation with terms such as: increases, improves, benefits, elevates,

leads to, alters, influences, results in, is effective for, causes, changes, contributes to, leads to, yields, impacts, decreases, harms, and depresses. Scientifically valid terms for correlations include: relates to, is associated with, predicts, and varies with.

49. I note that the plaintiffs' experts repeatedly misrepresent studies using causal language to describe studies that are unable to demonstrate causality. Such language incorrectly asserts that the evidence is stronger than it actually is.

1. RCTs, but not lower levels of evidence, overcome biases representing 'regression to the mean' and other factors that can mimic clinical improvement.

50. 'Regression to the mean' arises when researching issues, such as mood, depression, or levels of emotional distress that typically fluctuate over time. People are more likely to seek out treatment during low points rather than high points in their emotional lives. Thus, when tracking emotional states over time, the average of a group of people in a treatment group may often show an increase; however, without an untreated control group to which to compare them, researchers cannot know whether the group average would have increased anyway, with only the passage of time.

51. Blinding or masking participants in an RCT from which group they are in has been described as a preferred strategy since the 1950s, in order to exclude the possibility that a person's expectations of change caused any changes observed (the "placebo effect"). In practice, however, it has often made little or no significant difference. For example, a study using very high quality methods—meta-analysis of meta-analysis research—has revealed no statistical difference in the sizes of the effects detected by blinded/placebo-controlled studies from non-blinded/non-placebo-controlled studies of depression. (Moustgaard 2019.) That is, the pre-/post- treatment differences found in placebo groups are not as attributable to participants' expectations of improvement as

they are to expectable regression to the mean. (Hengartner 2020.)

2. When a 'no treatment control group' is untenable, RCTs use an 'active comparator' group instead.

52. It is not always possible to compare a group receiving a treatment to a group receiving only an inactive procedure, such as a placebo treatment or no treatment at all. In such situations, the standard, ethical, clinical research method is to compare two active treatments with each other.

53. The systematic reviews from England explicitly called for 'active comparator' studies to test whether medicalized transition of minors shows mental health benefits superior to those obtained from psychotherapy. (NICE 2020a at 40; NICE 2020b at 47.) Risk:benefit analysis cannot justify the greater risks associated with medicalization without evidence of correspondingly greater benefit.

D. Cohort studies are the highest level of evidence about medicalized transition currently available.

54. The highest-level study of medicalized transition of minors conducted thus far are cohort studies: gathering a sample of individuals who chose to undergo treatment and tracking them over time. Cohort studies are able to answer some questions that lower-level studies cannot, such as whether a high-functioning group improved over time versus having been composed of people who were already high-functioning. Cohort studies are, however, unable to demonstrate causality, to identify how much of any change was due to regression to the mean, or to detect any placebo effects.

E. Expert opinion represents the least reliable evidence.

55. As Figure 1 illustrates, evidence-based medicine opinion based on clinical experience is identified as the *least* reliable source of medical knowledge. Among other reasons, this is because non-systematic recollections of unstructured clinical experiences with self-selected

clientele in an uncontrolled setting is the most subject to bias. Indeed, mere "clinical experience" was long the basis of most medical and mental health clinical decisions, and it was precisely the scientific and clinical inadequacy of this type of "knowledge" that led to the development and widespread acceptance of the importance of evidence-based medicine. As Dr. Guyatt has written, "EBM places the unsystematic observations of individual clinicians lowest on the hierarchy," both because EBM "requires awareness of the best available evidence," and because "clinicians fall prey to muddled clinical reasoning and to neglect or misunderstanding of research findings." (Guyatt 2015 at 10, 15.)

F. Surveys and cross-sectional studies cannot demonstrate treatment effectiveness.

56. Surveys represent observational research rather than experimental research. (In science, experiments are studies involving a manipulation, not merely observation, by the researcher.) Surveys and cross-sectional studies can provide only correlational data and cannot demonstrate causality. (See Section IV below). It is not possible for a survey to yield evidence that a treatment is effective. No number of surveys can test a treatment, advancing it from 'experimental' to 'established' status.

57. Survey studies do not even appear on the *pyramid of evidence.* In accordance with the routine standards, systematic reviews of treatment studies exclude surveys.

58. I note that the plaintiffs' experts' reports rely largely on survey studies.

IV. Methodological defects limit or negate the evidentiary value of many studies of treatments for gender dysphoria in minors.

A. In science, to be valid, a claim must be objective, testable, and falsifiable.

59. In behavioral science, people's self-reports do not represent objective evidence. It is when emotional and other pressures are strongest that the distinction between and need for objective over subjective evidence is greatest. Surveys do not represent objective evidence. This is especially true of non-random surveys and polls, recruited through online social networks of the like-minded.

B. Correlation does not imply causation.

60. Studies representing lower levels of evidence are often used because they are faster and less expensive than studies representing higher levels. A disadvantage, however, is that they are often limited to identifying which features are *associated* with which other features, but they cannot show which ones are *causing* which. It is a standard property of statistical science that when a study reports a correlation, there are necessarily three possible explanations. Assuming the correlation actually exists (rather than represents a statistical fluke or bias), it is possible that X causes Y, that Y causes X, or that there is some other variable, Z, that causes both X and Y. (More than one of these can be true at the same time.) To be complete, a research analysis of a correlation must explore all three possibilities.

61. For example, assuming a correlation between treatment of gender dysphoria in minors and mental health actually exists (rather than is a fluke): (1) It is *possible* that treatment causes improvement in mental health. (2) Yet, it is also possible that having good mental health is (part of) what enabled transition to occur in the first place. That is, because of gate-keeping procedures in the clinical studies, those with the poorest mental health are typically not permitted to transition, causing the higher mental health scores to be sorted into the transitioned group. (See Section IV.E

on *Selection Bias*.) (3) It is also possible that a third factor, such as wealth or socioeconomic status, causes both the higher likelihood of transitioning (by being better able to afford it) and the likelihood of mental health (such as by avoiding the stresses of poverty or affording psychotherapy).

62. This principle of scientific evidence is why surveys do not (cannot) represent evidence of treatment effectiveness: Surveys are limited to correlations. (See Section III.F. on *Surveys*.)

C. When two or more treatments are provided at the same time, one cannot know which treatment caused observed changes (i.e., 'confounding').

63. Confounding is a well-known issue in clinical research design. As detailed in the present report, it applies throughout treatment studies of gender dysphoria. Patients who undergo medical transition procedures in research clinics routinely undergo mental health treatment (psychotherapy) at the same time. Without explicit procedures to distinguish them, it cannot be known which treatment produced which outcome (or in what proportions). Indeed, that mental health improvement came from mental health treatment is a more parsimonious (and therefore, scientifically superior) conclusion than is medicalized treatment causing mental health improvement.

D. Extrapolation to dissimilar populations and dissimilar conditions.

64. The purpose of clinical science is to establish from a finite sample of study participants information about the effectiveness and safety, or other variables, of a treatment that can be generalized to other people. Such extrapolation is only scientifically justified with populations matched on all relevant variables. The identification of those variables can itself be a complicated question, but when an experimental sample differs from another group on variables already known to be related, extrapolation cannot be assumed but must be demonstrated directly and explicitly.

65. Each of the systematic reviews from the UK, Sweden, and Finland emphasized that the

recently observed, greatly increased numbers of youth coming to clinical attention are a population different in important respects from the subjects of often-cited research studies. Conclusions from studies of adult-onset gender dysphoria and from childhood-onset gender dysphoria cannot be assumed to apply to the current patient populations of adolescent-onset gender dysphoria. The Cass Report correctly advised:

> It is also important to note that any data that are available do not relate to the current predominant cohort of later-presenting birth-registered female teenagers. This is because the rapid increase in this subgroup only began from around 2014-15. Since young people may not reach a settled gender expression until their mid-20s, it is too early to assess the longer-term outcomes of this group. (Cass 2022 at 36.)

The report also indicated:

> [I]t is important that it is not assumed that outcomes for, and side effects in, children treated for precocious puberty will necessarily be the same in children or young people with gender dysphoria. (Cass 2022 at 63.)

66. Finland's review repeated the observation of greatly (20 times) increased numbers, an entirely different demographic of cases, and increased proportions of psychiatric co-morbidities. (Finnish Palko Preparation Memo at 4-6.) The Swedish review highlighted "the uncertainty that follows from the yet unexplained increase in the number of care seekers, an increase particularly large among adolescents registered as females at birth." (Swedish Socialstyrelsen Support 2022 at 11.)

67. It is well known that males and females differ dramatically in the incidence of many mental health conditions, and in their responses to treatments for mental health conditions. Thus, research from male-to-female transitioners (the predominant population until recent years) cannot be extrapolated to female-to-male transitioners (the predominant population presenting at clinics today). Outcomes from patients who experienced clear pre-pubertal childhood gender dysphoria cannot be extrapolated to patients who first manifest diagnosable gender dysphoria well into puberty. Outcomes from clinics employing rigorous and openly reported gate-keeping procedures

cannot be extrapolated to clinics or clinicians employing only minimal or perfunctory assessments without external review. Developmental trajectories and outcomes from before the social media era cannot be assumed to apply to those of the current era or the future. Research from youth with formal diagnoses and attending clinics cannot be extrapolated to self-identifying youth and those responding to surveys advertised on social media sites.

68. Further, treatment of gender dysphoria in children and adolescents presents novel-use cases very dissimilar to the contexts in which puberty blockers and cross-sex hormones have previously been studied. Whereas use of puberty blockers to treat precocious puberty *avoids* the medical risks caused by undergoing puberty growth before the body is ready (thus outweighing other risks), use of blockers to treat gender dysphoria in patients already at their natural puberty pushes them *away* from the mean age of the healthy population. Instead of avoiding an objective problem, one is created: among other things, patients become subject to the issues and risks associated with being late-bloomers, *very* late-bloomers. This transforms the risk:benefit balance, where the offsetting benefit is primarily (however validly) cosmetic.

69. Similarly, administering testosterone to an adult male to treat testosterone deficiency addresses both a different condition and a different population than administration of that same drug to an adolescent female to treat gender dysphoria; the benefits and harms observed in the first case cannot be extrapolated to the second.

E. Mental health assessment used for gate-keeping medicalized transition establishes a *selection bias,* creating a statistical illusion of mental health improvement among the selected.

70. Importantly, clinics are expected to conduct mental health assessments of applicants seeking medicalized transition, disqualifying from medical services patients with poor mental health. (The adequacy of the assessment procedures of specific clinics and clinicians remains under

debate, however.) Such gate-keeping—which was also part of the original "Dutch Protocol" studies—can lead to misinterpretation of data unless care is explicitly taken. A side-effect of excluding those with significant mental health issues from medical transition is that when a researcher compares the average mental health of the gender dysphoric individuals first presenting to a clinic with the average mental health of those who completed medical transition, then the post-transition group would show better mental health—but only because of the *selection bias*, (Larzelere 2004; Tripepi 2010) even when the transition had no effect at all.

V. Systematic reviews of safety and effectiveness have been conducted by the health care ministries/departments of several governments. They *unanimously* concluded the evidence on medicalized transition in minors to be of poor quality.

A. Understanding safety and efficacy.

71. Plaintiffs' experts assert that use of puberty blockers and cross-sex hormones on adolescents is "safe." This claim is unsupported by any substantial scientific evidence, depreciates widely recognized risks of serious harm to minors so medicalized, and ignores both the many unknowns and the growing international doubts about their use.

72. At the outset, it is important to understand the meaning of "safety" in the clinical context. The criteria for assessing safety involve two independent components, and discussion of the safety of hormonal interventions on the natural development of children requires consideration of both of them. The term *safety* in the clinical context represents a "risk:benefit ratio," not an absolute statement that can be extrapolated across applications. In clinical research, assessing safety requires simultaneous consideration of both components of the risk:benefit ratio. That is, treatments are not deemed simply "safe" or "unsafe," as the plaintiffs' experts repeatedly use those words. These dual components are reflected in FDA regulation:

> There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that *the probable benefits* to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh *any probable risks*. (Code of Federal Regulations Title 21 Sec. 860.7, italics added.)

73. Thus, for example, as I explain in further detail below, because the Endocrine Society did not undertake (or rely on) any systematic review of the efficacy of hormonal interventions to relieve gender dysphoria in minors (i.e., their benefits), and WPATH did not undertake (or rely on) any systematic review of the safety of hormonal interventions in minors (i.e., their risks), neither gathered the evidence necessary to assess the risk:benefit ratio of medicalized transition in

minors.

74. In fact, as I also review below, after conducting systematic reviews, the English, Finnish, and Swedish national health care institutions all concluded that there is insufficient evidence to determine that hormonal interventions as treatments for gender dysphoria in minors are safe. Reasons for these consistent conclusions include lack of research, insufficient research quality among the existing investigations, and insufficient investigation of long-term safety.

75. To understand the uniform conclusions of these national health care bodies, it is important to understand that—at least where there is *prima facie* reason to be concerned that certain harms may result—when the research has not been done, the absence of evidence cannot be taken as evidence of the absence of such harms. "We don't know" does not permit the conclusion "It is safe." Plaintiffs' experts and many advocates in the field of transgender medicine make this error.

B. The McMaster University systematic review of systematic reviews.

76. McMaster University is recognized as a center of expertise in the performance of methodologically sound systematic reviews. In 2022, authors associated with that McMaster University team (Dr. Romina Brignardello-Petersen and Dr. Wojtek Wiercioch) conducted a systematic review, "Effects of gender affirming therapies in people with gender dysphoria: evaluation of the best available evidence," spanning all the available systematic reviews in this area, including their methodological strength, the evidence they cited, and the conclusions they reached. (Brignardello-Petersen & Wiercioch 2022.) Applying carefully disclosed criteria and methods, they identified on-point systematic reviews, and graded the methodological quality of each on-point review as high, moderate, low, or critically low. With regard to systematic reviews relating to the effects of puberty blockers or cross-sex hormones, the authors included in their

analysis all reviews that achieved at least a "low" rating of methodological quality, while excluding those rated as "very low." No systematic reviews earned a "high" methodological rating, except a review performed by the highly respected Cochrane Library of the effects of cross-sex hormones on transitioning natal males (Haupt 2020), but that most careful review in turn found *no* published studies on this topic of sufficient methodological soundness to satisfy its inclusion criteria and thus merit review. After this careful review of the data and analysis contained in available systematic reviews, the McMaster authors concluded:

> Due to important limitations in the body of evidence, there is great uncertainty about the effects of puberty blockers, cross-sex hormones, and surgeries in young people with gender dysphoria. This evidence alone is not sufficient to support whether using or not using these treatments. (Brignardello-Petersen & Wiercioch 2022 at 5.)

C. The quality of the systematic reviews from governmental bodies and professional associations.

77. To ensure consideration of all available evidence, I compiled into a single table all the cohort studies of safety and effectiveness included by any of the systematic reviews from the international health care systems and (although they were incomplete) by the U.S.-based clinical associations issuing guidelines or standards. I discuss their specific findings in the following sections.

78. New studies continue to be conducted and published. I have identified two additional studies that were published after these reviews were released, but that meet their inclusion criteria: Tordoff, *et al.,* 2022, and Chen, *et al.,* 2023. The findings from both these studies are consistent with those already included and are noted here for completeness.

Table 1. Cohort studies of effectiveness and safety of puberty-blockers and cross-sex hormones in minors.

	Finland (2019)	NICE (2020a,b)	Sweden (2022)	E.S. (2017)	AAP (2018)	Baker (2021) (WPATH)
Effectiveness GnRHa	Costa et al, 2015 de Vries et al, 2011	Costa et al, 2015 de Vries et al, 2011	Becker-Hebly et al, 2020 Carmichael et al, 2021 Costa et al, 2015 *** Hisle-Gorman et al, 2021			de Vries et al, 2011
Effectiveness Sex Hormones	de Vries et al, 2014*	Achille et al, 2020 Allen et al, 2019 Kaltiala et al, 2020 Lopez de Lara et al, 2020	*** *** Cantu et al, 2020* de Vries et al, 2014* ***			Achille et al, 2020 de Vries et al, 2014* López de Lara et al, 2020
Safety (Bones) GnRHa		Brik et al, 2020 Joseph et al, 2019 Khatchadourian et al, 2014 Klink et al, 2015 Vlot et al, 2017	Joseph et al, 2019 Klink et al, 2015 Navabi et al, 2021 Schagen et al, 2020 Stoffers et al, 2019 Vlot et al, 2017 Lee et al, 2020 van der Loos et al, 2021			
Safety (Bloods) GnRHa		Klaver et al, 2020 Schagen et al, 2016	Klaver et al, 2018 Klaver et al, 2020 Nokoff et al, 2020 Perl et al, 2020 Schagen et al, 2016 Schulmeister et al, 2021			
Safety (Bones) Sex Hormones	****	Khatchadourian et al, 2014 Klaver et al, 2020 Klink et al, 2015 Kuper et al, 2020 Stoffers et al, 2019 Vlot et al, 2017		Klink et al, 2015		
Safety (Bloods) Sex Hormones			Jarin, 2017 Mullins et al, 2021 Tack et al, 2016			

*Included both puberty-blockers and cross-sex hormones.
**The Endocrine Society review included bone/skeletal health, but did not explicate whether the scope included minors.
***Sweden explicitly excluded due to high risk of bias: Achille, *et al.,* (2020), Allen, *et al.* (2019), de Vries, *et al.,* (2011), and López de Lara, *et al.,* (2020).
****The Finnish review adopted the Endocrine Society review, but did not indicate whether minors were included.

D. United Kingdom

79. The National Health Service (NHS) of the United Kingdom conducted an independent review of its services for minors with gender dysphoria. (Cass 2022.) Included in that process were two systematic, comprehensive reviews of the research literature, conducted by England's National Institute for Health Care Excellence (NICE) in 2020. One regarded the efficacy, safety, and cost-effectiveness of Gonadotrophin-Releasing Hormone (GnRH) analogs (or "puberty blockers") in minors. (NICE 2020a.) The other regarded the efficacy, safety, and cost-effectiveness of cross-sex hormones, or "gender-affirming hormones," in minors. (NICE 2020b.) (Only efficacy and safety are relevant to the present report.)

80. The puberty-blocker review was tasked with reviewing the research on two relevant questions. For one:

> *In children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?* (NICE 2020a at 4.)

Clinical effectiveness of puberty-blockers was composed of three factors deemed "critical outcomes": impact on gender dysphoria, impact on mental health, and impact on quality of life. The second question addressed in the review was:

> *In children and adolescents with gender dysphoria, what is the short-term and long-term safety of GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?* (NICE 2020a at 6.)

Puberty-blocker safety was assessed as its effect on three categories of health: bone density, cognitive development or functioning, and "other."

81. The second review, for cross-sex hormone treatment, was tasked with the corresponding questions. For one:

> *In children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with gender-affirming hormones compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?* (NICE 2020b at 4.)

The critical outcomes were again deemed to be impact on gender dysphoria, on mental health, and on quality of life. The impact on mental health was composed of indicators of depression, anxiety, and suicidality and self-injury. The second question was:

> *In children and adolescents with gender dysphoria, what is the short-term and long-term safety of gender-affirming hormones compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?* (NICE 2020b at 7.)

Cross-sex hormone treatment safety was assessed as its effect on bone density and on "clinical parameters," which included insulin, cholesterol, and blood pressure levels.

82. These two reviews included a systematic consolidation of all the research evidence, following established procedures for preventing the "cherry-picking" or selective citation favouring or down-playing any one conclusion, carefully setting out the criteria for including or excluding specific studies from the review, and providing detailed analyses of each included study. The whole was made publicly available, consistent with good practice.

83. The reviews' results were unambiguous: for both puberty blockers and cross-sex hormones, "The critical outcomes for decision making are the impact on gender dysphoria, mental health and quality of life." The quality of evidence for these outcomes was assessed as "very low" using the established GRADE procedures for assessing clinical research evidence. (NICE 2020a at 4; NICE 2020b at 4.) The reviews also assessed as "very low" the quality of evidence regarding "body image, psychosocial impact, engagement with health care services, impact on extent of satisfaction with surgery and stopping treatment" or (in the case of cross-sex hormones) of "detransition". (NICE 2020a at 5; NICE 2020b at 6.) The review of puberty blockers concluded that of the existing research, "The studies included in this evidence review are all small,

uncontrolled observational studies, which are subject to bias and confounding," "They suggest little change with GnRH analogues [puberty blockers] from baseline to follow-up." (NICE 2020a at 13.) The cross-sex hormone review likewise reported a lengthy list of methodological defects or limitations affecting all available studies. (NICE 2020b at 13-14.)

84. The NHS changed the language on its website describing puberty blockers and cross sex hormones. It removed the statement that "The effects of treatment with GnRH analogues are considered to be fully reversible,"[2] replacing that text with:[3]

> Little is known about the long-term side effects of hormone or puberty blockers in children with gender dysphoria. . . . [I]t is not known what the psychological effects may be. It's also not known whether hormone blockers affect the development of the teenage brain or children's bones.

85. As mentioned in the McMaster review, the highly respected Cochrane Library, based in England, undertook a systematic review of studies of the safety and efficacy of the administration of cross-sex hormones to natal males. That review focused primarily on adults (age 16 and older). The results, including a detailed explanation of methodology and inclusion criteria, were published in 2020. Unfortunately, but importantly, the Cochrane review found *zero* studies, globally, that were sufficiently reliable to meet the inclusion criteria even at a "very low" level of evidentiary quality. The authors reported:

> Despite more than four decades of ongoing efforts to improve the quality of hormone therapy for women in transition, we found that no RCTs or suitable cohort studies have yet been conducted to investigate the efficacy and safety of hormonal treatment approaches for transgender women in transition….We found insufficient evidence to determine the efficacy or safety of hormonal treatment approaches…for transgender women in transition. The evidence is very incomplete, demonstrating a gap between current clinical practice and clinical research. (Haupt at 10-11.)

The authors' frustration at the total lack of reliable research was evident: "The lack of reliable data

[2] BBC. Retrieved from https://www.bbc.co.uk/sounds/play/m000kgsj; Kurkup, J. (2020, June 4). *The Spectator*. Available from https://www.spectator.co.uk/article/the-nhs-has-quietly-changed-its-trans-guidance-to-reflect-reality/
[3] NHS. Retrieved from https://www.nhs.uk/conditions/gender-dysphoria/treatment/

on hormone therapy for transitioning transgender women should encourage the development of well-planned RCTs and cohort studies to evaluate widespread empirical practice in the treatment of gender dysphoria." (Haupt at 10.)

E. Sweden

86. Sweden similarly commissioned a systematic review, published in 2022 and charged with addressing these three questions:

> *Are there any scientific studies explaining the increase in numbers seeking for gender dysphoria?*
>
> *Are there any scientific studies on long-term effects of treatment for gender dysphoria?*
>
> *What scientific papers on diagnosis and treatment of gender dysphoria has been published after the National Board of Health and Welfare in Sweden issued its national support for managing children and adolescents with gender dysphoria in 2015?* (SBU Scoping Review Summary 2019.)

The databases searched included CINAHL (EBSCO), Cochrane Library (Wiley), EMBASE (Embase.com), PsychINFO (EBASCO), PubMed (NLM), Scopus (Elsevier), and SocINDEX (EBSCO). A total of 8,867 abstracts were identified, from which 315 full text articles were assessed for eligibility. The review concluded that "literature on management and long-term effects in children and adolescents is sparse," that no RCTs have been conducted, and that there remains no explanation for the recent and dramatic increases in numbers of minors presenting with gender dysphoria. (SBU Scoping Review Summary 2019.) I have quoted other conclusions from the Swedish systematic review in Section II above.

F. Finland

87. Finland's Ministry of Social Affairs and Health commissioned a systematic review, completed in 2019, of the effectiveness and safety of medicalized transition. (COHERE Recommendation 2020.) The review spanned both minors and adults and included both puberty

blockers and cross-sex hormones (Pasternack 2019). Three reviewers tabulated the results. In total, 38 studies were identified, of which two pertained to minors: de Vries (2011) and Costa (2015). The report noted that, because the methodological quality of the studies was already "weak" (no study including any control groups), the assessors declined detailed quality assessment of the existing studies. (Pasternack 2019 at 3.) I have quoted other conclusions from the Finnish systematic review in Section II above.

G. Norway

88. Norway's investigation of its health care policy for gender dysphoric minors also revealed substantial safety concerns:

> There are unsettled questions related to puberty blockers in young people. A published study shows that puberty-inducing hormones cause slower height growth and a slower increase in bone density. It is also noted that the effects on cognitive development have not been mapped. Unexplained side effects and long-term effects of both puberty blockers (hormone treatment) and gender-affirming hormone treatments are increasingly being questioned. However, experience with other patient groups shows that long-term use of sex hormones can affect disease risk. When people with gender incongruence are treated, it is with significantly longer duration and intensity of hormone treatment than hormone treatments for other conditions. (Ukom 2023.)

VI. The Endocrine Society, WPATH, and the American Academy of Pediatrics did not conduct systematic reviews of safety and efficacy in establishing clinical guidelines, despite systematic reviews being the foundation and gold standard of evidence-based care.

89. I have also examined the reviews conducted by the U.S.-based professional associations that have published standards and guidelines for the treatment of gender dysphoric youth. As detailed herein, and unlike the European reviews, none of the U.S.-based professional associations conducted a systematic review of both effectiveness and safety, without which they are unable to assess the risk:benefit ratio posed by medicalized transition of minors.

A. The Endocrine Society reviewed cross-sex hormones, but not puberty blockers. They reviewed safety, but did not review effectiveness research.

90. The Endocrine Society appointed a task force which commissioned two systematic reviews as part of updating their 2009 recommendations. (Hembree 2017.) The scopes of the two reviews were limited to physiological effects of cross-sex hormones, narrowly defined: "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 second review summarized the available evidence regarding the effect of sex steroids on bone health in transgender individuals." (Hembree 2017 at 3873.) As described in the Endocrine Society Guidelines, those reviews did not, however, include the effectiveness of any treatment on mental health (quality of life, suicidality, rates of detransition, cosmetic or functional outcomes, or improvements in feelings of gender dysphoria). What appears to be the referenced review of lipids and cardiovascular outcomes (Maraka 2017) did not identitify any study of adolescents, noting "literature addressing this clinical question in the pediatric/adolescent population is completely lacking." (Maraka at 3921.) What appears to be the referenced review of bone health (Singh-Ospina 2017) identified only one small study on adolescents, involving 15 male-to-female and 19 female-to-male cases. (Klink 2015.) Notably,

the median duration of puberty-blocker administration was 1.2 years, leaving unknown the effects on children receiving blockers from puberty onset (usually age 9–10) to age 14 or 16.

91. Further, the Endocrine Society does not claim to have conducted or consulted any systematic review of the efficacy of puberty blockers or cross-sex hormones to reduce gender dysphoria or increase mental health or well-being by any metric. Nor does it claim to have conducted or consulted any systematic review of safety of any of these treatments for minors with respect to brain development, future fertility, actual reversibility, or any other factor of safety or adverse event other than cardiovascular disease and bone strength.

92. For all these reasons, I concur with the opinion of Dr. Guyatt, who has said that he finds "serious problems" with the Endocrine Society guidelines, among other reasons because the only systematic reviews those guidelines refer to did not look at the efficacy of the recommended hormonal interventions to improve gender dysphoria, which he termed "the most important outcome." (Block, Gender Dysphoria 2023 at 4.)

93. The current Endocrine Society guidelines, released in 2017, include this disclaimer:

> The Endocrine Society makes no warranty, express or implied, regarding the guidelines and specifically excludes any warranties of merchantability and fitness for a particular use or purpose. The Society shall not be liable for direct, indirect, special, incidental, or consequential damages related to the use of the information contained herein. (Hembree 2017 at 3895.)

The previous, 2009, version included no disclaimers. (Hembree 2009.)

B. WPATH reviewed effectiveness, but not the safety of medicalized transition of minors.

94. WPATH engaged in a multi-step process in updating its Standards of Care from version 7 to version 8. That process included commissioning a systematic review, which was published as Baker, *et al.* (2021) which included the disclaimer "The authors are responsible for its content. Statements in this report do not necessarily reflect the official views of or imply endorsement by

WPATH." (Baker 2021 at 14.)

95. The literature search was completed in June 2020, and spanned 13 questions. Two questions related to the effectiveness of medicalized transition of minors: Question #10 was "[W]hat are the effects of suppressing puberty with GnRH agonists on quality of life?", and question #11 was "[W]hat are the psychological effects (including quality of life) associated with hormone therapy?" (Sharma 2018; Baker 2021.) That is, the review included studies of the effectiveness of puberty blockers and cross-sex hormones, but, remarkably did not include any effort to determine the *safety* of either.

96. Baker (2021) identified that among all experimental evidence published on medicalized transition, a total of "Three studies focused on adolescents." (Baker 2021 at 1.) These were Achille, *et al.* (2020), López de Lara, *et al.* (2020), and de Vries, *et al.* (2011, 2014). (Baker 2021 considered the two de Vries articles as a single study, because the later one included the subset of patients from the earlier one who continued in treatment. I will refer to this set as four studies, however, to be consistent with the other reviews.) Notably, in contrast with WPATH's review, the Swedish review entirely excluded Achille *et al.* (2020), López de Lara *et al.* (2020), and de Vries *et al.* (2011) due to their high risks of bias. (SBU Scoping Review Appendix 2.) The Baker team did not used the GRADE system for assessing the quality of evidence, instead using the Methods Guide for Conducting Comparative Effectiveness Reviews.

97. The Baker team noted "no study reported separate results by gender identity for transgender youth." (Baker 2021 at 3.) They also found that "No study reported on hormone therapy among nonbinary people." (at 3.) (Despite this finding, WPATH SOC-8 now includes recommendations for people who identify as nonbinary.)

98. My assessment of the Baker review revealed that there were substantial discrepancies

and misleading ambiguities in their reporting: Baker, *et al.* indicated in the abstract that "Hormone therapy was associated with increased QOL [quality of life], decreased depression, and decreased anxiety" (Baker 2021 at 1,) and that "Associations were similar across gender identity and age" (Baker 2021 at 12). This is not what its actual data tables showed, however. Table 2 presented the only study of QOL specifically among adolescents included in the review and indicated that "Mean QOL scores did *not* change." (Baker 2021 at 7, italics added.)

99. The review, however, did not rate the quality of the studies of adolescents on their own, instead combining them with the studies of adults. (at 10, italics added.) Table 4 of that study presented three analyses of anxiety: One showed a decrease, and on the other two, "Mean anxiety score did *not* change." (at 11, italics added.) Finally, the review also concluded, "It was impossible to draw conclusions about the effects of hormone therapy on death by suicide." (at 12.) Even for the combined set, the review read the strength of evidence to be "low" for each of QOL, depression, and anxiety, and to be "insufficient" for death by suicide. (Baker 2021 at 13, Table 6.) Specifically, the review indicated, "There is insufficient evidence to draw a conclusion about the effect of hormone therapy on death by suicide among transgender people." (at 13, Table 6.) Overall, "The strength of evidence for these conclusions is low due to methodological limitations." (at 12.) Of particular concern was that "Uncontrolled confounding was a major limitation in this literature." (at 12.)

100. Additionally, although WPATH commissioned the Baker review, WPATH did not follow its results. Baker 2021 indicated the use of two systematic quality assessment methods, called RoB 2 and ROBINS-I (Baker 2021 at 3); however, WPATH modified the conclusions that that process yielded. WPATH SOC-8 states, "This evidence is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion."

(Coleman 2022 at S8.) Moreover:

> Recommendations in the SOC-8 are based on available evidence supporting interventions, a discussion of risks and harms, as well as feasibility and acceptability within different contexts and country settings. Consensus on the final recommendations was attained using the Delphi process that included all members of the guidelines committee and required that recommendation statements were approved by at least 75% of members. (Coleman 2022 at S8.)

101. By allowing "consensus-based expert opinion" to modify or overrule conclusions supported by systematic reviews that apply accepted criteria of evidentiary strength, WPATH has explicitly abandoned evidence-based medicine. As indicated already by the Pyramid of Evidence, "expert opinion" represents the *lowest* level of evidence in science, whereas systematic review, the highest. (Also, it is unclear what the authors mean by "background evidence.") To modify systematic results according to committee opinion is to re-introduce the very biases that the systematic process is meant to overcome. The WPATH document attempts to claim the authority of a systematic review, while reserving the ability to "overrule" results that WPATH members did not like.

102. As to evidence supporting hormonal interventions in minors, WPATH asserted that "a systematic review regarding outcomes of [hormonal] treatment in adolescents is not possible" due to the lack of "outcome studies that follow youth into adulthood." (Coleman 2022 at S46.) WPATH is correct that essential outcome studies have not been done, but incorrect that this authorizes issuance of guidelines or standards in the absence of a systematic review. As Dr. Guyatt has stated, "systematic reviews are always possible"—and indeed an important conclusion from such a review may be (as here) that insufficient evidence exists to support any evidence-based guideline. As Dr. Guyatt further elaborated, if an organization issues recommendations without performing an on-point systematic review, "they'd be violating standards of trustworthy guidelines." (Block, Dysphoria Rising, 2023 at 3.)

103. Finally, the WPATH SOC-8 were revised immediately after their release, removing all age minimums to all recommendations. None of these studies and none of these reviews support such a change, and WPATH cites no studies or other document in support of the change.

104. In sum, the WPATH SOC8 cannot be called evidence-based guidelines under any accepted meaning of that term.

C. The American Academy of Pediatrics did not conduct a systematic review either of safety or effectiveness.

105. While the AAP policy statement is often referenced, the AAP did not report conducting any systematic review of any aspect of transgender care in producing its policy statement on gender-diverse children and adolescents. (Rafferty 2018.) Further, the AAP policy statement on its face is the work of a single author rather than of any committee or the membership more broadly (Dr. Rafferty "conceptualized," "drafted," "reviewed," "revised," and "approved" the statement), and the statement explicitly states that it does not "indicate an exclusive course of treatment" nor "serve as a standard of medical care." (Rafferty 2018 at 1.)

VII. Definitions of sex, gender identity, and gender dysphoria.

A. Sex and sex-assigned-at-birth represent objective features.

106. Sex is an *objective* feature: It can be ascertained regardless of any declaration by a person, such as by chromosomal analysis or visual inspection. Gender identity, however, is *subjective:* There exists no means of either falsifying or verifying people's declarations of their gender identities. In science, it is the objective factors—and only the objective factors—that matter to a valid definition. Objectively, sex can be ascertained, not only in humans or only in the modern age, but throughout the animal kingdom and throughout its long history in natural evolution.

107. I use the term "sex" in this report with this objective meaning, which is consistent with definitions articulated by multiple medical organizations:

> Endocrine Society (Bhargava 2021 at 220.)
>
> > "Sex is dichotomous, with sex determination in the fertilized zygote stemming from unequal expression of sex chromosomal genes."
>
> American Academy of Pediatrics (Rafferty 2018 at 2 Table 1.):
>
> > "An assignment that is made at birth, usually male or female, typically on the basis of external genital anatomy but sometimes on the basis of internal gonads, chromosomes, or hormone levels."
>
> American Psychological Association (APA Answers 2014):
>
> > "Sex is assigned at birth, refers to one's biological status as either male or female, and is associated primarily with physical attributes such as chromosomes, hormone prevalence, and external and internal anatomy."
>
> American Psychological Association (APA Resolution 2021 at 1):
>
> > "While gender refers to the trait characteristics and behaviors culturally associated with one's sex assigned at birth, in some cases, gender may be distinct from the physical markers of biological sex (e.g., genitals, chromosomes)."
>
> American Psychiatric Association (Am. Psychiatric Ass'n Guide):
>
> > "Sex is often described as a biological construct defined on an anatomical, hormonal, or genetic basis. In the U.S., individuals are assigned a sex at birth based on external genitalia."

108. The phrases "assigned male at birth" and "assigned female at birth" are increasingly popular, but they lack any scientific merit. Science is the systematic study of natural phenomena,

and nothing objective changes upon humans' labelling or re-labelling it. That is, the objective sex of a newborn was the same on the day before as the day after the birth. Indeed, the sex of a fetus is typically known by sonogram or amniocentesis many months before birth. The use of the term "assign" insinuates that the label is arbitrary and that it was possible to have been assigned a different label that is equally objective and verifiable, which is untrue. Infants were born male or female before humans invented language at all. Indeed, it is exactly because an expected child's sex is known before birth that there can exist the increasingly popular "gender reveal" events. Biologically, the sex of an individual (for humans and almost all animal species) as male or female is irrevocably determined at the moment it is conceived. Terms such as "assign" obfuscate rather than clarify the objective evidence.

B. Gender identity refers to subjective feelings that cannot be defined, measured, or verified by science.

109. It is increasingly popular to define gender identity as a person's "inner sense," however, neither "inner sense" nor any similar phrase is scientifically meaningful. In science, a valid construct must be both objectively measurable and falsifiable with objective testing. The concept of an "inner sense" fits none of these requirements.

VIII. Gender Dysphoria is a mental health diagnosis.

110. Gender Dysphoria is a mental health condition defined by diagnostic criteria set out in the *Diagnostic and Statistical Manual of Mental Disorders* ("DSM") 5-TR. (American Psychiatric Ass'n 2022.) While the definitions contain multiple components and vary modestly for children, adolescents, and adults, all cases are characterized by a strong and lasting desire to be the opposite sex, and "clinically significant" distress of sufficient severity to impair the individuals' ability to function in their daily life setting. Gender dysphoria is nowhere defined as a medical (as opposed to mental health) condition, and it is not characterized by any disability or impairment or ill health affecting any part of the physical body.

IX. Distinct mental health phenomena must not be—but frequently are—confused or conflated.

111. One of the most widespread public misunderstandings about transsexualism and people with gender dysphoria is that all cases of gender dysphoria represent the same phenomenon; however, the clinical science has long and consistently demonstrated that prepubescent children expressing gender dysphoria represent a phenomenon distinct from that of adults starting to experience it. That is, gender dysphoric children are not simply younger versions of gender dysphoric adults. They differ in virtually every objective variable measured, including in their responses to treatments. A third presentation has recently become increasingly observed among people presenting to gender clinics: these cases appear to have an onset in adolescence—after the onset of puberty and before adulthood—and occur in the absence of any childhood history of gender dysphoria. Such cases have been called adolescent-onset or "rapid-onset" gender dysphoria (ROGD). Despite having only recently been observed, they have quickly and greatly outnumbered the better characterized types. Moreover, large numbers of adolescents are today self-identifying in surveys as "gender fluid" and "non-binary." These are not recognized mental health diagnoses, and do not relate in any known way to gender dysphoric groups that have been the subject of previous treatment outcome studies. Because each of these phenomena differ in multiple objective features, it is scientifically invalid to extrapolate findings from one type to the others.

A. Adult-Onset Gender Dysphoria consists predominantly of males sexually attracted to females.

112. Whereas Childhood-Onset Gender Dysphoria occurs in biological males and females and is strongly associated with later homosexuality (next section), Adult-Onset Gender Dysphoria consists primarily of biological males sexually attracted to females. (Lawrence 2010.) They typically report being sexually attracted to women and rarely showed gender atypical (effeminate)

behavior or interests in childhood (or adulthood). Some individuals express being sexually attracted to both men and women, and some profess asexuality, but very few indicate having a primary sexual interest only in men. (Blanchard 1998.) Cases of adult-onset gender dysphoria are typically associated with a sexual interest pattern involving themselves in female form (a paraphilia called autogynephilia). (Blanchard 1989a, 1989b, 1991.)

113. Because of the numerous objective differences between adult-, childhood-, and adolescent-onset gender dysphoria, it is not possible to extrapolate from these results to juvenile populations, which responsible authors are careful not to do.

B. Childhood-onset gender dysphoria (prepubertal-onset) is a distinct phenomenon characterized by high rates of desistance in the absence of social or medical transition.

114. For many decades, small numbers of prepubescent children have been brought to mental health professionals for help with their unhappiness with their sex and in the belief they would be happier living as the other sex. The large majority of childhood onset cases of gender dysphoria occur in biological males, with clinics reporting 2–6 biological male children to each female. (Cohen-Kettenis 2003; Steensma Evidence 2018; Wood 2013.)

1. Eleven cohort studies followed children not permitted social transition, all showing the majority to desist feeling gender dysphoric upon follow-up after puberty.

115. Currently, the studies of outcomes among children who experience gender dysphoria before puberty that provide the most evidentiary strength available are only "cohort studies," which follow people over time, recording the outcomes of the treatments they have undergone. Such studies supersede (i.e., overrule) the outcomes of surveys, which are much more prone to substantial error. As I have explained above, however, cohort studies can describe developmental pathways, but cannot provide evidence of causation.

116. In total, there have been 11 cohort studies showing the outcomes for these children, listed in Table 2. I first published this comprehensive list of studies in my own peer-reviewed article on the topic. (Cantor 2019.)

Table 2. Cohort studies of gender dysphoric, prepubescent children.

Count	Group	Study
2/16 4/16 10/16	gay trans-/crossdress straight/uncertain	Lebovitz, P. S. (1972). Feminine behavior in boys: Aspects of its outcome. *American Journal of Psychiatry, 128,* 1283–1289.
2/16 2/16 12/16	trans- uncertain gay	Zuger, B. (1978). Effeminate behavior present in boys from childhood: Ten additional years of follow-up. *Comprehensive Psychiatry, 19,* 363–369.
0/9 9/9	trans- gay	Money, J., & Russo, A. J. (1979). Homosexual outcome of discordant gender identity/role: Longitudinal follow-up. *Journal of Pediatric Psychology, 4,* 29–41.
2/45 10/45 33/45	trans-/crossdress uncertain gay	Zuger, B. (1984). Early effeminate behavior in boys: Outcome and significance for homosexuality. *Journal of Nervous and Mental Disease, 172,* 90–97.
1/10 2/10 3/10 4/10	trans- gay uncertain straight	Davenport, C. W. (1986). A follow-up study of 10 feminine boys. *Archives of Sexual Behavior, 15,* 511–517.
1/44 43/44	trans- cis-	Green, R. (1987). The "sissy boy syndrome" and the development of homosexuality. New Haven, CT: Yale University Press.
0/8 8/8	trans- cis-	Kosky, R. J. (1987). Gender-disordered children: Does inpatient treatment help? *Medical Journal of Australia, 146,* 565–569.
21/54 33/54	trans- cis-	Wallien, M. S. C., & Cohen-Kettenis, P. T. (2008). Psychosexual outcome of gender-dysphoric children. *Journal of the American Academy of Child and Adolescent Psychiatry, 47,* 1413–1423.
3/25 6/25 16/25	trans- lesbian/bi- straight	Drummond, K. D., Bradley, S. J., Badali-Peterson, M., & Zucker, K. J. (2008). A follow-up study of girls with gender identity disorder. *Developmental Psychology, 44*, 34–45.
47/127 80/127	trans- cis-	Steensma, T. D., McGuire, J. K., Kreukels, B. P. C., Beekman, A. J., & Cohen-Kettenis, P. T. (2013). Factors associated with desistence and persistence of childhood gender dysphoria: A quantitative follow-up study. *Journal of the American Academy of Child and Adolescent Psychiatry, 52,* 582–590.

17/139 122/139	trans- cis-	Singh, D., Bradley, S. J., Zucker, K. J. (2021). A follow-up study of boys with Gender Identity Disorder. *Frontiers in Psychiatry*, 12:632784.

*For brevity, the list uses "gay" for "gay and cis-", "straight" for "straight and cis-", etc.

117. The children in these studies were receiving professional mental health support during the study period, but did not "socially transition." In sum, despite coming from a variety of countries, conducted by a variety of labs, using a variety of methods, at various times across four decades, every study without exception has come to the identical conclusion: among prepubescent children who feel gender dysphoric, the majority cease to want to be the other gender over the course of puberty—ranging from 61–88% desistance across the large, prospective studies. Such cases are often referred to as "desisters," whereas children who continue to feel gender dysphoric are often called "persisters."

118. This interpretation of these studies is widely accepted, including by the Endocrine Society, which concluded:

> In most children diagnosed with GD/gender incongruence, it did not persist into adolescence. . . . [T]he large majority (about 85%) of prepubertal children with a childhood diagnosis did not remain GD/gender incongruent in adolescence. (Hembree 2017 at 3879.)

The developers of the Dutch Protocol, at the Vrije University gender clinic, likewise concluded based on these studies that "Although the persistence rates differed between the various studies…the results unequivocally showed that the gender dysphoria remitted after puberty in the vast majority of children." (Steensma & Cohen-Kettenis 2011 at 2.)

119. The consistent observation of high rates of desistance among pre-pubertal children who present with gender dysphoria demonstrates a pivotally important—yet often overlooked—feature: because gender dysphoria so often desists on its own, clinical researchers cannot assume that therapeutic intervention cannot facilitate or speed desistance for at least some patients. That

is, it cannot be assumed that gender identity is immune to influence such as from psychotherapy. Such is an empirical question, and there has not yet been any such research.

120. These same studies are often vaguely cited to assert that the high desistance rates uniformly reported in these 11 studies do not apply to children who have persisted until "the start of puberty" (which is taken to mean Tanner Stage 2), or in an alternative phrasing, that children "who persist until the start of puberty" are likely to continue to persist into adulthood. But these studies taken together do not support that degree of precision. Rather, the studies do not specify at exactly what developmental stage the reported desistance occurred—what they report is that the subjects had desisted by late adolescence or early adulthood. I am aware of no systematic study that establishes that— in the absence of social and/or medical transition—children who experience gender dysphoria are unlikely to desist if they have not desisted by the start of Tanner Stage 2.

2. One cohort study followed children who were permitted social transition. In contrast with children not permitted to transition socially, most persisted in expressing gender dysphoria.

121. In contrast, Olson et al. have now published a single cohort study of prepubescent children, ages 3–12 (average of 8), who had already made a complete, binary (rather than intermediate) social transition, including a change of pronouns. (Olson 2022.) The study did not employ DSM-5 diagnosis, as "Many parents in this study did not believe that such diagnoses were either ethical or useful and some children did not experience the required distress criterion." (Olson 2022.) Unlike the prior research studies, only 7.3% of these (socially transitioned) children ceased to feel gender dysphoric.

122. Although the team publishing this cohort study did not discuss it, their finding matches the prediction of other researchers, that social transition itself represents an active intervention, such that social transition may *cause* the persistence of gender dysphoria when it would have

otherwise resolved, avoiding any need for subsequent medicalization and its attendant risks. Conversely stated, social transition seems to prevent desistance. (Singh 2021; Zucker 2018, 2020.)

123. As recognized by multiple authors, the potential impact of social transition on rates of desistance is pivotal. The Endocrine Society cautions that "social transition...has been found to contribute to the likelihood of persistence." (Hembree 2017 at 3879.) WPATH has stated that after social transition, "A change back to the original gender role can be highly distressing and [social transition can] even result in postponement of this second transition on the child's part." (Coleman 2012 at 176.) In 2013, prominent Vrije University researchers observed:

> Childhood social transitions were important predictors of persistence, especially among natal boys. Social transitions were associated with more intense GD in childhood, but have never been independently studied regarding the possible impact of the social transition itself on cognitive representation of gender identity or persistence. [Social transition] may, with the hypothesized link between social transitioning and the cognitive representation of the self, influence the future rates of persistence. (Steensma 2013 at 588-589.)

3. There is no reliable method for predicting for which children who present with gender dysphoria will persist versus desist.

124. The Endocrine Society Guidelines stated in 2017 that "With current knowledge, we cannot predict the psychosexual outcome for any specific child" (Hembree 2017 at 3876), and this remains true today. Research has not yet identified any reliable procedure for discerning which children who present with gender dysphoria will persist, as against the large majority who will desist, absent transition and "affirmation." Such a method would be valuable, as the more accurately that potential persisters can be distinguished from desisters, the better the risks and benefits of options can be weighted. Such "risk prediction" and "test construction" are standard components of applied statistics in the behavioral sciences. Multiple research teams have reported that, on average, groups of persisters are somewhat more gender non-conforming than desisters, but not so different as to usefully predict the course of any particular child. (Singh 2021;

Steensma 2013.)

125. In contrast, one research team (the aforementioned Olson group) claimed the opposite, asserting that they developed a method of distinguishing persisters from desisters, using a single composite score representing a combination of children's "peer preference, toy preference, clothing preference, gender similarity, and gender identity." (Rae 2019 at 671.) They reported a statistical association (mathematically equivalent to a correlation) between that composite score and the probability of persistence. As they indicated, "Our model predicted that a child with a gender-nonconformity score of .50 would have roughly a .30 probability . . . of socially transitioning. By contrast, a child with gender-nonconformity score of .75 would have roughly a .48 probability." (Rae 2019 at 673.) Although the Olson team declared that "social transitions may be predictable from gender identification and preferences" (Rae 2019 at 669), their actual results suggest the opposite: the gender-nonconforming group who went on to transition (socially) had a mean composite score of .73 (which is less than .75), and the gender-nonconforming group who did not transition had a mean composite score of .61, also less than .75. (Rae 2019, Supplemental material at 6, Table S1.) Both of those are lower than the value of .75, so both of those would be more likely than not to desist, rather than to proceed to transition. That is, Olson's model does not distinguish likely from unlikely to transition; rather, it distinguishes unlikely from even less likely to transition.

126. Further, in the absence of long-term follow-up, it cannot be known what proportion of those who transition and persist through the early stages of puberty will later (for example as young adults) come to regret having transitioned and then *de*transition. Because only a minority of gender dysphoric children persist in feeling gender dysphoric in the first place, "transition-on-demand" increases the probability of unnecessary transition and unnecessary medical risks.

4. Temple Newhook's attempts to dismiss evidence of high rates of desistance from childhood gender dysphoria are invalid.

127. The unanimous consistency across all 11 cohort studies of (non-transitioned) gender dysphoric children offers high confidence in the conclusion that most childhood-onset cases desist during the course of puberty. In 2018, however, a commentary was published, contesting that conclusion, criticizing four studies. (Temple Newhook 2018.) Multiple accomplished international researchers studying outcomes of gender dysphoric children responded (Zucker 2018; Steensma & Cohen-Kettenis 2018), to which the Temple Newhook team wrote a rejoinder. (Winters 2018.) I have reviewed each of these arguments, finding that the Temple Newhook comments rely on demonstrable falsehoods, whereas the responses remain consistent with the peer-reviewed evidence. The Temple Newhook commentary has not altered the consensus of the international medical community, which continues to cite and rely upon these cohort studies.

128. Before delineating each of their arguments, it should be noted that the Temple Newhook team based their analysis on the wrong research reports, attacking only a straw-person version of the contents of the research literature. Table 3 repeats the 11 cohort studies (on the left left) and the four studies Temple Newhook criticized (right):

Table 3.

- Lebovitz (1972)
- Zuger (1978)
- Money & Russo (1979)
- Zuger (1984)
- Davenport (1986)
- Green (1987)
- Kosky (1987)
- Wallien & Cohen-Kettenis (2008)
- Drummond, *et al.* (2008)
- Steensma, *et al.* (2013)
- Singh, 2012/Singh, *et al.* (2021)[4]

- Wallien & Cohen-Kettenis (2008)
- Drummond, *et al.* (2008)
- Steensma, *et al.* (2011, 2013)

129. It should be noted that the Temple Newhook 2018 commentary does not represent a systematic review. Temple Newhook did not indicate search strategies, inclusion/exclusion criteria, coding methods, reliability checks, or other standard procedures used for ensuring objective and unbiased assessment of all relevant studies. Rather, the Temple Newhook analysis targeted a small and selective subset of the research available—a scientifically invalid endeavor, which the systematic review process is meant to prevent. Not only did Temple Newhook skip most of the relevant science, but conversely, Temple Newhook inserted the Steensma 2011 study, which should have been rejected. (The data it reported was already included in Wallien & Cohen-Kettenis 2008.) The Temple Newhook commentary claimed it was "systematically engaging scholarly literature." (Temple Newhook 2018 at 2.) However, as the above reference lists demonstrate, that commentary involved no such systematic procedures.

130. Temple Newhook does not report any research evidence of its own. Rather, the commentary hypothesizes issues they assert could, theoretically, have affected the rates of desistance consistently detected. Scientifically, such a criticism is vacuous: In science, it is always

[4] At the time of the 2018 Temple Newhook commentary, the Singh *et al.,* 2021 study was available as Singh, 2012.

possible for additional, external factors to have affected what was observed.

131. Also, as already detailed herein, the currently available level of evidence for outcomes of medicalized transition is the cohort study. The methodological issues highlighted by Temple Newhook are exactly why randomized, controlled trials (RCTs) need to be conducted, as such studies would be capable of resolving exactly those questions (in whichever direction). In the absence of randomized, controlled studies, however, the correct scientific process is to follow the results of the cohort studies (that is, the systematic reviews of the cohort studies).

132. In the science process, one cannot merely continue to retain a desired hypothesis, rejecting all counter-evidence until a perfect study emerges. This is especially important in clinical science, when the hypothesis relates to physical interventions, in children, with the potential to affect them for their entire lives. Rather, the scientific process proceeds by successive approximation, with results from the best available research replacing lesser quality research, increasing in confidence, but always with the possibility of changes imposed by future evidence.

133. By involving only a few of the full set of cohort studies, the Temple Newhook commentary removes one of the most compelling implications of the existing (cohort) studies: Their results are unanimous. However unlikely it might be for four studies to produce the same result randomly, it is even more unlikely for eleven studies all to come to the same result randomly.

134. Temple Newhook emphasized that gender identity issues differ across times and contexts/political environments, hypothesizing that children attending her clinic might differ from children attending the Toronto and the Amsterdam clinics. Returning once again to the full set of all studies, however, the evidence shows the very opposite: All studies yielded the same result, whether from the 1970s, 80s, 90s, 2000s, 2010s, and wherever in the world any clinic was. Acknowledging the possibility that future studies may lead to a different conclusion, the existing

evidence shows majority desistance, constantly and across all time periods.

135. Consideration of the full set of studies also indicates that the contrast is not Toronto and Amsterdam versus whatever "reality" Temple Newhook perceives. Rather, they show the contrast is between Temple Newhook and every facility in every country ever reporting desistance data on childhood-onset gender dysphoria. Moreover, despite Temple Newhook's mention of influences of political cultures, that commentary does not point out that Canada and the Netherlands are much more politically liberal than the U.S. Although the commentary offers the hypothesis that the Canadian and Dutch contexts might decrease persistence, the commentary does not include the inverse possibility: that these liberal environments might be *"iatrogenic"*—that is, causing dysphoria to continue when it might otherwise remit.

136. Also, the very evidence suggesting that gender dysphoria can be influenced by local environmental factors is itself evidence that gender identity is not, in fact, an innate and immutable feature, potentially amenable to change.

C. Adolescent-Onset Gender Dysphoria, the predominant clinical population today, is a distinct and largely unstudied phenomenon.

137. Concurrent with the advent of social media, a third profile began appearing clinically and socially, characteristically distinct from the two previously identified profiles. (Kaltiala-Heino 2015; Littman 2018.) Despite lacking any history before the current generation, this profile has now numerically overwhelmed the previously known and better characterized types in clinics and on Internet surveys. Unlike adult-onset or childhood-onset gender dysphoria, this group is predominately biologically female. This group typically presents in adolescence, but lacks the history of cross-gender behavior in childhood like the childhood-onset cases have. It is that feature

which led to the term Rapid Onset Gender Dysphoria (ROGD). (Littman 2018.)[5] Cases commonly appear to occur within clusters of peers in association with increased social media use (Littman 2018), and among people with autism or other mental health issues. (Kaltiala-Heino 2015; Littman 2018; Warrier 2020.) (See section XI on Mental Health.) The patterns reported by Littman have now been independently replicated by another study which also found it to be a predominantly female phenomenon, associated with very high rates of social media use, among youth with other mental health issues, and in association with peers expressing gender dysphoria issues. (Diaz 2023.) Due to the multiple differences across the epidemiological and other objective variables, there is no justification for extrapolating findings from adult-onset or childhood-onset gender dysphoria to this new presentation.

138. There do not yet exist any cohort studies of people with adolescent-onset gender dysphoria undergoing medicalized transition. Current studies are limited to surveys typically of volunteers from activist and support groups on the Internet.

139. Moreover, no study has yet been organized in such a way as to allow for a distinct analysis of the adolescent-onset group, as distinct from childhood-onset or adult-onset cases. Many published studies fail to distinguish between people who had childhood-onset gender dysphoria and have aged into adolescence versus people whose onset was not until adolescence. (Analogously, there are reports failing to distinguish people who had adolescent-onset gender dysphoria and aged into adulthood from adult-onset gender dysphoria.) Studies selecting groups according to their current age instead of their ages of onset produces confounded results, representing unclear mixes according to how many of each type of case wound up in the final

[5]After initial criticism, the publishing journal conducted a reassessment of the article. The article was expanded with additional detail and republished. The relevant results were unchanged. Littman's paper as revised has been widely cited.

sample.

X. Suicide and suicidality are distinct phenomena representing different mental health issues and indicating different clinical needs.

140. *Suicide* refers to completed suicides and the sincere intent to die. It is substantially associated with impulsivity, using more lethal means, and being a biological male. (Freeman 2017.) *Suicidality* refers to *para*-suicidal behaviors, including suicidal ideation, threats, and gestures.

A. Rates of suicidality among all adolescents have skyrocketed with the advent of social media.

141. The CDC's 2019 Youth Risk Behavior Survey found that 24.1% of female and 13.3% of male high school students reported "seriously considering attempting suicide." (Ivey-Stephenson 2019 at 48.)

142. The CDC survey reported not only that these already alarming rates of suicide attempt were still increasing (by 8.1%–11.0% per year), but also that this increase was occurring only among female students. No such trend was observed among male students. That is, the demographic increasingly reporting suicidality is the same demographic increasingly reporting gender dysphoria. (Ivey-Stephenson at 51.)

143. The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) produces a series of evidence-based resource guides which includes their Treatment for Suicidal Ideation, Self-Harm, and Suicide Attempts Among Youth. It noted (italics added):

> [F]rom 1999 through 2018, the suicide death rate doubled for females aged 15 to 19 and 20 to 24. For youth aged 10 to 14, the suicide death rate more than tripled from 2001 to 2018. Explanations for the increase in suicide may include bullying, social isolation, increase in technology and *social media*, increase in *mental illnesses*, and economic recession. (SAMHSA 2020 at 5.)

The danger potentially posed by social media follows from suicidality spreading as a social contagion, as suicidality increases after media reports, occurs in clusters of social groups, and in

adolescents after the death of a peer. (Gould & Lake 2013.)

144. Social media voices today loudly advocate "hormones-on-demand" while issuing hyperbolic warnings that teens will commit suicide unless this is not granted. Both adolescents and parents are exposed to the widely circulated slogan that "I'd rather have a living son than a dead daughter," and such baseless threats or fears are treated as a justification for referring to affirming gender transitions as 'life-saving' or 'medically necessary'. Such claims grossly misrepresent the research literature, however. Indeed, they are unethical: suicide prevention research and public health campaigns repeatedly warn against circulating messages that can be taken to publicize or even glorify suicide, due to the risk of copy-cat behavior they encourage. (Gould & Lake 2013.)

145. Systematic review of 44 studies of suicidal thoughts and behaviors in LGBTQ youth and suicidality found only a small association between suicidality and sexual minority stress. (Hatchel 2021.) The quantitative summary of the studies (an especially powerful type of systematic review called *meta-analysis*) found no statistically significant association between suicidality and any of having an unsupportive school climate, stigma and discrimination, or outness/openness. There were, however, significant associations between suicidality and indicators of social functioning problems, including violence from intimate partners, victimization from LGBT peers and from non-LGBT peers, and sexual risk taking.

B. *Suicidality* is substantially more common among females, and *suicide,* among males. Sexual orientation is strongly associated with suicidality, but much less associated with suicide.

146. Notwithstanding public misconceptions about the frequency of suicide and related behaviors, the highest rates of death by suicide are among middle-aged and elderly men in high income countries. (Turecki & Brent 2016 at 3.) Males are at three times greater risk of death by suicide than are females, whereas suicidal ideation, plans, and attempts are three times more

common among females. (Klonsky 2016; Turecki & Brent 2016.) In contrast with completed suicides, the frequency of suicidal ideation, plans, and attempts is highest during adolescence and young adulthood, with reported ideation rates spanning 12.1–33%. (Borges 2010; Nock 2008.) Relative to other countries, Americans report elevated rates of each of suicidal ideation (15.6%), plans (5.4%), and attempts (5.0%). (Klonsky 2016.) Suicide attempts occur up to 30 times more frequently than completed suicides. (Bachmann 2018.) The rate of completed suicides in the U.S. population is 14.5 per 100,000 people. (WHO 2022.)

147. There is substantial research associating sexual orientation with suicidality, but much less so with completed suicide. (Haas 2014.) More specifically, there is some evidence suggesting gay adult men are more likely to die by suicide than are heterosexual men, but there is less evidence of an analogous pattern among lesbian women. Regarding suicidality, surveys of self-identified LGB Americans repeatedly report rates of suicidal ideation and suicide attempts 2–7 times higher than their heterosexual counterparts. Because of this association of suicidality with sexual orientation, one must apply caution in interpreting findings allegedly about gender identity: because of the overlap between people who self-identify as non-heterosexual and as transgender or gender diverse, correlations detected between suicidality and gender dysphoria may instead reflect (be confounded by) sexual orientation. Indeed, other authors have made explicit their surprise that so many studies, purportedly of gender identity, entirely omitted measurement or consideration of sexual orientation, creating the situation where features that seem to be associated with gender identity instead reflect the sexual orientation of the members of the sample. (McNeil 2017.)

C. There is no evidence that medicalized transition reduces rates of suicide or suicidality.

148. It is repeatedly asserted that despite the known risks, despite the lack of research into

the reality or severity of unquantified risks, it is essential and "the only ethical response" to provide medical transition to minors because medical transition is known to reduce the likelihood of suicide among minors who suffer from gender dysphoria. This is simply untrue. *No studies* have documented any reduction in suicide rates in minors (or any population) as a result of medical transition. No methodologically sound studies have provided meaningful evidence that medical transition reduces suicidality in minors. Instead, multiple studies show tragically high rates of suicide after medical transition, with that rate beginning to spike several years after medical transition.

149. Among post-transition adults, completed suicide rates remain elevated. (Wiepjes 2020.) Among post-operative transsexual adults in Sweden's highly tolerant society, death by suicide is 19 times higher than among the cisgendered. (Dhejne 2011.) Systematic review of 17 studies of suicidality in transsexual adults confirmed suicide rates remain elevated even after complete transition. (McNeil 2017.) Among post-operative patients in the Netherlands, long-term suicide rates of six times to eight times that of the general population were observed depending on age group. (Asscheman 2011 at 638.) Also studying patients in the Netherlands, Wiepjes et al. (2020) reported the "important finding" that "suicide occurs similarly" before and after medical transition. (Wiepjes 2020 at 490.) In other words, *transition did not reduce suicide*. A very large dataset from the U.K. GIDS clinic showed that those referred to the GIDS clinic for evaluation and treatment for gender dysphoria committed suicide at a rate five times that of the general population, both before and after commencement of medical transition (Biggs 2022). Finally, in a still-ongoing longitudinal study of U.S. patients, Chen *et al.* have reported a shockingly high rate of completed suicide among adolescent subjects in the first two years *after* hormonal transition, although they provide no pre-treatment data for this population to compare against. (Chen 2023 at 245.)

150. WPATH's systematic review of the effectiveness of puberty blockers and cross-sex hormones on suicide in minors concluded that "It was impossible to draw conclusions about the effects of [either] hormone therapy on death by suicide." (Baker 2021 at 12.) In short, I am aware of no respected voice that asserts that medical transition reduces suicide among minors who suffer from gender dysphoria.

151. As to the separate and far more common phenomenon of suicidality, of course, that claim is widely made. McNeil's systematic review revealed, however, a complicated set of interrelated factors rather than supporting the common hypothesis that rates of suicidal ideation and suicidal attempts would decrease upon transition. Rates of suicidal ideation did not show the same pattern as suicide attempts, male-to-female transitioners did not show the same patterns as female-to-male transitioners, and social transition did not show the same patterns as medical transition. Importantly, the review included one study that reported "a positive relationship between higher levels of social support from leaders (e.g., employers or teachers) and increased suicide attempt, which they suggested may be due to attempts instigating increased support from those around the person, rather than causing it." (McNeil 2017 at 348.)

152. Moreover, the 2020 Kuper, *et al.* cohort study of minors receiving hormone treatment found *increases* in each of suicidal ideation (from 25% to 38%), attempts (from 2% to 5%), and non-suicidal self-injury (10% to 17%). (Kuper 2020 at Table 5.) Research has found social support to be associated with *increased* suicide attempts, suggesting the reported suicidality may represent attempts to evoke more support. (Bauer 2015; Canetto 2021.)

153. Overall, the research evidence is only minimally consistent with the hypothesis that an absence of transition causes mental health issues and suicide, but very strongly consistent with the hypothesis that mental health issues, such as *Borderline Personality Disorder* (BPD), cause both

suicidality and unstable identity formation (including gender identity confusion). (See section XI.) BPD is repeatedly documented to be greatly elevated among sexuality minorities (Reuter 2016; Rodriguez-Seiljas 2021; Zanarini 2021), and both suicidality and identity confusion are symptoms of that disorder. Thus, diverting distressed youth towards transition necessarily diverts youth away from receiving the psychotherapies designed for treating the issues actually causing their distress.

154. Despite that mental health issues, including suicidality, are repeatedly required by clinical standards of care to be resolved before transition, threats of suicide are instead oftentimes used as the very justification for labelling transition a "medical necessity". However plausible it might seem that failing to affirm transition causes suicidality, the epidemiological evidence does not support that hypothesis.

XI. Mental health profiles differ across adult-, adolescent-, and childhood-onset gender dysphoria.

A. Mental health issues in Adult-Onset Gender Dysphoria.

155. Systematic review of all studies examining mental health issues in transgender adults identified 38 such studies. (Dhejne 2016.) The review indicated that many studies were methodologically weak, but nonetheless consistently found (1) that the average rate of mental health issues among adults is highly elevated both before *and after* transition, (2) but that the average was less elevated among adults who completed transition. It could not be concluded that transition improves mental health, however. Patients were commonly receiving concurrent psychotherapy, introducing a confound (meaning, again, that it cannot be determined whether the change was caused by the transitioning or the mental health treatment). Further, several studies showed more than 40% of patients to become "lost to follow-up." It remains unknowable to what extent the information from the remaining participants accurately reflects the whole population.

B. Mental health issues in Childhood-Onset Gender Dysphoria.

156. Elevated rates of multiple mental health issues among gender dysphoric children are reported throughout the research literature. A formal analysis of children (ages 4–11) undergoing assessment at the Dutch child gender clinic showed that 52% fulfilled criteria for a formal DSM diagnosis of a clinical mental health condition other than Gender Dysphoria. (Wallien 2007 at 1307.) A comparison of the children attending the Canadian versus Dutch child gender dysphoria clinic showed only few differences between them, and a large proportion in both groups were diagnosable with clinically significant mental health issues. Results of standard assessment instruments (Child Behavior Check List, or CBCL) demonstrated that among 6–11-year-olds, 61.7% of the Canadian and 62.1% of the Dutch sample satisfied the diagnostic criteria for one or more mental health conditions other than gender dysphoria. (Cohen-Kettenis 2003 at 46-47.)

157. A systematic review of all studies of Autism Spectrum Disorders (ASDs) and Attention-Deficit Hyperactivity Disorder (ADHD) among children diagnosed with gender dysphoria was recently conducted. (Thrower 2020.) It was able to identify a total of 22 studies examining the prevalence of ASD or ADHD youth with gender dysphoria. Studies reviewing medical records of children and adolescents referred to gender clinics showed 6–26% to have been diagnosed with ASD. (Thrower 2020 at 695.) Moreover, those authors gave specific caution on the "considerable overlap between symptoms of ASD and symptoms of gender variance, exemplified by the subthreshold group which may display symptoms which could be interpreted as either ASD or gender variance. Overlap between symptoms of ASD and symptoms of GD may well confound results." (Thrower 2020 at 703.) The rate of ADHD among children with GD was 8.3–11%. Conversely, data from children (ages 6–18) with Autism Spectrum Disorders (ASDs) show they are more than seven times more likely to have parent-reported "gender variance." (Janssen 2016 at 63.)

158. As shown by the outcomes studies (see Section XIII), there is little reliable evidence that transition improves the mental well-being of children. As shown repeatedly by clinical guidelines from multiple professional associations, mental health issues are expected or required to be resolved *before* undergoing transition. The reasoning behind these conclusions is that children may be expressing gender dysphoria, not because they are experiencing what gender dysphoric adults report, but because they mistake what their experiences indicate or to what they might lead. For example, a child experiencing depression from social isolation might develop the hope—and the unrealistic expectation—that transition will help them fit in, as a member of the other sex.

159. In cases where gender dysphoria is secondary to a different issue, efforts at transition

are aiming at the wrong target and leave the primary issue(s) unaddressed. Given the highly reliable, repeatedly replicated finding that childhood-onset gender dysphoria resolves with puberty for the large majority of children, the evidence indicates that blocking a child's puberty blocks the child's natural maturation that itself would resolve the dysphoria.

C. Mental health issues in Adolescent-Onset Gender Dysphoria (ROGD).

160. The literature varies in the range of gender dysphoric adolescents with co-occurring disorders. In addition to self-reported rates of suicidality (see Section X), clinical assessments reveal elevated rates not only of depression (Holt 2016; Skagerberg 2013; Wallien 2007), but also anxiety disorders, disruptive behavior difficulties, Attention Deficit/Hyperactivity Disorder, Autism Spectrum Disorder, and personality disorders, especially Borderline Personality Disorder (BPD). (Anzani 2020; de Vries 2010; Jacobs 2014; Janssen 2016; May 2016; Strang 2014, 2016; Swedish Socialstyrelsen, Evolution 2020.)

161. Of particular concern in the context of adolescent-onset gender dysphoria is Borderline Personality Disorder (BPD; diagnostic criteria in Table X below). Symptoms of BPD overlap in important respects with symptoms commonly interpreted as signs of gender dysphoria, and it is increasingly hypothesized that very many cases appearing to be adolescent-onset gender dysphoria actually represent cases of BPD. (E.g. Anzani 2020; Zucker 2019.) That is, some people may be misinterpreting their experiencing of the broader "identity disturbance" of symptom Criterion 3 to represent a gender identity issue specifically. Like adolescent-onset gender dysphoria, BPD begins to manifest in adolescence, is three times more common in biological females than males, and occurs in 2–3% of the population, rather than 1-in-5,000 people. (Thus, if even only a portion of people with BPD experienced an identity disturbance, and focused that disturbance on gender identity resulting in transgender identification, they could easily overwhelm the number of genuine

cases of gender dysphoria.)

Table 4. DSM-5-TR Diagnostic Criteria for Borderline Personality Disorder.

> A pervasive pattern of instability of interpersonal relationships, self-image, and affects, and marked impulsivity beginning by early adulthood and present in a variety of contexts, as indicated by five (or more) of the following:
>
> 1. Frantic efforts to avoid real or imagined abandonment. (Note: Do not include suicidal or self-mutilating behaviour covered in Criterion 5.)
> 2. A pattern of unstable and intense interpersonal relationship characterized by alternating between extremes of idealization and devaluation.
> 3. *Identity disturbance: markedly and persistently unstable self-image or sense of self.*
> 4. Impulsivity in at least two areas that are potentially self-damaging (e.g., spending, sex, substance abuse, reckless driving, binge eating). (Note: Do not include suicidal or self-mutilating behavior covered in Criterion 5.)
> 5. *Recurrent suicidal behaviour, gestures, or threats, or self-mutilating behavior.*
> 6. Affective instability due to a marked reactivity of mood (e.g., intense episodic dysphoria, irritability, or anxiety usually lasting a few hours and only rarely more than a few days).
> 7. Chronic feelings of emptiness.
> 8. Inappropriate, intense anger or difficulty controlling anger (e.g., frequent displays of temper, constant anger, recurrent physical fights).
> 9. Transient, stress-related paranoid ideation or severe dissociative symptoms.
>
> (Italics added.)

(American Psychiatric Association 2022 at 752-753.)

162. Mistaking cases of BPD for cases of Gender Dysphoria may prevent such youth from receiving the correct mental health services for their condition. A primary cause for concern is symptom Criterion 5: *recurrent suicidality.* (See Section X on suicide and suicidality.) Regarding the provision of mental health care, the distinction between these conditions is crucial: A person with BPD going undiagnosed will not receive the appropriate treatments (the currently most effective of which is Dialectical Behavior Therapy). The problem was not about *gender* identity, but about having an *unstable* identity.

163. Regarding research, there have now been several attempts to document rates of suicidality among gender dysphoric adolescents. The scientific concern presented by BPD is that

it poses a potential confound: samples of gender dysphoric adolescents could appear to have elevated rates of suicidality, not because of the gender dysphoria (or transphobia in society), but because of the number of people with BPD in the sample.

D. Neuroimaging studies have associated brain features with sex and with sexual orientation, but not gender identity. .

164. Claims that transgender identity is an innate property resulting from brain structure remain unproven. Neuroimaging and other studies of brain anatomy repeatedly identify patterns distinguishing male from female brains, but when analyses search for those patterns among transgender individuals, "gender identity and gender incongruence could not be reliably identified." (Baldinger-Melich 2020 at 1345.) Although much smaller than male/female differences, statistically significant neurological differences are repeatedly associated with sexual orientation (termed "homosexual" vs "nonhomosexual" in the research literature). Importantly, despite the powerful associations between transsexuality and homosexuality, as explicated by Blanchard, many studies analyzing gender identity failed to control for sexual orientation, representing a problematic and centrally important confound. I myself pointed this out in the research literature, noting that neuroanatomical differences attributed to gender dysphoria should instead be attributed to sexual orientation. (Cantor 2011, Cantor 2012.) A more recent review of the science, by Guillamon, et al. (2016), agreed, stating:

> Following this line of thought, Cantor (2011, 2012, but also see Italiano, 2012) has recently suggested that Blanchard's predictions have been fulfilled in two independent structural neuroimaging studies. Specifically, Savic and Arver (2011) using VBM on the cortex of untreated nonhomosexual MtFs and another study using DTI in homosexual MtFs (Rametti et al., 2011b) illustrate the predictions. *Cantor seems to be right*". (Guillamon 2016 at 1634, italics added; see also Italiano 2012.)

In addition to this confound, because snapshot neurobiological studies can provide only correlational data, it would not be not possible for such studies to distinguish whether brain

differences cause gender identity or if gender atypical behavior modifies the brain over time, such as through neuroplasticity. As noted by one team of neuroscientists, "[I]t remains unclear if the differences in brain phenotype of transgender people may be the result of a sex-atypical neural development or of a lifelong experience of gender non-conformity." (Fisher 2020 at 1731.) In sum, at present assertions that transgender identity is caused by neurology represent faith, not science.

XII. Medicalized transition of gender remains *experimental,* lacking causal evidence of mental health improvement.

A. Criteria distinguishing *'experimental'* from *'established'*.

165. In science, the term "experimental" has a specific technical meaning. Within the scientific method, research studies can be *observational* or *experimental.* Among observational studies, such as surveys, the researchers do not administer any treatment and instead only describe the features of the group observed. Among experimental studies, treatments are actively administered by the researchers, who then compare the treated and untreated groups (or compare a group to itself, before versus after treatment). Also, within a given treatment study, the term "experimental treatment" would be used to distinguish it from the "control treatment" or "treatment-as-usual" being provided to the control group.

166. Outside research studies and within public and legal contexts, the term 'experimental' typically denotes '*unverified by experimental evidence'.* A treatment would continue to be experimental until the demonstration of (1) reliable, clinically meaningful improvement and (2) the reliable estimation of safety risks in randomized, controlled trials (RCTs) or research of equivalent level of evidence. A treatment would remain experimental while its effects, including side effects, remain uninvestigated.

167. Being long-standing, popular, or familiar do not, of themselves, impact whether a treatment is experimental—they suggest opportunities for the experiments to have been done. Clinicians' feelings of self-confidence do not impact status as experimental.

B. International consensus explicitly regards gender transition to be experimental.

168. In England, after a thorough review of the literature and the current practice, Dr. Cass stated that the critical and currently unanswered question "is whether the evidence for the use and

safety of the medication is strong enough as judged by reasonable clinical standards." She recognized that these treatments cannot formally be called "experimental" not because they are proven, but because the experiments needed to test their efficacy and safety have not only not been done, but are not even being attempted. (Cass 2022 at 37.) To address this, Dr. Cass called for "the rapid establishment of the necessary research infrastructure to prospectively enrol young people being considered for hormone treatment into a formal research programme." (Cass Review Letter 2022). In response, in its interim service specification NHS England states that it "will only commission GnRHa [i.e., puberty blockers] in the context of a formal research protocol." (NHS 2022 at 12.)

169. Finland, by law, restricts all assessment and treatment activities for gender dysphoric minors to its two research clinics, Helsinki University Central Hospital and Tampere University Hospital. (COHERE Summary.) Further, after conducting a systematic review of the research, the council responsible for the assessment of public health care services in Finland (COHERE Finland) concluded, "In light of available evidence, gender reassignment of minors is *an experimental practice.*" (COHERE Summary, italics added.)

170. Sweden's research on gender transition is conducted at the Karolinska Institutet in Stockholm. In 2015, that facility registered its research on medicalized transition with the U.S. National Institutes for Health (NIH), noting "[H]ormonal treatment includes inhibition of one's own sex hormone production followed by treatment with testosterone or estrogen levels that are normal for the opposite sex. *Seen as experimental model,* this is a process that provides an opportunity to study the sex hormone dependent influences." (Clinicaltrials.gov.) In its policy updates in 2021, Sweden limited medicalized treatments for gender dysphoria in minors to clinical research studies approved by the Swedish national research ethics board ("EPM"). (Medscape

Psychiatry 2021.)

171. Norway reviewed its own national policy on transition in minors in 2023, explicitly concluding such medical procedures to be experimental. (Ukom 2023.)

172. The widely cited Dutch studies were co-conducted by Dr. Thomas Steensma. Despite being an originator and international leader of medicalized transition of gender dysphoric minors, Dr. Steensma stated in an interview in 2021 that he still considers it to be experimental: "Little research has yet been done on the treatment with puberty inhibitors and hormones in young people. That is why it is also *seen as experimental*." Dr. Steensma decried other clinics for "blindly adopting our research" despite the indications that those results may not actually apply: "We don't know whether studies we have done in the past are still applicable to today. Many more children are registering, and also a different type." Steensma opined that "every doctor or psychologist who is involved in transgender care should feel the obligation to do a good pre- and post-test." (Tetelepta 2021.) But few if any are doing so.

C. Claims that medical transition is "medically necessary" are undefined, unsupported, and self-interested.

173. While European health authorities have examined the science and concluded that medical transition for minors remains "experimental" and of unproven benefit, terminology has been distorted in the U.S. because the U.S. lacks a public health care system and the terms "medically necessary" and "experimental" impact health insurance coverage. "Medically necessary" justifies coverage for these procedures; advocates know or fear that the term "experimental" will preclude coverage.

174. WPATH's 2016 statement asserting "medical necessity" was explicitly made in order to facilitate insurance claims, as is clear in their document entitled, "Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A." (WPATH

Position Statement.) The AMA released a similar statement supporting insurance coverage for medical transition as a result of being assertedly medically necessary.[6] U.S. medical associations' advocacy corresponds to the financial interests of their members.

175. Moreover, there do not exist a scientific definition or objective criteria of "medically necessary." An analysis published in the *Canadian Medical Association Journal,* however (not pertaining to gender dysphoria or transition), attempted to define 'medically necessary.' (Caulfield 2012.) The article quoted Timothy Caulfield, Research Chair in Health, Law, and Policy at the University of Alberta (Edmonton), Canada: "As for putting great effort into coming up with a tidy, all-encompassing definition of 'medically necessary'—it's probably a waste of time…Given the history of the concept of 'medically necessary' and the numerous failed attempts to define it, a practical, operational and meaningful definition is likely unattainable." (Caulfield at 1771–1772.) According to Mark Stabile, director of the School of Public Policy and Governance and professor of economics and public policy at the Rotman School of Management at the University of Toronto, "Providers of those services will naturally be critical of the decision if they feel that the demand for their services will decline as a result." (Caulfield at 1772.)

D. WPATH repeatedly warns of untested hypotheses, continuing unknowns, and lack of research.

176. The latest (2022) WPATH Standards of Care v8 document avoided the word "experimental" in its guidelines, but instead repeatedly deployed terms and phrases that are synonymous with being experimental: "The criteria in this chapter [on assessment of adults] have been significantly revised from SOC-7 to reduce requirements and unnecessary barriers to care. *It is hoped that future research will explore the effectiveness* of this model." (Coleman 2022 at S33, italics added.)

[6] Available from https://www.ama-assn.org/system/files/2019-03/transgender-coverage-talking-points.pdf

177. The WPATH Standards of Care v8 (Coleman 2022.) indicates the lack of experimental evidence available again and again (italics added):

- "It primarily includes an assessment approach that uses specific criteria that are examined by [a Health Care Provider, or] HCP in close cooperation with a TGD adult and does not include randomized controlled trials or long-term longitudinal research" (at S33.)
- "While there was *limited supportive research,* this recommendation was considered to be good clinical practice as it allows a more reversible experience prior to the irreversible experience of surgery" (at S40.)
- "Due to *the limited research in this area,* clinical guidance is based primarily on individual case studies and the expert opinion of HCPs" (at S41.)
- "While available research shows consistent positive outcomes for the majority of TGD adults who choose to transition…some TGD adults may decompensate or experience a worsened condition following transition. *Little research has been conducted to systematically examine variables that correlate with poor or worsened biological, psychological, or social conditions following transition"* (at S42.)
- "Future research would shed more light on gender identity development if conducted over long periods of time with diverse cohort groups" (at S45.)
- "In addition, elevated scrotal temperatures can be associated with poor sperm characteristics, and genital tucking could theoretically affect spermatogenesis and fertility (Marsh 2019) although *there are no definitive studies evaluating these adverse outcomes.* Further *research is needed to determine the specific benefits and risks* of tucking in youth" (at S54.)
- *"There is no formal research evaluating* how menstrual suppression may impact gender incongruence and/or dysphoria" (at S54-55.)
- "Currently, there are only preliminary results from retrospective studies evaluating transgender adults and the decisions they made when they were young regarding the consequences of medical-affirming treatment on reproductive capacity. It is important not to make assumptions about what future adult goals an adolescent may have" (at S57.)
- *"Only limited empirical research exists* to evaluate such interventions" (at S75.)
- *"Research has not been conclusive* about when in the life span such detransition is most likely to occur, or what percentage of youth will eventually experience gender fluidity and/or a desire to detransition" (at S77.)
- "Research on pitch-lowering surgeries is limited" (at S139.)
- "The number and quality of research studies evaluating pitch-lowering surgeries are currently insufficient" (at S141.)
- "To date, *research on the long-term impact of [Gender Affirming Hormone Treatment*

or] GAHT on cancer risk is limited…We have *insufficient evidence* to estimate the prevalence of cancer of the breast or reproductive organs among TGD populations (Joint et al., 2018.)" (at S144.)

- "Contraceptive *research gaps within this population are profound. No studies have examined* how the use of exogenous androgens (e.g., testosterone) may modify the efficacy or safety profile of hormonal contraceptive methods (e.g., combined estrogen and progestin hormonal contraceptives, progestin-only based contraceptives) or non-hormonal and barrier contraceptive methods" (at S162.)
- "TGD individuals AFAB undergoing abortion still represents a critical gap in research" (at S162.)
- "The effects of current TGD-related medical treatments on sexuality are heterogeneous (Ozer et al., 2022; T'Sjoen et al., 2020), and *there has been little research on the sexuality of TGD adolescents"* (at S163.)
- "While sex-positive approaches to counseling and treatment for sexual difficulties experienced by TGD individuals have been proposed (Fielding, 2021; Jacobson et al., 2019; Richards, 2021), to date *there is insufficient research on the effectiveness of such interventions"* (at S163.)

XIII. There have been 11 cohort studies of puberty blockers and cross-sex hormones in minors. They provide no reliable evidence of effectiveness for improving mental health relative to mental health treatments that lack medical risk.

178. Several studies are cited by plaintiffs' experts and in the media as purporting to show that medical transition in minors brings important improvements in mental health beyond the issues of suicide and suicidality that I have already addressed. In fact, there is no reliable evidence of any such benefit.

179. In this section, I summarize the results of all cohort studies investigating the mental health outcomes of puberty blockers and cross-sex hormones on minors. These include all such studies identified by any of the systematic reviews of effectiveness from England, Sweden, Finland, and WPATH. (Listed in Table 1, *Cohort studies of effectiveness and safety of puberty blockers and cross-sex hormones in minors.*)

180. As enumerated in the following section, all of these studies that reported improved mental health among transitioners were also providing psychotherapy at the same time. (See Section VI on confounding.) None of these studies was able to differentiate which of them was contributing to the improvement.

181. The problem imposed by confounding medicalized transition with psychotherapy is widely recognized. As explicated in the NICE review from England:

> [V]ery little data are reported on how many children and adolescents needed additional mental health support, and for what reasons, or whether additional interventions, and what form and duration (for example drug treatment or counselling) that took. This is a possible confounder for the treatment outcomes in the studies because *changes in critical and important outcomes may be attributable to external care rather than the psychological support or GnRH analogues used in the studies.* (NICE 2020a at 41, italics added.)

Similarly, WPATH's own systematic review noted that "[T]his conclusion is limited by high risk of bias in study designs, small sample sizes, and *confounding with other interventions."* (Baker

2021 at 1, italics added.)

182. The need to disentangle the roles of these two treatments has been largely ignored despite that several issues depend upon them. If medicalized transition does not show mental health improvement superior to that of mental health treatment, it cannot readily be called "medically necessary" for insurance purposes or other institutional needs. Clinicians may be subjecting minors to known and potential (but unstudied) harms without any scientific justification.

183. Moreover, without a control group for comparison (i.e., another group of similar age, sex, and mental health status), these studies are also unable to identify when and if any changes are due to regression to the mean or maturation over time.

A. Of the cohort studies, four found little to no improvement in mental health.

184. Kaltiala, *et al.* (2020) similarly reported that after cross-sex hormone treatment, "Those who had psychiatric treatment needs or problems in school, peer relationships and managing everyday matters outside of home continued to have problems during real-life." (Kaltiala 2020 at 213.) They concluded:

> Medical gender reassignment is not enough to improve functioning and relieve psychiatric comorbidities among adolescents with gender dysphoria. Appropriate interventions are warranted for psychiatric comorbidities and problems in adolescent development. (Kaltiala 2020 at 213.)

185. Cantu, *et al.* (2020) studied 80 youth, 11–18 years of age (average of 15.1 years), measuring patients' levels of anxiety, depression, and suicidality. This sample was 18.75% male-to-female, 72.5% female-to-male, and 8.75% nonbinary, but the report did not include the patients' ages of onset. The study authors compared youth according to those receiving puberty blockers only, cross-sex hormones only, both treatments, or neither. No significant differences in mental health were detected on any of these variables. Of the 27 youth reporting suicidality before

medicalized treatment, 81% continued to report suicidality after medicalized treatment. Remarkably, although the authors reported that "the results of this study suggest that no clinically significant changes in mood symptoms occur" (Cantu 2020 at 199), they did not convey the logical interpretation that transition failed to help these youth. Instead, they emphasized that "findings suggest changes may actually take longer to occur." (Cantu 2020 at 196.)

186. Carmichael, *et al.* (2021) released their findings from the Tavistock and Portman clinic in the U.K. (Carmichael 2021.) Study participants were ages 12–15 (Tanner stage 3 and above for natal males, Tanner stage 2 and above for natal females) and were repeatedly tested before beginning puberty-blocking medications and then every six months thereafter. Cases exhibiting serious mental illnesses (*e.g.*, psychosis, bipolar disorder, anorexia nervosa, severe body-dysmorphic disorder unrelated to gender dysphoria) were excluded. Relative to the time point before beginning puberty suppression, there were *no* significant changes in any psychological measure, from either the patients' or their parents' perspective.

187. Hisle-Gorman, *et al.* (2021) analyzed military families' healthcare data to compare 963 transgender and gender-diverse youth before versus after hormonal treatment, using their non-gender dysphoric siblings as a control group. The study participants included youth undergoing puberty-blocking as well as those undergoing cross-sex hormone treatment, but these subgroups did not differ from each other. Study participants had a mean age of 18 years when beginning hormonal treatments, but their initial clinical contacts and diagnoses occurred at a mean age of 10 years. According to the study, "mental health care visits overall did not significantly change following gender-affirming pharmaceutical care" (Hisle-Gorman 2021 at 1448), yet, "psychotropic medication use *increased*," (Hisle-Gorman 2021 at 1448, italics added.) indicating *deteriorating* mental health.

B. Six of the cohort studies confounded medical treatment with psychotherapy.

188. The initial enthusiasm for medical blocking of puberty followed largely from early reports from the Dutch clinical research team suggesting at least some mental health improvement. (de Vries 2011, 2014.)

189. The Dutch clinical research team followed up a cohort of youth at their clinic undergoing puberty suppression (de Vries 2011), and later cross-sex hormone treatment and surgical sex reassignment (de Vries 2014). The youth improved on several variables upon follow-up as compared to pre-suppression measurement, including depressive symptoms and general functioning. No changes were detected in feelings of anxiety, or anger, or in gender dysphoria itself as a result of puberty suppression. Moreover, natal females suffered *increased* body dissatisfaction both with their secondary sex characteristics and with nonsexual characteristics. (Biggs 2020.)

190. The reports' own authors noted that while it remains possible that the improvement on some variables was due to the puberty blockers, it was also possible that the improvement was due to the mental health support or to natural maturation. The study authors noted this explicitly: "All these factors may have contributed to the psychological well-being of these gender dysphoric adolescents." (de Vries 2011 at 2281.)

191. van der Miesen, et al. (2020) provided an update of the Dutch clinic's sample, reporting continued improvement in transitioners' psychological functioning, but the medical and psychological treatments remained confounded. Also, the authors indicate that the changing demographic and other features among gender dysphoric youth might have caused the treated group to differ from the control group in unknown ways. The study authors expressly noted, "The present study can, therefore, not provide evidence about the direct benefits of puberty suppression

over time and long-term mental health outcomes." (van der Miesen 2020 at 703.)

192. Allen, *et al.* (2019) reported on a sample of 47 youth, ages 13–20, undergoing cross-sex hormone treatment. They reported observing increases in measures of well-being and decreases in measures of suicidality; however, as the authors also noted, "whether a patient is actively receiving psychotherapy" may have been a confounding variable. (Allen 2019.)

193. Becker-Hebley, *et al.* (2021) assessed the quality of life and overall functioning of a sample of German youth both before and after undergoing treatment with GnRHa, CSHT, or both. Excluded from participating were youth with severe psychiatric issues, including suicidality. Of the sample, 79% of the sample participated in psychotherapy at the same time. As the study authors were careful to indicate, "Because this study did not test for statistically significant differences between the four intervention groups or before and after treatment, the findings cannot be generalized to other samples of transgender adolescents." (Becker-Hebly 2021 at 1755.)

194. In Kuper, *et al.* (2020), a multidisciplinary team from Dallas used a battery of mental health tests to assess 148 youth undergoing either puberty-blocking or cross-sex hormone treatment. The tests revealed highly inconsistent results: Most revealed no significant change, some indicated improvement, and some indicated deterioration. Because 144 of the 148 participants were also in treatment with a therapist or counselor (Kuper at 7, Table 4), no conclusions can be drawn regarding the cause of the improvements. Similarly, 47% of the sample were receiving psychiatric medication at the time of their initial assessments, but it was 61% of the sample at the follow-up time: It cannot be known to what extent mental health improvement was associated with transition-related or with psychiatric medication. Importantly, the variables demonstrating deterioration included each of the ones indicating suicidality and self-harm: At follow-up time, the sample showed *higher* levels of suicidal ideation (from 25% to 38%), suicide

attempts (from 2% to 5%), and "non-suicidal self-injury" (from 10% to 17%) (Kuper at 8, Table 5).

195. This evidence of worsening mental health was highly obscured in the Kuper report, however. Rather than provide the standard comparison of pre- and post-treatment rates, Kuper instead listed the post-treatment rates along side the full *lifetime* rates: "Lifetime and follow-up rates were 81% and 39% for suicidal ideation, 16% and 4% for suicide attempt, and 52% and 18% for NSSI, respectively" (p. 1). Rates from over a lifetime are necessarily higher numbers, and putting them where pre-treatment rates normally appear conveys the statistical illusion of a decrease, exactly opposite to the actual pattern.

C. Two found no advantage of medicalization over psychotherapy.

196. Costa, *et al.* (2015) provided preliminary outcomes from a small study conducted with patients of the GIDS clinic in the UK. They compared the psychological functioning of one group of youth receiving psychological support with a second group receiving both psychological support as well as puberty blocking medication (representing an "active comparator" group. See Section III.C.2). The "untreated" group, however, was different from the treated group in another important respect, in that these were the patients who began with such severe psychiatric co-morbidities that they were deemed ineligible to begin puberty blockers until mental health improved. Further, the study suffered a dramatic loss-to-follow-up, with almost two thirds of participants dropping out across just 18 months. (Biggs 2019.) In this preliminary report, both groups improved in psychological functioning over the course of the study, but no statistically significant difference between the groups was detected at any point. (Costa 2015 at 2212, Table 2.) In any event, all these findings have been superseded, however, and are moot. The final outcomes report for this cohort was subsequently published (as Carmichael 2021, above), finding

that neither group actually had experienced any significant improvement at all. (Carmichael 2021.)

197. Achille, *et al.* (2020) at Stony Brook Children's Hospital in New York studied a sample of 95 youth with gender dysphoria, but 45 were lost-to-follow-up within just 12 months, failing to complete follow-up surveys at 6 month and or 1 year. That is, outcomes were available only for the 50 who remained in the study. As well as receiving puberty blocking medications, "Most subjects were followed by mental health professionals. Those that were not were encouraged to see a mental health professional." (Achille 2020 at 2.) Upon follow-up, some incremental improvements were noted; however, after statistically adjusting for psychiatric medication and engagement in counselling, "*most predictors did not reach statistical significance*." (Achille 2020 at 3, italics added.) That is, puberty blockers did not improve mental health any more than did mental health care on its own. More specifically, only one of the 12 predictors reached statistical significance. (Achille 2020 at Table 4.) That is, medicalized transition was not associated with improved mental health beyond improvement associated with the mental health care received. Moreover, the single predictor reaching the threshold for statistical significance is not reliable: the study authors made a methodological error by failing to account for the multiple comparisons it conducted. Had the study applied the standard adjustment for correcting for multiple comparisons, that remaining predictor would also have ceased to be statistically significant.

198. Tordoff, et al. (2022) reported on the mental health of youth (mean age 15.8) as they underwent their first year of puberty blocker or cross-sex hormone treatment. Of the initial 104, 62.5% were receiving psychotherapy at the same time. (Tordoff 2022 at 5 Table 1.) An unknown number of participants were also receiving psychiatric medications, which the report acknowledged as a potential confounding factor. There were 104 participants at the beginning of the study, but by the end, only 65 remained. Importantly, the report failed to indicate its procedures

for assessing the mental health readiness of prospective transitioners, and the results are highly susceptible to selection bias between those deemed eligible for hormones or puberty blockers, and those who were not.

D. One failed to report whether psychotherapy was provided.

199. Chen, *et al.* (2023) reported finding some improvement in some mental health variables associated with the cosmetic changes after two years of cross-sex hormone treatment in a sample of 315 youth (mean age, 16 years). Unlike the other studies, Chen et al. did not report how many participants were receiving psychotherapy or psychiatric medication at the same time as the hormone treatments. It is therefore not possible to assess to what extent any changes were due to hormone treatment versus the potential confounds. Because the study did not include a control group, it is not possible to assert that changes were due to hormone treatment rather than representing regression to the mean. Potential conclusions are also hampered by the large proportion of mental health data that were missing: Of the 315 youth in the sample, analyses could be conducted with only 208–217 (Chen 2023, supp. Material at 12, Table S5). The purported changes in mental health variables were statistically significant, but not clinically meaningful. The depression test used by Chen et al consisted of 21 items, with each item contributing up to 3-points to the total score. For example:

> 0 I do not feel sad.
> 1 I feel sad.
> 2 I am sad all the time and I can't snap out of it.
> 3 I am so sad and unhappy that I can't stand it.

Thus, the total scores range from 0 to 63. Scores 0–13 represent minimal difficulty; 14–19 represent mild depression; 20–28, moderate; and 29–63, severe. The change that Chen et al. found after two years of hormone treatment was from 16.39 to 13.95 (at Table S5). Changes of this size are unlikely to be associated with patients reporting they feel better. Such scores are below the

"minimum clinically important difference". (Button 2015.) Although the report did not include data on co-morbid mental health diagnoses, it noted that two patients receiving cross-hormone treatment died by suicide (representing 0.6% mortality within just two years). (Chen 2023 at 240.)

200. In addition to the incomplete reporting of key aspects of the project and large proportion of missing data, Chen et al appears to have provided only a selected subportion of the information it collected. A knowledgeable journalist investigating transgender issues, Jesse Singal, identified documentation representing the full set of information the Chen et al team planned to collect. I have verified that documentation and have come to the same conclusion. As described by Singal:

> In their study protocol, including a version that they submitted into a preregistration database, the researchers hypothesized that members of this cohort would experience improvement on eight measures, including ones that are just about universally recognized by youth gender researchers as important outcomes, such as gender dysphoria, suicidality, and self-harm. Then, in the published *NEJM* paper, the researchers changed their hypothesis and six of those variables were nowhere to be found. The two remaining—anxiety and depression—moved in a positive direction for trans boys (natal females) but not trans girls (natal males). The researchers reported on three other variables, too, without explaining how they picked them (two improved for trans girls and boys, and one just for trans boys). (Singal 2023.)

201. This appears to represent "cherry-picking" of the findings being reported, rather than a comprehensive reporting on the complete set of evidence. Further, Chen et al. failed to balance the concrete and strikingly high rate of *completed* suicide among their sample against the very incremental mental health changes they claim, even though the ethical and clinical importance of those suicides is obvious.

XIV. Known and potential harms associated with administration of puberty blockers and cross-sex hormones to children and adolescents.

202. As I have explained, any conclusion about safety requires knowledge about and balancing of both risks and benefits.

203. In concluding that safety has not been established (see Section V above), national health authorities, authors of systematic reviews, and researchers have identified a number of harms which are either known to result from administration of puberty blockers and cross-sex hormones to children and adolescents, or can be reasonably anticipated but have not been sufficiently studied to reach any conclusion as to the likelihood or severity of harm.

204. When applying research regarding harms to clinical policy, several considerations need to be included: (1) The harms of medicalized transition of gender does or may differ between male-to-female and female-to-male cases, differ between ages of transition, and differ according to age-of-onset of the gender dysphoria. Evidence and conclusions about harms (and safety) cannot be generalized or extrapolated across such cases. (2) The evidence has strongly shown that after social transition of gender, minors are much more likely than otherwise to undergo medicalized transition of gender. Thus, the appropriate assessment of the risk:benefit ratio for social transition must include the increased risks posed by the medicalized path to which it is likely to lead. (3) The evidence has shown strongly that youth who undergo puberty blocking are highly likely to undergo cross-sex hormone treatment. Thus, the appropriate risk:benefit evaluation must also consider its potential implications over the full lifespan.

205. Systematic reviews of the evidence have identified fewer than 10 studies investigating potential harms of medicalized transition of minors at all, (NICE 2020a at 6.) and most of these have been limited to bone and skeletal health. As concluded by the NICE systematic review, “A key limitation to identifying the effectiveness and safety of GnRH analogues for children and

adolescents with gender dysphoria is the lack of reliable comparative studies." (NICE 2020a at 40.) With that said, numerous harms are either known, or reasonably anticipated by respected health authorities but thus far unmeasured.

A. Sterilization without proven fertility preservation options.

206. Clinical guidelines for the medical transition of gender among children include the need to caution and counsel patients and parents about what are euphemistically called "options for fertility preservation." (e.g., Endocrine Society Guidelines, Hembree 2017 at 3872.) For children who are placed on puberty blockers at Tanner Stage 2, however, because most continue onto cross-sex hormones once they begin a medicalized approach to their dysphoria, no viable fertility preservation options exist. The decision to undergo medicalized transition also represents the decision never to have biological children of one's own.

207. For the large new population of young people who are first being put on puberty blockers and/or cross-sex hormones at a somewhat later stage of puberty, no studies at all have been done of when, whether, or with what probability either males or females can achieve healthy fertility if they later regret their transition decision and cease taking puberty blockers and/or cross-sex hormones. Much less has this been studied as a function of the stage of development at which they began puberty blockers and/or cross-sex hormones, and how long their gonads were subjected to cross-sex hormones.

B. Permanent loss of capacity for breast-feeding in adulthood.

208. While the removal of the breasts of a biological female adolescent or young adult may be cosmetically revised, it is functionally irreversible; even if the person later regrets and detransitions before or during adulthood, breast-feeding a child will never be possible. To the adolescent determined to transition, this may seem no cost at all. To the future adult mother, it may

be a very severe harm indeed.

C. Lifetime lack of orgasm and sexual function.

209. There has not been systematic investigation of the effects on adult sexuality among people medically transitioned at an early stage of puberty. Notably, Dr. Marci Bowers, current President of WPATH, and surgeon with substantial experience conducting penis-to-vagina operations, opined, "If you've never had an orgasm pre-surgery, and then your puberty's blocked, it's very difficult to achieve that afterwards…I consider that a big problem, actually. It's kind of an overlooked problem that in our 'informed consent' of children undergoing puberty blockers, we've in some respects overlooked that a little bit." (Shrier 2021.) In my opinion as a psychologist and sex and couple's therapist, this represents a large potential harm to future relationships and mental health to "overlook," and must be taken into consideration in any serious risk:benefit analysis of "safety."

D. Hormonal treatments during puberty interfere with neurodevelopment and cognitive development.

210. It is well known that pubertal hormone levels drive important stages of neural development and resulting capabilities, although the mechanisms are not yet well understood. Dr. John Strang (Research Director of the Gender Development Program at Children's National Hospital in Washington, D.C.) (Terhune 2022), the Cass Report from the U.K., and the systematic review from Finland all reiterated the central importance and unknown effects of GnRH-agonists on windows, or "sensitive periods," in brain development, notably including adolescence. As Dr. Cass put it:

> A further concern is that adolescent sex hormone surges may trigger the opening of a critical period for experience-dependent rewiring of neural circuits underlying executive function (i.e. maturation of the part of the brain concerned with planning, decision making and judgement). If this is the case, brain maturation may be temporarily or permanently disrupted by puberty blockers, which could have

> significant impact on the ability to make complex risk-laden decisions, as well as possible longer-term neuropsychological consequences. To date, there has been very limited research on the short-, medium- or longer-term impact of puberty blockers on neurocognitive development. (Cass Review Letter 2022 at 6.)

211. In a meta-analysis (a highly rigorous type of systematic review) of studies of neuropsychological performance, non-transsexual males undergoing puberty earlier show a different cognitive profile than those underdoing puberty later. The association of brain development with age of pubertal onset exists in humans as well as non-human animals. (Shirazi 2022.)

212. Even in adults, neuroscience studies employing MRI and other methods have shown that the blockade of normal levels of hormones associated with puberty and adulthood degrade brain performance. Thus, when GnRH-agonists are administered to adult biological women, several brain networks decrease in activity and cognitive performance, such as in working memory, declines. (Craig 2007; Grigorova 2006.)

213. In light of this science, multiple voices have expressed concern that blocking the process of puberty during its natural time could have a negative and potentially permanent impact on brain development (Cass 2022 at 38–39; Chen 2020; Hembree 2017 at 3874.) As Chen *et al.* (2020) observed:

> [I]t is possible these effects are temporary, with youth 'catching up'…However, pubertal suppression may prevent key aspects of development during a sensitive period of brain organization. Neurodevelopmental impacts might emerge over time, akin to the 'late effects' cognitive findings associated with certain [other] oncology treatments. (Chen 2020 at 249.)

Chen et al. (2020) noted that no substantial studies have been conducted to identify such impacts outside "two small studies" (at 248) with conflicting results. I have not identified any systematic review of neurodevelopment or cognitive capacity.

214. A related concern is that by slowing or preventing stages of neural development,

puberty blockers may impair precisely the mature cognitive capabilities that would be necessary to evaluation of, and meaningful informed consent to, the type of life-changing impacts that accompany cross-sex hormones. (See Section XV.)

E. Substantially delayed puberty is associated with medical harms.

215. The research cited by the WPATH Standards of Care includes the evidence that children whose natural puberty started very late (top 2.3% in age) have elevated risks of multiple health issues in adulthood. (Zhu & Chan 2017.) These include elevations in metabolic and cardiovascular disease, lower height, and decreased bone mineral density. It has not been studied whether these correlations also occur in children whose puberty is chemically delayed. Undergoing puberty much later than one's peers is also associated with poorer psychosocial functioning and lesser educational achievement. (Koerselman & Pekkarinen 2018.)

F. Elevated risk of Parkinsonism in adult females.

216. Epidemiological research has shown adult, non-transsexual women who undergo surgical removal of both ovaries to have substantially elevated odds of developing parkinsonism, including Parkinson's Disease, relative to age-matched women randomly selected from the local population in an on-going epidemiological study. (Rocca 2022.) The effect was greater among younger women, showing 7–8 times greater odds among women under 43. The observed delay between removal of ovaries and the onset of parkinsonism was 26.5 years. Whether chemically suppressing the ovaries of a biological female via puberty blockers during adolescence followed by cross-sex hormones will cause a similar increase in parkinsonism, or when, remains unknown.

G. Reduced bone density.

217. The systematic reviews by Sweden, Finland, and England all included bone health as an outcome. *The New York Times* also recently commissioned its own independent review of the

available studies. (Twohey & Jewett 2022.) These reviews all identified subsets of the same group of eight studies of bone health. (Carmichael 2021; Joseph 2019; Klink 2015; Navabi 2021; Schagen 2020; Stoffers 2019; van der Loos 2021; Vlot 2017.) These studies repeatedly arrived at the same conclusion. As described by *The New York Times* review:

> [I]t's increasingly clear that the drugs are associated with deficits in bone development. During the teen years, bone density typically surges by about 8 to 12 percent a year. The analysis commissioned by *The Times* examined seven studies from the Netherlands, Canada and England involving about 500 transgender teens from 1998 through 2021. Researchers observed that while on blockers, the teens did not gain any bone density, on average—and lost significant ground compared to their peers.[7] (Twohey & Jewett 2022.)

218. There is some evidence that some of these losses of bone health are regained in some of these youth when cross-sex hormones are later administered. The rebounding appears to be limited to female-to-male cases, while bone development remains deficient among male-to-female cases.

219. The long-term effects of the deficient bone growth of people who undergo hormonal interventions at puberty remain unstudied. The trajectory of bone quality over the human lifetime includes decreases during aging in later adulthood. Because these individuals may enter their senior years with already deficient bone health, greater risks of fracture and other issues are expectable in the long term. As the *New York Times'* analysts summarized, "That could lead to heightened risk of debilitating fractures earlier than would be expected from normal aging—in their 50s instead of 60s." Such harms, should they occur, would not be manifest during the youth and younger adulthood of these individuals. This distinction also represents one of the differences between adult transitioners and childhood transitioners and why their experiences cannot be extrapolated between them.

[7] The eighth study was Lee, *et al.,* 2020, which reported the same deficient bone development.

220. There does not exist an evidence-based method demonstrated to prevent these outcomes. The recommendations offered by groups endorsing puberty blockers are quite limited. As summarized by *The Times:*

> A full accounting of blockers' risk to bones is not possible. While the Endocrine Society recommends baseline bone scans and then repeat scans every one to two years for trans youths, WPATH and the American Academy of Pediatrics provide little guidance about whether to do so. Some doctors require regular scans and recommend calcium and exercise to help to protect bones; others do not. Because most treatment is provided outside of research studies, there's little public documentation of outcomes. (Twohey & Jewett 2022.)

H. Short-term/Immediate side-effects of puberty blockers include sterile abscesses, leg pain, headache, mood swings, and weight gain.

221. The Cass Report summarized that "In the short-term, puberty blockers may have a range of side effects such as headaches, hot flushes, weight gain, tiredness, low mood and anxiety, all of which may make day-to-day functioning more difficult for a child or young person who is already experiencing distress." (Cass 2022 at 38.)

222. In 2016, the U.S. FDA began requiring drug manufacturers to add a warning about the psychiatric side effects, after reports of suicidal ideation and a suicide attempt began to emerge among children prescribed GnRH-agonists (for precocious puberty).[8] The warning label on Lupron reads that "Psychiatric events have been reported in patients…such as crying, irritability, impatience, anger and aggression."

223. Other than the suicide attempt, such adverse effects may seem minor relative to the major health and developmental risks I have reviewed above, and they may be dismissed by children and by parents confronted by fears of suicidality and an urgent hope that transition will resolve the child's unhappiness and mental health issues. However, when assessing risk:benefit

[8] Reuters Special Report; 2022, Oct. 6. Retrieved from https://www.reuters.com/investigates/special-report/usa-transyouth-care/

ratio for "safety" against the undemonstrated benefits claimed for hormonal interventions, these observed harms should not be ignored.

I. Long-term use of cross-sex hormones in adult transsexuals is associated with unfavorable lipid profiles (cholesterol and triglycerides) and other issues.

224. As the Cass Report correctly and succinctly indicated, "Sex hormones have been prescribed for transgender adults for several decades, and the long-term risks and side effects are well understood. These include increased cardiovascular risk, osteoporosis, and hormone-dependent cancers." (Cass 2022 at 36.)

225. Minors who begin puberty blockers and proceed to cross-sex hormones—as almost all do—will require continuing treatment with cross-sex hormones for life, unless they go through the very difficult process of detransition. Because a lifetime dependence on cross-sex hormones is the expected course, the known adverse effects of cross-sex hormones on adults must also be part of the risk:benefit analysis of the "safety" of putting a minor on cross-sex hormones (and indeed, of the initial decision to put a child on puberty blockers).

226. Systematic review identified 29 studies of the effects of cross-sex hormone treatment on cardiovascular health in adults. (Maraka 2017.) By the two-year follow-up mark among female-to-male transitioners, hormone administration was associated with increased serum triglycerides (indicating poorer health), increased low-density-lipid (LDL) cholesterol (indicating poorer health), and decreased high-density-lipid (HDL) cholesterol (indicating poorer health). Among male-to-female transitioners at the two-year mark, cross-sex hormone treatment was associated with increased serum triglycerides (indicating poorer health).

XV. Assertions that puberty blockers act only as a "fully reversible" "pause button" are not supported by scientific evidence.

227. Plaintiffs' experts, along with many advocates and organizations, have boldly asserted that the administration of puberty blockers to adolescents is "fully reversible." The assertion is not consistent with or supported by any objective assessment of the existing science. Although withdrawal of the medication will allow the pubertal process to resume, that is very far from establishing that the impact of that interruption of natural development is "fully reversible." The evidence is not that the person's life will proceed as if the medical intervention never happened, as the popularized phrase suggests. Rather, the evidence repeatedly indicates that stopping a healthy child's natural onset of puberty imposes multiple substantial harms, risks, or opportunity costs.

228. First, as I have previously mentioned (Section IV.D), it is scientifically invalid to extrapolate results from using puberty blockers to prevent precocious puberty by delaying the pubertal process to its normal age range, to using them to *prevent* normally occurring healthy puberty, merely assuming the effects and side-effects will be the same. The two are very different populations and very different uses.

229. Second, not all the effects of GnRHa's in otherwise healthy children are known: It is therefore not possible to assess whether all effects are reversed or to what extent. Indeed, within the scientific method, it is never possible to demonstrate that any intervention is "fully reversible." In science, it always remains possible for future evidence to identify an effect that does not reverse. To assert that all the effects of GnRHa's are fully reversible is to assert that all its effects have been investigated and checked for reversibility, which is false.

230. Third, and more concretely, I have reviewed above a large number of medical and developmental risks which multiple responsible voices have associated with administration of

puberty blockers to adolescents, and which are either established by studies or have not been shown not to exist. In the face of this knowledge and lack of knowledge, it is scientifically unsupported and irresponsible to assert that this use of puberty blockers is "fully reversible" and "just a pause."

231. Here, I identify additional psycho-social developmental impacts of delaying healthy, naturally-occurring puberty which are likely to be irreversible, but have not been meaningfully studied.

A. Stopping puberty does not stop time: Patients' peers continue to develop and mature, with patients falling increasingly behind.

232. Initiating puberty blockers at Tanner Stage 2 (at the very first signs of puberty, typically ages 9 or 10) holds the child in a prepubescent state, while their peer group and classmates continue to grow. By the time many patients begin cross-sex hormone treatment, their peers will have completed puberty and progressed far into adolescence. Puberty may become unblocked, but these children have irreversibly lost the opportunity and experience of developing with their peers and must instead do so alone.

233. Being a "late bloomer," indeed among the latest possible bloomers, has psychological consequences of its own. Having the body and mind of a prepubescent child while one's friends have grown into physically mature sixteen-year-olds is extreme. Despite being a teenager chronologically, remaining prepubescent both physically and mentally while the lives of one's peers have advanced to teenagers' interests only increases the isolation of children already reporting social distress. There does not exist a means of distinguishing how much of any improvement in mental health that might be observed across these years in a particular study is simply the result of finally undergoing at least some pubertal development and finally catching up with one's peers in at least some parameters.

234. Concretely, undergoing puberty much later than one's peers (as a result of naturally

occurring rather than medically induced conditions) has been associated with poorer psychosocial functioning and lesser educational achievement. (Koerselman & Pekkarinen 2018.) Whether this holds true when the late puberty is the result of puberty blockers has not been studied.

B. Blocking puberty blocks the awareness of sexuality and sexual orientation that can play an important role in the individual's understanding of gender identity.

235. As demonstrated unanimously by the cohort studies of prepubescent children with gender dysphoria, the great majority cease to feel gender dysphoric during the course of puberty. (Section IX.B.) Studies also find that many such children subsequently identify as gay or lesbian, providing a potential alternative source and understanding of their atypical childhood gender interests. But for all children, blocking puberty necessarily blocks the onset of adult sexual interest, sexual arousal, and sexual response which are part of "the usual process of sexual orientation and gender identity development." (Cass 2022 at 38.) That is, blocking the experience of sexual feelings and development blocks normal phenomena that enable the young person to understand sexuality and sexual orientation, as distinct from gender identity. As Dr. Cass summarized:

> We do not fully understand the role of adolescent sex hormones in driving the development of both sexuality and gender identity through the early teen years, so by extension we cannot be sure about the impact of stopping these hormone surges on psychosexual and gender maturation. We therefore have no way of knowing whether, rather than buying time to make a decision, puberty blockers may disrupt that decision-making process. (Cass Review Letter 2022 at 5.)

Thus, contrary to the hypothesis that providing time might permit more considered understanding and decision-making, the prevention of puberty blocks the awareness of a central factor that may well influence that understanding.

236. Because puberty blockers prevent prepubescent children from developing any understanding of sexual arousal and sexual relationships, such children are necessarily incapable of providing informed consent. There does not exist—indeed, there cannot exist—an age-

appropriate way to equip a child who has not gone through puberty to make an informed decision about age-inappropriate issues, such as their future sex life, choices of sexual partners, sex-bonded relationships including marriage, and sacrificing ever experiencing orgasm.

C. Blocking puberty may block development of adult decision-making capacity.

237. As I have explained above, there are reasons to fear that use of puberty blockers may have permanent negative effects on brain development. That long-term risk aside, blocking puberty nevertheless threatens to prevent the child from growing towards adult decision-making capability during precisely the years in which he or she is being asked to make life-altering decisions about gender identity, gender presentation and cross-sex hormones. Pubertal brain development includes pervasive change in structural and functional connectivity (Chen 2020), re-balancing its capabilities between the acquisition of skills and knowledge and their application. Foremost among these are acquiring the abilities to control impulsivity and engage in rational and long-term decision-making (Crone & Steinbeis 2017), in association with development of a brain region called the "prefrontal cortex," and similarly acquiring the capacity to process adult social interaction, in association with the development of a network of brain areas (Kilford 2016), collectively called the "social brain." To understand medicalized transition of gender and its known and unknown consequences is one of the most complicated questions that a young person today could face, and a prepubescent brain is not equipped to process that information rationally, objectively, and with a whole lifetime rather than immediate desires and social pressures in mind.

D. Time spent on puberty blockers poses significant opportunity costs.

238. One of the primary, if not the foremost, justifications for medically transitioning children and adolescents is to reduce the psychological distress they report. That hypothesis interprets these children's psychological concerns (e.g., anxiety and depression) to gender

dysphoria and/or external sources (e.g., transphobia). As I have noted here previously, however, many gender dysphoric children and adolescents suffer from multiple other mental health issues. In several studies of minors on puberty blockers, a substantial portion of the subjects do not report ongoing psychological care. If years spent on puberty blockers in the hopes that that will relieve distress distract from systematic efforts to directly address comorbidities through psychotherapy, then it diverts the minors from treatment which exhibits substantial evidence of effectiveness for improving mental health and lacks the multiple and significant side-effects of puberty blockers.

XVI. Assessments of clinical guidelines, standards, and position statements.

239. Several sets of recommendations have been offered regarding the clinical treatment of people with gender dysphoria. In this section, I comment on these protocols or recommendations individually.

A. The Dutch Protocol (aka Dutch Approach).

240. The Netherlands' child gender identity clinic in Amsterdam associated with the Vrije University (VU) was one of the international leaders in the use of hormonal interventions to treat gender dysphoria in minors. Researchers associated with that clinic have generated a large portion of the seminal research literature in the field. Key early publications from that group spelled out criteria and procedures that are collectively referred to as the "Dutch Protocol," and this approach has been widely influential internationally.

241. The purpose of the protocol was to compromise conflicting desires and considerations including: clients' initial wishes upon assessment; the long-established and repeated observation that those wishes will change in the majority of (but not in all) childhood cases; and that cosmetic aspects of medical transition are perceived to be better when they occur earlier rather than later in pubertal development.

242. The VU team summarized and explicated their approach in their paper, *Clinical management of gender dysphoria in children and adolescents: The Dutch Approach*. (de Vries & Cohen-Kettenis 2012.) Key components of the Dutch Approach are:

- no social transition at all considered before age 12 (watchful waiting period),
- no puberty blockers considered before age 12,
- cross-sex hormones considered only after age 16, and
- resolution of mental health issues before any transition.

243. For youth under age 12, "the general recommendation is watchful waiting and carefully

observing how gender dysphoria develops in the first stages of puberty." (de Vries & Cohen-Kettenis 2012 at 301.)

244. The age cut-offs of the Dutch Approach were not based on any research demonstrating their superiority over other potential age cut-offs. Rather, they were chosen to correspond to the ages of consent to medical procedures under Dutch law. Nevertheless, whatever the original rationale, the data from this clinic simply contain no information about the safety or efficacy of employing these measures at younger ages.

245. The authors of the Dutch Approach repeatedly and consistently emphasize the need for extensive mental health assessment, including clinical interviews, formal psychological testing with validated psychometric instruments, and multiple sessions with the child and the child's parents.

246. Within the Dutch Approach, there is no social transition before age twelve. That is, social affirmation of the new gender may not begin until age 12—as desistance is less likely to occur past that age. "Watchful Waiting" refers to a child's developmental period up to that age. Watchful waiting does not mean do nothing but passively observe the child. Rather, such children and families typically present with substantial distress involving both gender and non-gender issues, and it is during the watchful waiting period that a child (and other family members as appropriate) would undergo therapy, resolving other issues which may be exacerbating psychological stress or dysphoria. As noted by the Dutch clinic, "[T]he adolescents in this study received extensive family or other social support [and they] were all regularly seen by one of the clinic's psychologists or psychiatrists." (de Vries 2011 at 2281.) One is actively treating the person, while carefully "watching" the dysphoria.

247. The use of hormonal interventions described in the Dutch Protocol, while markedly

more conservative than today's practice in many U.S. clinics, has recently been criticized in detail in a peer-reviewed article as unjustified by reliable evidence (Biggs 2022; Levine 2023; Levine 2022). Certainly, the published research evidence base concerning safety and efficacy available to the VU clinicians is and was no greater than the global evidence base that the NICE review recently labelled as uniformly of "very low quality."

248. Because clinical practices are often justified by alluding to the Dutch Protocol, however, it is important to be aware of the limitations on the use of hormones and puberty blockers specified by the Dutch Protocol and listed above (and thus the limits of the clinical evidence published out of the VU clinic) which are regularly ignored by clinicians in the U.S.

B. World Professional Association for Transgender Health (WPATH).

249. The WPATH standards of care have been lauded as long-established and high quality procedures. This does not reflect any objective assessment, however. The previous WPATH standards (version 7) were subjected to standardized evaluation, the Appraisal of Guidelines for Research and Evaluation ("AGREE II") method. (Dahlen 2021.) That assessment concluded "[t]ransition-related [clinical practice guidelines] tended to lack methodological rigour and rely on patchier, lower-quality primary research." (Dahlen 2021 at 6.) The WPATH guidelines were not merely given low scores, but received unanimous ratings of "Do not recommend." (Dahlen 2021 at 7.)

250. Immediately after the release of the current (2023) version of WPATH's standards (version 8), WPATH fundamentally altered it by removing from it minimum ages previously required for undergoing social or medical transition of gender. (WPATH Correction 2022.) This is despite the fact that age is the central component to young people's emerging understanding of their sexual identities through social identity formation, pubertal development, and the onset of

sexual interest. The removal of age restrictions was not based on any research evidence at all—WPATH provided no reference to any study as justification, and the WPATH leadership have been explicit in indicating that the change was intended to prevent clinical care providers from legal liability for physicians rejecting those minimums. The implementation of such fundamental and dramatic changes, in the complete absence of any supporting science whatsoever, negates entirely any claim that WPATH represents evidence-based or empirically-supported treatment. As explicated herein, on Table 1, the systematic review on which WPATH based its standards for minors included exactly one study on puberty blockers and three studies on cross-sex hormones. All other references represent cherry-picked citations of studies rejected by its own systematic process. Moreover, even among the four studies in WPATH's review, three were rejected by the Swedish review, due to the low quality of the science they contained.

C. Endocrine Society (ES).

251. As I have noted, in preparing its guidelines the Endocrine Society did not conduct systematic reviews of evidence relating to efficacy of any hormonal intervention in children or adolescents, and instead conducted reviews on only two safety-related endpoints.

252. Although outside the professional expertise of endocrinologists, mental health issues were also addressed by the Endocrine Society, repeating the need to handle such issues before engaging in transition, "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." (Hembree 2017 at 3877.) This ordering—to address mental health issues before embarking on transition—avoids relying on the unproven belief that transition will solve such issues.

253. The Endocrine Society did not endorse any affirmation-only approach. The guidelines

were neutral with regard to social transitions before puberty, instead advising that such decisions be made only under clinical supervision: "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." (Hembree 2017 at 3870.)

254. The Endocrine Society guidelines make explicit that, after gathering information from adolescent clients seeking medical interventions and their parents, the clinician "provides correct information to prevent unrealistically high expectations [and] assesses whether medical interventions may result in unfavorable psychological and social outcomes." (Hembree 2017 at 3877.)

255. The 2017 update of the Endocrine Society's guidelines added a disclaimer not previous appearing:

> The guidelines cannot guarantee any specific outcome, nor do they establish a standard of care….The Endocrine Society makes no warranty, express or implied, regarding the guidelines and specifically excludes any warranties of merchantability and fitness for a particular use or purpose. The Society shall not be liable for direct, indirect, special, incidental, or consequential damages related to the use of the information contained herein. (Hembree 2017 at 3895-3896.)

256. The Endocrine Society guidelines do not rely on any systematic review of evidence of *efficacy* of any form of treatment for gender dysphoria. The Dahlen et al. team also subjected these guidelines to review according to the AGREE II criteria, and two out of three independent reviewers concluded that they should *not* be used clinically. (Dahlen 2021 at 7.)

D. American Academy of Pediatrics (AAP).

257. A "Policy Statement" issued by the American Academy of Pediatrics (AAP) in 2018, but on its face declared to represent exclusively the work of one author who alone is "accountable for all aspects of the work," is unique among the major medical associations in being the only one to endorse an affirmation-on-demand policy, including social transition before puberty without

any watchful waiting period. (Rafferty 2018.) Although changes in recommendations can obviously be appropriate in response to new research evidence, the AAP identified no such new evidence to justify a radical departure from the "therapy first" approach of the Dutch Protocol. Rather, the research studies AAP cited in support of its policy simply did not say what AAP claimed they did. In fact, the references that AAP cited as the basis of their policy instead outright contradicted that policy, repeatedly endorsing watchful waiting. (Cantor 2019.) Moreover, of all the outcomes research published, the AAP policy cited *one*, and that without mentioning the outcome data it contained. (Cantor 2019.)

258. Immediately following the publication of the AAP policy, I conducted a point-by-point fact-check of the claims it asserted and the references it cited in support. I submitted that to the *Journal of Sex & Marital Therapy*, a well-known research journal of my field, where it underwent blind peer review and was published. I append that article as part of this report. *See* Appendix 2. A great deal of published attention ensued; however, the AAP has yet to respond to the errors I demonstrated its policy contained. Writing for *The Economist* about the use of puberty blockers, Helen Joyce asked AAP directly, "Has the AAP responded to Dr Cantor? If not, have you any response now?" The AAP Media Relations Manager, Lisa Black, responded: "We do not have anyone available for comment."

XVII. Assessment of plaintiffs' experts' reports.

259. In the body of my report above I have addressed the nature and strength of the scientific evidence concerning the primary scientific issues raised in the expert reports of Plaintiffs' experts. Here, I add a few remarks directed to specific evidentiary or logical defects in the opinions offered by specific experts.

A. Antommaria

260. Dr. Antommaria argues first that "Gender-affirming medical care is supported by evidence of its safety and efficacy," repeatedly citing as his evidence the Endocrine Society which "uses a rigorous method to develop its clinical practice guidelines." (Antommaria Report at 4−5.) Although Dr. Antommaria outlined what those methods entailed for other issues, Dr. Antommaria failed to indicate that those methods were not applied for this one: Puberty blockers were not included in the Endocrine Society's commissioned systematic reviews at all, nor did the Endocrine Society's systematic reviews look at mental health effects of either puberty blockers or cross-sex hormones. Their review was limited only to selected physiological effects of cross-sex hormones. Moreover, the wording of the Endocrine Society review leaves ambiguous whether minors were included at all or if the review was limited to adults. Dr. Antommaria added to the Endocrine Society review a single-blind study (Burinkul 2021), which pertained to adults only, not children.

261. Dr. Antommaria argues next that low quality evidence can sometimes be sufficient for clinical recommendations. In so doing, Dr. Antommaria makes the logical error of confusing what is "necessary" with what is "sufficient." Where the Endocrine Society indicates that a multidisciplinary team is necessary for recommendations, Dr. Antommaria insinuates having such a team is sufficient for making such decisions—even in the absence of meaningful evidence as to either risks or benefits. As I have detailed above, multiple respected international health authorities

or advisory bodies disagree, deeming the available evidence *insufficient* on which to base clinical recommendations for the use of hormonal interventions in children and adolescents. (Section V.) In actuality, the Endocrine Society included no review of outcomes at all, made no claims about potential success, and even denies responsibility for outcomes. (See Section XVI.C.)

262. The only research study Dr. Antommaria cites here is de Vries, *et al.*, 2014: That study provided both psychotherapy and medicalized transition at the same time, making it impossible to know which one led to the report mental health improvements. (See section XIII.B.)

263. Dr. Antommaria next claims that it would even be unethical to conduct an RCT of medicalized transition. Each of the reasons he gave, however, is incorrect. He indicated "clinical equipoise must exist." (Antommaria Report at 15)—that there must exist genuine uncertainty about which procedure is superior, whereas he and the colleagues he surrounds himself with feel entirely certain. Dr. Antommaria is incorrect about this ethical principle: According to bioethicist Benjamin Freedman, the originator of the concept of clinical equipoise, writing in the *New England Journal of Medicine*, "The requirement is satisfied if there is genuine uncertainty within *the expert medical community*—not necessarily on the part of the individual investigator—about the preferred treatment." (Freedman 1987.) The international expert medical community is indeed highly uncertain, as thoroughly documented both herein and in the international medical press, such as the British Medical Journal's recent article: *Gender Dysphoria in youth people is rising and so is professional disagreement.* (Block 2023.)

264. Moreover, it is Dr. Antommaria's certainty (and that of whomever else he feels he is entitled to speak for) that is unjustified. As already documented herein, nonmedicalized treatments have already shown benefits indistinguishable from those from medicalized transition.

265. Dr. Antommaria writes that RCTs would be unethical also because medicalized

transition could not be compared with a non-pharmacological or placebo treatment. Both claims are incorrect. The routine and ethical alternative procedure in clinical science is to use what is called an "active comparator," as was spelled out in the NICE reviews from England. (NICE 2020a at 40; NICE 2020b at 47.) In such an RCT, participants would be randomly assigned into a psychotherapy-only group or a psychotherapy + medicalization group.

266. Dr. Antommaria's other argument against RCTs is his belief that "A randomized trial is unlikely to enroll enough participants." (Antommaria Report at 16.) That belief is also baseless. Healthcare systems of *entire countries* throughout Europe are limiting *all* medicalized transition of minors to research studies.

267. Dr. Antommaria next relies on WPATH, asserting that it "conducted selected systematic reviews of the literature." (The WPATH review is published as Baker, *et al.,* 2021.) Missing from Dr. Antommaria's report was that WPATH did not include any safety-related data in minors, either of puberty blockers or of cross-sex hormones in their systematic review. (Section IV.B.) Also, as I have noted above, WPATH did not even attempt any review with respect to outcomes of hormonal interventions in adolescents.

268. Dr. Antommaria's only reference to the international systematic reviews (indeed, the only such reference by any of the plaintiffs' experts) is the single paragraph, beginning on page 18, indicating that the reviews "do not make treatment recommendations" and therefore do not actually contradict the WPATH and Endocrine Society recommendations. Dr. Antommaria is either confused or intentionally dodging the regular practice and relevant recommendations. The routine procedure for establishing evidence-based practice is a two-step process, the first being the conduct of the systematic review, and the second being its integration with financial, political, and other constraints to yield the recommendations themselves. For example, the UK conducted

reviews (released under NICE) which were then incorporated into recommendations (released under Cass). WPATH conducted a review (released as Baker *et al,* 2021), which was allegedly incorporated into their guidelines (released under Coleman *et al,* 2022). What Dr. Antommaria is alleging to be a mismatch between "the Endocrine Society's and WPATH's clinical practice guidelines and recent European documents" (Antommaria Report at 18), is merely Dr. Antommaria's own failure to compare reviews with reviews and guidelines with guidelines. I have reviewed the actual recommendations from European health authorities and advisory commissions above.

269. Dr. Antommaria writes, "None of the documents recommend criminalizing gender-affirming medical care as does VCAP." (Antommaria Report at 19.) The means by which a state or other government implements research results and protects citizens from harm is a political rather than a scientific or clinical question, and I can offer no expert opinion. (See section I.C.) I am, however, a citizen of two countries (Canada and the United States), working within the very different health care systems of each. From that experience, I can observe that countries with centralized public health care systems (such as Canada and European nations), have direct control over what treatments are or are not administered within those nations, while the decentralized and often private health care system of the U.S. must rely on different mechanisms of control.

270. In his next argument, Dr. Antommaria contests the results of the entire set of cohort studies, all of which found that most pre-pubescent children with gender dysphoria cease to feel dysphoric by puberty. Against these eleven studies, Dr. Antommaria cited a single study, Wiepjes, *et al.,* 2018, but misrepresented its contents: Dr. Antommaria attributed to Wiepjes that "individuals who fulfill the criteria for gender-affirming medical care generally continue in their gender identity." (Antommaria Report at 22.) Dr. Antommaria's application of the word

"individuals" hides from the court that Wiepjes' conclusion applied to the adults while *the reverse was true for the children:* Wiepjes included 5,433 adults age 18 or older and 548 children under age 12. (Wiepjes 2018 at Table 1.) Of the adults, 69.9% went on to medicalized treatment, whereas only 40.3% of the children did. Dr. Antommaria's choice of the ambiguous word "individuals" misleads the court, erroneously applying the results from adults to the children, declaring to the court the very opposite of what Wiepjes actually showed. In any case, as I have reviewed above, a phalanx of respected voices in the field, including the Endocrine Society, disagree with Dr. Antommaria and instead agree with my reading that the cohort studies do support the conclusion that a large majority of prepubertal children who suffer from gender dysphoria will desist. (Section IX.B.)

271. Dr. Antommaria's only other argument is that cohort studies of children "have substantial limitations" (Antommaria Report at 22.) citing a single commentary as support, Newhook, *et al.,* 2018. As detailed herein (Section IX.B), Temple Newhook, *et al.* criticized four studies of prepubescent children with gender dysphoria for using (in Temple Newhook's view) overly broad diagnostic criteria. I have detailed above a number of reasons why Temple Newhook's criticism is invalid, and that article has been additionally rebutted in a peer-reviewed paper. (Zucker 2018, *The Myth of Persistence*.) Moreover, Dr. Antommaria's argument introduces an additional error by insinuating that all of the relevant cohort studies used the same criteria as the four studies that Temple Newhook contested, but failed to inform the court that the other seven studies, using different criteria, came to exactly the same conclusion as the four. (See Section IX.B.) That is, Dr. Antommaria's invocation of Temple Newhook's argument cannot contradict the unanimous finding. The international systematic reviews also expressed the conclusion I provided herein and not that of Temple Newhook.

272. Dr. Antommaria's insinuation that gender dysphoria persists in most children also conflicts with the conclusion of the Endocrine Society, which Dr. Antommaria otherwise repeatedly accepts as authoritative. According to the Endocrine Society:

> Combining all outcome studies to date, the GD/gender incongruence of a *minority* of prepubertal children appears to persist in adolescence….In adolescence, a significant number of these desisters identify as homosexual or bisexual. (Hembree 2017 at 3876, italics added.)

273. Dr. Antommaria indicates that watchful waiting applies only to prepubescent children, insinuating that adolescent-onset cases differ, are unlikely to desist, and therefore do not require a watchful waiting period. That insinuation is incorrect: There do not exist cohort (or superior level) research studies on adolescent-onset cases. There are no meaningful data regarding persistence and desistance for this large, new population. It is not knowable whether their outcomes will resemble those of adult-onset cases (despite differing on all objective variables), or will resemble those of childhood-onset cases (despite also differing from theirs), or will show altogether different outcomes.

274. As detailed herein, all the international health care systems that have conducted or commissioned systematic reviews concluded medicalized transition to be *experimental*. (See Section V.) Dr. Antommaria denies that consensus, arguing that "The clinical use of puberty blockers and gender affirming hormones treatment is not experimental" because "the goal of clinical practice is to benefit individual patients" rather than "to contribute to generalizable knowledge." (Antommaria Report at 23.)[9] Dr. Antommaria's argument is mere word-play: He swaps the common use of "experimental" meaning "untested" with the technical use of

[9] Dr. Antommaria also contested the word "new;" however, newness is not a criterion in science or its assessment. Moreover, that *cross-sex* hormones were used for transition in 1966 does not disconfirm that using *puberty blockers* is new, and their use *in adults* does not disconfirm their use *in minors* being new. In this context, "new" clearly refers to whether there has been sufficient time undergoing sufficient examination for a treatment's effects to be reliably predicted.

"experimental" meaning "currently enrolled in a clinical trial". That is, Dr. Antommaria's argument is that, so long as the physician doesn't plan on recording and reporting the results, then prescribing the drug doesn't count as an "experiment"—even if the safety and effectiveness of the drug is utterly unproven—so the drug itself does not count as experimental. Under Dr. Antommaria's faulty logic, every treatment could avoid ever being called "experimental" so long as no one ever performed the experiment to test it. In fact, the quoted health authorities largely use the word in the sense "unproven," while calling for researchers to undertake the well-designed experiments which have not yet been done.

275. Dr. Antommaria's defence of using off-label, non-FDA-approved uses of drugs is entirely peripheral. Treatment safety and effectiveness do not have a one-to-one correspondence with FDA-approval. The fact that some other drugs are used widely and safely for some other off-label indications does not imply in the least that off-label use of this drug (puberty blockers) for this use (preventing normal, healthy puberty in children) is safe.

276. Dr. Antommaria argues that "VCAP's legislative findings do not provide a sufficient basis for singling out the provision of gender-affirming medical care to adolescents with gender dysphoria." (Antommaria Report at 30.) However inadvertently, Dr. Antommaria actually provides exactly that basis himself in his next paragraph: These medical procedures are permitted to treat problems that are "*medically verifiable.*" (Antommaria Report at 31.) Both of Dr. Antommaria's examples (central precocious puberty and complete androgen insensitivity syndrome) are indeed medically verifiable with objective testing, and the medication is applied to bring the patient within healthy norms. By contrast, gender dysphoria is entirely subjective, ascertained by self-report only, with no means of objective verification possible, and the medication is applied precisely to take the patient *outside* of healthy norms.

277. Standards for clinical practice comprise multiple, mutually reinforcing principles and procedures. This overlap can sometimes permit some flexibility in some circumstances where the other principles with high reliability can compensate, such as allowing some reports of pain and sensations when diagnosing a physical disease before prescribing a short-acting and low-risk medication. Dr. Antommaria's recommendations for medicalized transition, however, entail the simultaneous removal of multiple overlapping protections, leaving no meaningful protection at all. Dr. Antommaria is accepting, at face-value only, purely subjective reports, of a diagnosis with no objective evidence of validity, offering long-term and life-long physical intervention, on the basis of the lowest possible quality evidence, despite all objective counterevidence, and without first exhausting the safer and less invasive alternatives.

B. Janssen

278. Dr. Janssen indicates he was deposed as an expert witness by the plaintiffs in BPJ v WV Board of Education. I testified as an expert witness for the defense in that case.

279. Dr. Janssen's report does not provide the science of medicalized transition of minors. I could find no citation or mention of any of the systematic reviews of the topic, whether from an international health care system or a professional guild. Dr. Janssen cited a vanishingly small set of highly cherry-picked publications (ten in total), which do not reflect the state of the science.

280. Four of Dr. Janssen's ten citations represent self- (and/or parent-) report surveys (*i.e.*, Durwood, *et al.,* 2017; Olson, *et al.,* 2016; Turban, *et al.,* 2020a, 2020b). Surveys do not have the scientific rigour to qualify as medical evidence and are rejected by all systematic reviews as insufficient. (See Section IV.A.)

281. Two of Dr. Janssen's citations do not pertain to gender dysphoria at all (i.e., Costello, *et al.,* 2003; Wilens, *et al.,* 2002). Dr. Janssen cites these as general support of the general idea

that adolescents with one mental health diagnosis are likely to have others. That much is true. Dr. Janssen does not, however, include that the pattern of mental illnesses among gender dysphoric youth are different from the pattern of mental illnesses of other adolescents. Dr. Janssen also fails to take his own argument to its parsimonious conclusion: It is because adolescents are experiencing many mental health concerns that Adolescent-Onset Gender Dysphoria may represent simply another of those concerns, amenable to mental health treatment, like those other concerns.

282. Dr. Janssen cites de Vries, *et al.,* 2014, claiming it showed, not only that transition improves mental health, but also that transition is the only treatment that does. Dr. Janssen's claim is untrue and contradicts the study's own authors, who noted "the positive results may also be attributable to supportive parents, open-minded peers, and the social and financial support (treatment is covered by health insurance) that gender dysphoric individuals can receive in the Netherlands." Also, the participants in this study were receiving not only medicalized services, but also psychotherapy, which can also have caused the mental health improvements. (See section III.B.) Despite his bold claim, it is not scientifically possible for Dr. Janssen (or anyone else) to know whether mental health improvement came from the mental health treatment or medicalization.

283. Moreover, Dr. de Vries continues to express the very opposite of what Dr. Janssen attributed to her: Writing in 2023, she repeated that "rigorous longitudinal outcomes studies that provide evidence about whether this approach [hormonal interventions in minors] is effective and safe are needed" and that "Future studies that compare outcomes with different care models are needed." (de Vries 2023 at 276.)

284. Dr. Janssen similarly cited Chen, *et al.,* 2023, to support his claim that "gender transition can—and often does—alleviate co-occurring mental health issues" (Janssen Declaration

at 9.) Yet, the Chen study cannot support that claim either: Chen, *et al.* did not disclose whether the youth in their study were receiving mental health treatment and whether that was responsible for the improvements they reported finding. It does not "compare outcomes with different care models" as Dr. de Vries emphasized were needed. Without that information, it is again impossible for Dr. Janssen to know what he claims to know.

285. Dr. Janssen claims that "well-established research demonstrates the effectiveness of treatment for gender dysphoria in adolescence," citing Turban, *et al.,* 2018. Dr. Janssen's claim misrepresents that source. What Turban, *et al.,* 2018, actually said was that such treatment "has been evaluated in two studies on the same cohort of Dutch adolescents," explicitly warning that "the results come from only one clinic and concern a highly selected sample...Whether the same positive results can be expected for the larger number of adolescents that are treated at clinics that vary in their approach to gender variant adolescence *has yet to be determined."* (Turban 2018 at 640, italics added.) Additionally, the Turban citation in turn cites de Vries, *et al.,* 2014, which I have discussed above. I note also that of the 10 publications Dr. Janssen cites, three were written by the same author (i.e., Turban, 2017, 2020a, 2020b), signalling the cherry-picked nature of the sources Dr. Janssen has chosen to cite.

C. Ladinsky

286. Dr. Ladinsky's report does not provide a complete or accurate account of the relevant research literature, repeatedly citing the three U.S.-based association policies and not any of the systematic reviews available. There was no citation to any other source behind any other claim from page 5 to page 19. Citation numbers 2 through 17 are all to those same documents, which are already evaluated in the present report. The few other sources cited fail to support Dr. Ladinsky's claims.

287. Dr. Ladinsky attributed to Spack, *et al*. (2012) that suicidality and other poor outcomes would result from gender dysphoria "if left untreated," insinuating that "untreated" meant not permitted medical transition. In actuality, Spack, *et al.* (2012) was unambiguous:

> Gender dysphoric children who do not receive *counseling* have a high risk of behavioural and emotional problems and psychiatric diagnoses." (at 422.)

Spack (2013) warned:

> Mental health intervention should persist for the long term, *even after surgery, as patients continue to be at mental health risk, including for suicide.* While the causes of suicide are multifactorial, the possibility cannot be ruled out that some patients unrealistically believe that surgery(ies) solves their psychological distress. (at 484.)

288. Dr. Ladinsky claims of Alabama's law that "If the law goes into effect, based on my expert opinion, it will cause serious harms to my patients as well as other transgender youth throughout Alabama." (Ladinsky Declaration at 17.) Dr. Ladinsky cites no evidence, analysis, or methodology justifying that conclusion or any indication of engaging in any scientific process or applying any criteria that an expert would use to come to such a conclusion.

289. Dr. Ladinsky indicates having reviewed the declarations previously submitted for the present case by me and by other experts for the state. The only point of mine contested by Dr. Ladinsky was my claim that:

> [I]in the absence of long-term follow-up, it cannot be known what proportions come to regret having transitioned and then detransition. Because only a minority of gender dysphoric children persist in feeling gender dysphoric in the first place, "transition-on-demand" increases the probability of unnecessary transition and unnecessary medical risks. (Cantor Declaration, Preliminary Injunction Hearing, ¶43.)

Dr. Ladinsky's only counter-argument is to say that she herself does not permit transition-on-demand in her patients. Whatever Dr. Ladinsky's own practices are and whatever her views of what constitutes adequate investigation may be, reports of the failures of gender clinics to employ meaningful gatekeeping are emerging throughout the Western world. Moreover, it remains true

that Dr. Ladinsky cannot know the long-term outcomes of patients after they have left her care.

290. Dr. Ladinsky emphasizes that "Suicidality is of particular concern" if medicalizing hormones are not provided to minors, citing three articles, Wiepjes, *et al* (2018), de Vries, *et al* (2014), and Turban, *et al* (2020). Dr. Ladinsky is mistaken. Wiepjes, *et al* (2018) contains no information on suicide or suicidality—neither word appears in the document at all. Similarly, de Vries, *et al,* 2014, reported no evidence on suicidality, providing results only on general psychological well-being. Turban, *et al* (2020) reported on a survey in which a high proportion of survey-takers reported suicidality at some time in their life, but provided no evidence whether that rate was due to gender identity or to any of other mental health issues, such as Borderline Personality Disorder, which are highly overrepresented in samples of gender dysphoric youth. (See section XI.C.)

D. McNamara

291. Dr. McNamara indicates that she bases the validity of her argument on the standards of the National Academy of Medicine, as applied by WPATH and the Endocrine Society. Her claim is demonstrably incorrect. According to the document Dr. McNamara cited from the Academy, clinical practice guidelines "are informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options." (Institute of Medicine, Clinical Practice Guidelines, 2011 at 4.) As documented here already, the Endocrine Society did not include any review of puberty blockers or cross-sex hormones in minors, and WPATH's review did not include the safety of any treatment in minors, instead expressly allowing clinical opinion to substitute for valid experimental evidence. (See Section XVI; Block, Gender Dysphoria 2023.) The several European health care systems did, however, conduct such reviews and concluded the very opposite to Dr. McNamara.

292. Dr. McNamara repeatedly employs circular reasoning. Her report repeatedly refers to medicalized transition as "essential" or "established," based on the *absence* of compelling evidence of harm or inefficacy. As already noted, the absence of evidence is not evidence of the absence of, in this case, harm. Her logic is entirely counter to the scientific method. Whether medicalized transition is essential is the very question being assessed. The claim cannot be simply asserted or assumed until proven otherwise. The scientific procedure for investigating such issues is called "null hypothesis testing." Differences, including clinical improvements, are assumed to be zero until proven otherwise.

293. Dr. McNamara, like Dr. Antommaria, misrepresents or misunderstands the role of RCTs in clinical science, arguing that RCTs cannot be conducted because study participants would become aware of whether they were in the treatment group or the control group. (That is, participants could not be masked or "blinded.") Their error is that studies do not need to be masked to be an RCT: for example, as reported in *The Lancet,* 40% of RCTs published in PubMed during a study period were not, in fact, masked. (Chan & Atman 2005 at 1160.) Although masked RCTs can be superior to non-masked RCTs, the impossibility of masking in certain contexts does not authorize clinicians or clinical scientists simply to skip RCTs altogether and proceed with confidence as if they had been completed and the treatment demonstrated to be successful—which they have not. (See also Section III.C on masked, placebo-controlled research designs.)

294. Dr. McNamara claims that the international medical consensus supports medicalized transition of gender in minors. She cited no source for that claim. As thoroughly documented herein, all international health care systems conducting systematic reviews have in recent years come to exactly the opposite conclusion. Moreover, Dr. McNamara's language is ambiguous. Her words "supports treatment of gender dysphoria" are entirely consistent with using psychotherapy

to alleviate gender dysphoria *without* medicalized transition, which more accurately reflects international consensus.

295. Dr. McNamara claims, "Defendants' experts have previously asserted that essential medical treatment for gender dysphoria causes suicide; however, no study has found a worsening of various mental health measures among recipients of essential medical treatment for gender dysphoria." (McNamara Report at 11.) Regarding her first sentence, I have made no such statement. Dr. McNamara's second sentence is demonstrably incorrect. The Kuper, *et al.* (2020) cohort study (see Section V.C) reported the suicidality of an adolescent sample before and after hormone treatment. Table 5 of that study (Kuper at 8) showed suicidal ideation to be 25% before and 38% after treatment, suicidal attempts to be 2% before and 5% after, and non-suicidal self-harm to have been 10% before and 17% after. For reasons already outlined herein, Kuper's data cannot establish causation, but indeed show decreases in mental health, thus calling for caution and further research rather than suggesting such treatment to be "safe" for these children.

296. Dr. McNamara's dismissal of the systematic review of Dhejne is counter to both clinical ethics and clinical science. It is true that the Dhejne review pertained to adults rather than adolescents, and it is possible that transitioned adolescents might show a pattern opposite of what transitioned adults do. Because it remains substantially unstudied and unknown on what features adolescent cases might resemble adult cases (or prepubescent cases), evidence about the experiences and outcomes among adults after transition cannot be dismissed as irrelevant to the risk:benefit equation for adolescents. Because suicidality is elevated among adults, it is at least plausible that it will also be higher among adolescents. Both research ethics and medical ethics require that this possibility be thoroughly investigated and ruled out with high quality evidence rather than assume the opposite to be true. The combination of the Dhejne evidence from adults

and the Kuper evidence from adolescents together provide strong reason to apply every possible caution before proceeding.

E. Shumer

297. Dr. Shumer indicates that he testified as an expert witness for the plaintiffs in Roe, *et al* v Utah High School Activities Association, *et al.* I testified as an expert witness for the defense in that case, which is currently in process.

298. I have already addressed the substance of most of Dr. Shumer's mistaken assertions regarding the science relevant to hormonal and surgical interventions in minors as a treatment for gender dysphoria. Here, I address a few remaining points from his report.

299. Dr. Shumer faults VCAP Finding 1 because its "description of sex fails to include gender identity, which is an essential medical component of sex for every person" (Shumer Report at 27); however, the VCAP description is correct. In his report, Dr. Shumer conveys a definition of sex which not only is incorrect, but also contradicts the very document he cited as his source of that definition. Dr. Shumer wrote:

> Sex is comprised of several components, including, among others, internal reproductive organs, external genitalia, chromosomes, hormones, *gender identity,* and secondary sex characteristics. (Shumer Report at 6, italics added.)

He attributed that definition to:

> Institute of Medicine. The health of lesbian, gay, bisexual, and transgender people: building a foundation for better understanding. Washington, DC: The National Academic Press; 2011.

In direct contradiction with Dr. Shumer's claim, Institute of Medicine does not, in fact, include gender identity in its definition of sex. Its definition is:

> To discuss the context surrounding the health of LGBT populations, the committee has adopted working definitions for a number of key terms. *Sex* is understood here as a biological construct, referring to the genetic, hormonal, anatomical, and physiological characteristics on whose basis one is labeled at birth as either male or female. (Institute of Medicine, Health, 2011 at 25, italics original.)

That is, the Institute of Medicine—just like Alabama—explicitly limited sex to biological, objective features, as I have defined it in the present declaration. The major clinical associations also limit the definition of sex to objective features, also excluding gender identity (see Section VII.A), again in direct opposition to Dr. Shumer's claim.

300. Dr. Shumer claims that attempting to change a person's understanding of their gender identity "has been found to be both harmful and ineffective" (Shumer Report at 8), on the basis of the evidence in two articles based on a 2015 survey. Dr. Shumer's interpretation of those articles is invalid, however: It is not possible for a survey to demonstrate that anything is either harmful or ineffective. These are both causal claims that surveys are not capable of demonstrating. (See Section III.F.) Not only is there no study that has found that relying on psychotherapy and counseling support for a child or adolescent who suffers from gender dysphoria leads to worse outcomes than does hormonal intervention whether with or without psychotherapy, but also the studies that have compared these treatments failed to find superiority of medicalized transition (See Section XIII.)

301. Activists and social media increasingly, but erroneously, apply the term "conversion therapy," moving farther and farther from what the research has reported. "Conversion therapy" (or "reparative therapy" and other names) has referred to efforts to change a person's sexual orientation. More recently, any therapy failing to provide affirmation-on-demand is labeled "conversion therapy." (D'Angelo, *et al.,* 2020.) Although the media and social media habitually add "T" to "GLB" in discussing these issues, the research on "conversion therapy" has investigated only sexual orientation, and its results cannot be extrapolated to gender identity by mere analogy.

302. Dr. Shumer claims, "gender identity, like other components of sex, has a strong biological foundation" (Shumer Report at 9), but again misrepresents the sources he cited. The

research has shown statistically significant differences associated with *sexual orientation,* not gender identity. Although Dr. Shumer cited Heylens, *et al.* (2012) to claim that there are "genetic underpinnings to gender identity development," Dr. Shumer did not, however, share the rest of Heylens' observation, noting this confounding: "In all the cases reported to be concordant for GID [i.e., 'match on gender identity'] there was also concordance for sexual orientation." (Heylens 2012 at 755.) The Endocrine Society guidelines similarly noted the association with sexual orientation. Contrary to Shumer's claim of a "strong" biological foundation, the Endocrine Society emphasized that whatever hypotheses may currently be in play, *no* genetic marker (or other physical marker) enabling verification of transgender status has been identified. (Hembree 2017 at 3875.) Shumer cites no evidence of any biological or other objective marker (let alone a "strong" one) able to identify transgender identity.

303. Dr. Shumer's comparison of gender identity with congenital adrenal hyperplasia (CAH) is invalid. CAH is a biological disorder with objective features that can be objectively detected, entirely unlike gender dysphoria, which remains entirely subjective with no objective means of verification or falsification.

304. Dr. Shumer's "rationale for medical treatment of gender dysphoria in adolescents" (Shumer Report at 11–12) is invalid. He cites five "studies demonstrating positive results of gender-affirming care" (Shumer Report at 11.); however, none of these studies uses a design capable of demonstrating causality. In contrast with Dr. Shumer's (mis)use of causal language, none of these studies is able to distinguish changes due to medicalized transition from changes due to the psychotherapy that the patients were receiving at the same time. (See Section IV.C.)

305. Dr. Shumer repeatedly employs strong terms in describing his opinions; however, these represent only vague and rhetorical terms without scientific definition. For examples, there are no

objective criteria for concluding: when clinician's assessment of a patient has developed "a deep understanding" (Shumer Report at 14); which patients represent "appropriately selected patients" (at 24); which of conflicting clinicians are "highly trained" (at 28); what constitutes a "skillful elicitation of a patient's experience" (at 28); when an assessment represents a "comprehensive evaluation" (at 30); who has been "carefully evaluated" (at 34); or, outside of any systematic review, what still constitutes "robust research" (at 15).

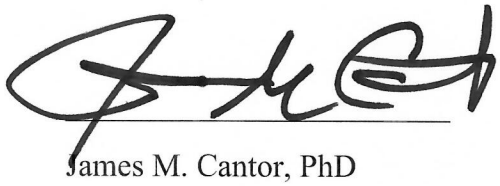
306. Dr. Shumer refers to the WPATH standards of care as "based on the best available science." (Shumer Report at 16.) As I have detailed above, the WPATH SOC does not satisfy the definition of "evidence-based medicine," and extensively ignores "the best available science." (Section XVI.B.)

307. Dr. Shumer asserts separately that "withdrawal of hormones in adulthood often is successful in achieving fertility when it is desired." (Shumer Report at 25.) He does not cite sources that support "often," and does not cite any study that demonstrates achievement of healthy fertility for subjects whose natural puberty was blocked and who then received cross-sex hormones for an extended period of years, as is the course of treatment for gender dysphoric children that Dr. Shumer commends. That is, Dr. Shumer's report addresses the very limited evidence of the effects of using only one or the other of these medications, but fails to include the effects of their combination.

308. Dr. Shumer faults VCAP Finding 12, claiming that "GnRHa is used when it is determined that the progression of puberty would cause significant harm to the adolescent." (Shumer Report at 33.) It is not possible to make such a prediction for any patient—the existing evidence is only correlational, not causal. Dr. Shumer claims, "The benefit of treatment is not unproven or poorly studied." (Shumer Report at 33.) That claim contradicts the conclusion of all

systematic reviews of GnRHa safety. The evidence Dr. Shumer cites as support for his claim are the WPATH and Endocrine Society guidelines; however, neither association included GnRHa safety in their systematic reviews.

Dated: 19 May 2023



James M. Cantor, PhD

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LIST OF APPENDICES

Appendix 1

Curriculum Vita

Appendix 2

Cantor, J. M. (2020). Transgender and gender diverse children and adolescents: Fact-checking of AAP policy. *Journal of Sex & Marital Therapy, 46,* 307–313. doi: 10.1080/0092623X.2019.1698481

Appendix 1

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EDUCATION

Postdoctoral Fellowship Jan., 2000–May, 2004
Centre for Addiction and Mental Health • Toronto, Canada

Doctor of Philosophy Sep., 1993–Jun., 2000
Psychology • McGill University • Montréal, Canada

Master of Arts Sep., 1990–Jan., 1992
Psychology • Boston University • Boston, MA

Bachelor of Science Sep. 1984–Aug., 1988
Interdisciplinary Science • Rensselaer Polytechnic Institute • Troy, NY
Concentrations: Computer science, mathematics, physics

EMPLOYMENT HISTORY

Director Feb., 2017–Present
Toronto Sexuality Centre • Toronto, Canada

Senior Scientist (Inaugural Member) Aug., 2012–May, 2018
Campbell Family Mental Health Research Institute
Centre for Addiction and Mental Health • Toronto, Canada

Senior Scientist Jan., 2012–May, 2018
Complex Mental Illness Program
Centre for Addiction and Mental Health • Toronto, Canada

Head of Research Nov., 2010–Apr. 2014
Sexual Behaviours Clinic
Centre for Addiction and Mental Health • Toronto, Canada

Research Section Head Dec., 2009–Sep. 2012
Law & Mental Health Program
Centre for Addiction and Mental Health • Toronto, Canada

Psychologist May, 2004–Dec., 2011
Law & Mental Health Program
Centre for Addiction and Mental Health • Toronto, Canada

Clinical Psychology Intern Sep., 1998–Aug., 1999
Centre for Addiction and Mental Health • Toronto, Canada

Teaching Assistant Sep., 1993–May, 1998
Department of Psychology
McGill University • Montréal, Canada

Pre-Doctoral Practicum Sep., 1993–Jun., 1997
Sex and Couples Therapy Unit
Royal Victoria Hospital • Montréal, Canada

Pre-Doctoral Practicum May, 1994–Dec., 1994
Department of Psychiatry
Queen Elizabeth Hospital • Montréal, Canada

ACADEMIC APPOINTMENTS

Associate Professor Jul., 2010–May, 2019
Department of Psychiatry
University of Toronto Faculty of Medicine • Toronto, Canada

Adjunct Faculty Aug. 2013–Jun., 2018
Graduate Program in Psychology
York University • Toronto, Canada

Associate Faculty (Hon) Oct., 2017–Dec., 2017
School of Behavioural, Cognitive & Social Science
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Assistant Professor Jun., 2005–Jun., 2010
Department of Psychiatry
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Adjunct Faculty Sep., 2004–Jun., 2010
Clinical Psychology Residency Program
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PUBLICATIONS

1. Cantor, J. M. (2023). Paraphilia, gender dysphoria, and hypersexuality. In R. F. Krueger & P. H. Blaney (Eds.), *Oxford textbook of psychopathology* (4th ed.) (pp. 549–575). New York: Oxford University Press.
2. Cantor, J. M. (2020). Transgender and gender diverse children and adolescents: Fact-checking of AAP policy. *Journal of Sex & Marital Therapy, 46,* 307–313. doi: 10.1080/0092623X.2019.1698481
3. Shirazi, T., Self, H., Cantor, J., Dawood, K., Cardenas, R., Rosenfield, K., Ortiz, T., Carré, J., McDaniel, M., Blanchard, R., Balasubramanian, R., Delaney, A., Crowley, W., S Marc Breedlove, S. M., & Puts, D. (2020). Timing of peripubertal steroid exposure predicts visuospatial cognition in men: Evidence from three samples. *Hormones and Behavior, 121, 104712*.
4. Stephens, S., Seto, M. C., Cantor, J. M., & Lalumière, M. L. (2019). The Screening Scale for Pedophilic Interest-Revised (SSPI-2) may be a measure of pedohebephilia. *Journal of Sexual Medicine, 16,* 1655−1663. doi: 10.1016/j.jsxm.2019.07.015
5. McPhail, I. V., Hermann, C. A., Fernane, S., Fernandez, Y. M., Nunes, K. L., & Cantor, J. M. (2019). Validity in phallometric testing for sexual interests in children: A meta-analytic review. *Assessment, 26,* 535–551. doi: 10.1177/1073191117706139
6. Cantor, J. M. (2018). Can pedophiles change? *Current Sexual Health Reports, 10,* 203–206. doi: 10.1007/s11930-018-0165-2
7. Cantor, J. M., & Fedoroff, J. P. (2018). Can pedophiles change? Response to opening arguments and conclusions. *Current Sexual Health Reports, 10,* 213–220. doi: 10.1007/s11930-018-0167-0z
8. Stephens, S., Seto, M. C., Goodwill, A. M., & Cantor, J. M. (2018). Age diversity among victims of hebephilic sexual offenders. *Sexual Abuse, 30,* 332–339. doi: 10.1177/1079063216665837
9. Stephens, S., Seto, M. C., Goodwill, A. M., & Cantor, J. M. (2018). The relationships between victim age, gender, and relationship polymorphism and sexual recidivism. *Sexual Abuse, 30,* 132−146. doi: 10.1177/1079063216630983
10. Stephens, S., Newman, J. E., Cantor, J. M., & Seto, M. C. (2018). The Static-99R predicts sexual and violent recidivism for individuals with low intellectual functioning. *Journal of Sexual Aggression, 24,* 1–11. doi: 10.1080/13552600.2017.1372936
11. Cantor, J. M. (2017). Sexual deviance or social deviance: What MRI research reveals about pedophilia. *ATSA Forum, 29*(2). Association for the Treatment of Sexual Abusers. Beaverton, OR. http://newsmanager.commpartners.com/atsa/issues/2017-03-15/2.html
12. Walton, M. T., Cantor, J. M., Bhullar, N., & Lykins, A. D. (2017). Hypersexuality: A critical review and introduction to the "Sexhavior Cycle." *Archives of Sexual Behavior, 46,* 2231–2251. doi: 10.1007/s10508-017-0991-8
13. Stephens, S., Leroux, E., Skilling, T., Cantor, J. M., & Seto, M. C. (2017). A taxometric analysis of pedophilia utilizing self-report, behavioral, and sexual arousal indicators. *Journal of Abnormal Psychology, 126,* 1114–1119. doi: 10.1037/abn0000291
14. Fazio, R. L., Dyshniku, F., Lykins, A. D., & Cantor, J. M. (2017). Leg length versus torso length in pedophilia: Further evidence of atypical physical development early in life. *Sexual Abuse: A Journal of Research and Treatment, 29,* 500–514. doi: 10.1177/1079063215609936

15. Seto, M. C., Stephens, S., Lalumière, M. L., & Cantor, J. M. (2017). The Revised Screening Scale for Pedophilic Interests (SSPI-2): Development and criterion-related validation. *Sexual Abuse: A Journal of Research and Treatment, 29,* 619–635. doi: 10.1177/1079063215612444
16. Stephens, S., Cantor, J. M., Goodwill, A. M., & Seto, M. C. (2017). Multiple indicators of sexual interest in prepubescent or pubescent children as predictors of sexual recidivism. *Journal of Consulting and Clinical Psychology, 85,* 585–595. doi: 10.1037/ccp0000194
17. Stephens, S., Seto, M. C., Goodwill, A. M., & Cantor, J. M. (2017). Evidence of construct validity in the assessment of hebephilia. *Archives of Sexual Behavior, 46,* 301–309. doi: 10.1007/s10508-016-0907-z
18. Walton, M. T., Cantor, J. M., & Lykins, A. D. (2017). An online assessment of personality, psychological, and sexuality trait variables associated with self-reported hypersexual behavior. *Archives of Sexual Behavior, 46,* 721–733. doi: 10.1007/s10508-015-0606-1
19. Cantor, J. M., Lafaille, S. J., Hannah, J., Kucyi, A., Soh, D. W., Girard, T. A., & Mikulis, D. J. (2016). Independent component analysis of resting-state functional magnetic resonance imaging in pedophiles. *Journal of Sexual Medicine, 13,* 1546–1554. doi: 10.1016/j.jsxm.2016.08.004
20. Cantor, J. M., & McPhail, I. V. (2016). Non-offending pedophiles. *Current Sexual Health Reports, 8,* 121–128. doi: 10.1007/s11930-016-0076-z
21. Cantor, J. M. (2015). Milestones in sex research: What causes pedophilia? In J. S. Hyde, J. D. DeLamater, & E. S. Byers (Eds.), *Understanding human sexuality* (6th Canadian ed.) (pp. 452–453). Toronto: McGraw-Hill Ryerson.
22. Cantor, J. M. (2015). Pedophilia. In R. Cautin & S. Lilienfeld (Eds.), *Encyclopedia of clinical psychology.* Malden, MA: Wiley-Blackwell. doi: 10.1002/9781118625392.wbecp184
23. Nunes, K. L., & Cantor, J. M. (2015). Sex offenders. In P. Whelehan & A. Bolin (Eds.), *International encyclopedia of human sexuality.* Malden, MA: Wiley-Blackwell.
24. Cantor, J. M., Lafaille, S., Soh, D. W., Moayedi, M., Mikulis, D. J., & Girard, T. A. (2015). Diffusion Tensor Imaging of pedophilia. *Archives of Sexual Behavior, 44,* 2161–2172. doi: 10.1007/s10508-015-0599-9
25. Cantor, J. M., & McPhail, I. V. (2015). Sensitivity and specificity for the phallometric test of hebephilia. *Journal of Sexual Medicine, 12,* 1940–1950. doi: 10.1111/jsm12970
26. Dyshniku, F., Murray, M. E., Fazio, R. L., Lykins, A. D., & Cantor, J. M. (2015). Minor physical anomalies as a window into the prenatal origins of pedophilia. *Archives of Sexual Behavior, 44,* 2151–2159. doi: 10.1007/s10508-015-0564-7
27. Fazio, R. L., & Cantor, J. M. (2015). Factor structure of the Edinburgh Handedness Inventory versus the Fazio Laterality Inventory in a population with established atypical handedness. *Applied Neuropsychology, 22,* 156–160. doi: 10.1080/23279095.2014.940043
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29. Sutton, K. S., Stratton, N., Pytyck, J., Kolla, N. J., & Cantor, J. M. (2015). Patient characteristics by type of hypersexuality referral: A quantitative chart review of 115 consecutive male cases. *Journal of Sex and Marital Therapy, 41,* 563−580. doi: 10.1080/0092623X.2014.935539

30. Cantor, J. M. (2014). Gold star pedophiles in general sex therapy practice. In Y. M. Binik and K. Hall (Eds.), *Principles and practice of sex therapy* (5th ed.) (pp. 219–234). New York: Guilford.
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33. Fazio, R. L., Lykins, A. D., & Cantor, J. M. (2014). Elevated rates of atypical-handedness in paedophilia: Theory and implications. *Laterality, 19,* 690−704. doi: 10.1080/1357650X.2014.898648
34. Lykins, A. D., & Cantor, J. M. (2014). Vorarephilia: A case study in masochism and erotic consumption. *Archives of Sexual Behavior, 43,* 181–186. doi: 10.1007/s10508-013-0185-y
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37. Cantor, J. M. (2012). Brain research and pedophilia: What it says and what it means [Invited article]. *Sex Offender Law Report, 13,* 81–85.
38. Cantor, J. M. (2012). Is homosexuality a paraphilia? The evidence for and against. *Archives of Sexual Behavior, 41,* 237–247. doi: 10.1007/s10508-012-9900-3
39. Lykins, A. D., Cantor, J. M., Kuban, M. E., Blak, T., Dickey, R., Klassen, P. E., & Blanchard, R. (2010). Sexual arousal to female children in gynephilic men. *Sexual Abuse: A Journal of Research and Treatment, 22,* 279–289. doi: 10.1177/1079063210372141
40. Lykins, A. D., Cantor, J. M., Kuban, M. E., Blak, T., Dickey, R., Klassen, P. E., & Blanchard, R. (2010). The relation between peak response magnitudes and agreement in diagnoses obtained from two different phallometric tests for pedophilia. *Sexual Abuse: A Journal of Research and Treatment, 22,* 42–57. doi: 10.1177/1079063209352094
41. Cantor, J. M., Blanchard, R., & Barbaree, H. E. (2009). Sexual disorders. In P. H. Blaney & T. Millon (Eds.), *Oxford textbook of psychopathology* (2nd ed.) (pp. 527–548). New York: Oxford University Press.
42. Barbaree, H. E., Langton, C. M., Blanchard, R., & Cantor, J. M. (2009). Aging versus stable enduring traits as explanatory constructs in sex offender recidivism: Partitioning actuarial prediction into conceptually meaningful components. *Criminal Justice and Behavior: An International Journal, 36,* 443–465. doi: 10.1177/0093854809332283
43. Blanchard, R., Kuban, M. E., Blak, T., Cantor, J. M., Klassen, P. E., & Dickey, R. (2009). Absolute versus relative ascertainment of pedophilia in men. *Sexual Abuse: A Journal of Research and Treatment, 21,* 431–441. doi: 10.1177/1079063209347906

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45. Cantor, J. M. (2008). MRI research on pedophilia: What ATSA members should know [Invited article]. *ATSA Forum, 20*(4), 6–10.
46. Cantor, J. M., Kabani, N., Christensen, B. K., Zipursky, R. B., Barbaree, H. E., Dickey, R., Klassen, P. E., Mikulis, D. J., Kuban, M. E., Blak, T., Richards, B. A., Hanratty, M. K., & Blanchard, R. (2008). Cerebral white matter deficiencies in pedophilic men. *Journal of Psychiatric Research, 42,* 167–183. doi: 10.1016/j.jpsychires.2007.10.013
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53. Seto, M. C., Cantor, J. M., & Blanchard, R. (2006). Child pornography offenses are a valid diagnostic indicator of pedophilia. *Journal of Abnormal Psychology, 115,* 610–615. doi: 10.1037/0021-843X.115.3.610
54. Zucker, K. J., Mitchell, J. N., Bradley, S. J., Tkachuk, J., Cantor, J. M., & Allin, S. M. (2006). The Recalled Childhood Gender Identity/Gender Role Questionnaire: Psychometric properties. *Sex Roles, 54,* 469–483. doi 10.1007/s11199-006-9019-x
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61. Cantor, J. M., Binik, Y. M., & Pfaus, J. G. (1999). Chronic fluoxetine inhibits sexual behavior in the male rat: Reversal with oxytocin. *Psychopharmacology*, *144*, 355–362.
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63. Johnson, M. K., O'Connor, M., & Cantor, J. (1997). Confabulation, memory deficits, and frontal dysfunction. *Brain and Cognition*, *34*, 189–206.
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65. Pilkington, N. W., & Cantor, J. M. (1996). Perceptions of heterosexual bias in professional psychology programs: A survey of graduate students. *Professional Psychology: Research and Practice*, *27*, 604–612.

PUBLICATIONS

LETTERS AND COMMENTARIES

1. Cantor, J. M. (2015). Research methods, statistical analysis, and the phallometric test for hebephilia: Response to Fedoroff [Editorial Commentary]. *Journal of Sexual Medicine, 12,* 2499–2500. doi: 10.1111/jsm.13040
2. Cantor, J. M. (2015). In his own words: Response to Moser [Editorial Commentary]. *Journal of Sexual Medicine, 12,* 2502–2503. doi: 10.1111/jsm.13075
3. Cantor, J. M. (2015). Purported changes in pedophilia as statistical artefacts: Comment on Müller et al. (2014). *Archives of Sexual Behavior, 44,* 253–254. doi: 10.1007/s10508-014-0343-x
4. McPhail, I. V., & Cantor, J. M. (2015). Pedophilia, height, and the magnitude of the association: A research note. *Deviant Behavior, 36,* 288–292. doi: 10.1080/01639625.2014.935644
5. Soh, D. W., & Cantor, J. M. (2015). A peek inside a furry convention [Letter to the Editor]. *Archives of Sexual Behavior, 44,* 1–2. doi: 10.1007/s10508-014-0423-y
6. Cantor, J. M. (2012). Reply to Italiano's (2012) comment on Cantor (2011) [Letter to the Editor]. *Archives of Sexual Behavior, 41,* 1081–1082. doi: 10.1007/s10508-012-0011-y
7. Cantor, J. M. (2012). The errors of Karen Franklin's *Pretextuality* [Commentary]. *International Journal of Forensic Mental Health, 11,* 59–62. doi: 10.1080/14999013.2012.672945
8. Cantor, J. M., & Blanchard, R. (2012). White matter volumes in pedophiles, hebephiles, and teleiophiles [Letter to the Editor]. *Archives of Sexual Behavior, 41, 749–752.* doi: 10.1007/s10508-012-9954-2
9. Cantor, J. M. (2011). New MRI studies support the Blanchard typology of male-to-female transsexualism [Letter to the Editor]. *Archives of Sexual Behavior, 40*, 863–864. doi: 10.1007/s10508-011-9805-6
10. Zucker, K. J., Bradley, S. J., Own-Anderson, A., Kibblewhite, S. J., & Cantor, J. M. (2008). Is gender identity disorder in adolescents coming out of the closet? *Journal of Sex and Marital Therapy, 34,* 287–290.
11. Cantor, J. M. (2003, Summer). Review of the book *The Man Who Would Be Queen* by J. Michael Bailey. *Newsletter of Division 44 of the American Psychological Association, 19*(2), 6.
12. Cantor, J. M. (2003, Spring). What are the hot topics in LGBT research in psychology? *Newsletter of Division 44 of the American Psychological Association, 19*(1), 21–24.
13. Cantor, J. M. (2002, Fall). Male homosexuality, science, and pedophilia. *Newsletter of Division 44 of the American Psychological Association, 18*(3), 5–8.
14. Cantor, J. M. (2000). Review of the book *Sexual Addiction: An Integrated Approach. Journal of Sex and Marital Therapy, 26*, 107–109.

EDITORIALS

1. Cantor, J. M. (2012). Editorial. *Sexual Abuse: A Journal of Research and Treatment, 24*.

2. Cantor, J. M. (2011). Editorial note. *Sexual Abuse: A Journal of Research and Treatment, 23,* 414.
3. Barbaree, H. E., & Cantor, J. M. (2010). Performance indicates for *Sexual Abuse: A Journal of Research and Treatment* (SAJRT) [Editorial]. *Sexual Abuse: A Journal of Research and Treatment, 22,* 371–373.
4. Barbaree, H. E., & Cantor, J. M. (2009). *Sexual Abuse: A Journal of Research and Treatment* performance indicators for 2007 [Editorial]. *Sexual Abuse: A Journal of Research and Treatment, 21,* 3–5.
5. Zucker, K. J., & Cantor, J. M. (2009). Cruising: Impact factor data [Editorial]. *Archives of Sexual Research, 38,* 878–882.
6. Barbaree, H. E., & Cantor, J. M. (2008). Performance indicators for *Sexual Abuse: A Journal of Research and Treatment* [Editorial]. *Sexual Abuse: A Journal of Research and Treatment, 20,* 3–4.
7. Zucker, K. J., & Cantor, J. M. (2008). The *Archives* in the era of online first ahead of print[Editorial]. *Archives of Sexual Behavior, 37,* 512–516.
8. Zucker, K. J., & Cantor, J. M. (2006). The impact factor: The *Archives* breaks from the pack [Editorial]. *Archives of Sexual Behavior, 35,* 7–9.
9. Zucker, K. J., & Cantor, J. M. (2005). The impact factor: “Goin’ up” [Editorial]. *Archives of Sexual Behavior, 34,* 7–9.
10. Zucker, K., & Cantor, J. M. (2003). The numbers game: The impact factor and all that jazz [Editorial]. *Archives of Sexual Behavior, 32,* 3–5.

FUNDING HISTORY

Principal Investigators:	Doug VanderLaan, Meng-Chuan Lai
Co-Investigators:	James M. Cantor, Megha Mallar Chakravarty, Nancy Lobaugh, M. Palmert, M. Skorska
Title:	*Brain function and connectomics following sex hormone treatment in adolescents experience gender dysphoria*
Agency:	Canadian Institutes of Health Research (CIHR), Behavioural Sciences-B-2
Funds:	$650,250 / 5 years (July, 2018)
Principal Investigator:	Michael C. Seto
Co-Investigators:	Martin Lalumière , James M. Cantor
Title:	*Are connectivity differences unique to pedophilia?*
Agency:	University Medical Research Fund, Royal Ottawa Hospital
Funds:	$50,000 / 1 year (January, 2018)
Principal Investigator:	Lori Brotto
Co-Investigators:	Anthony Bogaert, James M. Cantor, Gerulf Rieger
Title:	*Investigations into the neural underpinnings and biological correlates of asexuality*
Agency:	Natural Sciences and Engineering Research Council (NSERC), Discovery Grants Program
Funds:	$195,000 / 5 years (April, 2017)
Principal Investigator:	Doug VanderLaan
Co-Investigators:	Jerald Bain, James M. Cantor, Megha Mallar Chakravarty, Sofia Chavez, Nancy Lobaugh, and Kenneth J. Zucker
Title:	*Effects of sex hormone treatment on brain development: A magnetic resonance imaging study of adolescents with gender dysphoria*
Agency:	Canadian Institutes of Health Research (CIHR), Transitional Open Grant Program
Funds:	$952,955 / 5 years (September, 2015)
Principal Investigator:	James M. Cantor
Co-Investigators:	Howard E. Barbaree, Ray Blanchard, Robert Dickey, Todd A. Girard, Phillip E. Klassen, and David J. Mikulis
Title:	*Neuroanatomic features specific to pedophilia*
Agency:	Canadian Institutes of Health Research (CIHR)
Funds:	$1,071,920 / 5 years (October, 2008)
Principal Investigator:	James M. Cantor
Title:	*A preliminary study of fMRI as a diagnostic test of pedophilia*
Agency:	Dean of Medicine New Faculty Grant Competition, Univ. of Toronto
Funds:	$10,000 (July, 2008)

Principal Investigator:	James M. Cantor
Co-Investigator:	Ray Blanchard
Title:	*Morphological and neuropsychological correlates of pedophilia*
Agency:	Canadian Institutes of Health Research (CIHR)
Funds:	$196,902 / 3 years (April, 2006)

KEYNOTE AND INVITED ADDRESSES

1. Cantor, J. M. (2022, December 5). The science of gender dysphoria and transgenderism. Lund University, Latvia. https://files.fm/f/4bzznufvb
2. Cantor, J. M. (2021, September 28). *No topic too tough for this expert panel: A year in review.* Plenary Session for the 40th Annual Research and Treatment Conference, Association for the Treatment of Sexual Abusers.
3. Cantor, J. M. (2019, May 1). *Introduction and Q&A for 'I, Pedophile.'* StopSO 2nd Annual Conference, London, UK.
4. Cantor, J. M. (2018, August 29). *Neurobiology of pedophilia or paraphilia? Towards a 'Grand Unified Theory' of sexual interests.* Keynote address to the International Association for the Treatment of Sexual Offenders, Vilnius, Lithuania.
5. Cantor, J. M. (2018, August 29). *Pedophilia and the brain: Three questions asked and answered.* Preconference training presented to the International Association for the Treatment of Sexual Offenders, Vilnius, Lithuania.
6. Cantor, J. M. (2018, April 13). *The responses to* I, Pedophile *from We, the people.* Keynote address to the Minnesota Association for the Treatment of Sexual Abusers, Minneapolis, Minnesota.
7. Cantor, J. M. (2018, April 11). *Studying atypical sexualities: From vanilla to* I, Pedophile. Full day workshop at the Minnesota Association for the Treatment of Sexual Abusers, Minneapolis, Minnesota.
8. Cantor, J. M. (2018, January 20). *How much sex is enough for a happy life?* Invited lecture to the University of Toronto Division of Urology Men's Health Summit, Toronto, Canada.
9. Cantor, J. M. (2017, November 2). Pedophilia as a phenomenon of the brain: Update of evidence and the public response. Invited presentation to the 7th annual SBC education event, Centre for Addiction and Mental Health, Toronto, Canada.
10. Cantor, J. M. (2017, June 9). Pedophilia being in the brain: The evidence and the public's reaction. Invited presentation to *SEXposium at the ROM: The science of love and sex,* Toronto, Canada.
11. Cantor, J. M., & Campea, M. (2017, April 20). *"I, Pedophile" showing and discussion.* Invited presentation to the 42nd annual meeting of the Society for Sex Therapy and Research, Montréal, Canada.
12. Cantor, J. M. (2017, March 1). *Functional and structural neuroimaging of pedophilia: Consistencies across methods and modalities.* Invited lecture to the Brain Imaging Centre, Royal Ottawa Hospital, Ottawa, Canada.
13. Cantor, J. M. (2017, January 26). *Pedophilia being in the brain: The evidence and the public reaction.* Inaugural keynote address to the University of Toronto Sexuality Interest Network, Toronto, Ontario, Canada.
14. Cantor, J. M. (2016, October 14). *Discussion of CBC's "I, Pedophile."* Office of the Children's Lawyer Educational Session, Toronto, Ontario, Canada.
15. Cantor, J. M. (2016, September 15). *Evaluating the risk to reoffend: What we know and what we don't.* Invited lecture to the Association of Ontario Judges, Ontario Court of Justice Annual Family Law Program, Blue Mountains, Ontario, Canada. [Private link only: https://vimeo.com/239131108/3387c80652]
16. Cantor, J. M. (2016, April 8). *Pedophilia and the brain: Conclusions from the second*

generation of research. Invited lecture at the 10th annual Risk and Recovery Forensic Conference, Hamilton, Ontario.

17. Cantor, J. M. (2016, April 7). *Hypersexuality without the hyperbole.* Keynote address to the 10th annual Risk and Recovery Forensic Conference, Hamilton, Ontario.
18. Cantor, J. M. (2015, November). *No one asks to be sexually attracted to children: Living in Daniel's World.* Grand Rounds, Centre for Addiction and Mental Health. Toronto, Canada.
19. Cantor, J. M. (2015, August). *Hypersexuality: Getting past whether "it" is or "it" isn't.* Invited address at the 41st annual meeting of the International Academy of Sex Research. Toronto, Canada.
20. Cantor, J. M. (2015, July). *A unified theory of typical and atypical sexual interest in men: Paraphilia, hypersexuality, asexuality, and vanilla as outcomes of a single, dual opponent process.* Invited presentation to the 2015 Puzzles of Sexual Orientation conference, Lethbridge, AL, Canada.
21. Cantor, J. M. (2015, June). *Hypersexuality.* Keynote Address to the Ontario Problem Gambling Provincial Forum. Toronto, Canada.
22. Cantor, J. M. (2015, May). *Assessment of pedophilia: Past, present, future.* Keynote Address to the International Symposium on Neural Mechanisms Underlying Pedophilia and Child Sexual Abuse (NeMUP). Berlin, Germany.
23. Cantor, J. M. (2015, March). *Prevention of sexual abuse by tackling the biggest stigma of them all: Making sex therapy available to pedophiles.* Keynote address to the 40th annual meeting of the Society for Sex Therapy and Research, Boston, MA.
24. Cantor, J. M. (2015, March. *Pedophilia: Predisposition or perversion?* Panel discussion at Columbia University School of Journalism. New York, NY.
25. Cantor, J. M. (2015, February). *Hypersexuality.* Research Day Grand Rounds presentation to Ontario Shores Centre for Mental Health Sciences, Whitby, Ontario, Canada.
26. Cantor, J. M. (2015, January). *Brain research and pedophilia: What it means for assessment, research, and policy.* Keynote address to the inaugural meeting of the Netherlands Association for the Treatment of Sexual Abusers, Utrecht, Netherlands.
27. Cantor, J. M. (2014, December). *Understanding pedophilia and the brain: Implications for safety and society.* Keynote address for The Jewish Community Confronts Violence and Abuse: Crisis Centre for Religious Women, Jerusalem, Israel.
28. Cantor, J. M. (2014, October). *Understanding pedophilia & the brain.* Invited full-day workshop for the Sex Offender Assessment Board of Pennsylvania, Harrisburg, PA.
29. Cantor, J. M. (2014, September). *Understanding neuroimaging of pedophilia: Current status and implications.* Invited lecture presented to the Mental Health and Addition Rounds, St. Joseph's Healthcare, Hamilton, Ontario, Canada.
30. Cantor, J. M. (2014, June). *An evening with Dr. James Cantor.* Invited lecture presented to the Ontario Medical Association, District 11 Doctors' Lounge Program, Toronto, Ontario, Canada.
31. Cantor, J. M. (2014, April). *Pedophilia and the brain.* Invited lecture presented to the University of Toronto Medical Students lunchtime lecture. Toronto, Ontario, Canada.
32. Cantor, J. M. (2014, February). *Pedophilia and the brain: Recap and update.* Workshop presented at the 2014 annual meeting of the Washington State Association for the Treatment of Sexual Abusers, Cle Elum, WA.

33. Cantor, J. M., Lafaille, S., Hannah, J., Kucyi, A., Soh, D., Girard, T. A., & Mikulis, D. M. (2014, February). *Functional connectivity in pedophilia.* Neuropsychiatry Rounds, Toronto Western Hospital, Toronto, Ontario, Canada.
34. Cantor, J. M. (2013, November). *Understanding pedophilia and the brain: The basics, the current status, and their implications.* Invited lecture to the Forensic Psychology Research Centre, Carleton University, Ottawa, Canada.
35. Cantor, J. M. (2013, November). *Mistaking puberty, mistaking hebephilia.* Keynote address presented to the 32nd annual meeting of the Association for the Treatment of Sexual Abusers, Chicago, IL.
36. Cantor, J. M. (2013, October). *Understanding pedophilia and the brain: A recap and update.* Invited workshop presented at the 32nd annual meeting of the Association for the Treatment of Sexual Abusers, Chicago, IL.
37. Cantor, J. M. (2013, October). *Compulsive-hyper-sex-addiction: I don't care what we all it, what can we* do*?* Invited address presented to the Board of Examiners of Sex Therapists and Counselors of Ontario, Toronto, Ontario, Canada.
38. Cantor, J. M. (2013, September). *Neuroimaging of pedophilia: Current status and implications.* McGill University Health Centre, Department of Psychiatry Grand Rounds presentation, Montréal, Québec, Canada.
39. Cantor, J. M. (2013, April). *Understanding pedophilia and the brain.* Invited workshop presented at the 2013 meeting of the Minnesota Association for the Treatment of Sexual Abusers, Minneapolis, MN.
40. Cantor, J. M. (2013, April). *The neurobiology of pedophilia and its implications for assessment, treatment, and public policy.* Invited lecture at the 38th annual meeting of the Society for Sex Therapy and Research, Baltimore, MD.
41. Cantor, J. M. (2013, April). *Sex offenders: Relating research to policy.* Invited roundtable presentation at the annual meeting of the Academy of Criminal Justice Sciences, Dallas, TX.
42. Cantor, J. M. (2013, March). *Pedophilia and brain research: From the basics to the state-of-the-art.* Invited workshop presented to the annual meeting of the Forensic Mental Health Association of California, Monterey, CA.
43. Cantor, J. M. (2013, January). *Pedophilia and child molestation.* Invited lecture presented to the Canadian Border Services Agency, Toronto, Ontario, Canada.
44. Cantor, J. M. (2012, November). *Understanding pedophilia and sexual offenders against children: Neuroimaging and its implications for public safety.* Invited guest lecture to University of New Mexico School of Medicine Health Sciences Center, Albuquerque, NM.
45. Cantor, J. M. (2012, November). *Pedophilia and brain research.* Invited guest lecture to the annual meeting of the Circles of Support and Accountability, Toronto, Ontario, Canada.
46. Cantor, J. M. (2012, January). *Current findings on pedophilia brain research.* Invited workshop at the San Diego International Conference on Child and Family Maltreatment, San Diego, CA.
47. Cantor, J. M. (2012, January). *Pedophilia and the risk to re-offend.* Invited lecture to the Ontario Court of Justice Judicial Development Institute, Toronto, Ontario, Canada.
48. Cantor, J. M. (2011, November). *Pedophilia and the brain: What it means for assessment, treatment, and policy.* Plenary Lecture presented at the Association for the Treatment of Sexual Abusers, Toronto, Ontario, Canada.

49. Cantor, J. M. (2011, July). *Towards understanding contradictory findings in the neuroimaging of pedophilic men.* Keynote address to 7th annual conference on Research in Forensic Psychiatry, Regensberg, Germany.
50. Cantor, J. M. (2011, March). *Understanding sexual offending and the brain: Brain basics to the state of the art.* Workshop presented at the winter conference of the Oregon Association for the Treatment of Sexual Abusers, Oregon City, OR.
51. Cantor, J. M. (2010, October). *Manuscript publishing for students.* Workshop presented at the 29th annual meeting of the Association for the Treatment of Sexual Abusers, Phoenix, AZ.
52. Cantor, J. M. (2010, August). *Is sexual orientation a paraphilia?* Invited lecture at the International Behavioral Development Symposium, Lethbridge, Alberta, Canada.
53. Cantor, J. M. (2010, March). *Understanding sexual offending and the brain: From the basics to the state of the art.* Workshop presented at the annual meeting of the Washington State Association for the Treatment of Sexual Abusers, Blaine, WA.
54. Cantor, J. M. (2009, January). *Brain structure and function of pedophilia men.* Neuropsychiatry Rounds, Toronto Western Hospital, Toronto, Ontario.
55. Cantor, J. M. (2008, April). *Is pedophilia caused by brain dysfunction?* Invited address to the University-wide Science Day Lecture Series, SUNY Oswego, Oswego, NY.
56. Cantor, J. M., Kabani, N., Christensen, B. K., Zipursky, R. B., Barbaree, H. E., Dickey, R., Klassen, P. E., Mikulis, D. J., Kuban, M. E., Blak, T., Richards, B. A., Hanratty, M. K., & Blanchard, R. (2006, September). *MRIs of pedophilic men.* Invited presentation at the 25th annual meeting of the Association for the Treatment of Sexual Abusers, Chicago.
57. Cantor, J. M., Blanchard, R., & Christensen, B. K. (2003, March). *Findings in and implications of neuropsychology and epidemiology of pedophilia.* Invited lecture at the 28th annual meeting of the Society for Sex Therapy and Research, Miami.
58. Cantor, J. M., Christensen, B. K., Klassen, P. E., Dickey, R., & Blanchard, R. (2001, July). *Neuropsychological functioning in pedophiles.* Invited lecture presented at the 27th annual meeting of the International Academy of Sex Research, Bromont, Canada.
59. Cantor, J. M., Blanchard, R., Christensen, B., Klassen, P., & Dickey, R. (2001, February). *First glance at IQ, memory functioning and handedness in sex offenders.* Lecture presented at the Forensic Lecture Series, Centre for Addiction and Mental Health, Toronto, Ontario, Canada.
60. Cantor, J. M. (1999, November). *Reversal of SSRI-induced male sexual dysfunction: Suggestions from an animal model.* Grand Rounds presentation at the Allan Memorial Institute, Royal Victoria Hospital, Montréal, Canada.

PAPER PRESENTATIONS AND SYMPOSIA

1. Cantor, J. M. (2020, April). "I'd rather have a trans kid than a dead kid": Critical assessment of reported rates of suicidality in trans kids. *Paper presented at the annual meeting of the Society for the Sex Therapy and Research.* Online in lieu of in person meeting.
2. Stephens, S., Lalumière, M., Seto, M. C., & Cantor, J. M. (2017, October). *The relationship between sexual responsiveness and sexual exclusivity in phallometric profiles.* Paper presented at the annual meeting of the Canadian Sex Research Forum, Fredericton, New Brunswick, Canada.
3. Stephens, S., Cantor, J. M., & Seto, M. C. (2017, March). *Can the SSPI-2 detect hebephilic sexual interest?* Paper presented at the annual meeting of the American-Psychology Law Society Annual Meeting, Seattle, WA.
4. Stephens, S., Seto, M. C., Goodwill, A. M., & Cantor, J. M. (2015, October). *Victim choice polymorphism and recidivism.* Symposium Presentation. Paper presented at the 34th annual meeting of the Association for the Treatment of Sexual Abusers, Montréal, Canada.
5. McPhail, I. V., Hermann, C. A., Fernane, S. Fernandez, Y., Cantor, J. M., & Nunes, K. L. (2014, October). *Sexual deviance in sexual offenders against children: A meta-analytic review of phallometric research.* Paper presented at the 33rd annual meeting of the Association for the Treatment of Sexual Abusers, San Diego, CA.
6. Stephens, S., Seto, M. C., Cantor, J. M., & Goodwill, A. M. (2014, October). *Is hebephilic sexual interest a criminogenic need?: A large scale recidivism study.* Paper presented at the 33rd annual meeting of the Association for the Treatment of Sexual Abusers, San Diego, CA.
7. Stephens, S., Seto, M. C., Cantor, J. M., & Lalumière, M. (2014, October). *Development and validation of the Revised Screening Scale for Pedophilic Interests (SSPI–2).* Paper presented at the 33rd annual meeting of the Association for the Treatment of Sexual Abusers, San Diego, CA.
8. Cantor, J. M., Lafaille, S., Hannah, J., Kucyi, A., Soh, D., Girard, T. A., & Mikulis, D. M. (2014, September). *Pedophilia and the brain: White matter differences detected with DTI.* Paper presented at the 13th annual meeting of the International Association for the Treatment of Sexual Abusers, Porto, Portugal.
9. Stephens, S., Seto, M., Cantor, J. M., Goodwill, A. M., & Kuban, M. (2014, March). *The role of hebephilic sexual interests in sexual victim choice.* Paper presented at the annual meeting of the American Psychology and Law Society, New Orleans, LA.
10. McPhail, I. V., Fernane, S. A., Hermann, C. A., Fernandez, Y. M., Nunes, K. L., & Cantor, J. M. (2013, November). *Sexual deviance and sexual recidivism in sexual offenders against children: A meta-analysis.* Paper presented at the 32nd annual meeting of the Association for the Treatment of Sexual Abusers, Chicago, IL.
11. Cantor, J. M. (2013, September). *Pedophilia and the brain: Current MRI research and its implications.* Paper presented at the 21st annual World Congress for Sexual Health, Porto Alegre, Brazil. [Featured among Best Abstracts, top 10 of 500.]
12. Cantor, J. M. (Chair). (2012, March). *Innovations in sex research.* Symposium conducted at the 37th annual meeting of the Society for Sex Therapy and Research, Chicago.
13. Cantor, J. M., & Blanchard, R. (2011, August). fMRI versus phallometry in the diagnosis of pedophilia and hebephilia. In J. M. Cantor (Chair), *Neuroimaging of men's object*

preferences. Symposium presented at the 37th annual meeting of the International Academy of Sex Research, Los Angeles, USA.

14. Cantor, J. M. (Chair). (2011, August). *Neuroimaging of men's object preferences.* Symposium conducted at the 37th annual meeting of the International Academy of Sex Research, Los Angeles.
15. Cantor, J. M. (2010, October). A meta-analysis of neuroimaging studies of male sexual arousal. In S. Stolerú (Chair), *Brain processing of sexual stimuli in pedophilia: An application of functional neuroimaging.* Symposium presented at the 29th annual meeting of the Association for the Treatment of Sexual Abusers, Phoenix, AZ.
16. Chivers, M. L., Seto, M. C., Cantor, J. C., Grimbos, T., & Roy, C. (April, 2010). *Psychophysiological assessment of sexual activity preferences in women.* Paper presented at the 35th annual meeting of the Society for Sex Therapy and Research, Boston, USA.
17. Cantor, J. M., Girard, T. A., & Lovett-Barron, M. (2008, November). *The brain regions that respond to erotica: Sexual neuroscience for dummies.* Paper presented at the 51st annual meeting of the Society for the Scientific Study of Sexuality, San Juan, Puerto Rico.
18. Barbaree, H., Langton, C., Blanchard, R., & Cantor, J. M. (2007, October). *The role of age-at-release in the evaluation of recidivism risk of sexual offenders.* Paper presented at the 26th annual meetingof the Association for the Treatment of Sexual Abusers, San Diego.
19. Cantor, J. M., Kabani, N., Christensen, B. K., Zipursky, R. B., Barbaree, H. E., Dickey, R., Klassen, P. E., Mikulis, D. J., Kuban, M. E., Blak, T., Richards, B. A., Hanratty, M. K., & Blanchard, R. (2006, July). *Pedophilia and brain morphology.* Abstract and paper presented at the 32nd annual meeting of the International Academy of Sex Research, Amsterdam, Netherlands.
20. Seto, M. C., Cantor, J. M., & Blanchard, R. (2006, March). *Child pornography offending is a diagnostic indicator of pedophilia*. Paper presented at the 2006 annual meeting of the American Psychology-Law Society Conference, St. Petersburg, Florida.
21. Blanchard, R., Cantor, J. M., Bogaert, A. F., Breedlove, S. M., & Ellis, L. (2005, August). *Interaction of fraternal birth order and handedness in the development of male homosexuality.* Abstract and paper presented at the International Behavioral Development Symposium, Minot, North Dakota.
22. Cantor, J. M., & Blanchard, R. (2005, July). *Quantitative reanalysis of aggregate data on IQ in sexual offenders.* Abstract and poster presented at the 31st annual meeting of the International Academy of Sex Research, Ottawa, Canada.
23. Cantor, J. M. (2003, August). *Sex reassignment on demand: The clinician's dilemma.* Paper presented at the 111th annual meeting of the American Psychological Association, Toronto, Canada.
24. Cantor, J. M. (2003, June). *Meta-analysis of VIQ–PIQ differences in male sex offenders.* Paper presented at the Harvey Stancer Research Day, Toronto, Ontario, Canada.
25. Cantor, J. M. (2002, August). *Gender role in autogynephilic transsexuals: The more things change…* Paper presented at the 110th annual meeting of the American Psychological Association, Chicago.

26. Cantor, J. M., Christensen, B. K., Klassen, P. E., Dickey, R., & Blanchard, R. (2001, June). *IQ, memory functioning, and handedness in male sex offenders.* Paper presented at the Harvey Stancer Research Day, Toronto, Ontario, Canada.
27. Cantor, J. M. (1998, August). *Convention orientation for lesbian, gay, and bisexual students*. Papers presented at the 106th annual meeting of the American Psychological Association.
28. Cantor, J. M. (1997, August). *Discussion hour for lesbian, gay, and bisexual students*. Presented at the 105th annual meeting of the American Psychological Association.
29. Cantor, J. M. (1997, August). *Convention orientation for lesbian, gay, and bisexual students*. Paper presented at the 105th annual meeting of the American Psychological Association.
30. Cantor, J. M. (1996, August). *Discussion hour for lesbian, gay, and bisexual students*. Presented at the 104th annual meeting of the American Psychological Association.
31. Cantor, J. M. (1996, August). *Symposium: Question of inclusion: Lesbian and gay psychologists and accreditation*. Paper presented at the 104th annual meeting of the American Psychological Association, Toronto.
32. Cantor, J. M. (1996, August). *Convention orientation for lesbian, gay, and bisexual students*. Papers presented at the 104th annual meeting of the American Psychological Association.
33. Cantor, J. M. (1995, August). *Discussion hour for lesbian, gay, and bisexual students*. Presented at the 103rd annual meeting of the American Psychological Association.
34. Cantor, J. M. (1995, August). *Convention orientation for lesbian, gay, and bisexual students*. Papers presented at the 103rd annual meeting of the American Psychological Association.
35. Cantor, J. M. (1994, August). *Discussion hour for lesbian, gay, and bisexual students*. Presented at the 102nd annual meeting of the American Psychological Association.
36. Cantor, J. M. (1994, August). *Convention orientation for lesbian, gay, and bisexual students*. Papers presented at the 102nd annual meeting of the American Psychological Association.
37. Cantor, J. M., & Pilkington, N. W. (1992, August). *Homophobia in psychology programs: A survey of graduate students.* Paper presented at the Centennial Convention of the American Psychological Association, Washington, DC. (ERIC Document Reproduction Service No. ED 351 618)
38. Cantor, J. M. (1991, August). *Being gay and being a graduate student: Double the memberships, four times the problems*. Paper presented at the 99th annual meeting of the American Psychological Association, San Francisco.

POSTER PRESENTATIONS

1. Klein, L., Stephens, S., Goodwill, A. M., Cantor, J. M., & Seto, M. C. (2015, October). *The psychological propensities of risk in undetected sexual offenders.* Poster presented at the 34th annual meeting of the Association for the Treatment of Sexual Abusers, Montréal, Canada.
2. Pullman, L. E., Stephens, S., Seto, M. C., Goodwill, A. M., & Cantor, J. M. (2015, October). *Why are incest offenders less likely to recidivate?* Poster presented at the 34th annual meeting of the Association for the Treatment of Sexual Abusers, Montréal, Canada.
3. Seto, M. C., Stephens, S. M., Cantor, J. M., Lalumiere, M. L., Sandler, J. C., & Freeman, N. A. (2015, August). *The development and validation of the Revised Screening Scale for Pedophilic Interests (SSPI-2).* Poster presentation at the 41st annual meeting of the International Academy of Sex Research. Toronto, Canada.
4. Soh, D. W., & Cantor, J. M. (2015, August). *A peek inside a furry convention.* Poster presentation at the 41st annual meeting of the International Academy of Sex Research. Toronto, Canada.
5. VanderLaan, D. P., Lobaugh, N. J., Chakravarty, M. M., Patel, R., Chavez, S. Stojanovski, S. O., Takagi, A., Hughes, S. K., Wasserman, L., Bain, J., Cantor, J. M., & Zucker, K. J. (2015, August). *The neurohormonal hypothesis of gender dysphoria: Preliminary evidence of cortical surface area differences in adolescent natal females.* Poster presentation at the 31st annual meeting of the International Academy of Sex Research. Toronto, Canada.
6. Cantor, J. M., Lafaille, S. J., Moayedi, M., Mikulis, D. M., & Girard, T. A. (2015, June). *Diffusion tensor imaging (DTI) of the brain in pedohebephilic men: Preliminary analyses.* Harvey Stancer Research Day, Toronto, Ontario Canada.
7. Newman, J. E., Stephens, S., Seto, M. C., & Cantor, J. M. (2014, October). *The validity of the Static-99 in sexual offenders with low intellectual abilities.* Poster presentation at the 33rd annual meeting of the Association for the Treatment of Sexual Abusers, San Diego, CA.
8. Lykins, A. D., Walton, M. T., & Cantor, J. M. (2014, June). *An online assessment of personality, psychological, and sexuality trait variables associated with self-reported hypersexual behavior.* Poster presentation at the 30th annual meeting of the International Academy of Sex Research, Dubrovnik, Croatia.
9. Stephens, S., Seto, M. C., Cantor, J. M., Goodwill, A. M., & Kuban, M. (2013, November). *The utility of phallometry in the assessment of hebephilia.* Poster presented at the 32nd annual meeting of the Association for the Treatment of Sexual Abusers, Chicago.
10. Stephens, S., Seto, M. C., Cantor, J. M., Goodwill, A. M., & Kuban, M. (2013, October). *The role of hebephilic sexual interests in sexual victim choice.* Poster presented at the 32nd annual meeting of the Association for the Treatment of Sexual Abusers, Chicago.
11. Fazio, R. L., & Cantor, J. M. (2013, October). *Analysis of the Fazio Laterality Inventory (FLI) in a population with established atypical handedness.* Poster presented at the 33rd annual meeting of the National Academy of Neuropsychology, San Diego.
12. Lafaille, S., Hannah, J., Soh, D., Kucyi, A., Girard, T. A., Mikulis, D. M., & Cantor, J. M. (2013, August). *Investigating resting state networks in pedohebephiles.* Poster presented at the 29th annual meeting of the International Academy of Sex Research, Chicago.

13. McPhail, I. V., Lykins, A. D., Robinson, J. J., LeBlanc, S., & Cantor, J. M. (2013, August). *Effects of prescription medication on volumetric phallometry output.* Poster presented at the 29th annual meeting of the International Academy of Sex Research, Chicago.
14. Murray, M. E., Dyshniku, F., Fazio, R. L., & Cantor, J. M. (2013, August). *Minor physical anomalies as a window into the prenatal origins of pedophilia.* Poster presented at the 29th annual meeting of the International Academy of Sex Research, Chicago.
15. Sutton, K. S., Stephens, S., Dyshniku, F., Tulloch, T., & Cantor, J. M. (2013, August). *Pilot group treatment for "procrasturbation."* Poster presented at 39th annual meeting of the International Academy of Sex Research, Chicago.
16. Sutton, K. S., Pytyck, J., Stratton, N., Sylva, D., Kolla, N., & Cantor, J. M. (2013, August). *Client characteristics by type of hypersexuality referral: A quantitative chart review.* Poster presented at the 39th annual meeting of the International Academy of Sex Research, Chicago.
17. Fazio, R. L., & Cantor, J. M. (2013, June). *A replication and extension of the psychometric properties of the Digit Vigilance Test.* Poster presented at the 11th annual meeting of the American Academy of Clinical Neuropsychology, Chicago.
18. Lafaille, S., Moayedi, M., Mikulis, D. M., Girard, T. A., Kuban, M., Blak, T., & Cantor, J. M. (2012, July). *Diffusion Tensor Imaging (DTI) of the brain in pedohebephilic men: Preliminary analyses.* Poster presented at the 38th annual meeting of the International Academy of Sex Research, Lisbon, Portugal.
19. Lykins, A. D., Cantor, J. M., Kuban, M. E., Blak, T., Dickey, R., Klassen, P. E., & Blanchard, R. (2010, July). *Sexual arousal to female children in gynephilic men.* Poster presented at the 38th annual meeting of the International Academy of Sex Research, Prague, Czech Republic.
20. Cantor, J. M., Girard, T. A., Lovett-Barron, M., & Blak, T. (2008, July). *Brain regions responding to visual sexual stimuli: Meta-analysis of PET and fMRI studies.* Abstract and poster presented at the 34th annual meeting of the International Academy of Sex Research, Leuven, Belgium.
21. Lykins, A. D., Blanchard, R., Cantor, J. M., Blak, T., & Kuban, M. E. (2008, July). *Diagnosing sexual attraction to children: Considerations for DSM-V.* Poster presented at the 34th annual meeting of the International Academy of Sex Research, Leuven, Belgium.
22. Cantor, J. M., Blak, T., Kuban, M. E., Klassen, P. E., Dickey, R. and Blanchard, R. (2007, October). *Physical height in pedophilia and hebephilia.* Poster presented at the 26th annual meeting of the Association for the Treatment of Sexual Abusers, San Diego.
23. Cantor, J. M., Blak, T., Kuban, M. E., Klassen, P. E., Dickey, R. and Blanchard, R. (2007, August). *Physical height in pedophilia and hebephilia.* Abstract and poster presented at the 33rd annual meeting of the International Academy of Sex Research, Vancouver, Canada.
24. Puts, D. A., Blanchard, R., Cardenas, R., Cantor, J., Jordan, C. L., & Breedlove, S. M. (2007, August). *Earlier puberty predicts superior performance on male-biased visuospatial tasks in men but not women.* Abstract and poster presented at the 33rd annual meeting of the International Academy of Sex Research, Vancouver, Canada.
25. Seto, M. C., Cantor, J. M., & Blanchard, R. (2005, November). *Possession of child pornography is a diagnostic indicator of pedophilia.* Poster presented at the 24th annual meeting of the Association for the Treatment of Sexual Abusers, New Orleans.

26. Blanchard, R., Cantor, J. M., Bogaert, A. F., Breedlove. S. M., & Ellis, L. (2005, July). *Interaction of fraternal birth order and handedness in the development of male homosexuality.* Abstract and poster presented at the 31st annual meeting of the International Academy of Sex Research, Ottawa, Canada.
27. Cantor, J. M., & Blanchard, R. (2003, July). *The reported VIQ–PIQ differences in male sex offenders are artifactual?* Abstract and poster presented at the 29th annual meeting of the International Academy of Sex Research, Bloomington, Indiana.
28. Christensen, B. K., Cantor, J. M., Millikin, C., & Blanchard, R. (2002, February). *Factor analysis of two brief memory tests: Preliminary evidence for modality-specific measurement.* Poster presented at the 30th annual meeting of the International Neuropsychological Society, Toronto, Ontario, Canada.
29. Cantor, J. M., Blanchard, R., Paterson, A., Bogaert, A. (2000, June). *How many gay men owe their sexual orientation to fraternal birth order?* Abstract and poster presented at the International Behavioral Development Symposium, Minot, North Dakota.
30. Cantor, J. M., Binik, Y., & Pfaus, J. G. (1996, November). *Fluoxetine inhibition of male rat sexual behavior: Reversal by oxytocin*. Poster presented at the 26th annual meeting of the Society for Neurosciences, Washington, DC.
31. Cantor, J. M., Binik, Y., & Pfaus, J. G. (1996, June). *An animal model of fluoxetine-induced sexual dysfunction: Dose dependence and time course*. Poster presented at the 28th annual Conference on Reproductive Behavior, Montréal, Canada.
32. Cantor, J. M., O'Connor, M. G., Kaplan, B., & Cermak, L. S. (1993, June). *Transient events test of retrograde memory: Performance of amnestic and unimpaired populations*. Poster presented at the 2nd annual science symposium of the Massachusetts Neuropsychological Society, Cambridge, MA.

EDITORIAL AND PEER-REVIEWING ACTIVITIES

Editor-in-Chief

Sexual Abuse: A Journal of Research and Treatment Jan., 2010–Dec., 2014

Editorial Board Memberships

Journal of Sexual Aggression Jan., 2010–Dec., 2021
Journal of Sex Research, The Jan., 2008–Aug., 2020
Sexual Abuse: A Journal of Research and Treatment Jan., 2006–Dec., 2019
Archives of Sexual Behavior Jan., 2004–Present
The Clinical Psychologist Jan., 2004–Dec., 2005

Ad hoc Journal Reviewer Activity

American Journal of Psychiatry
Annual Review of Sex Research
Archives of General Psychiatry
Assessment
Biological Psychiatry
BMC Psychiatry
Brain Structure and Function
British Journal of Psychiatry
British Medical Journal
Canadian Journal of Behavioural Science
Canadian Journal of Psychiatry
Cerebral Cortex
Clinical Case Studies
Comprehensive Psychiatry
Developmental Psychology
European Psychologist
Frontiers in Human Neuroscience
Human Brain Mapping
International Journal of Epidemiology
International Journal of Impotence Research
International Journal of Sexual Health
International Journal of Transgenderism
Journal of Abnormal Psychology
Journal of Clinical Psychology
Journal of Consulting and Clinical Psychology
Journal of Forensic Psychology Practice
Journal for the Scientific Study of Religion
Journal of Sexual Aggression
Journal of Sexual Medicine
Journal of Psychiatric Research
Nature Neuroscience
Neurobiology Reviews
Neuroscience & Biobehavioral Reviews
Neuroscience Letters
Proceedings of the Royal Society B (Biological Sciences)
Psychological Assessment
Psychological Medicine
Psychological Science
Psychology of Men & Masculinity
Sex Roles
Sexual and Marital Therapy
Sexual and Relationship Therapy
Sexuality & Culture
Sexuality Research and Social Policy
The Clinical Psychologist
Traumatology
World Journal of Biological Psychiatry

GRANT REVIEW PANELS

2017–2021 Member, College of Reviewers, *Canadian Institutes of Health Research,* Canada.

2017 Committee Member, Peer Review Committee—Doctoral Research Awards A. *Canadian Institutes of Health Research*, Canada.

2017 Member, International Review Board, Research collaborations on behavioural disorders related to violence, neglect, maltreatment and abuse in childhood and adolescence. *Bundesministerium für Bildung und Forschung [Ministry of Education and Research],* Germany.

2016 Reviewer. National Science Center [*Narodowe Centrum Nauki*], Poland.

2016 Committee Member, Peer Review Committee—Doctoral Research Awards A. *Canadian Institutes of Health Research*, Canada.

2015 Assessor (Peer Reviewer). Discovery Grants Program. *Australian Research Council,* Australia.

2015 Reviewer. *Czech Science Foundation,* Czech Republic.

2015 Reviewer, "Off the beaten track" grant scheme. *Volkswagen Foundation,* Germany.

2015 External Reviewer, Discovery Grants program—Biological Systems and Functions. *National Sciences and Engineering Research Council of Canada*, Canada

2015 Committee Member, Peer Review Committee—Doctoral Research Awards A. *Canadian Institutes of Health Research*, Canada.

2014 Assessor (Peer Reviewer). Discovery Grants Program. *Australian Research Council,* Australia.

2014 External Reviewer, Discovery Grants program—Biological Systems and Functions. *National Sciences and Engineering Research Council of Canada*, Canada.

2014 Panel Member, Dean's Fund—Clinical Science Panel. *University of Toronto Faculty of Medicine*, Canada.

2014 Committee Member, Peer Review Committee—Doctoral Research Awards A. *Canadian Institutes of Health Research*, Canada.

2013 Panel Member, Grant Miller Cancer Research Grant Panel. *University of Toronto Faculty of Medicine*, Canada.

2013 Panel Member, Dean of Medicine Fund New Faculty Grant Clinical Science Panel. *University of Toronto Faculty of Medicine,* Canada.

2012 Board Member, International Review Board, Research collaborations on behavioural disorders related to violence, neglect, maltreatment and abuse in childhood and adolescence (2nd round). *Bundesministerium für Bildung und Forschung [Ministry of Education and Research],* Germany.

2012 External Reviewer, University of Ottawa Medical Research Fund. *University of Ottawa Department of Psychiatry*, Canada.

2012 External Reviewer, Behavioural Sciences—B. *Canadian Institutes of Health Research*, Canada.

2011 Board Member, International Review Board, Research collaborations on behavioural disorders related to violence, neglect, maltreatment and abuse in childhood and adolescence. *Bundesministerium für Bildung und Forschung [Ministry of Education and Research],* Germany.

TEACHING AND TRAINING

PostDoctoral Research Supervision
Law & Mental Health Program, Centre for Addiction and Mental Health, Toronto, Canada

Dr. Katherine S. Sutton	Sept., 2012–Dec., 2013
Dr. Rachel Fazio	Sept., 2012–Aug., 2013
Dr. Amy Lykins	Sept., 2008–Nov., 2009

Doctoral Research Supervision
Centre for Addiction and Mental Health, Toronto, Canada

Michael Walton • University of New England, Australia	Sept., 2017–Aug., 2018
Debra Soh • York University	May, 2013–Aug, 2017
Skye Stephens • Ryerson University	April, 2012–June, 2016

Masters Research Supervision
Centre for Addiction and Mental Health, Toronto, Canada

Nicole Cormier • Ryerson University	June, 2012–present
Debra Soh • Ryerson University	May, 2009–April, 2010

Undergraduate Research Supervision
Centre for Addiction and Mental Health, Toronto, Canada

Kylie Reale • Ryerson University	Spring, 2014
Jarrett Hannah • University of Rochester	Summer, 2013
Michael Humeniuk • University of Toronto	Summer, 2012

Clinical Supervision (Doctoral Internship)
Clinical Internship Program, Centre for Addiction and Mental Health, Toronto, Canada

Katherine S. Sutton • Queen's University	2011–2012
David Sylva • Northwestern University	2011–2012
Jordan Rullo • University of Utah	2010–2011
Lea Thaler • University of Nevada, Las Vegas	2010–2011
Carolin Klein • University of British Columbia	2009–2010
Bobby R. Walling • University of Manitoba	2009–2010

TEACHING AND TRAINING

Clinical Supervision (Doctoral- and Masters- level practica)
Centre for Addiction and Mental Health, Toronto, Canada

Tyler Tulloch • Ryerson University	2013–2014
Natalie Stratton • Ryerson University	Summer, 2013
Fiona Dyshniku • University of Windsor	Summer, 2013
Mackenzie Becker • McMaster University	Summer, 2013
Skye Stephens • Ryerson University	2012–2013
Vivian Nyantakyi • Capella University	2010–2011
Cailey Hartwick • University of Guelph	Fall, 2010
Tricia Teeft • Humber College	Summer, 2010
Allison Reeves • Ontario Institute for Studies in Education/Univ. of Toronto	2009–2010
Helen Bailey • Ryerson University	Summer, 2009
Edna Aryee • Ontario Institute for Studies in Education/Univ. of Toronto	2008–2009
Iryna Ivanova • Ontario Institute for Studies in Education/Univ. of Toronto	2008–2009
Jennifer Robinson • Ontario Institute for Studies in Education/Univ. of Toronto	2008–2009
Zoë Laksman • Adler School of Professional Psychology	2005–2006
Diana Mandelew • Adler School of Professional Psychology	2005–2006
Susan Wnuk • York University	2004–2005
Hiten Lad • Adler School of Professional Psychology	2004–2005
Natasha Williams • Adler School of Professional Psychology	2003–2004
Lisa Couperthwaite • Ontario Institute for Studies in Education/Univ. of Toronto	2003–2004
Lori Gray, née Robichaud • University of Windsor	Summer, 2003
Sandra Belfry • Ontario Institute for Studies in Education/Univ. of Toronto	2002–2003
Althea Monteiro • York University	Summer, 2002
Samantha Dworsky • York University	2001–2002
Kerry Collins • University of Windsor	Summer, 2001
Jennifer Fogarty • Waterloo University	2000–2001
Emily Cripps • Waterloo University	Summer, 2000
Lee Beckstead • University of Utah	2000

PROFESSIONAL SOCIETY ACTIVITIES

OFFICES HELD

2018–2019	Local Host. Society for Sex Therapy and Research.
2015	Member, International Scientific Committee, World Association for Sexual Health.
2015	Member, Program Planning and Conference Committee, Association for the Treatment of Sexual Abusers
2012–2013	Chair, Student Research Awards Committee, Society for Sex Therapy & Research
2012–2013	Member, Program Planning and Conference Committee, Association for the Treatment of Sexual Abusers
2011–2012	Chair, Student Research Awards Committee, Society for Sex Therapy & Research
2010–2011	Scientific Program Committee, International Academy of Sex Research
2002–2004	Membership Committee • APA Division 12 (Clinical Psychology)
2002–2003	Chair, Committee on Science Issues, APA Division 44
2002	Observer, Grant Review Committee • Canadian Institutes of Health Research Behavioural Sciences (B)
2001–2009	Reviewer • APA Division 44 Convention Program Committee
2001, 2002	Reviewer • APA Malyon-Smith Scholarship Committee
2000–2005	Task Force on Transgender Issues, APA Division 44
1998–1999	Consultant, APA Board of Directors Working Group on Psychology Marketplace
1997	Student Representative • APA Board of Professional Affairs' Institute on TeleHealth
1997–1998	Founder and Chair • APA/APAGS Task Force on New Psychologists' Concerns
1997–1999	Student Representative • APA/CAPP Sub-Committee for a National Strategy for Prescription Privileges
1997–1999	Liaison • APA Committee for the Advancement of Professional Practice
1997–1998	Liaison • APA Board of Professional Affairs
1993–1997	Founder and Chair • APA/APAGS Committee on LGB Concerns

PROFESSIONAL SOCIETY ACTIVITIES

MEMBERSHIPS

2017–2021 Member • *Canadian Sex Research Forum*

2009–Present Member • *Society for Sex Therapy and Research*

2007–Present Fellow • *Association for the Treatment and Prevention of Sexual Abuse*

2006–Present Full Member (elected) • *International Academy of Sex Research*

2006–Present Research and Clinical Member • *Association for the Treatment and Prevention of Sexual Abuse*

2003–2006 Associate Member (elected) • *International Academy of Sex Research*

2002 Founding Member • CPA Section on Sexual Orientation and Gender Identity

2001–2013 Member • *Canadian Psychological Association* (CPA)

2000–2015 Member • *American Association for the Advancement of Science*

2000–2015 Member • *American Psychological Association* (APA)

APA Division 12 (Clinical Psychology)

APA Division 44 (Society for the Psychological Study of LGB Issues)

2000–2020 Member • *Society for the Scientific Study of Sexuality*

1995–2000 Student Member • *Society for the Scientific Study of Sexuality*

1993–2000 Student Affiliate • *American Psychological Association*

1990–1999 Member, American Psychological Association of Graduate Students (APAGS)

CLINICAL LICENSURE/REGISTRATION

Certificate of Registration, Number 3793
College of Psychologists of Ontario, Ontario, Canada

AWARDS AND HONORS

2022 Distinguished Contribution Award
Association for the Treatment and Prevention of Sexual Abuse (ATSA)

2011 Howard E. Barbaree Award for Excellence in Research
Centre for Addiction and Mental Health, Law and Mental Health Program

2004 fMRI Visiting Fellowship Program at Massachusetts General Hospital
American Psychological Association Advanced Training Institute and NIH

1999–2001 CAMH Post-Doctoral Research Fellowship
Centre for Addiction and Mental Health Foundation and Ontario Ministry of Health

1998 Award for Distinguished Contribution by a Student
American Psychological Association, Division 44

1995 Dissertation Research Grant
Society for the Scientific Study of Sexuality

1994–1996 McGill University Doctoral Scholarship

1994 Award for Outstanding Contribution to Undergraduate Teaching
"TA of the Year Award," from the McGill Psychology Undergraduate Student Association

MAJOR MEDIA

(Complete list available upon request.)

Feature-length Documentaries

Vice Canada Reports. *Age of Consent.* 14 Jan 2017.
Canadian Broadcasting Company. *I, Pedophile.* Firsthand documentaries. 10 Mar 2016.

Appearances and Interviews

11 Mar 2020. Ibbitson, John. It is crucial that Parliament gets the conversion-therapy ban right. *The Globe & Mail.*
25 Jan 2020. Ook de hulpvaardige buurman kan verzamelaar van kinderporno zin. *De Morgen.*
3 Nov 2019. Village of the damned. *60 Minutes Australia.*
1 Nov 2019. HÅKON F. HØYDAL. Norsk nettovergriper: – Jeg hater meg selv: Nordmannen laster ned overgrepsmateriale fra nettet – og oppfordrer politiet til å gi amnesti for slike som ham.
10 Oct 2019. Smith, T. Growing efforts are looking at how—or if—#MeToo offenders can be reformed. *National Public Radio.*
29 Sep 2019. Carey, B. Preying on Children: The Emerging Psychology of Pedophiles. *New York Times.*
29 Apr 2019. Mathieu, Isabelle. La poupée qui a troublé les Terre-Neuviens. *La Tribune.*
21 Mar 2019. Pope Francis wants psychological testing to prevent problem priests. But can it really do that? *The Washington Post.*
12 Dec 2018. Child sex dolls: Illegal in Canada, and dozens seized at the border. Ontario Today with Rita Celli. *CBC.*
12 Dec 2018. Celli, R. & Harris, K. Dozens of child sex dolls seized by Canadian border agents. *CBC News.*
27 Apr 2018. Rogers, Brook A. The online 'incel' culture is real–and dangerous. *New York Post.*
25 Apr 2018. Yang, J. Number cited in cryptic Facebook post matches Alek Minassian's military ID: Source. *Toronto Star.*
24 Ap 2018 Understanding 'incel'. *CTV News.*
27 Nov 2017. Carey, B. Therapy for Sexual Misconduct? It's Mostly Unproven. *New York Times.*
14 Nov 2017. Tremonti, A. M. The Current. *CBC.*
9 Nov2017. Christensen, J. Why men use masturbation to harass women. *CNN.* http://www.cnn.com/2017/11/09/health/masturbation-sexual-harassment/index.html
7 Nov 2017. Nazaryan, A. Why is the alt-right obsessed with pedophilia? *Newsweek.*
15 Oct 2017. Ouatik, B. Déscouvre. Pédophilie et science. *CBC Radio Canada.*
12 Oct 2017. Ouatik, B. Peut-on guérir la pédophilie? *CBC Radio Canada.*
11 Sep 2017. Burns, C. The young paedophiles who say they don't abuse children. *BBC News.*
18 Aug 2017. Interview. *National Post Radio.* Sirius XM Canada.
16 Aug 2017. Blackwell, Tom. Man says he was cured of pedophilia at Ottawa clinic: 'It's like a weight that's been lifted': But skeptics worry about the impact of sending pedophiles into the world convinced their curse has been vanquished. *National Post.*
26 Apr 2017. Zalkind, S. Prep schools hid sex abuse just like the catholic church. *VICE.*
24 Apr 2017. Sastre, P. Pédophilie: une panique morale jamais n'abolira un crime. *Slate France.*
12 Feb 2017. Payette, G. Child sex doll trial opens Pandora's box of questions. *CBC News.*
26 Nov 2016. Det morke uvettet ["The unknown darkness]". *Fedrelandsvennen.*
13 July 2016. Paedophilia: Shedding light on the dark field. *The Economist.*

1 Jul 2016. Debusschere, B. Niet iedereen die kinderporno kijkt, is een pedofiel: De mythes rond pedofilie ontkracht. *De Morgen.*
12 Apr 2016. O'Connor, R. Terence Martin: The Tasmanian MP whose medication 'turned him into a paedophile'. *The Independent.*
8 Mar 2016. Bielski, Z. 'The most viscerally hated group on earth': Documentary explores how intervention can stop pedophiles. *The Globe and Mail.*
1 Mar 2016. Elmhirst, S. What should we do about paedophiles? *The Guardian.*
24 Feb 2016. The man whose brain tumour 'turned him into a paedophile'. *The Independent.*
24 Nov 2015. Byron, T. The truth about child sex abuse. *BBC Two.*
20 Aug 2015. The Jared Fogle case: Why we understand so little about abuse. *Washington Post.*
19 Aug 2015. Blackwell, T. Treat sex offenders for impotence—to keep them out of trouble, Canadian psychiatrist says. *National Post.*
2 Aug 2015. Menendez, J. BBC News Hour. *BBC World Service.*
13 Jul 2015. The nature of pedophilia. *BBC Radio 4.*
9 Jul 2015. The sex-offender test: How a computerized assessment can help determine the fate of men who've been accused of sexually abusing children. *The Atlantic.*
10 Apr 2015. NWT failed to prevent sex offender from abusing stepdaughter again. *CBC News.*
10 Feb 2015. Savage, D. "The ethical sadist." In Savage Love. *The Stranger.*
31 Jan 2015. Begrip voor/van pedofilie [Understanding pedophilia]. *de Volkskrant.*
9 Dec 2014. Carey, B. When a rapist's weapon is a pill. *New York Times*.
1 Dec 2014. Singal, J. Can virtual reality help pedophiles? *New York Magazine.*
17 Nov2014. Say pedófile, busco aydua. *El Pais.*
4 Sep 2014. Born that way? *Ideas, with Paul Kennedy.* CBC Radio One.
27 Aug 2014. Interrogating the statistics for the prevalence of paedophilia. BBC.
25 Jul 2014. Stephenson, W. The prevalence of paedophilia. *BBC World Service.*
21 Jul 2014. Hildebrandt, A. Virtuous Pedophiles group gives support therapy cannot. *CBC.*
26 Jan 2014. Paedophilia a result of faulty wiring, scientists suggest. *Daily Mail.*
22 Dec 2013. Kane, L. Is pedophilia a sexual orientation? *Toronto Star.*
21 Jul 2013. Miller, L. The turn-on switch: Fetish theory, post-Freud. *New York Magazine.*
1 Jul 2013. Morin, H. Pédophilie: la difficile quête d'une origine biologique. *Le Monde.*
2 Jun 2013. Malcolm, L. The psychology of paedophilia. *Australian National Radio.*
1 Mar 2013. Kay, J. The mobbing of Tom Flanagan is unwarranted and cruel. *National Post.*
6 Feb 2013. Boy Scouts board delays vote on lifting ban on gays. *L.A. Times.*
31 Aug 2012. CNN Newsroom interview with Ashleigh Banfield. *CNN.*
24 Jun 2012. CNN Newsroom interview with Don Lemon. *CNN.*

EXPERT WITNESS TESTIMONY

1.	2023	L.W. v Dept of Health	Middle District, TN
2.	2023	K.C. v Medical Lic Board of Indiana	Southern District, IN
3.	2022	Baunee v Dept of Corrections	Onondaga County, NY
4.	2022	Bridge v Oklahoma State Dept of Education	Western District, OK
5.	2022	Dekker, et al. v Florida Agency for Health Care Admin	Tallahassee, FL
6.	2022	Roe v Utah High School Activities Assn.	Salt Lake County, UT
7.	2022	A.M. v Indiana Public Schools	Southern District, IN
8.	2022	Ricard v Kansas	Geery County, KS
9.	2022	Re Commitment of Baunee	Syracuse, NY
10.	2022	Hersom & Doe v WVa Health & Human Services	Southern District, WV
11.	2022	Eknes-Tucker v Alabama	Montgomery Cnty, AL
12.	2022	PFLAG, et al. v Texas	Travis County, TX
13.	2022	Doe v Texas	Travis County, TX
14.	2022	BPJ v West Virginia Board of Education	Southern District, WV
15.	2021	Cross et al. v Loudoun School Board	Loudoun, VA
16.	2021	Cox v Indiana Child Services	Child Services, IN
17.	2021	Josephson v University of Kentucky	Western District, KY
18.	2021	Re Commitment of Michael Hughes (Frye Hearing)	Cook County, IL
19.	2021	Arizona v Arnett Clifton	Maricopa County, AZ
20.	2019	US v Peter Bright	Southern District, NY
21.	2019	Spiegel-Savoie v Savoie-Sexten (Custody Hearing)	Boston, MA
22.	2019	Re Commitment of Steven Casper (Frye Hearing)	Kendall County, IL
23.	2019	Re Commitment of Inger (Frye Hearing)	Poughkeepsie, NY
24.	2019	Canada vs John Fitzpatrick (Sentencing Hearing)	Toronto, ON, Canada
25.	2018	Re Commitment of Little (Frye Hearing)	Utica, NY
26.	2017	Re Commitment of Nicholas Bauer (Frye Hearing)	Lee County, IL
27.	2017	US vs William Leford (Presentencing Hearing)	Warnock, GA
28.	2015	Florida v Jon Herb	Naples, FL
29.	2010	Re Detention of William Dutcher	Seattle, WA

Appendix 2

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Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy

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ABSTRACT

The American Academy of Pediatrics (AAP) recently published a policy statement: *Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents*. Although almost all clinics and professional associations in the world use what's called the *watchful waiting* approach to helping gender diverse (GD) children, the AAP statement instead rejected that consensus, endorsing *gender affirmation* as the only acceptable approach. Remarkably, not only did the AAP statement fail to include any of the actual outcomes literature on such cases, but it also misrepresented the contents of its citations, which repeatedly said the very opposite of what AAP attributed to them.

The American Academy of Pediatrics (AAP) recently published a policy statement entitled, *Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents* (Rafferty, AAP Committee on Psychosocial Aspects of Child and Family Health, AAP Committee on Adolescence, AAP Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness, 2018). These are children who manifest discontent with the sex they were born as and desire to live as the other sex (or as some alternative gender role). The policy was quite a remarkable document: Although almost all clinics and professional associations in the world use what's called the *watchful waiting* approach to helping transgender and gender diverse (GD) children, the AAP statement rejected that consensus, endorsing only *gender affirmation.* That is, where the consensus is to delay any transitions after the onset of puberty, AAP instead rejected waiting before transition. With AAP taking such a dramatic departure from other professional associations, I was immediately curious about what evidence led them to that conclusion. As I read the works on which they based their policy, however, I was pretty surprised—rather alarmed, actually: These documents simply did not say what AAP claimed they did. In fact, the references that AAP cited as the basis of their policy instead outright contradicted that policy, repeatedly endorsing *watchful waiting*.

The AAP statement was also remarkable in what it left out—namely, the actual outcomes research on GD children. In total, there have been 11 follow-up studies of GD children, of which AAP cited one (Wallien & Cohen-Kettenis, 2008), doing so without actually mentioning the outcome data it contained. The literature on outcomes was neither reviewed, summarized, nor subjected to meta-analysis to be considered in the aggregate—It was merely disappeared. (The list of all existing studies appears in the appendix.) As they make clear, *every* follow-up study of GD children, without exception, found the same thing: Over puberty, the majority of GD children cease to want to transition. AAP is, of course, free to establish whatever policy it likes on

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whatever basis it likes. But any assertion that their policy is based on evidence is demonstrably false, as detailed below.

AAP divided clinical approaches into three types—conversion therapy, watchful waiting, and gender affirmation. It rejected the first two and endorsed *gender affirmation* as the only acceptable alternative. Most readers will likely be familiar already with attempts to use conversion therapy to change sexual orientation. With regard to gender identity, AAP wrote:

> "[C]onversion" or "reparative" treatment models are used to prevent children and adolescents from identifying as transgender or to dissuade them from exhibiting gender-diverse expressions. … Reparative approaches have been proven to be not only unsuccessful[38] but also deleterious and are considered outside the mainstream of traditional medical practice.[29,39–42]

The citations were:

38. Haldeman DC. The practice and ethics of sexual orientation conversion therapy. *J Consult Clin Psychol.* 1994;62(2):221–227.

29. Adelson SL; American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice parameter on gay, lesbian, or bisexual sexual orientation, gender nonconformity, and gender discordance in children and adolescents. *J Am Acad Child Adolesc Psychiatry.* 2012;51(9):957–974.

39. Byne W. Regulations restrict practice of conversion therapy. *LGBT Health.* 2016;3(2):97–99.

40. Cohen-Kettenis PT, Delemarrevan de Waal HA, Gooren LJ. The treatment of adolescent transsexuals: changing insights. *J Sex Med.* 2008;5(8):1892–1897.

41. Bryant K. Making gender identity disorder of childhood: historical lessons for contemporary debates. *Sex Res Soc Policy.* 2006;3(3):23–39.

42. World Professional Association for Transgender Health. *WPATH De-Psychopathologisation Statement.* Minneapolis, MN: World Professional Association for Transgender Health; 2010.

AAP's claims struck me as odd because *there are no studies of conversion therapy for gender identity.* Studies of conversion therapy have been limited to *sexual orientation,* and, moreover, to the sexual orientation *of adults,* not to gender identity and not of children in any case. The article AAP cited to support their claim (reference number 38) is indeed a classic and well-known review, but it is a review of sexual orientation research *only.* Neither gender identity, nor even children, received a single mention in it. Indeed, the narrower scope of that article should be clear to anyone reading even just its title: "The practice and ethics of *sexual orientation* conversion therapy" [italics added].

AAP continued, saying that conversion approaches for GD children have already been rejected by medical consensus, citing five sources. This claim struck me as just as odd, however—I recalled associations banning conversion therapy for sexual orientation, but not for gender identity, exactly because there is no evidence for generalizing from adult sexual orientation to childhood gender identity. So, I started checking AAP's citations for that, and these sources too pertained only to sexual orientation, not gender identity (specifics below). What AAP's sources *did* repeatedly emphasize was that:

A. Sexual orientation of adults is unaffected by conversion therapy and any other [known] intervention;
B. Gender dysphoria in childhood before puberty desists in the majority of cases, becoming (cis-gendered) homosexuality in adulthood, again regardless of any [known] intervention; and
C. Gender dysphoria in childhood persisting after puberty tends to persist entirely.

That is, in the context of GD children, it simply makes no sense to refer to externally induced "conversion": The majority of children "convert" to cisgender or "desist" from transgender

regardless of any attempt to change them. "Conversion" only makes sense with regard to adult sexual orientation because (unlike childhood gender identity), adult homosexuality never or nearly never spontaneously changes to heterosexuality. Although gender identity and sexual orientation may often be analogous and discussed together with regard to social or political values and to civil rights, they are nonetheless distinct—with distinct origins, needs, and responses to medical and mental health care choices. Although AAP emphasized to the reader that "gender identity is not synonymous with 'sexual orientation'" (Rafferty et al., 2018, p. 3), they went ahead to treat them as such nonetheless.

To return to checking AAP's fidelity to its sources: Reference 29 was a practice guideline from the Committee on Quality Issues of the American Academy of Child and Adolescent Psychiatry (AACAP). Despite AAP applying this source to *gender identity,* AACAP was quite unambiguous regarding their intent to speak to sexual orientation and *only* to sexual orientation: "Principle 6. Clinicians should be aware that there is no evidence that *sexual orientation* can be altered through therapy, and that attempts to do so may be harmful. There is no established evidence that change in a predominant, enduring *homosexual* pattern of development is possible. Although sexual fantasies can, to some degree, be suppressed or repressed by those who are ashamed of or in conflict about them, sexual desire is not a choice. However, behavior, social role, and—to a degree—identity and self-acceptance are. Although operant conditioning modifies sexual fetishes, it does not alter *homosexuality*. Psychiatric efforts to alter *sexual orientation* through 'reparative therapy' *in adults* have found little or no change in *sexual orientation,* while causing significant risk of harm to self-esteem" (AACAP, 2012, p. 967, italics added).

Whereas AAP cites AACAP to support gender affirmation as the only alternative for treating GD children, AACAP's actual view was decidedly neutral, noting the lack of evidence: "Given the lack of empirical evidence from randomized, controlled trials of the efficacy of treatment aimed at eliminating gender discordance, the potential risks of treatment, and longitudinal evidence that gender discordance persists in only a small minority of untreated cases arising in childhood, further research is needed on predictors of persistence and desistence of childhood gender discordance as well as the long-term risks and benefits of intervention before any treatment to eliminate gender discordance can be endorsed" (AACAP, 2012, p. 969). Moreover, whereas AAP rejected watchful waiting, what AACAP recommended was: "In general, it is desirable to help adolescents who may be experiencing gender distress and dysphoria to defer sex reassignment until adulthood" (AACAP, 2012, p. 969). So, not only did AAP attribute to AACAP something AACAP never said, but also AAP withheld from readers AACAP's actual view.

Next, in reference 39, Byne (2016) also addressed only sexual orientation, doing so very clearly: "Reparative therapy is a subset of conversion therapies based on the premise that *same-sex attraction* are reparations for childhood trauma. Thus, practitioners of reparative therapy believe that exploring, isolating, and repairing these childhood emotional wounds will often result in reducing *same-sex attractions*" (Byne, 2016, p. 97). Byne does not say this of gender identity, as the AAP statement misrepresents.

In AAP reference 40, Cohen-Kettenis et al. (2008) did finally pertain to gender identity; however, this article never mentions conversion therapy. (!) Rather, in this study, the authors presented that clinic's lowering of their minimum age for cross-sex hormone treatment from age 18 to 16, which they did on the basis of a series of studies showing the high rates of success with this age group. Although it did strike me as odd that AAP picked as support against conversion therapy an article that did not mention conversion therapy, I could imagine AAP cited the article as an example of what the "mainstream of traditional medical practice" consists of (the logic being that conversion therapy falls outside what an 'ideal' clinic like this one provides). However, what this clinic provides is the very *watchful waiting* approach that AAP rejected. The approach

espoused by Cohen-Kettenis (and the other clinics mentioned in the source—Gent, Boston, Oslo, and now formerly, Toronto) is to make puberty-halting interventions available at age 12 because: "[P]ubertal suppression may give adolescents, together with the attending health professional, more time to explore their gender identity, without the distress of the developing secondary sex characteristics. The precision of the diagnosis may thus be improved" (Cohen-Kettenis et al., 2008, p. 1894).

Reference 41 presented a very interesting history spanning the 1960s–1990s about how feminine boys and tomboyish girls came to be recognized as mostly pre-homosexual, and how that status came to be entered into the DSM at the same time as homosexuality was being *removed* from the DSM. Conversion therapy is never mentioned. Indeed, to the extent that Bryant mentions treatment at all, it is to say that treatment is entirely irrelevant to his analysis: "An important omission from the *DSM* is a discussion of the kinds of treatment that GIDC children should receive. (This omission is a general orientation of the DSM and not unique to GIDC)" (Bryant, 2006, p. 35). How this article supports AAP's claim is a mystery. Moreover, how AAP could cite a 2006 history discussing events of the 1990s and earlier to support a claim about the *current* consensus in this quickly evolving discussion remains all the more unfathomable.

Cited last in this section was a one-paragraph press release from the World Professional Association for Transgender Health. Written during the early stages of the American Psychiatric Association's (APA's) update of the DSM, the statement asserted simply that "The WPATH Board of Directors strongly urges the de-psychopathologisation of gender variance worldwide." Very reasonable debate can (and should) be had regarding whether gender dysphoria should be removed from the DSM as homosexuality was, and WPATH was well within its purview to assert that it should. Now that the DSM revision process is years completed however, history has seen that APA ultimately retained the diagnostic categories, rejecting WPATH's urging. This makes AAP's logic entirely backwards: That WPATH's request to depathologize gender dysphoria was *rejected* suggests that it is *WPATH's* view—and therefore the AAP policy—which fall "outside the mainstream of traditional medical practice." (!)

AAP based this entire line of reasoning on their belief that conversion therapy is being used "to prevent children and adolescents from identifying as transgender" (Rafferty et al., 2018, p. 4). That claim is left without citation or support. In contrast, what is said by AAP's sources is "delaying affirmation should *not* be construed as conversion therapy or an attempt to change gender identity" in the first place (Byne, 2016, p. 2). Nonetheless, AAP seems to be doing exactly that: simply relabeling any alternative approach as equivalent to conversion therapy.

Although AAP (and anyone else) may reject (what they label to be) conversion therapy purely on the basis of political or personal values, there is no evidence to back the AAP's stated claim about the existing science on gender identity at all, never mind gender identity of children.

AAP also dismissed the watchful waiting approach out of hand, not citing any evidence, but repeatedly calling it "outdated." The criticisms AAP provided, however, again defied the existing evidence, with even its own sources repeatedly calling watchful waiting the current standard. According to AAP:

> [G]ender affirmation is in contrast to the outdated approach in which a child's gender-diverse assertions are held as "possibly true" until an arbitrary age (often after pubertal onset) when they can be considered valid, an approach that authors of the literature have termed "watchful waiting." This outdated approach does not serve the child because critical support is withheld. Watchful waiting is based on binary notions of gender in which gender diversity and fluidity is pathologized; in watchful waiting, it is also assumed that notions of gender identity become fixed at a certain age. The approach is also influenced by a group of early studies with validity concerns, methodologic flaws, and limited follow-up on children who identified as TGD and, by adolescence, did not seek further treatment ("desisters").[45,47]

The citations from AAP's reference list are:

45. Ehrensaft D, Giammattei SV, Storck K, Tishelman AC, Keo-Meier C. Prepubertal social gender transitions: what we know; what we can learn—a view from a gender affirmative lens. *Int J Transgend.* 2018;19(2):251–268

47. Olson KR. Prepubescent transgender children: what we do and do not know. *J Am Acad Child Adolesc Psychiatry.* 2016;55(3):155–156.e3

I was surprised first by the AAP's claim that watchful waiting's delay to puberty was somehow "arbitrary." The literature, including AAP's sources, repeatedly indicated the pivotal importance of puberty, noting that outcomes strongly diverge at that point. According to AAP reference 29, in "*prepubertal* boys with gender discordance—including many without any mental health treatment—the cross gender wishes usually fade over time and do not persist into adulthood, with only 2.2% to 11.9% continuing to experience gender discordance" (Adelson & AACAP, 2012, p. 963, italics added), whereas "when gender variance with the desire to be the other sex is present *in adolescence,* this desire usually does persist through adulthood" (Adelson & AACAP, 2012, p. 964, italics added). Similarly, according to AAP reference 40, "Symptoms of GID *at prepubertal ages* decrease or even disappear in a considerable percentage of children (estimates range from 80–95%). Therefore, any intervention in childhood would seem premature and inappropriate. However, GID persisting *into early puberty* appears to be highly persistent" (Cohen-Kettenis et al., 2008, p. 1895, italics added). That follow-up studies of prepubertal transition differ from postpubertal transition is the very meaning of non-arbitrary. AAP gave readers exactly the reverse of what was contained in its own sources. If AAP were correct in saying that puberty is an arbitrarily selected age, then AAP will be able to offer another point to wait for with as much empirical backing as puberty has.

Next, it was not clear on what basis AAP could say that watchful waiting withholds support—AAP cited no support for its claim. The people in such programs often receive substantial support during this period. Also unclear is on what basis AAP could already know exactly which treatments are "critical" and which are not—Answering that question is the very purpose of this entire endeavor. Indeed, the logic of AAP's claim appears entirely circular: It is only if one were already pre-convinced that gender affirmation is the only acceptable alternative that would make watchful waiting seem to withhold critical support—What it delays is gender affirmation, the method one has already decided to be critical.

Although AAP's next claim did not have a citation appearing at the end of its sentence, binary notions of gender were mentioned both in references 45 and 47. Specifically, both pointed out that existing outcome studies have been about people transitioning from one sex to the other, rather than from one sex to an in-between status or a combination of masculine/feminine features. Neither reference presented this as a reason to reject the results from the existing studies of complete transition however (which is how AAP cast it). Although it is indeed true that the outcome data have been about complete transition, some future study showing that partial transition shows a different outcome would not invalidate what is known about complete transition. Indeed, data showing that partial transition gives better outcomes than complete transition would, once again, support the watchful waiting approach which AAP rejected.

Next was a vague reference alleging concerns and criticisms about early studies. Had AAP indicated what those alleged concerns and flaws were (or which studies they were), then it would be possible to evaluate or address them. Nonetheless, the argument is a red herring: Because all of the later studies showed the same result as did the early studies, any such allegation is necessarily moot.

Reference 47 was a one-and-a-half page commentary in which the author off-handedly mentions criticisms previously made of three of the eleven outcome studies of GD children, but does not provide any analysis or discussion. The only specific claim was that studies (whether early or late) had limited follow-up periods—the logic being that had outcome researchers lengthened the follow-up period, then people who seemed to have desisted might have returned to the clinic as

cases of "persistence-after-interruption." Although one could debate the merits of that prediction, AAP instead simply withheld from the reader the result from the original researchers having tested that very prediction directly: Steensma and Cohen-Kettenis (2015) conducted another analysis of their cohort, by then ages 19–28 (mean age 25.9 years), and found that 3.3% (5 people of the sample of 150) later returned. That is, in long-term follow-up, the childhood sample showed 66.7% desistence instead of 70.0% desistance.

Reference 45 did not support the claim that watchful-waiting is "outdated" either. Indeed, that source said the very opposite, explicitly referring to watchful waiting as the *current* approach: "Put another way, if clinicians are straying from SOC 7 guidelines for social transitions, not abiding by the watchful waiting model *favored by the standards,* we will have adolescents who have been consistently living in their affirmed gender since age 3, 4, or 5" (Ehrensaft et al., 2018, p. 255). Moreover, Ehrensaft et al. said there are cases in which they too would still use watchful waiting: "When a child's gender identity is unclear, the watchful waiting approach can give the child and their family time to develop a clearer understanding and is not necessarily in contrast to the needs of the child" (p. 259). Ehrensaft et al. are indeed critical of the watchful waiting model (which they feel is applied too conservatively), but they do not come close to the position the AAP policy espouses. Where Ehrensaft summaries the potential benefits and potential risks both to transitioning and not transitioning, the AAP presents an ironically binary narrative.

In its policy statement, AAP told neither the truth nor the whole truth, committing sins both of commission and of omission, asserting claims easily falsified by anyone caring to do any fact-checking at all. AAP claimed, "This policy statement is focused specifically on children and youth that identify as TGD rather than the larger LGBTQ population"; however, much of that evidence was about sexual orientation, not gender identity. AAP claimed, "Current available research and expert opinion from clinical and research leaders … will serve as the basis for recommendations" (pp. 1–2); however, they provided recommendations entirely unsupported and even in direct opposition to that research and opinion.

AAP is advocating for something far in excess of mainstream practice and medical consensus. In the presence of compelling evidence, that is just what is called for. The problems with Rafferty, however, do not constitute merely a misquote, a misinterpretation of an ambiguous statement, or a missing reference or two. Rather, AAP's statement is a systematic exclusion and misrepresentation of entire literatures. Not only did AAP fail to provide compelling evidence, it failed to provide the evidence at all. Indeed, AAP's recommendations are *despite* the existing evidence.

Disclosure statement

No potential conflict of interest was reported by the author.

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Steensma, T. D., & Cohen-Kettenis, P. T. (2015). More than two developmental pathways in children with gender dysphoria? *Journal of the American Academy of Child and Adolescent Psychiatry*, *52*, 147–148. doi:10.1016/j.jaac.2014.10.016

Wallien, M. S. C., & Cohen-Kettenis, P. T. (2008). Psychosexual outcome of gender-dysphoric children. *Journal of the American Academy of Child and Adolescent Psychiatry*, *47*, 1413–1423. doi:10.1097/CHI.0b013e31818956b9

Appendix

Count	Group	Study
2/16 4/16 10/16	gay* trans-/crossdress straight*/uncertain	Lebovitz, P. S. (1972). Feminine behavior in boys: Aspects of its outcome. *American Journal of Psychiatry, 128,* 1283–1289.
2/16 2/16 12/16	trans- uncertain gay	Zuger, B. (1978). Effeminate behavior present in boys from childhood: Ten additional years of follow-up. *Comprehensive Psychiatry, 19,* 363–369.
0/9 9/9	trans- gay	Money, J., & Russo, A. J. (1979). Homosexual outcome of discordant gender identity/role: Longitudinal follow-up. *Journal of Pediatric Psychology, 4,* 29–41.
2/45 10/45 33/45	trans-/crossdress uncertain gay	Zuger, B. (1984). Early effeminate behavior in boys: Outcome and significance for homosexuality. *Journal of Nervous and Mental Disease, 172,* 90–97.
1/10 2/10 3/10 4/10	trans- gay uncertain straight	Davenport, C. W. (1986). A follow-up study of 10 feminine boys. *Archives of Sexual Behavior, 15,* 511–517.
1/44 43/44	trans- cis-	Green, R. (1987). *The "sissy boy syndrome" and the development of homosexuality*. New Haven, CT: Yale University Press.
0/8 8/8	trans- cis-	Kosky, R. J. (1987). Gender-disordered children: Does inpatient treatment help? *Medical Journal of Australia, 146,* 565–569.
21/54 33/54	trans- cis-	Wallien, M. S. C., & Cohen-Kettenis, P. T. (2008). Psychosexual outcome of gender-dysphoric children. *Journal of the American Academy of Child and Adolescent Psychiatry, 47,* 1413–1423.
3/25 6/25 16/25	trans- lesbian/bi- straight	Drummond, K. D., Bradley, S. J., Badali-Peterson, M., & Zucker, K. J. (2008). A follow-up study of girls with gender identity disorder. *Developmental Psychology, 44*, 34–45.
17/139 122/139	trans- cis-	Singh, D. (2012). *A follow-up study of boys with gender identity disorder*. Unpublished doctoral dissertation, University of Toronto.
47/127 80/127	trans- cis-	Steensma, T. D., McGuire, J. K., Kreukels, B. P. C., Beekman, A. J., & Cohen-Kettenis, P. T. (2013). Factors associated with desistence and persistence of childhood gender dysphoria: A quantitative follow-up study. *Journal of the American Academy of Child and Adolescent Psychiatry, 52,* 582–590.

*For brevity, the list uses "gay" for "gay and cis-", "straight" for "straight and cis-", etc.

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

BRIANNA BOE, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
UNITED STATES OF AMERICA,	)	
	)	
Intervenor Plaintiff,	)	
	)	
v.	)	Civil Action No. 2:22-cv-184-LCB
	)	
HON. STEVE MARSHALL, in his official capacity as Attorney General of the State of Alabama, *et al.*,	)	
	)	
Defendants.	)	

SUPPLEMENTAL EXPERT REPORT OF
JAMES CANTOR, PH.D.

Table of Contents

1. I have previously submitted my report, dated May 19, 2023, as an expert witness in this case ("Cantor Report"). Since that time, substantial additional materials have become available pertinent to my testimony in this case. This supplemental report contains my assessments of these additional materials as they relate to the opinions that I have previously rendered in this case. My updated *curriculum vitae* is provided as Appendix C to this report.

2. These materials include internal documents provided by WPATH under subpoena, which remain under a protective order of the court, and which I discuss in my separate Appendix A. In addition to the WPATH documents, I have reviewed other recently-published materials that are directly relevant to my previously rendered opinions including: new peer-reviewed studies published in the research literature, systematic reviews updating the contents of the scientific literature, and the policy changes and conclusions increasingly offered by international authorities and recognized topic experts.

I. New research, employing methods superior to prior investigations, reports that transition failed to improve mental health indicators.

3. In my previous report, I offered analysis and opinions on the body of research looking at the impact of social transition on desistance (Cantor Report, Section IX.B.) and on suicide and suicidality, particularly in the context of gender dysphoria (Cantor Report, Section X.). Important peer-reviewed publications since the date of my prior report further confirm my conclusions.

A. Morandini et al. (2023): Social transition is not associated with improvement in mental health.

4. Until recently, studies of the social transition of minors used only subjective descriptions of their mental health—either the self-reports of the socially transitioning youth or reports from their parents. Often, these studies relied not merely on self-reports, but on self-

reported retrospective memory—that is, subjects' recollections of how they felt at prior times. Those studies yielded contradictory results: Some reported social transition to be associated with improved mental health and well-being (e.g., Kuvalanka et al. 2017; Olson et al. 2016), and others reported a lack of improvement (e.g., Sievert et al. 2021; Wong et al. 2019).

5. The first study of the mental health impact of social transition based on objective and contemporaneous assessments conducted by professionals has now been published in the peer-reviewed literature: Morandini et al. (2023) is a study by a team of co-authors including one from the gender dysphoria clinic at Vrije University, Amsterdam (a widely recognized source of the most-cited literature in *support* of medical transition of minors). The authors examined "whether children and adolescents diagnosed with gender dysphoria who socially transitioned showed fewer psychological difficulties than those (also with gender dysphoria) who were still living in their birth-assigned gender." (Morandini et al. 2023 at 1052.)

6. The study improves on prior studies in multiple aspects, including the use of objective and comprehensive mental health assessments conducted by professional clinicians instead of only subjective self-reports; having a larger sample for analysis; conducting separate analyses for: i) the prepubescent versus adolescent age youth, ii) the male-to-female versus female-to-male transitioners, and iii) living status (biological sex or adopted gender) versus the names used (birth name versus new name). Ultimately, the analyses identified no significant differences in any of the mental health indicators (mood disorders, anxiety disorders, or suicide attempts).[1]

7. The researchers concluded that, for children and adolescents diagnosed with gender dysphoria:

[1] The study noted a single potential exception among the 12 analyses conducted, suggesting the possibility that, among the male-to-female transitioners, when social transition was defined as living status, the frequency of mood disorders might have been lower. Subsequent analysis, however, suggested that to be a statistically spurious finding, "as more sensitive analyses that treated age as a continuous rather than as a categorical variable, failed to support that finding." (Morandini et al. 2023 at 1053.)

> Overall, there were no significant effects of social transition or name change on mental health status. (Abstract.)
>
> Living in role and birth-assigned gender were not associated with mood, anxiety, or suicide attempts. (at 1052.)
>
> The present findings, although preliminary, suggest that social gender transition is not associated with mental health status in children and adolescents, at least in the short term. These findings are consistent with the only other study that directly compared clinic-referred youth experiencing gender dysphoria who had socially transitioned with those who had not. (at 1058.)

8. In the report of their results, the researchers also warned against over-interpreting or over-simplifying their findings. Although their study represents an improvement on prior studies analyzing social transition, I agree with these researchers' reminder that cross-sectional evidence such as theirs can be superseded in the future by studies using still superior methods, such as randomized, controlled trials (RCTs), as explained in my initial report. (Cantor Report, Section III.C.)

B. Glintborg et al. (2023) and Kaltiala (2023): Two large and relatively high quality studies find no mental health benefit from medicalized transition.

9. In my prior report, I provided analysis on the then-existing cohort studies examining medicalized transition. (Cantor Report, Section XIII.) Since then, two new large and important studies have been published, one out of Denmark (Glintborg et al. 2023), and the other out of Finland (Kaltiala et al. 2023).

10. Each of these studies examined the medical and mental health records of *all* patients within their respective countries who were diagnosed with Gender Identity Disorder (Denmark) or referred to the centralized national gender identity clinics (Finland) across a large number of years (3812 patients across 21 years in Denmark, in Glintborg et al., and 3665 patients across 28 years in Finland in Kaltiala et al.). This method avoided the severe limitations caused by selection bias, as well as the small samples sizes of many studies in this field.

11. Both studies measured mental health of subjects and controls across time based on clinical records. Because of the centralized administration of the Danish and Finnish public healthcare systems, the researchers had a relatively complete medical database available for analysis. This method avoided the limitations associated with self-reports and memory that I have detailed in my prior report (Cantor Report, Section IV.).

12. In both studies, before beginning medicalized transition (with cross-sex hormones) people diagnosed with or referred for gender dysphoria exhibited extremely elevated levels of other mental health issues, consistent with prior studies. Overall, Glintborg et al. found that "[Metrics of poor mental health] were stable after initiation of gender-affirming hormone treatment, without sign of decrease after date of first prescription of gender-affirming hormone." (at 342:2.) Kaltiala et al. similarly found that "the proportion requiring specialist-level psychiatric treatment actually increased more among those who underwent medical GR [gender reassignment]" as compared to otherwise comparable patients who did not, and reported that their "findings . . . do not suggest that medical GR interventions resolve psychiatric morbidity among people experiencing gender distress." (at 6:1.)

13. In Glintborg et al., analyses of the rates of psychiatric diagnoses before versus after medicalized transition revealed: At year one, post-transition rates of psychiatric illness greatly increased beyond their already elevated levels, relative to the non-transsexual control groups. By year five, psychiatric illness rates remained highly elevated, but approximating the level of elevation from before medicalized transition, relative to the control groups. Analyses of the rates of psychiatric medication use found that the gender dysphoric subjects exhibited greater use of psychiatric medication before transition relative to controls, and that this higher reliance on psychiatric medication had increased further one year after transition, and further still by year

five.

14. In Glintborg et al., the people undergoing medicalized transition were age 15 and older (1,142 people under age 18, and 2,670 people age 18 or older). The researchers noted that they conducted their analysis both with and without people under 18, and they found the results not to differ.

15. Consistent with the conclusions in my prior report, these data demonstrated that (1) people with gender dysphoria have extremely elevated rates of other mental health issues, (2) medicalized transition is not followed by improvement in mental health, and (3) in the year after transition, mental health *worsened.* Glintborg et al. noted the possibility that undergoing the mental health assessments required before medicalized transition is what caused the apparent increase in rates of psychiatric illnesses recorded. They did not, however, include the alternative possibility that the increase followed from transitioners' realization that the interventions were not resolving their mental health issues and that the subsequent improvements (when observed at all) followed from the increased use of psychiatric medication they were also receiving to address the psychiatric issues directly.[2]

C. McGregor et al. (in press) compared gender dysphoric youth who did versus did not receive puberty-blockers, but extensive differences between the samples confounded the results.

16. McGregor et al. (in press), a currently in-press article, purports to show that medicalized transition is associated with better mental health scores, contrary to my conclusions in my prior report. The study identified itself, correctly, as a "retrospective cohort" study. *Retrospective* cohort studies are faster and less expensive to conduct than *prospective* cohort

[2] I also observe a continuing drumbeat of anecdotal reports by detransitioners that medicalized transition did not improve their preexisting mental health problems. See, e.g. the several detransitioners' narratives reported in Pamela Paul, *As kids, they thought they were trans. They no longer do.*, New York Times, February 2, 2022.

studies, but provide less conclusive and more ambiguous results. Prospective studies identify a sample and follow them up again later to analyze what features changed among the participants, whereas retrospective studies select the participants at the end point and then go back to examine hospital or other records to explore what features differed at the beginning.

17. The McGregor study was conducted at the Gender Multispecialty Service (GeMS) program of Boston Children's Hospital. As noted in the study, the GeMS program assesses the mental health of children twice: once, prior to approving them for puberty-blocking medication, and a second time, prior to approving them for cross-sex hormone treatment. Also as noted in the study, adolescents already too old for puberty-blocking medication (i.e., past Tanner Stage 3) receive only the latter assessment.

18. Unfortunately, the analysis conducted and reported by the McGregor team was so flawed as to be meaningless: They compared the 40 children who sought and received puberty-blockers and are now seeking cross-sex hormone treatment (i.e., children who were assessed *and passed* the mental health screening) with the roughly 400 adolescents seeking cross-sex hormones who had not yet been screened for mental health at all. As a result, one cannot validly conclude that the greater mental health scores of the children receiving puberty-blockers were caused by the puberty-blockers. This retrospective study has no means of ruling out the much more logical conclusion that the children who received puberty-blockers only seem mentally healthier because the less healthy ones had already been screened out of that set.

19. Another fatal error of McGregor et al. is that they compared *childhood-onset* gender dysphoria with *adolescent-onset* gender dysphoria. As noted in my prior report, these represent distinct patient populations with distinct features, which McGregor neglected to discuss despite reporting the same distinctions. (Cantor Report, Section IX.C.) As summarized by the

McGregor authors:

> These two groups were significantly different across all assessed demographic domains. The blocker population was significantly younger, more likely to be assigned male at birth, more likely to affirm a female gender, and more likely to identify as white. (McGregor et al. (in press) at 3.)

A comparison across two groups that already differ in so many potentially important ways is necessarily uninformative: As the authors correctly emphasized about their own results, "causation [of the differences in mental health between the two groups] cannot and should not be assumed." (at 5.) Indeed, the authors reported that once they controlled for age, the correlation they report between receiving puberty blockers and lower levels of suicidal thoughts *disappeared* (at 6.). In sum, that the older ROGD group showed poorer mental health than the childhood-onset group is consistent with the ROGD hypothesis presented in my prior report: for at least many cases, ROGD represents an outcome mental health vulnerability.

20. I note that the McGregor et al. authors agree with a critical risk of harm detailed in my initial report—that puberty blockers alone may permanently sterilize a child, stating that "blockade impairs hormone-driven development of the ovaries or testes, and this may substantially reduce *or eliminate* future fertility potential in the absence of experimental options" (at 5, emphasis added.). The reference to "experimental options" is an oblique way of admitting that reliable restoration of fertility after prolonged puberty blockade has not been demonstrated.

D. Thompson et al. (2023): A new systematic review confirms the absence of reliable evidence that medical transition is a safe and beneficial treatment for gender dysphoric adolescents.

21. As indicated in my prior report, *systematic review* is the process employed by Evidence-Based Medicine to prevent the cherry-picking of studies favoring one side of an issue and helping ensure clinical decisions are based on the totality of the evidence. (Cantor Report, Section III.) My prior report cited all the systematic reviews then available from the peer-

reviewed literature and national health care systems that conducted them. (Cantor Report, Section V.)

22. Since then, Thompson et al. (2023) published a new systematic review in the peer-reviewed journal, *PLoS Global Public Health,* spanning the physical and mental health outcomes of puberty-blocking medications, of cross-sex hormone administration, and of surgery (primarily, double mastectomy) in adolescents between ages 12 and 18. The review employed the widely recognized procedures for reducing bias, including: pre-registration (in the publicly available PROSPERO database of systematic reviews) to prevent "publication bias"; explication of its data extraction methods (employing the PRISMA guidelines), to prevent incomplete assessments of studies; full disclosure of inclusion/exclusion criteria and a listing of all the studies included and all the studies excluded (along with specifying which criteria excluded studies failed to meet), to prevent cherry-picking of studies favoring any one conclusion; and a standard criterion-based assessment of the risk of bias posed by each study it included.[3]

23. The Thompson review identified 19 relevant research reports from six countries. Of the 19 studies, five reported on the mental health outcomes (benefits to mental health being the goal of the physical transition). The physical health outcomes assessed were bone density, liver enzymes, haemoglobin, glucose metabolism, lipid profile, and blood pressure—such risks to physical health are among the harms which must be weighed against proven benefits to assess treatment risk:benefit ratios.

24. This systematic review reiterated the conclusions of the prior systematic reviews:

- The evidence base for the outcomes of gender dysphoria treatment in adolescents is lacking. It is impossible from the included data to draw definitive conclusions

[3] Although the most widely used instrument for assessing risk of bias is GRADE, Thompson et al. used the Crowe Critical Appraisal Tool (CCAT, version 1.4). The GRADE method focuses on the research methods used in conducting a study, whereas the CCAT method includes several aspects about the article reporting those findings. Thus, GRADE assessments emphasize the reliability of findings, whereas CCAT assessments also reflect the introduction to and discussions of those results from that study's authors.

regarding the safety of treatment. (at 2.)

- It is clear that we simply do not know enough about the observed phenomenon referred to as AOGD [*adolescent-onset gender dysphoria*], nor do we fully understand the huge increase in numbers of adolescents (and especially NF [*natal females*]) presenting for GD [*gender dysphoria*] intervention in recent years, nor the comorbidities and long-term outcomes. (at 42.)

- [A]s pointed out in the interim report for the Cass review…good quality evidence is most definitely still lacking. (at 42.)

- This review series has highlighted a lack of quality evidence in relation to adolescent GD [*gender dysphoria*] in general: epidemiology, comorbidity, and treatment impact is difficult to robustly assess. Without an improvement in the scientific field, clinicians, parents, and young people are left ill-equipped to make safe and appropriate decisions. (at 43.)

25. Regarding the levels of evidence of the existing research, Thompson et al. noted that no survey studies were of sufficient quality for inclusion, that the pertinent studies are at the "cohort study" level of evidence, and that no randomized controlled trials (RCTs) yet exist. As quoted above, Thompson et al. called for improvement in the science of this question, and included no indication that RCTs could not be conducted.

E. Christensen et al. (2023): A new systematic review confirms my conclusion of insufficient evidence to conclude that medical transition reduces suicide or suicidality.

26. My prior report summarized the existing science on suicide and suicidality. (Cantor Report, Section X.). Since then, Christensen et al. (2023) has conducted the first systematic review of that research, which has now been published in the peer-reviewed journal, *Child Psychiatry & Human Development*, and its results align with the conclusion in my prior report that there is no evidence of sufficient quality to conclude that medicalized transition reduces rates of suicide or suicidality.

27. Christensen et al. reviewed studies of preventing suicide in transgender youth ages 24 and under, including medicalized transition and other interventions (such as crisis intervention or online media). The review followed well-established and high-quality review procedures,

including the PRISMA guidelines for data extraction, and applying a criterion-based assessment of the risk of bias posed by the included studies.

28. In total, Christensen et al. identified 17 studies, eight of which pertained specifically to medicalized transition. These eight yielded only inconsistent results, with some, but not other studies reporting statistically significant differences in rates of suicidality among medically transitioned youth. That review confirmed the summary provided in my prior report and reported that:

- Common flaws that created high risk of bias included self-reporting, lack of controls for comparability, small sample sizes, and lack of generalizability. (at 7.);
- Despite the pressing need for suicide prevention within this population, there has been a lack of high-quality evidence focusing on prevention of suicide amongst transgender youth. (at 7–8.);
- [N]o randomized controlled trials to date investigate the impact of interventions on rates of suicidal ideation and suicide attempt in transgender and gender diverse youth. . . (at 9.);
- [T]he overall quality of evidence is low, and the risk of bias is high. There is an urgent need for high-quality studies of interventions to reduce risk of suicide amongst transgender youth. . . (at 9.).

29. My own summary of the available science was that "No methodologically sound studies have provided meaningful evidence that medical transition reduces suicidality." (Cantor Report, ¶ 148.) Christensen et al., after conducting a formal systematic review, reached the same conclusion: "It is yet largely unproven what the effect of such interventions may be on rates of suicidal ideation and attempt—let alone completion—amongst transgender and gender-diverse youth" (Christensen et al. 2023 at 9.). The objective research evidence simply does not support claims that medicalized transition represents a "life-saving" procedure.

30. Importantly, of the 17 studies included in this review, only two existed before 2019.[4] That is, both the Endocrine Society guidelines (published in 2017) and the AAP policy (published in 2018) lack the benefit of the relevant studies nearly entirely. The published systematic review conducted by WPATH (i.e., Baker et al. 2021) cited zero of these 17 studies.

31. Moreover, Christensen et al. reiterated the fact that there have been no RCT studies, and called for high quality studies to be conducted (without any indication that it would be unethical to conduct such RCTs). (Christensen et al. 2023 at 9.).

II. Multiple new detransition studies confirm features consistent with the hypothesis that ROGD is largely a social contagion phenomenon.

32. As indicated in my previous report, respected national health care systems of several countries have warned of the risk that medical transition of minors can lead to detransition and severe regret due to irreversible physical harms. (Cantor Report, Section V.) Because detransition (1) can occur several years after transition, (2) is not typically reported to the clinic that provided transition (Littman (2021)), (3) thus cannot be distinguished by the clinic from dropping out of a clinical study for other reasons, and (4) is not systematically tracked by any centralized database in the U.S., reliable knowledge about the features and frequencies of detransition cannot develop at the same rate as other aspects of study. The scientific study of detransition has only just begun, with even the Version 8 of WPATH's Standards of Care (SOC-8) noting that basic information about detransition remains unknown (SOC-8 at S77.). In this situation, it is unjustified and misleading to claim that the paucity of evidence suggests that rates

[4] Namely:
Lytle, M. C., Silenzio, V., Homan, C. M., Schneider, P., & Caine, E. D. (2018). Suicidal and help-seeking behaviors among youth in an online lesbian, gay, bisexual, transgender, queer, and questioning social network. *Journal of Homosexuality, 65,* 1916–1933.
Russell, S. T., Pollitt, A. M., Li, G., & Grossman, A. H. (2018) Chosen name use is linked to reduced depressive symptoms, suicidal ideation, and suicidal behavior among transgender youth. *Journal of Adolescent Health, 63,* 503–505.

of detransition are low, rather than merely reflecting the difficulty of data collection and as a result the greater the time that will be required for such research to be completed.

33. Scientific interest in this issue is extremely high, and evidence is only now beginning to accumulate. In the comparatively short time since my previous report, many new studies of detransition have appeared in the peer-reviewed literature:

Littman, L., O'Malley, S., Kerschner, H., & Bailey, J. M. (2023). Detransition and desistance among previously trans-identified young adults. *Archives of Sexual Behavior*. doi: 10.1007/s10508-023-02716-1

MacKinnon, K. R., Gould, W. A., Enxuga, G., Kia, H., Abramovich, A., Lam, J. S. H., & Ross, L. E. (2023). Exploring the gender care experiences and perspectives of individuals who discontinued their transition or detransitioned in Canada. *PlosONE*. doi: 10.1371/journal.pone.0293868

MacKinnon, K. R., Kia, H., Gould, W. A., Ross, L. E., Abramovich, A., Enxuga, G., & Lam, J. S. H. (in press). A typology of pathways to detransition: Considerations for care practice with transgender and gender diverse people who stop or reverse their gender transition. *Psychology of Sexual Orientation and Gender Diversity*. doi: 10.1037/sgd0000678

Sanders, T., du Plessis, C., Mullens, A. B., & Brömdal, A. (2023). Navigating detransition borders: An exploration of social media narratives. *Archives of Sexual Behavior, 52,* 1061–1072.

Sansfaçon, A. P., Gelly, M. A., Gravel, R., Medico, D., Baril, A., Susset, F., & Paradis, A. (2023). A nuanced look into youth journeys of gender transition and detransition. *Infant and Child Development, 32,* e2402.

Sansfaçon, A. P., Gravel, É., Gelly, M., Planchat, T., Paradis, A., & Medico, D. (in press) A retrospective analysis of the gender trajectories of youth who have discontinued a transition. *International Journal of Transgender Health.* doi: 10.1080/26895269.2023.2279272

These empirical studies have employed a range of techniques to examine detransitioners' characteristics, including semi-structured interviews, thematic analysis of social media sites, and quantitative surveys using independently validated instruments.

34. The most scientifically rigorous of these is Littman et al. (2023). To recruit detransitioners to participate in this peer-reviewed study, the researchers noted that "Efforts were made to reach communities with differing perspectives about gender dysphoria, desistance,

transition, and detransition" (at 60.). The study's sample consisted of individuals 91% of whom were biologically female, ranging in age from 18 to 33 years (mean of 24.9 years), and 81% white. The majority of participants described themselves as politically liberal (68%), non-religious (82%), and supportive of gay marriage rights (86%) and transgender rights (91%).

35. The results of this quantitative, peer-reviewed study confirmed the conclusions of the qualitative studies interviewing detransitioners and prior survey studies: The majority of the detransitioners reported that the phenomenon referred to as rapid onset gender dysphoria (ROGD) correctly describe their experience (53%), with 23% indicating they did not know, and 24% reporting it did not. Co-morbid psychiatric diagnoses were acknowledged by the majority, consistent with prior studies. Self-harm was extremely prevalent in the sample before and during their period of transgender identification, 71% and 64% respectively. Interestingly (and urgently calling for further research), self-reported self harm dropped radically to 23% among this sample after they detransitioned and returned to a gender identity aligned with their biological sex.

36. The study results also supported the social contagion hypothesis of ROGD:

> Participants in the current study were asked if, at the time of transgender identification, they belonged to a friendship group where one or more members of the group became transgender-identified around the same time. The majority (60.3%) answered in the affirmative (with 24.4% referring to offline friendship groups, 14.1% referring to online friendship groups, and 21.8% referring to both). More than a third of participants responded that the majority of their offline and online friends became transgender-identified (34.6% and 38.5%, respectively) and participants acknowledged that their offline and online friendship groups engaged in mocking people who were not transgender-identified (42.3% and 41.0%, respectively). (Littman et al. 2023 at 68.)

It bears emphasizing this finding that more than a third of these (overwhelmingly female) respondents reported that "the *majority*" of their friends at some point became transgender-identified. In my opinion, this finding is entirely inconsistent with claims that transgender

identity is innate and immutable, like sexual orientation, rather than influenced by social and psychological factors.

37. Importantly, study participants were asked about the informed consent procedures they received from the clinicians providing the medicalized transition services. The majority (61.5%) reported receiving hormonal treatments from clinicians using only the informed consent, rather than a gate-keeping model, and, although they received some information, the results indicated that:

> 66.7% felt they were inadequately informed about risks and 31.3% felt this about benefits. Only one participant (2.1%) reported that a clinician provided information about treatment alternatives to cross-sex hormones . . . 75.0% of participants reported that they received inadequate information about these alternatives, [and fewer than] one-tenth (8.3%) of participants indicated that they were informed by their clinician about the lack of long-term studies about natal females with late-onset gender dysphoria. Similarly, only 12.5% were informed that the risks, benefits, and outcomes for medical transition of late-onset gender dysphoric youth have not been well studied. (Littman et al. 2023, at 70–71.)

III. New epidemiological evidence supports the hypothesis that ROGD is merely one symptom of a wide pattern of sharp declines in the mental health of especially female adolescents, corresponding with the increased social pressures introduced by social media in the smartphones era.

38. As noted in my previous report, the peer-reviewed evidence repeatedly differentiates between the previous, well-established types of gender dysphoria (childhood-onset gender dysphoria and adult-onset gender dysphoria; see Cantor Report, Sections IX.A. & IX.B.), and the only recently observed pattern of adolescent-onset or rapid-onset gender dysphoria (ROGD; see Cantor Report, Sections IX.C.).[5] Some advocates reject the social contagion explanation of the sudden epidemiological change, citing political, social, and therapeutic implications they claim

[5] One of the peer-reviewed sources I cited was Diaz and Bailey (year), published in *Archives of Sexual Behavior.* After my report was submitted, that article was republished as:

Diaz, S. & Bailey, J. M. (2023). Rapid-onset gender dysphoria: Parent reports on 1,655 possible cases. *Journal of Open Inquiry in the Behavioral Sciences.* doi: 10.58408/issn.2992-9253.2023.01.01.00000012

follow from that conclusion (see Section XI.B. below); however no other interpretation has been offered that is capable of explaining the evidence.

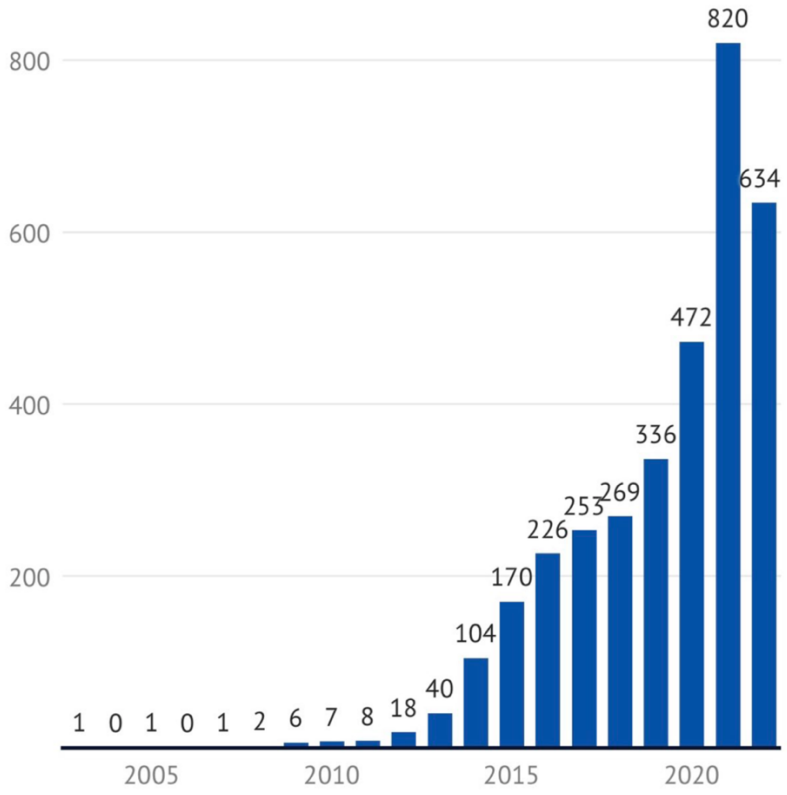
39. Since the preparation of my prior report, highly relevant new evidence has been reported by multiple, highly reliable sources (including national surveys), that endorse the patterns predicted by the social contagion explanation. Large quantities of mental health data have been produced recently due to the interest in investigating the impact of COVID on public mental health. What this research has repeatedly revealed is that, although there have been some decreases in mental health indicators during the COVID era, the major decline began nearly a decade before the COVID era (Villas-Boas et al. 2023) and instead corresponds with the new ubiquity of smartphones and social media among adolescents.

40. As demonstrated by the following sources, each of these exponential changes has occurred simultaneously and primarily within the same demographic group outlined in my prior report: adolescent, biological females, with psychosocial vulnerabilities making them more susceptible to social influence. Neither the claims of sexual minority stress nor any other hypothesis apart from the new influence of smartphones and social media predicts or provides any explanation for these several concurrent and ubiquitous patterns, below.

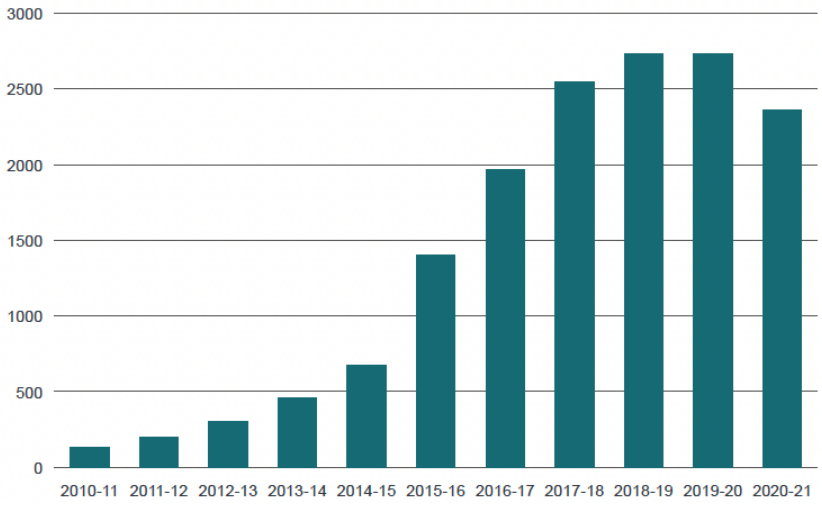
A. Additional data show an exponential increase in gender dysphoria referrals coincident with the wide uptake of social media.

41. First, evidence from additional sources simply confirms the presence and timing of the exponential increases in numbers of reported cases of gender dysphoria throughout the industrialized world, as already noted in my previous report.

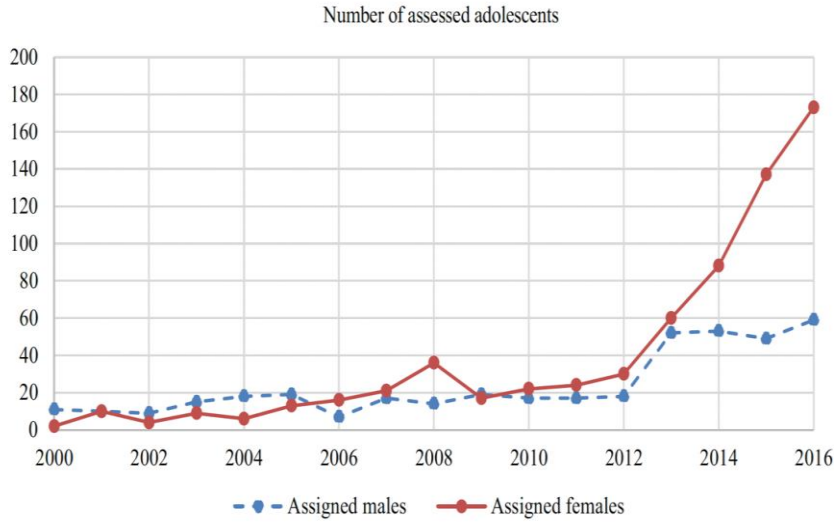
42. **Australia**: The Royal Children's Hospital gender service reports the following data on referrals to its gender service, with an exponential rise beginning in 2011–2012. (Bachelard 2023.)



43. **United Kingdom**: In her interim report, Dr. Cass provides the following data on referrals for gender dysphoria in the U.K., following almost exactly the same timing and curve. (Cass 2022 at 34.)

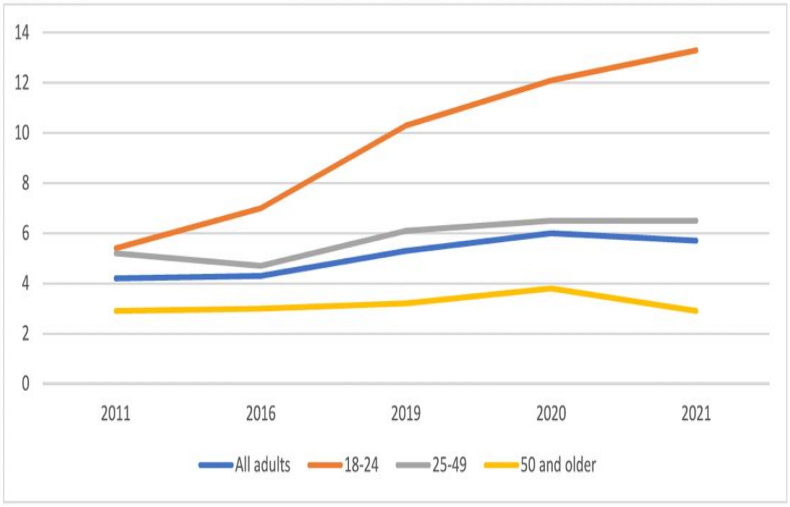


44. **The Netherlands:** Data from the Netherlands shows the same pattern and timing and breaks out the fact that the phenomenon is primarily affecting biological females. (Arnoldussen 2020.)

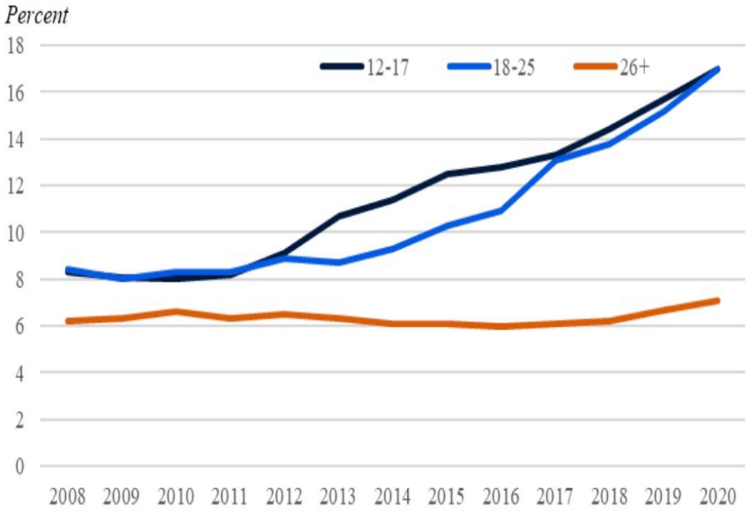


B. Additional data also show a sharp increase in mental health conditions broadly among teens occurred concurrent with the wide uptake of social media.

45. Brunette et al. (2023) plotted data from U.S. National Survey on Drug Use and Health demonstrating that increases in depression began at the same time and occurred among younger rather than older adults:



46. Data from the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA 2022) likewise show the rapid rise in depressive episodes, more than doubling, accompanying the social media age, and mostly affecting youth under 25:



C. The post-2011 crisis in mental health, like the explosion of gender dysphoria referrals, has been a largely female phenomenon.

47. The sudden and dramatic increases in depression primarily occurred among biologically *female* adolescents. The U.S. Centers for Disease Control and Prevention (CDC) released the results of its biannual *Youth Risk Behavior Survey* (CDC 2023). The report confirmed that mental health and suicidal thoughts and behaviors worsened significantly between 2011 and 2021. It also found these problems primarily affecting biological females, noting:

> Across almost all measures of substance use, experiences of violence, mental health, and suicidal thoughts and behaviors, female students are faring more poorly than male students. These differences, and the rates at which female students are reporting such negative experiences, are stark. […] In 2021, almost 60% of female students experienced persistent feelings of sadness or hopelessness during the past year and nearly 25% made a suicide plan. (CDC 2023 at 2.)

48. Twenge (2022) showed an exponential increase in major depression rates among U.S. adolescents (ages 12–17) beginning in 2011, as reported by the U.S. National Study of Drug Use and Health, illustrating again this to be primarily among females:

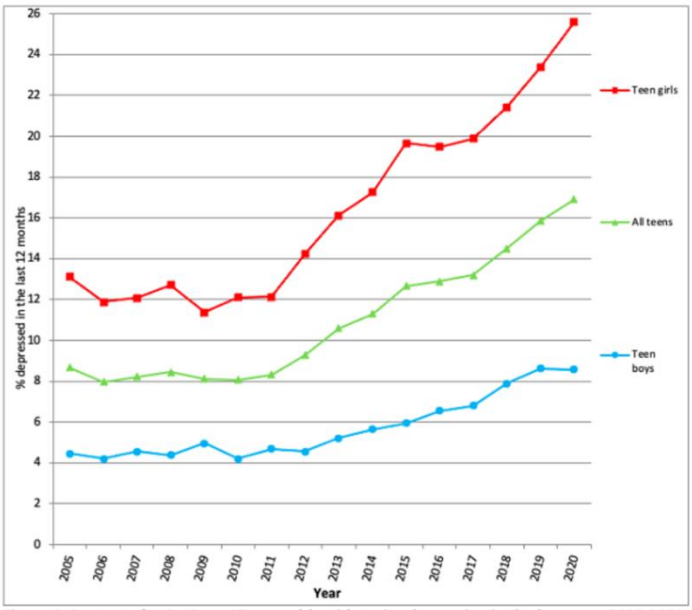


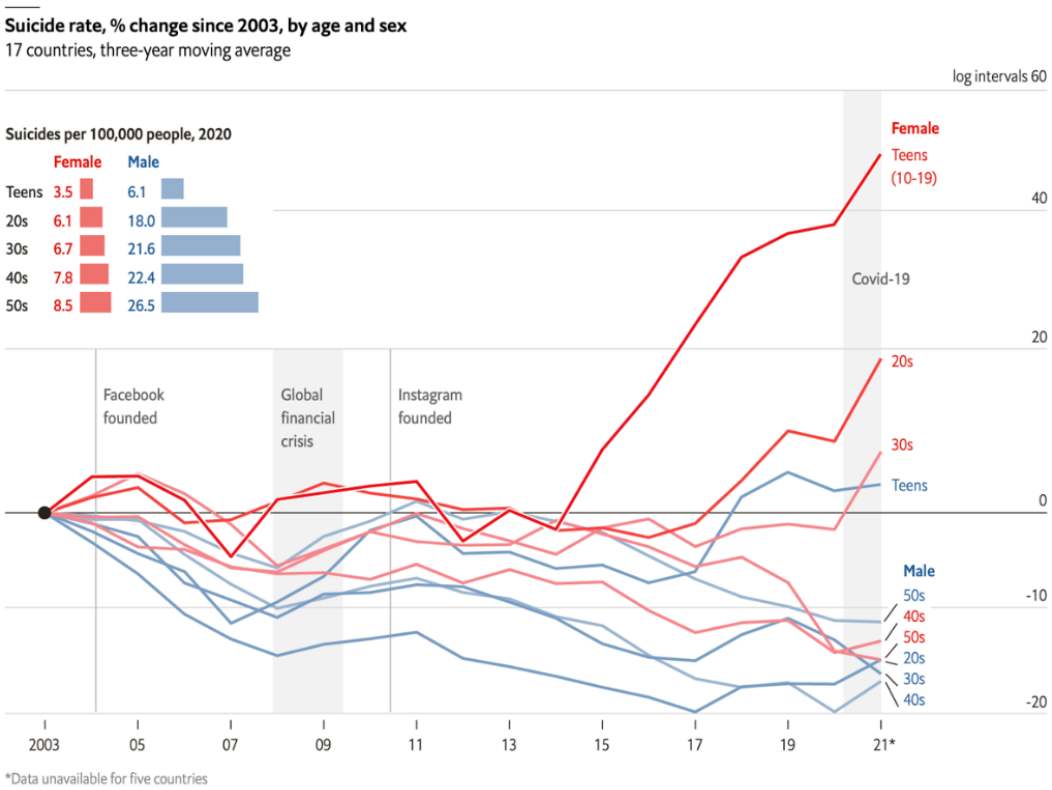
Figure 2: Percent of U.S. 12- to 17-year-olds with major depression in the last year, 2005-2020
Source: National Study of Drug Use and Health. NOTE: Depression assessed using DSM criteria.

(Twenge 2022 at 3.)

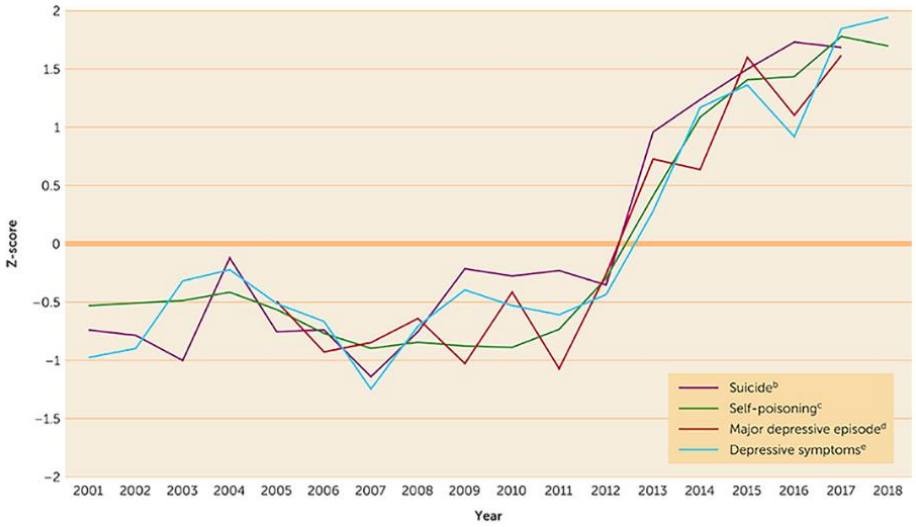
49. Tragically, the same pattern extends beyond depression and mental health to actual completed suicide. While suicide rates for most groups have fallen or remained constant since 2011, completed suicide rates for adolescent girls instead have skyrocketed:

> Suicide rates have been falling overall, but girls—who kill themselves less often than other groups—are an exception. Among girls aged 10–19, suicide rates rose from an average of 3.0 per 100,000 people in 2003 to 3.5 per 100,000 in 2020. The rate among boys, although higher at 6.1 per 100,000 population, has barely changed. (Economist 2023.)

Changes in suicide rates, by biological sex and age group. (Economist 2023.)



50. Twenge (2020) compared multiple indicators of poor mental health among U.S. girls and young women across 2001–2018, again illustrating the dramatic worsening beginning in 2011. "In most cases, the increases in indicators of poor mental health have been larger among girls and young women than among boys and young men" (Twenge 2020 at 19.). These findings confirm the patterns I have previously identified.



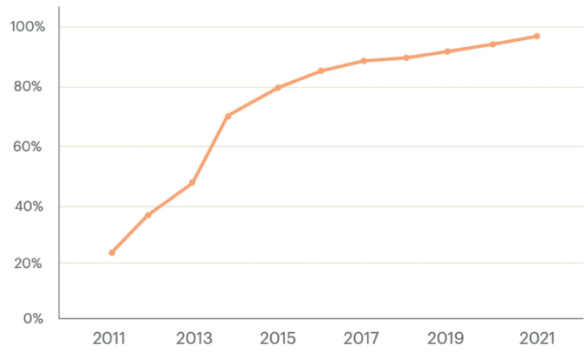
D. The 2011 onset of increased mental health problems and increased gender dysphoria referrals has been recognized as co-occurring with the uptake of smartphones among adolescents.

51. New reports increasingly recognize social media and smartphone usage as the common link behind the proliferation of mental health disorders among adolescents (Brunette et al. 2023; Haltigan et al. 2023), including the recent health advisory by the American Psychological Association on social media use among adolescents (APA (2023).). The APA advisory concluded:

> Research suggests that using social media for social comparisons related to physical appearance, as well as excessive attention to and behaviors related to one's own photos and feedback on those photos, are related to poorer body image, disordered eating, and depressive symptoms, *particularly among girls.* (APA 2023 at 8, emphasis added.)

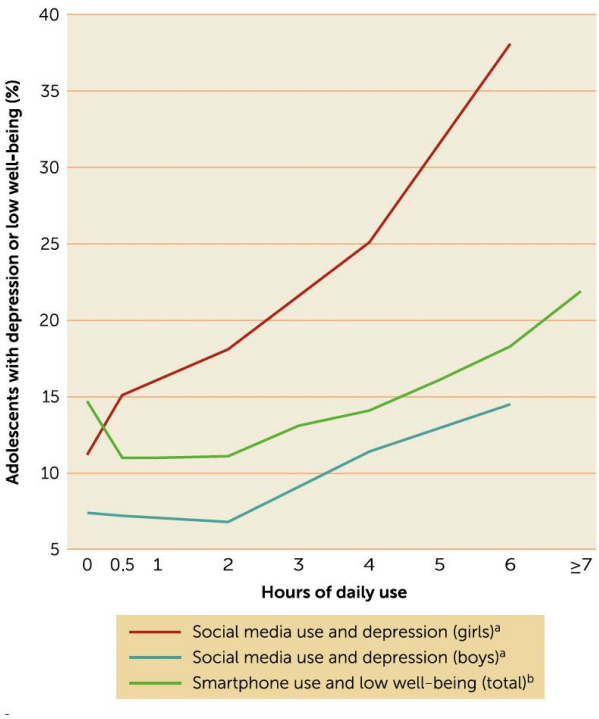
These conclusions further confirm the conclusions of systematic review associating smartphone usage and poorer mental health (Sohn et al. 2019).

52. The timing of the increase in gender dysphoria referrals exactly correspond with the penetration of smartphones and social media into adolescent lives: Data published by Pew Research illustrates that the rates of smartphone usage among teenagers also began its dramatic rise in 2011−2012:



(Lebrow 2022.)

53. Twenge (2020) documents that it is precisely the heavy users of social media who are most likely to report being depressed, feeling unhappy, or exhibiting suicidality. Again, the association is, by far, most striking for adolescent girls:



(Twenge 2020 at 22.)

54. In their peer-reviewed, nation-wide analysis of Finland's centralized gender identity services (GIS), Kaltiala et al. observed:

> The increase in all the younger people contacting GIS and in psychiatric needs among them have taken place simultaneously with the emergence of the widely recognized crisis in mental health among adolescents and young adults throughout the Western world [44, 45], largely associated with the increasing use of social media [44–46]. Social influences that reduce stigma and barriers to care for people suffering from incongruence between their sexed body and lived gender experience likely improve mental health in this group and social media may offer invaluable support and belongingness that buffers against minority stress. However, social media influences may also result in adolescent and emerging adult females – who present particularly frequently with identity confusion [47] – seeking for a solution to their distress through GR [11] and overshadow the need for psychiatric treatment. (Kaltiala et al. 2023 at 6.)

The sources cited by Kaltiala et al. in this paragraph are:

> 11: Marchiano, L. (2017). Outbreak: On transgender teens and psychic epidemics. *Psychological Perspectives, 60,* 345–366.

44: Twenge, J. M. (2020). Increases in depression, self-harm, and suicide among U.S. adolescents after 2012 and links to technology use: Possible mechanisms. *Psychiatric Research and Clinical Practice, 2,* 19–25.

45: Krokstad, S., Weiss, D. A., Krokstad, M. A., Rangul, V., Kvaløy, K., Ingul, J. M., Bjerkeset, O., Twenge, J., & Sund, E. R. (2022). Divergent decennial trends in mental health according to age reveal poorer mental health for young people: Repeated cross-sectional population-based surveys from the HUNT Study, Norway. *BMJ Open, 12,* e057654.

46: Abbasi, J. (2023). Surgeon general sounds the alarm on social media use and youth mental health crisis. *JAMA, 330,* 11–12.

47: Bogaerts, A., Claes, L., Buelens, T., Verschueren, M., Palmeroni, N., , Bastiaens T., & Luyckx, K. (2021). Identity synthesis and confusion in early to late adolescents: Age trends, gender differences, and associations with depressive symptoms. *Journal of Adolescence, 87,* 106–116.

IV. New studies on risks of harm corroborate the dangers posed to children and adolescents by medicalized transition.

55. As I outlined in my prior report, an analysis of the safety and/or efficacy of any particular approach requires a balancing of the probable benefits in light of probable risks. (Cantor Report, Section V.A.) My prior report also detailed both the known and the potential, but largely unstudied, harms associated with administration of puberty blockers and cross-sex hormones to children and adolescents, one of which is irreversible sterilization. (Cantor Report, Section XIV.)

56. Since I prepared my report, a systematic review of the research studying the desire of transgender individuals to become biological parents has now been completed and published, information relevant to the possibility that medical transition will later be perceived by the patient as having inflicted severe harm. Stolk et al. (2023) reviewed of a total of 76 individual studies. The review found that that the majority of adults undergoing medicalized transition desired to become parents in the future; however, fertility preservation utilization rates were nonetheless low. That disconnect obviously leaves large room for future regret and harm.

57. By contrast, Stolk et al. found that among transgender adolescents, only a minority

stated a desire to become biological parents in the future. Stolk et al. did not however, find any study that measured by how such desires *change* over time, once those who transition as adolescents mature into adult life. The much greater levels of desire to become a parent reported by transgender adults suggests the hypothesis that this desire increases as one enters and lives adult life, although a longitudinal study would be necessary to conclude this with confidence. Also not included in Stolk et al. was information comparing levels of asserted desire to be a parent in the future among *non*-transgender adolescents with asserted desire on the part of non-transgender adults. Such a comparison that might give critical insight into the general stability (or lack of stability) of such desires across time and maturation.

58. Notably, Stolk et al. recognize that cross-sex hormone treatment beginning at Tanner Stage 2 ends the possibility of future fertility. The review noted also that WPATH guidelines include no procedures that would prevent this effective sterilization. Rather, WPATH guidelines include only the recommendation that individuals undergoing medicalized transition receive counseling about that loss of capacity for biological children. Neither the review nor WPATH provides any indication of how effective such counseling can be with, for example, a 10-year-old or prepubescent child making the irreversible decision never to become a biological parent. No evidence or methodology exists for validating whether any consent or assent obtained from such a child could be meaningfully informed.

V. Evidence-based medicine warns against strong recommendations based on low quality evidence.

59. In his declaration, Dr. Antommaria did not contest that the evidence cited in support of the medicalized transition of minors was of low quality; however, Dr. Antommaria asserted that it is standard practice for clinical guidelines to issue strong recommendations on the basis of

only low quality evidence. (Antommaria Report at 11–15.) New documentation, including peer-reviewed publications and the now identified sources of WPATH's procedures, indicate instead that recommendation strength being discordant with evidence strength conflicts with evidence-based medicine. First, Chapter 14 of WHO (2014) is titled "*Strong recommendations when the evidence is low quality,*" and makes this principle explicit:

> GRADE guidance *warns against discordant recommendations* because when either the benefits or harms of an intervention are uncertain, one cannot be confident that an intervention does more good than harm. Strong recommendations are directives that are meant to be followed by all or almost all guideline users and under all or almost all foreseeable circumstances. […] Because of this, discordant recommendations may entrench practices whose benefit is uncertain. For instance, a discordant recommendation may lead the users of a WHO guideline to carry out interventions that are detrimental individually or collectively or to waste scarce resources on ineffective interventions. (WHO 2014 at 170–71, emphasis added.)

60. A new peer-reviewed article, published in *BMC Medical Research Methodology,* compared quality of evidence with strength of recommendations for all the National Clinical Guidelines (NCGs) of Ireland after 2019, when that country's national health care system adopted the GRADE approach to evidence-based medicine—Chong et al. (2023). Chong et al. first summarized the basic principle behind evidence-based medicine:

> 1) Strong recommendations confirm confidence that the desirable effects outweigh the undesired consequences and 2) conditional/weak recommendations are made when there is uncertainty regarding potential harms or disadvantages. […] For the development of trustworthy guidelines there should be concordance between the quality (certainty) of the evidence and the strength of the recommendations. (Chong et al. 2023 at 2.)

61. Moreover, when there is only low quality evidence to support a treatment that risks harm, the primary recommendations are recommendations *against* that treatment, not *for* it, as Dr. Antommaria misleadingly insinuates. Dr. Antommaria fails to disclose how many of the strong recommendations based on weak evidence he cited were strong recommendations *against*

the procedure because of the weak evidence, rather than *for* the procedure *despite* only weak evidence.

62. As Chong et al. noted: When the evidence of benefit is of low or very low quality, but the evidence of harm is high or moderate, then the recommendation is a strong recommendation *against* the treatment, and when the evidence shows that two treatments have potentially equivalent effectiveness but that one clearly poses less risk (such as with psychotherapy versus medicalized transition), then the recommendation is a strong recommendation *against* the higher risk treatment. (Chong et al. 2023 at 3.)

63. WHO (2014) provides the same instructions:

> When guideline development groups are confident that the desirable consequences (benefits) of an intervention outweigh its undesirable consequences (risks or harms), they will likely issue a strong recommendation in favour of the intervention; when they are confident that the opposite is true, they issue a strong recommendation against the intervention. In cases in which the balance between desirable and undesirable consequences is less certain, the guideline development group will issue a conditional recommendation. (WHO 2014 at 169.)

For example, when there is only low or very low quality evidence of benefit (such as with mental health benefits from medicalized transition), but high or moderate level evidence of harm (such as with the sterilization from cross-sex hormones administered to prepubescent reproductive organs), the proper application of the principles of GRADE as clearly set out in these sources yields a strong recommendation *against* the intervention, not for it.

64. Both Chong et al. (2023) and WHO (2014) do identify five situations which represent exceptions to the concordance principle, in which strong recommendations may be appropriate despite low quality evidence. These give situations are listed below. Notably, four of them are recommendations *against* the treatment:

Situations in which a strong recommendation may be indicated despite low quality evidence.

Situation	Evidence Quality		Recommendation
	Benefits	Harms	
Uncertain benefit, certain harm	Low or very low	High or moderate	Strong recommendation *against* the more harmful/costly option
Potentially equivalent options, one clearly less risky or costly than the other	Low or very low	High or moderate	Strong recommendation *against* the more harmful/costly option
High confidence in benefits being similar, but one option potentially more risky/costly	High or moderate	Low or very low	Strong recommendation *against* the potentially more harmful/costly option
Potential catastrophic harm	Immaterial (very low to high)	Low or very low	Strong recommendation *against* the more harmful/costly option
Life-threatening emergency	Low or very low	Immaterial (very low to high)	Strong recommendation in favor of the intervention

65. A "life-threatening situation" is one for which it is well documented that death would result in very substantial proportion of the affected individuals. WHO (2014) offers as an example that, as multidrug resistant tuberculosis so often results in death, it is acceptable to recommend a fluoroquinolone, despite the evidence of its lesser generally effectiveness and greater toxicity than front-line treatment. (WHO 2014 at 172.) As the science I have reviewed makes very clear, it is not possible to assert that a child or adolescent presenting at gender clinic presents a comparable "life-threatening situation." Nor does any responsible voice (nor even WPATH) assert that the risks posed by administering puberty blockers or cross-sex hormones to

minors are "immaterial." In short, the *only* situation in which the principles of evidence-based medicine permit a strong recommendation based on low quality evidence does not apply.

VI. New studies and statements from medical associations and respected international experts confirm the lack of professional consensus and lack of science supporting the medicalized transition of minors.

66. In my prior report, I cited extensive evidence that claims of a "medical consensus" in favor of medicalized transition of children (often supported by nothing more than pointing to "guidelines" published by professional interest groups) are demonstrably false. (Cantor Report, Section II.F.) Since then, new studies, as well as statements from a variety of medical associations, have further endorsed that conclusion.

A. The World Health Organization (WHO) has removed children and adolescents from its upcoming guidelines on transgender health, making explicit this was because of the lack of evidence.

67. WHO (2014) explicitly identifies its methods as scientific and evidence-based:

> [I]n its normative and standard-setting work, WHO is and will remain a science- and evidence-based organization with a focus on public health. Guidelines are the fundamental means through which the Organization fulfils its technical leadership in health […] WHO's legitimacy and technical authority lie in its rigorous adherence to the systematic use of evidence as the basis for all policies. (WHO 2014 at 1.)

WPATH explicitly names WHO as one of the sources upon which it relied for its methodology in producing SOC-8—see Section VII. below. SOC-8 also employs the WHO diagnostic system (ICD-11) instead of the APA system (DSM-5-TR). Despite WPATH's consistent endorsement of WHO standards, however, WHO itself has come to the opposite conclusion of WPATH on the application of these standards to transgender children and adolescents.

68. On 18 December 2023, the World Health Organization announced the development of a guideline on the health of transgender and gender diverse people, including the provision of gender-affirming care. (WHO 2023.) On 15 January 2024, WHO announced that the guideline

would pertain only to adults (WHO 2024a), stating in a published "FAQ" that the reason for excluding minors was specifically because of the insufficient and inconsistent evidence:

> Why will the guideline only cover adults and not also children or adolescents?
>
> The scope will cover adults only and not address the needs of children and adolescents, because on review, the evidence base for children and adolescents is limited and variable regarding the longer-term outcomes of gender affirming care for children and adolescents. (WHO 2024b at 3.)

B. The *UK Council for Psychotherapy* has now issued official guidance regarding (what it termed) gender critical views and to emphasize that exploratory therapy must not be conflated with conversion therapy.

69. The *United Kingdom Council for Psychotherapy* (UKCP) is the national registering body for psychotherapists in the UK, comprising 80 member organizations. It is the primary organization in that country for the education, training, accreditation, and regulation for psychotherapy and psychotherapeutic counselling. After the submission of my prior report, that body issued a statement explaining its guidance for psychotherapy with gender dysphoric minors:

> Psychotherapists and psychotherapeutic counsellors who hold [gender critical] views are likely to believe that the clinically most appropriate approach to working therapeutically with individuals who present with gender dysphoria, particularly children and young people, is exploratory therapy, rather than medicalised interventions such as puberty blockers, cross-sex hormones or reassignment surgery. […] Exploratory therapy should not in any circumstances be confused with conversion therapy, which seeks to change or deny a person's sexual orientation and/or gender identity. (UKCP 2023.)

The statement quoted the Chair of the UKCP, Dr. Christian Buckland, saying:

> The UKCP continues to recognise the fact that there are different professional beliefs on many differing topics within the psychotherapeutic community. […] Medical interventions can potentially be irreversible, and there are risks associated with all medical treatments. Therefore, it is imperative that all underlying aspects to someone's dysphoria are given the attention and exploration they deserve through professional psychotherapies, in order that the overall risks can be appropriately assessed prior to considering medical intervention. (UKCP 2023.)

70. Thus, the UKCP statement directly contradicts the plaintiffs' experts' claims, but further confirms and reiterates the contents of my prior report, including the lack of professional consensus over treatment models (Cantor Report, ¶¶ 34–37), erroneous misuse of the term "conversion therapy" (Cantor Report, ¶ 301), and the risks associated with medicalized transition (Cantor Report, Section XIV.).

C. A new survey of endocrinologists who prescribe gender-affirming hormone treatment demonstrates split opinion, not consensus.

71. A new study surveying board-certified endocrinologists who prescribe gender-affirming hormone treatment (GAHT) to adults found that "GAHT can and is currently being prescribed in large numbers without a prerequisite of psychosocial evaluation from a MHP [mental health provider]." (Bisno et al. 2023 at 469.) Bisno et al. noted that this *lack* of thorough evaluation is consistent with guidelines published by special interest groups with a financial interest in administrating that therapy:

> The Endocrine Society published guidelines in 2017 recommending *against* an obligatory psychosocial evaluation, which was affirmed in the recently published World Professional Association for Transgender Health Standards of Care Version 8 from 2022. (Bisno et al. 2023 at 465.)

By contrast, however, Bisno et al. found that "42.9% of the respondents reported that their practice required documentation of a psychosocial evaluation from a mental health professional before initiating GAHT." The authors concluded that, despite the Endocrine Society and WPATH guidelines, "Endocrinologists who prescribe GAHT are divided about requiring a baseline psychosocial evaluation before prescribing GAHT." (Bisno et al. 2023 at 465.)

72. The fact that almost half of the surveyed physicians reported using clinical criteria *tighter* than those of WPATH and the Endocrine Society indicates their belief that those guidelines provide insufficient protection against harm.

73. The authors of Bisno et al. reported reasons given by some doctors who agreed with the WPATH/Endocrine Society advocacy to remove any requirement for a psychosocial evaluation before prescribing puberty blockers or cross-sex hormones. Interestingly, the reasons tgiven do not reflect evidence-based conclusions about benefits, harms, or risks from medical transition. Rather, the reasons were:

- **Access**: Too "few MHPs [mental health providers] are training in gender-affirming health care" (at 466.) which made it "challenging to find a MHP" (at 467.);
- **Cost**: Too few MHPs "participate in any insurance plan," while "up to 40% of the transgender population is publicly insured or uninsured" (at 467.); and
- **Advocacy goals**: Dispensing with a mental health evaluation would "minimize the association of transgender identity with mental illness" (at 469.).

These reasons do not reflect principles of evidence-based medicine. Rather, they serve to increase potential patients' ability to obtain and afford the services of these endocrinologists. Indeed, these motivations represent the very kinds of conflict of interest that both IoM (2011) and WHO (2014) warn about and seek to guard against—see Section VII.A. below.

D. The American Academy of Pediatrics (AAP) now acknowledges that its 2018 policy statement on gender dysphoric children was not based on a systematic review of the relevant research.

74. As noted in my prior report (Cantor Report, Section XVI.D.) and detailed in my peer-reviewed fact-check (Cantor 2020), the AAP's policy statement on transgender youth misrepresented and directly contradicted the contents of the then-available scientific literature. Neither AAP nor the sole author of its policy statement (Rafferty et al. 2018) conducted either a systematic review or even a competent narrative review of the relevant science. In the several years since that time, AAP has produced no correction or other response to the numerous, documented errors that statement contained.

75. Since the submission of my prior report, AAP Board of Directors has reaffirmed that

same 2018 policy. (Wyckoff 2023.) Remarkably, the AAP did so still without conducting a systematic (or any other) review of the now much expanded relevant science. This is despite: (1) the long list of factual errors I and others had already documented regarding the scientific assertions contained in the policy, (2) the hundreds of relevant peer-reviewed studies published only after that 2018 policy, and (3) the systematic reviews from all over the world that also became available only after 2018, unanimously contradicting the very basis of that policy.

76. The statement AAP made in announcing the policy reaffirmation in its journal, *Pediatrics,* included the assertion by the AAP CEO that the "policy authors and AAP leadership are confident the principles presented in the original policy [Rafferty et al. (2018)] remain in the best interest of children." (Wyckoff 2023.) The principles that the public expects and assumes, however, are the principles of evidence-based medicine, and the principles of evidence-based medicine require a systematic review, which the AAP has neglected to perform, now twice. Additionally, unlike in 2018, there now exist systematic reviews already available from multiple authorities that *do* adhere to the principles of evidence-based medicine, but the AAP has entirely disregarded those available resources.

77. The AAP's announcement did include a statement that it intends to conduct a systematic review in the future, only *after* reaffirming its policy. Such a cart-before-the-horse strategy is clearly positioned to facilitate reaching a predetermined conclusion. Indeed, the AAP statement did not acknowledge any scientific need for a systematic review, and instead highlighted "the board's concerns about restrictions to access to health care with bans on gender-affirming care." As noted in earlier in this report, such declarations from professional guilds represent a conflict of interest—see Section VII.A below. Because of the financial incentives to physicians providing these services, patients' "access to health care" is indistinguishable from

AAP's access to its customer market.

E. New statements from respected international experts increasingly warn of dangers of excessive medicalization and discourage medical transition of children.

78. My prior declaration identified multiple international health care systems reversing their policies that had initially facilitated the medicalized transition of minors. (Cantor Report, Section II.) The international recognition that the earlier policies fail to reflect the medical science and have not been shown to benefit children continues to grow with the still-increasing evidence. It is evident that the U.S. medical policies are growing increasingly isolated from the international medical and scientific consensus in light of the scientific evidence.

79. In a recent open letter in the *Wall Street Journal*, 21 scientists and clinicians from nine countries, all experts in caring for gender dysphoric youth, issued a warning to the U.S. that "Youth gender transition is pushed without evidence: Psychotherapy, not hormones and surgery, is increasingly the first line of treatment abroad." (Kaltiala, Takala, et al. 2023.) The authors emphasized:

> The politicization of transgender healthcare in the U.S. is unfortunate. The way to combat it is for medical societies to align their recommendations with the best available evidence—rather than exaggerating the benefits and minimizing the risks. (Kaltiala, Takala, et al. 2023.)

80. One of the authors of this open letter, Dr. Riittakerttu Kaltiala, is the chief psychiatrist in the department of adolescent psychiatry at the Tempere University Hospital, one of the leading teaching hospitals in Finland. She served as the head of Finland's national pediatric gender program, which began with, and for several years followed, the "Dutch protocol" which includes prescribing puberty blockers for some exceptional gender dysphoric children, starting at age 12. (Cantor Report, Section XVI.A.) Dr. Kaltiala is now, however, vocally advocating against these hormonal interventions which she says "interrupt and disrupt [the] crucial

psychological and physical developmental stage" of puberty. In her recently published essay entitled "Gender-affirming care is dangerous," she recounts that—as her clinic tracked their patients— "the young people we were treating were not thriving. Instead, their lives were deteriorating . . . they were doing worse" and that "some previous patients started to come back to tell us they now regretted their transition." (Kaltiala 2023.) Dr. Kaltiala states that "the [evidentiary] foundation on which the Dutch protocol was based is crumbling," and that "regret is far more widespread" than commonly acknowledged. "For example, one new study shows that nearly 30 percent of patients in [a transitioned] sample ceased filling their hormone prescriptions within four years." (Kaltiala 2023.)

81. The Editor-in-Chief of the *British Medical Journal* (among the most respected medical journals in the world) likewise recently described the international shift away from medicalized transition in favor of psychological support in a recent article, explicitly calling out medical societies in the U.S. which are departing from the evidence:

> The US, however, has moved in the opposite direction. An investigation by The BMJ finds that more and more young people are being offered medical and surgical intervention for gender transition, sometimes bypassing any psychological support. Much of this clinical practice is supported by guidance from medical societies and associations, but closer inspection of that guidance finds that the strength of clinical recommendations is not in line with the strength of the evidence. The risk of overtreatment of gender dysphoria is real. (Abbasi 2023 at 553.)

82. One of the most widely known experts and pioneers of the treatment of gender dysphoria in minors, Dr. Susan Bradley of Canada, recently expressed regret at having employed puberty blockers to treat gender dysphoric minors. She now states:

> We were wrong. . .They're not as irreversible as we always thought, and they have longer term effects on kids' growth and development, including making them sterile and quite a number of things affecting their bone growth. (Duggan 2023.)

F. Dr. Gordon Guyatt confirms that so-called guidelines or standards promoting medicalized transition of minors are not based on or consistent with evidence-based medicine.

83. As I have previously explained, Dr. Gordon Guyatt, Distinguished Professor of Medicine and of Health Research Methods at McMaster University, is recognized as the "father" of evidence-based-medicine. (Cantor Report, Section III.B.) Plaintiffs' experts repeatedly cited Dr. Guyatt in the course of describing the standards by which clinical research is (or should be) assessed, asserting that medicalized transition is consistent with evidence-based-medicine. On the contrary, multiple recent public statements by Dr. Guyatt now confirm that he agrees with my application of the principles of evidence-based medicine to the research on gender dysphoric minors and disagrees with that being put forward by the plaintiffs' experts.

84. Dr. Guyatt has recently stated:

> Current American guidelines for managing gender dysphoria in adolescents [are] untrustworthy. Don't acknowledge the very low certainty evidence regarding alternatives and do not make the very guarded weak/conditional recommendations appropriate for such evidence.[6]

In this post, Dr. Guyatt linked to article in the *British Medical Journal* (BMJ) that relied in part on the author's interview of Dr. Guyatt about the Endocrine Society's guidelines on medicalized transition. The BMJ article in turn quoted and summarized an interview with Dr. Guyatt as follows:

> Guyatt, who co-developed GRADE, found "serious problems" with the Endocrine Society guidelines, noting that the systematic reviews didn't look at the effect of the interventions on gender dysphoria itself, arguably "the most important outcome."
>
> He [Guyatt] also noted that the Endocrine Society had at times paired strong recommendations—phrased as "we recommend"—with weak evidence.… "GRADE discourages strong recommendations with low or very low quality

[6] Retrieved from Gordon H. Guyatt (@GuyattGH), X, https://twitter.com/GuyattGH/status/1641183448063967233?s=20 (last visited February 1, 2024).

> evidence except under very specific circumstances," Guyatt told The BMJ. Those exceptions are "very few and far between." (Block 2023 at 2–3.)

Dr. Guyatt's comments directly oppose Dr. Antommaria's assertion that the Endocrine Society's guideline development procedure was "rigorous." (Antommaria Report at 5.) Dr. Guyatt also directly contradicts Dr. Antommaria's suggestion that it is valid and routine to make strong recommendations on the basis of weak evidence. (Antommaria Report at 14–15.)

85. In another interview, this time with *The New York Times*, Dr. Guyatt was asked about AAP's decision to promulgate a policy on the medicalized transition of minors without having conducted a systematic review. (Ghorayshi 2023.) *The Times* described his response as follows:

> The move is "very clearly putting the cart before the horse," said Dr. Gordon Guyatt, a clinical epidemiologist at McMaster University who helped develop the field of evidence-based medicine.
>
> Based on previous systematic reviews, Dr. Guyatt said, the A.A.P.'s report will most likely find low-quality evidence for pediatric gender care. "The policies of the Europeans are much more aligned with the evidence than are the Americans'," he said. (Ghorayshi 2023.)

G. Both topic experts and research methodology experts continue to discredit the publications of Dr. Jack Turban.

86. The plaintiffs' experts repeatedly cite works by Dr. Turban claiming that those works support the medicalized transition of minors, but which I demonstrated in my report to be misinterpretations of survey data which he analyzed incorrectly. (Cantor Report, Section XVII.) Since then, numerous public statements from Dr. Turban demonstrate his lack of knowledge of even the basic methods of evidence-based medicine, with topic experts documenting numerous errors in his analyses.

87. As noted in my previous report, a substantial proportion of the evidence from the plaintiffs' experts relies upon analyses by Dr. Turban of a 2015 survey, and survey studies represent only very low quality evidence of clinical outcomes. Since the preparation of my

report, further evidence has emerged documenting the unreliability of Dr. Turban's findings and conclusions, including re-analyses of his data by established topic experts, peer-reviewed evaluation of his conclusions, editorial re-review of his work that compelled corrections be published, and his own testimony under oath indicating the limits to his own knowledge of evidence-based medicine research methods.

88. In his recent article, Dr. Turban challenged the validity of rapid onset gender dysphoria (ROGD) on the basis of his analysis of the U.S. Transgender Survey of 2015 (the same survey as reported in his prior works). (Turban et al. 2023a.) Survey-takers (transgender adults, ages 18 and older) were asked "At about what age did you begin to feel that your gender was 'different' from your assigned birth sex?" (Turban et al. 2023 at 2.) To approximate childhood-onset cases with pubertal/adolescent-onset cases, Turban's analysis split the survey-takers into those who responded age ≤10 versus >10. He then concluded that because "a substantial proportion of participants (40.8%) reported that they did not come to realize their TGD identities until adolescence or later," this contradicted "the assumption of identity transience for this group that is an inherent component of the ROGD hypothesis," citing Littman et al. (2018). Immediately upon the release of Turban's claim, multiple authors exposed Turban's confusion: Transience is not a component of the ROGD hypothesis in the first place. (Kulatunga-Moruzi, 2023; Sapir et al. 2023.)

89. Sapir et al. identified a long list of further flaws in Turban et al. (2023a), including:

(1) analyzes the wrong age cohorts in USTS-15,

(2) uses a dubious proxy for "realization,"

(3) uses an unreasonable definition of "disclosure,"

(4) provides misleading analysis of time to disclosure,

(5) misrepresents and underestimates the significance of their sample's female skew, and (6) omits ROGD-relevant data. (Sapir et al. 2023 at 1.)

Sapir et al. demonstrated that, once re-analyzed correctly, the U.S. Transgender Survey data actually *support* the ROGD hypothesis. (See also Cantor Report, Section IX.C.)

90. The plaintiffs' experts also repeatedly cited Turban et al. (2022), which has now also been revealed to contain substantial errors. In that article, *Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults,* Dr. Turban's team asserted that having received cross-sex hormone treatment during adolescence (ages 14–17) was associated with lower odds of reporting suicidality within the year before the survey. Since the submission of my prior declaration, errors in Dr. Turban's data tables and other issues have been identified that were sufficiently serious to require the publication of a correction—Turban et al. (2023c). Jackson's peer-reviewed assessment of studies of the effectiveness of so-called gender-affirming treatment on suicidality identified in Turban et al. (2022) the same deficiencies that have pervaded Turban's earlier studies:

> As mentioned, any current or prior mental health treatments besides hospitalization secondary to suicide attempt(s) were not gathered and controlled for.
>
> It is possible that assessing the confounding of mental-health differences by comparing suicidality over the past year to a lifetime history is insufficient.
>
> There will be a higher likelihood of the presence of lifetime suicidal ideation but none for the past year not just due to mental health differences but as a function of increased age.
>
> There was no accounting for effects due to psychiatric diagnostic history. (Jackson 2023 at 11.)

It is not possible to conclude from Turban et al. (2022) that hormone treatment caused improvement, because of (any of) the several other uncontrolled (confounding) factors that could also explain the reported scores.

91. The identification in Jackson (2023) of uncontrolled and confounding variables in Turban et al. (2022) corresponds to what Biggs also identified and described as the primary question:

> Why 'the range of confounding variables' omits interventions which have been identified in other published studies using the same data—including those with shared authors—as having positive associations with the same outcomes. (Biggs 2022 at 1.)

92. The plaintiff's experts also repeatedly cited Turban et al. (2020), which now has been further critiqued for asserting conclusions not justified by its data. In that article, *Pubertal suppression for transgender youth and risk of suicidal ideation,* Dr. Turban's team asserted that having received puberty-suppressing medication during adolescence was associated with lower odds of suicidality. Jackson, however, found the same deficiencies in Turban et al. (2020) as in Turban's other studies:

> The presence of mental health treatment, substance use, or psychiatric diagnostic history was neither mentioned nor controlled for. (Jackson 2023 at 11.)

Moreover, although some of the preliminary analyses that did not account for other variables at the same time (i.e., univariate analyses) suggested the possibility of statistical significance, they were not significant when the other variables were included at the same time:

> Suicidal ideation within the past year did not reach statistical significance. Lifetime suicide attempts did not reach statistical significance depending on receipt of blockers in univariate analyses and thus were not assessed with multivariate analysis. (Jackson 2023 at 11.)

93. The Jackson (2023) identification of shortcomings correspond and confirm those previously reported by Biggs (2020):

> With multivariate analysis, only one of these nine measures yielded a statistically significant association (at 2227.).
>
> Psychological problems are, therefore, a confounding factor that will create a spurious association between suicidality and treatment (at 2228.).

In sum, it is not possible to conclude from Turban et al. (2020) that puberty-blockers caused improvement, for reasons including inadequate statistical analysis and that uncontrolled (confounding) factors could also explain the suicidality patterns observed.

94. Subsequent to my previous report, Dr. Turban's lack of understanding of the procedures and principles of the systematic review process and of evidence-based medicine has been documented in the public record. Dr. Turban served as an expert witness for the plaintiffs in *Poe et al v Drummond et al*. (Oklahoma, Northern District, Case No. 23-cv-00177-JFH-SH).[7] In his rebuttal declaration in that case, dated July 7, 2023, Dr. Turban told the court:

> Defendants' experts attempt to misleadingly bolster the importance of these reports from select European countries by calling them "systematic reviews." But all a "systematic review" means is that the authors of the reports pre-defined the search terms they used when conducting literature reviews in various databases.[2] (Turban Rebuttal Declaration at 2.)

Dr. Turban is mistaken, however, having omitted critical components of a systematic review. As the Harvard website cited by Turban (in his footnote 2 to the above quote) states, a systematic review is not defined merely by disclosing search terms used to find relevant studies, but also in (a) application of "standardized, systematic methods and pre-selected eligibility criteria reduce the risk of bias in identifying, selecting and analyzing relevant studies," an then conducting "an assessment of the validity or risk of bias of each included study," and finally "a systematic synthesis, analysis and presentation of the findings of the included studies."[8]

[7] I was engaged as an expert witness for the Defendants in that case.
[8] Harvard Countway Library. Systematic Reviews and Meta Analysis Q&A. Accessed: July 6, 2023. Available at: https://guides.library.harvard.edu/meta-analysis/GettingStarted.

95. Any accurate description of the concept of a systematic review within the discipline of evidence-based medicine would include at least these criteria. Dr. Turban, however, appears ignorant of the importance both of evaluating "the validity or risk of bias" of each study, and "a systematic . . . analysis . . . of the findings" of each study. The description of the core components of a systematic review given by the source cited by Dr. Turban does, however, correspond very closely to the one I provided in my prior report. (Cantor Report ¶¶ 40, 41.)

VII. WPATH extensively violated international conflict of interest standards in the course of developing SOC-8, while claiming to comply with them.

96. In my previous report, I provided extensive analysis and opinion on WPATH that included its review of safety and effectiveness in establishing clinical guidelines (Cantor Report, Section VI.B.), its assessment of the research gaps in the area (Cantor Report, Section XII.D.), and an assessment of its published standards (Cantor Report, Section XVI.B.). Further analysis reveals that WPATH was possessed of extensive conflicts of interest throughout the production of Version 8 of its Standards of Care (SOC-8), while making false representations that it was complying with accepted conflict of interest principles for that process.

97. For reference, the following assessment refers to these documents:

Sharma et al. (2018).
: WPATH's pre-registration in the PROSPERO database of the systematic review it planned, identifying each of the specific research questions it would examine.

Baker et al. (2021).
: WPATH's systematic review of studies on the mental health of hormone therapy on transgender people, three of which were on minors.

WPATH (2022) aka Coleman et al. (2022).
: WPATH's completed *Standards of Care*, version 8 (SOC-8).

WHO (2019) aka WHO (2019a).
: The *International Classification of Diseases*, version 11 (ICD-11) of the World Health Organization.

WHO (2014).

> The *WHO Handbook for Guideline Development* (2nd edition) of the World Health Organization. Chapter 6 pertains to the management of conflicts of interest. Chapter 14 pertains to the issuing of strong recommendations on the basis of low quality evidence.

IoM (2011).

> Institute of Medicine. (2011). *Clinical Practice Guidelines We Can Trust.* Washington, DC: The National Academies Press.

98. SOC-8 indicates its guideline development methods in its appendix, on page S247:[9]

> 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 that addressed transparency, the conflict-of-interest policy, committee composition and group process. (Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice, 2011; World Health Organization, 2019a).

An attempt to verify the claim of reliance on those documents leads to dead ends, however.

99. The entry in WPATH's reference list for WHO (2019a) is to:

> World Health Organization. (2019a). *International Statistical Classification of Diseases and Related Health Problems (11th ed.).* World Health Organization. https://icd.who.int/browse11/lm/en#/http://id.who.int/icd/entity/90875286" (SOC-8 at p. S244.)

That document, however (the ICD-11, WHO 2019a), is not a methods manual at all. It does not provide procedures for developing clinical guidelines, for conflict of interest or any other issue.

100. The other document that WPATH cited as its source, "IoM (2011)," does not appear on WPATH's reference list at all, but it appears to refer to the Institute of Medicine's *Clinical Practice Guidelines We Can Trust* (2011). The actual WHO manual for clinical guidelines development is WHO (2014), the *WHO Handbook for Guideline Development,* referenced as above. This handbook is missing altogether from WPATH's reference list.

[9] SOC-8 also indicates its methods on page S8 providing the text below, with no citation, and noting that "SOC-8 incorporated *the* recommendations" (emphasis added) rather than "SOC-8 incorporated recommendations."

> "The process for development of the SOC-8 incorporated the recommendations on clinical practice guideline development set forth by the National Academies of Medicine and the World Health Organization, which addressed transparency, conflict-of-interest policy, committee composition, and group process."

101. Both IoM (2011) and WHO (2014)[10] provide conflict of interest guidelines, and they detail procedures that WPATH clearly violated: WPATH's SOC-8 were produced entirely by an association and a group of individuals whom both sets of international standards instruct should be excluded or whose role and influence should be strongly limited.

A. WPATH itself suffers a strong "associational conflict of interest" in producing clinical practice guidelines for treatment of gender dysphoria.

102. IoM (2011) and WHO (2014) describe and seek to prevent conflicts of interest pertaining both to individuals developing clinical practice guidelines (CPGs) *and* to the professional associations of those individuals. On the associational level, the international standard (as indicated by the very sources upon which WPATH claimed to have relied) is for such assessments to be conducted by experts at arm's length from those services—sufficiently familiar with topic but *not* professionally engaged in performing the clinical practices under review. IoM (2011) notes:

> Many guidelines developed by medical societies and other private organizations are self-funded, through membership dues, donations, or other means. CPGs funded by medical societies dependent on membership dues may be cause for concern regarding conflict of interest if their recommendations would likely affect their members' income. (IoM 2011 at 47.)

103. This conflict of interest is strongly present in the case of WPATH and its development of SOC-8. WPATH's financial well-being depends upon the number of its dues-paying members which, in turn, depends upon WPATH acting in its members' financial interests: The more people who undergo transition, the greater the market available to WPATH's dues-paying members.

104. Additionally, it is strongly in the financial interest of WPATH members, and thus of

[10] Even though WPATH does not cite WHO (2014), for the purposes of this supplemental report I reference this document as it is the relevant, and current, World Health Organization guidance on conflict of interest.

WPATH, that medicalized transition be deemed eligible for medical insurance as broadly as possible. For example, because medical insurance does not cover "experimental" treatments, WPATH's claims that medicalized transition of minors is *not* experimental represents a very direct conflict between expanding its members' potential market and protecting minors from undergoing experimental treatments unknowingly.

105. This association-level conflict of interest pertains not only to WPATH, but also to the other associations producing guidelines in the U.S., including the Endocrine Society and the American Academy of Pediatrics (AAP) — organizations whose policy I assessed in my initial report (Cantor Report, Sections VI & XVI.). By contrast, examples of health care authorities that are not afflicted with a conflict between the interests of service providers and the interests of patients are the national health care systems, such as those of England, Sweden, and Finland. (Examined in Cantor Report, Sections II & V.) Because their health care systems are *publicly* funded, they are not susceptible to the same association-level conflicts.

106. In direct opposition with IoM's caution to *avoid* association-level conflict of interest, WPATH essentially *required* this conflict, making membership in WPATH a requirement for appointment of professionals to the guideline development team:

> Except for the Chair (Eli Coleman) who was appointed by the WPATH board to maintain a continuity from previous SOC editions, members of the Guideline Steering Committee were selected by the WPATH Board *from WPATH members* applying for these positions…Chapter Leads and Members were *required to be WPATH Full Members* in good standing. . . .[11] (SOC-8 at S248, emphasis added.)

B. WPATH did not screen for or disclose the personal financial and intellectual conflicts of interest of those who participated in developing SOC-8.

107. With respect to individuals who participate in creating a clinical guideline, IoM

[11] Only members of the public, such as parents of gender dysphoric children participating as "stakeholders," were not required to be WPATH members.

(2011) and WHO (2014) emphasize the importance of avoiding both *financial* conflicts of interest (direct and indirect), and *intellectual* conflicts of interest. These documents corroborate and detail the accepted methods to avoid conflict of interest and ensure objective assessment of any particular topic. These widely accepted principles and methods match the summary I set out in my initial report (Cantor Report, Section I.C.). Most importantly, these respected documents agree that the experts best equipped for assessing clinical practice guidelines are *not* the people whose livelihood, prestige, and/or ideological commitments are tied to providing the clinical services under review. Such people have both financial and professional incentives and thus a natural bias towards declaring their services to be effective and safe. IoM (2011) cites peer-reviewed studies that document the real-world effect of this conflict of interest can have:

> Hutchings [& Raine (2006)] identified 22 studies examining the impact of individual participant specialty or profession. Overall, the authors observed that those who performed a procedure, versus those who did not, were more likely to rate more indications as appropriate for that procedure. […] Murphy and colleagues (1998) offer other relevant findings in a systematic review in which they compared guideline recommendations produced by groups of varying composition. The authors concluded that differences in group composition may lead to contrasting recommendations; more specifically, members of a clinical specialty are more likely to promote interventions in which their specialty plays a part. (IoM 2011 at 84.)

108. Instead of complying with recognized conflict of interest principles, WPATH gathered a team of individuals all or most of whom stood to benefit financially from expanding the number of youth approved to obtain medical transition services and expanding the availability of insurance to cover such services; neglected to assess or disclose direct financial benefits to those individuals; publicly (but falsely) declared that none of these individuals had any conflict of interest; claimed it followed established procedures to limit conflicts of interest that it did not follow; excluded the sources of its procedures from its references; and redacted critical information relevant to these conflicts from the documentation it supplied to the present

proceedings under subpoena (in particular, the names of those who advocated for various positions during the process).

109. The team of individuals whom WPATH gathered did not represent the range of opinions among topic experts and did not reflect the diversity of relevant stakeholders. On the contrary, WPATH limited membership on its team to individuals who paid dues to WPATH and excluded from participation any professional with a point of view which would have kept such a professional from joining WPATH. As a result, WPATH's process excluded the input of detransitioners, as well as of the practitioners, researchers, and prominent voices within European health authorities who are expressing scepticism and concern about performing medical transition procedures on minors.

110. Instead, the committee consisted of individuals whose academic and scholarly standing stood to benefit from WPATH's product. As I detail below, the WPATH procedure consisted of exactly the biased and one-sided methods that the IoM and WHO procedures are designed to prevent.

1. WPATH disregarded and failed to disclose extensive direct *financial* conflicts of interest.

111. As noted, both IoM (2011) and WHO (2014) indicate that receiving income from providing the clinical practices being evaluated by the guidelines represents a direct financial conflict of interest. The WPATH policy and disclosure forms, however, did not actually ask participants to disclose (and therefore WPATH did not disclose to the public) participants' *direct* financial interests and thus conflicts of interest. Instead, WPATH asked only about the rare and relatively minor instances of *indirect* financial conflicts of interest.

112. WHO (2014) describes financial conflicts of interest as:

> A financial conflict of interest arises when an individual or organization receives income or monetary support that is related to, or could be affected by, the outcome of the WHO meeting or activity in which they are involved….Financial interests include, for example: *personal financial gain such as paid work,* consulting income or honoraria and travel stipends. . . . (WHO 2014 at 63, emphasis added.)

IoM (2011) provides similar language, dividing financial conflicts of interest into direct, commercial conflicts and non-commercial conflicts:

> Direct financial commercial activities include *clinical services from which a committee member derives a substantial proportion of his or her income;* consulting; board membership for which compensation of any type is received. . . (IoM 2011 at 79, emphasis added.)

and

> Examples of noncommercial financial activities include research grants and other types of support from governments, foundations, or other nonprofit organizations. (IoM 2011 at 79.)

Physicians and therapists in private practice or clinics treating people with gender dysphoria very clearly meet these criteria.

113. Despite ignoring the very clear and explicit indications from both IoM (2011) and WHO (2014) as to what constitutes conflicts of interest, WPATH declared to the public in SOC-8:

> Conflict of interests were reviewed as part of the selection process for committee members and at the end of the process before publication. No conflicts of interest were deemed significant or consequential. (SOC-8 at 177.)

Contrary to this public representation, most or all WPATH committee members possess conflicts of interest that WPATH denied.

114. Widely accepted conflict of interest guidelines recognize that the clinical experiences of individuals who receive income from pertinent clinical activities can have information helpful to guideline developers—indeed the IoM and WHO procedures permit such individuals to function as consultants or stakeholders rather than bar them altogether from participation.

WPATH did not use such methods for managing conflicts of interest, however. Instead, WPATH simply denied such conflicts existed.

115. The importance of the contradiction between WPATH's failure to inquire about and prevent direct financial conflict of interest on the one hand, and what it assured the public on the other, cannot be exaggerated: The guidelines it published contained a list of what it claimed to have been improvements over prior guidelines, explicitly naming management of conflict of interest as such an improvement, noting:

> The main differences in the methodology of the SOC-8 when compared with other versions of the SOC are: […] Management of *conflicts of interest.* (SOC-8 at S247, emphasis added.)

2. WPATH disregarded and failed to disclose extensive *intellectual* conflicts of interest.

116. WHO (2014) defines intellectual conflicts of interest as roles or positions that might interfere with the objective assessment of a body of evidence, providing the following as examples:

- *prior publication of a study or systematic review* that is part of the evidence base under consideration in the guideline;
- prior *public declaration of a firm opinion or position*, as in public testimony during a regulatory or judicial process, or in an editorial in a journal; or
- professional or personal affiliation with an organization advocating for products or services related to the subject of the guideline. (WHO 2014 at 63.)

WHO (2014) also emphasizes that:

> The GDG [guideline development group] should be composed of individuals with diverse perspectives, training and experiences to keep the recommendations from reflecting a single viewpoint that was conceived before examining and discussing the systematic review of the evidence. (WHO 2014 at 71.)

IoM (2011) similarly defines intellectual conflicts of interest:

> A person whose work or professional group fundamentally is jeopardized, or enhanced, by a guideline recommendation is said to have intellectual COI.

> Intellectual COI includes authoring a publication or acting as an investigator on a peer-reviewed grant directly related to recommendations under consideration. (IoM 2011 at 79.)

Adopting language offered by Dr. Gordon Guyatt et al., this includes "academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation." (Guyatt et al. 2010 at 739.)

117. The importance of appropriate handling of conflicts of interest is not limited to influences on actual decision making. The IoM emphasizes also that "Regardless of the nature of COI or its effects on guideline development, perception of bias undermines guideline users' confidence in guideline trustworthiness as well as public trust in science" (IoM 2011 at 79.)

118. The publicly available list of authors of SOC-8 nonetheless reveals individuals well-known for their many "public declarations," prior publications stating "firm opinions or positions" favoring what they label "gender affirming care," belittling potential risks and harms, and for their strongly expressed political views.

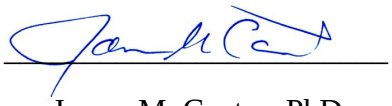
119. Moreover, WPATH itself as an organization has engaged in stridently worded political advocacy and endorsement of specific interpretations of research literature,[12] including its urging that the services its members provide should be eligible for health care insurance coverage, which its members would then receive as income. Thus, WPATH itself and all of its members are necessarily affected by what WHO (2014) identifies as an intellectual conflict of interest resulting from "professional or personal affiliation with an organization advocating for . . . services related to the subject of the guideline."

120. Again, conflict of interest guidelines do recognize that topic experts who receive income from pertinent clinical activities can have valuable information for guidelines developers,

[12] See, for example, the press releases and political advocacy documents posted at https://www.wpath.org/policies, WPATH/USPATH Public Statements (last accessed February 2, 2024).

and the recommendations allow for such individuals to function as consultants or stakeholders, rather than bar them altogether from participation. WPATH did not, however, practice methods for managing conflicts of interest. Instead, WPATH simply denied that such conflicts existed and provided no supervision, tracking, or management of undue influence.

Dated: February 2, 2024



James M. Cantor, PhD

APPENDIX A: CONFIDENTIAL

APPENDIX B: References

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Other Materials

Documents produced by WPATH under subpoena (BOEAL_WPATH_000001 to BOEAL_WPATH_101726), in particular the documents identified by production number in this supplemental report.

Plaintiffs' and Defendants' expert reports in this case, in particular those reports identified in this supplemental report.

The rebuttal declaration of Dr. Jack Turban, dated July 7, 2023, in the case of *Poe et al v Drummond et al*. (Oklahoma, Northern District, Case No. 23-cv-00177-JFH-SH).

X (formerly Twitter) post of Gordon H. Guyatt (@GuyattGH), https://twitter.com/GuyattGH/status/1641183448063967233?s=20 (last visited February 1, 2024).

X (formerly Twitter) post of Colin Wright (@SwipeWright) https://twitter.com/SwipeWright/status/1571999221401948161?s=20&t=ouHIObZhEllVU-QR9tZYiQ (last visited February 2, 2024).

WPATH/USPATH Public Statements, available at https://www.wpath.org/policies

APPENDIX C: Curriculum Vitae

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Toronto, Ontario, Canada M5B 1J3

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EDUCATION

Postdoctoral Fellowship Jan., 2000–May, 2004
Centre for Addiction and Mental Health • Toronto, Canada

Doctor of Philosophy Sep., 1993–Jun., 2000
Psychology • McGill University • Montréal, Canada

Master of Arts Sep., 1990–Jan., 1992
Psychology • Boston University • Boston, MA

Bachelor of Science Sep. 1984–Aug., 1988
Interdisciplinary Science • Rensselaer Polytechnic Institute • Troy, NY
Concentrations: Computer science, mathematics, physics

EMPLOYMENT HISTORY

Director Feb., 2017–Present
Toronto Sexuality Centre • Toronto, Canada

Senior Scientist (Inaugural Member) Aug., 2012–May, 2018
Campbell Family Mental Health Research Institute
Centre for Addiction and Mental Health • Toronto, Canada

Senior Scientist Jan., 2012–May, 2018
Complex Mental Illness Program
Centre for Addiction and Mental Health • Toronto, Canada

Head of Research Nov., 2010–Apr. 2014
Sexual Behaviours Clinic
Centre for Addiction and Mental Health • Toronto, Canada

Research Section Head Dec., 2009–Sep. 2012
Law & Mental Health Program
Centre for Addiction and Mental Health • Toronto, Canada

Psychologist May, 2004–Dec., 2011
Law & Mental Health Program
Centre for Addiction and Mental Health • Toronto, Canada

Clinical Psychology Intern Sep., 1998–Aug., 1999
Centre for Addiction and Mental Health • Toronto, Canada

Teaching Assistant Sep., 1993–May, 1998
Department of Psychology
McGill University • Montréal, Canada

Pre-Doctoral Practicum Sep., 1993–Jun., 1997
Sex and Couples Therapy Unit
Royal Victoria Hospital • Montréal, Canada

Pre-Doctoral Practicum May, 1994–Dec., 1994
Department of Psychiatry
Queen Elizabeth Hospital • Montréal, Canada

ACADEMIC APPOINTMENTS

Associate Professor Jul., 2010–May, 2019
Department of Psychiatry
University of Toronto Faculty of Medicine • Toronto, Canada

Adjunct Faculty Aug. 2013–Jun., 2018
Graduate Program in Psychology
York University • Toronto, Canada

Associate Faculty (Hon) Oct., 2017–Dec., 2017
School of Behavioural, Cognitive & Social Science
University of New England • Armidale, Australia

Assistant Professor Jun., 2005–Jun., 2010
Department of Psychiatry
University of Toronto Faculty of Medicine • Toronto, Canada

Adjunct Faculty Sep., 2004–Jun., 2010
Clinical Psychology Residency Program
St. Joseph's Healthcare • Hamilton, Canada

PUBLICATIONS

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24. Cantor, J. M., Lafaille, S., Soh, D. W., Moayedi, M., Mikulis, D. J., & Girard, T. A. (2015). Diffusion Tensor Imaging of pedophilia. *Archives of Sexual Behavior, 44,* 2161–2172. doi: 10.1007/s10508-015-0599-9
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65. Pilkington, N. W., & Cantor, J. M. (1996). Perceptions of heterosexual bias in professional psychology programs: A survey of graduate students. *Professional Psychology: Research and Practice*, *27*, 604–612.

PUBLICATIONS

LETTERS AND COMMENTARIES

1. Cantor, J. M. (2015). Research methods, statistical analysis, and the phallometric test for hebephilia: Response to Fedoroff [Editorial Commentary]. *Journal of Sexual Medicine, 12,* 2499–2500. doi: 10.1111/jsm.13040
2. Cantor, J. M. (2015). In his own words: Response to Moser [Editorial Commentary]. *Journal of Sexual Medicine, 12,* 2502–2503. doi: 10.1111/jsm.13075
3. Cantor, J. M. (2015). Purported changes in pedophilia as statistical artefacts: Comment on Müller et al. (2014). *Archives of Sexual Behavior, 44,* 253–254. doi: 10.1007/s10508-014-0343-x
4. McPhail, I. V., & Cantor, J. M. (2015). Pedophilia, height, and the magnitude of the association: A research note. *Deviant Behavior, 36,* 288–292. doi: 10.1080/01639625.2014.935644
5. Soh, D. W., & Cantor, J. M. (2015). A peek inside a furry convention [Letter to the Editor]. *Archives of Sexual Behavior, 44,* 1–2. doi: 10.1007/s10508-014-0423-y
6. Cantor, J. M. (2012). Reply to Italiano's (2012) comment on Cantor (2011) [Letter to the Editor]. *Archives of Sexual Behavior, 41,* 1081–1082. doi: 10.1007/s10508-012-0011-y
7. Cantor, J. M. (2012). The errors of Karen Franklin's *Pretextuality* [Commentary]. *International Journal of Forensic Mental Health, 11,* 59–62. doi: 10.1080/14999013.2012.672945
8. Cantor, J. M., & Blanchard, R. (2012). White matter volumes in pedophiles, hebephiles, and teleiophiles [Letter to the Editor]. *Archives of Sexual Behavior, 41, 749–752.* doi: 10.1007/s10508-012-9954-2
9. Cantor, J. M. (2011). New MRI studies support the Blanchard typology of male-to-female transsexualism [Letter to the Editor]. *Archives of Sexual Behavior, 40*, 863–864. doi: 10.1007/s10508-011-9805-6
10. Zucker, K. J., Bradley, S. J., Own-Anderson, A., Kibblewhite, S. J., & Cantor, J. M. (2008). Is gender identity disorder in adolescents coming out of the closet? *Journal of Sex and Marital Therapy, 34,* 287–290.
11. Cantor, J. M. (2003, Summer). Review of the book *The Man Who Would Be Queen* by J. Michael Bailey. *Newsletter of Division 44 of the American Psychological Association, 19*(2), 6.
12. Cantor, J. M. (2003, Spring). What are the hot topics in LGBT research in psychology? *Newsletter of Division 44 of the American Psychological Association, 19*(1), 21–24.
13. Cantor, J. M. (2002, Fall). Male homosexuality, science, and pedophilia. *Newsletter of Division 44 of the American Psychological Association, 18*(3), 5–8.
14. Cantor, J. M. (2000). Review of the book *Sexual Addiction: An Integrated Approach. Journal of Sex and Marital Therapy, 26*, 107–109.

EDITORIALS

1. Cantor, J. M. (2012). Editorial. *Sexual Abuse: A Journal of Research and Treatment, 24*.

2. Cantor, J. M. (2011). Editorial note. *Sexual Abuse: A Journal of Research and Treatment, 23,* 414.
3. Barbaree, H. E., & Cantor, J. M. (2010). Performance indicates for *Sexual Abuse: A Journal of Research and Treatment* (SAJRT) [Editorial]. *Sexual Abuse: A Journal of Research and Treatment, 22,* 371–373.
4. Barbaree, H. E., & Cantor, J. M. (2009). *Sexual Abuse: A Journal of Research and Treatment* performance indicators for 2007 [Editorial]. *Sexual Abuse: A Journal of Research and Treatment, 21,* 3–5.
5. Zucker, K. J., & Cantor, J. M. (2009). Cruising: Impact factor data [Editorial]. *Archives of Sexual Research, 38,* 878–882.
6. Barbaree, H. E., & Cantor, J. M. (2008). Performance indicators for *Sexual Abuse: A Journal of Research and Treatment* [Editorial]. *Sexual Abuse: A Journal of Research and Treatment, 20,* 3–4.
7. Zucker, K. J., & Cantor, J. M. (2008). The *Archives* in the era of online first ahead of print[Editorial]. *Archives of Sexual Behavior, 37,* 512–516.
8. Zucker, K. J., & Cantor, J. M. (2006). The impact factor: The *Archives* breaks from the pack [Editorial]. *Archives of Sexual Behavior, 35,* 7–9.
9. Zucker, K. J., & Cantor, J. M. (2005). The impact factor: "Goin' up" [Editorial]. *Archives of Sexual Behavior, 34,* 7–9.
10. Zucker, K., & Cantor, J. M. (2003). The numbers game: The impact factor and all that jazz [Editorial]. *Archives of Sexual Behavior, 32,* 3–5.

FUNDING HISTORY

Principal Investigators:	Doug VanderLaan, Meng-Chuan Lai
Co-Investigators:	James M. Cantor, Megha Mallar Chakravarty, Nancy Lobaugh, M. Palmert, M. Skorska
Title:	*Brain function and connectomics following sex hormone treatment in adolescents experience gender dysphoria*
Agency:	Canadian Institutes of Health Research (CIHR), Behavioural Sciences-B-2
Funds:	$650,250 / 5 years (July, 2018)
Principal Investigator:	Michael C. Seto
Co-Investigators:	Martin Lalumière , James M. Cantor
Title:	*Are connectivity differences unique to pedophilia?*
Agency:	University Medical Research Fund, Royal Ottawa Hospital
Funds:	$50,000 / 1 year (January, 2018)
Principal Investigator:	Lori Brotto
Co-Investigators:	Anthony Bogaert, James M. Cantor, Gerulf Rieger
Title:	*Investigations into the neural underpinnings and biological correlates of asexuality*
Agency:	Natural Sciences and Engineering Research Council (NSERC), Discovery Grants Program
Funds:	$195,000 / 5 years (April, 2017)
Principal Investigator:	Doug VanderLaan
Co-Investigators:	Jerald Bain, James M. Cantor, Megha Mallar Chakravarty, Sofia Chavez, Nancy Lobaugh, and Kenneth J. Zucker
Title:	*Effects of sex hormone treatment on brain development: A magnetic resonance imaging study of adolescents with gender dysphoria*
Agency:	Canadian Institutes of Health Research (CIHR), Transitional Open Grant Program
Funds:	$952,955 / 5 years (September, 2015)
Principal Investigator:	James M. Cantor
Co-Investigators:	Howard E. Barbaree, Ray Blanchard, Robert Dickey, Todd A. Girard, Phillip E. Klassen, and David J. Mikulis
Title:	*Neuroanatomic features specific to pedophilia*
Agency:	Canadian Institutes of Health Research (CIHR)
Funds:	$1,071,920 / 5 years (October, 2008)
Principal Investigator:	James M. Cantor
Title:	*A preliminary study of fMRI as a diagnostic test of pedophilia*
Agency:	Dean of Medicine New Faculty Grant Competition, Univ. of Toronto
Funds:	$10,000 (July, 2008)

Principal Investigator:	James M. Cantor
Co-Investigator:	Ray Blanchard
Title:	*Morphological and neuropsychological correlates of pedophilia*
Agency:	Canadian Institutes of Health Research (CIHR)
Funds:	$196,902 / 3 years (April, 2006)

KEYNOTE AND INVITED ADDRESSES

1. Cantor, J. M. (2022, December 5). The science of gender dysphoria and transgenderism. Lund University, Latvia. https://files.fm/f/4bzznufvb
2. Cantor, J. M. (2021, September 28). *No topic too tough for this expert panel: A year in review.* Plenary Session for the 40th Annual Research and Treatment Conference, Association for the Treatment of Sexual Abusers.
3. Cantor, J. M. (2019, May 1). *Introduction and Q&A for 'I, Pedophile.'* StopSO 2nd Annual Conference, London, UK.
4. Cantor, J. M. (2018, August 29). *Neurobiology of pedophilia or paraphilia? Towards a 'Grand Unified Theory' of sexual interests.* Keynote address to the International Association for the Treatment of Sexual Offenders, Vilnius, Lithuania.
5. Cantor, J. M. (2018, August 29). *Pedophilia and the brain: Three questions asked and answered.* Preconference training presented to the International Association for the Treatment of Sexual Offenders, Vilnius, Lithuania.
6. Cantor, J. M. (2018, April 13). *The responses to* I, Pedophile *from We, the people.* Keynote address to the Minnesota Association for the Treatment of Sexual Abusers, Minneapolis, Minnesota.
7. Cantor, J. M. (2018, April 11). *Studying atypical sexualities: From vanilla to* I, Pedophile. Full day workshop at the Minnesota Association for the Treatment of Sexual Abusers, Minneapolis, Minnesota.
8. Cantor, J. M. (2018, January 20). *How much sex is enough for a happy life?* Invited lecture to the University of Toronto Division of Urology Men's Health Summit, Toronto, Canada.
9. Cantor, J. M. (2017, November 2). Pedophilia as a phenomenon of the brain: Update of evidence and the public response. Invited presentation to the 7th annual SBC education event, Centre for Addiction and Mental Health, Toronto, Canada.
10. Cantor, J. M. (2017, June 9). Pedophilia being in the brain: The evidence and the public's reaction. Invited presentation to *SEXposium at the ROM: The science of love and sex,* Toronto, Canada.
11. Cantor, J. M., & Campea, M. (2017, April 20). *"I, Pedophile" showing and discussion.* Invited presentation to the 42nd annual meeting of the Society for Sex Therapy and Research, Montréal, Canada.
12. Cantor, J. M. (2017, March 1). *Functional and structural neuroimaging of pedophilia: Consistencies across methods and modalities.* Invited lecture to the Brain Imaging Centre, Royal Ottawa Hospital, Ottawa, Canada.
13. Cantor, J. M. (2017, January 26). *Pedophilia being in the brain: The evidence and the public reaction.* Inaugural keynote address to the University of Toronto Sexuality Interest Network, Toronto, Ontario, Canada.
14. Cantor, J. M. (2016, October 14). *Discussion of CBC's "I, Pedophile."* Office of the Children's Lawyer Educational Session, Toronto, Ontario, Canada.
15. Cantor, J. M. (2016, September 15). *Evaluating the risk to reoffend: What we know and what we don't.* Invited lecture to the Association of Ontario Judges, Ontario Court of Justice Annual Family Law Program, Blue Mountains, Ontario, Canada. [Private link only: https://vimeo.com/239131108/3387c80652]
16. Cantor, J. M. (2016, April 8). *Pedophilia and the brain: Conclusions from the second*

generation of research. Invited lecture at the 10th annual Risk and Recovery Forensic Conference, Hamilton, Ontario.

17. Cantor, J. M. (2016, April 7). *Hypersexuality without the hyperbole.* Keynote address to the 10th annual Risk and Recovery Forensic Conference, Hamilton, Ontario.
18. Cantor, J. M. (2015, November). *No one asks to be sexually attracted to children: Living in Daniel's World.* Grand Rounds, Centre for Addiction and Mental Health. Toronto, Canada.
19. Cantor, J. M. (2015, August). *Hypersexuality: Getting past whether "it" is or "it" isn't.* Invited address at the 41st annual meeting of the International Academy of Sex Research. Toronto, Canada.
20. Cantor, J. M. (2015, July). *A unified theory of typical and atypical sexual interest in men: Paraphilia, hypersexuality, asexuality, and vanilla as outcomes of a single, dual opponent process.* Invited presentation to the 2015 Puzzles of Sexual Orientation conference, Lethbridge, AL, Canada.
21. Cantor, J. M. (2015, June). *Hypersexuality.* Keynote Address to the Ontario Problem Gambling Provincial Forum. Toronto, Canada.
22. Cantor, J. M. (2015, May). *Assessment of pedophilia: Past, present, future.* Keynote Address to the International Symposium on Neural Mechanisms Underlying Pedophilia and Child Sexual Abuse (NeMUP). Berlin, Germany.
23. Cantor, J. M. (2015, March). *Prevention of sexual abuse by tackling the biggest stigma of them all: Making sex therapy available to pedophiles.* Keynote address to the 40th annual meeting of the Society for Sex Therapy and Research, Boston, MA.
24. Cantor, J. M. (2015, March. *Pedophilia: Predisposition or perversion?* Panel discussion at Columbia University School of Journalism. New York, NY.
25. Cantor, J. M. (2015, February). *Hypersexuality.* Research Day Grand Rounds presentation to Ontario Shores Centre for Mental Health Sciences, Whitby, Ontario, Canada.
26. Cantor, J. M. (2015, January). *Brain research and pedophilia: What it means for assessment, research, and policy.* Keynote address to the inaugural meeting of the Netherlands Association for the Treatment of Sexual Abusers, Utrecht, Netherlands.
27. Cantor, J. M. (2014, December). *Understanding pedophilia and the brain: Implications for safety and society.* Keynote address for The Jewish Community Confronts Violence and Abuse: Crisis Centre for Religious Women, Jerusalem, Israel.
28. Cantor, J. M. (2014, October). *Understanding pedophilia & the brain.* Invited full-day workshop for the Sex Offender Assessment Board of Pennsylvania, Harrisburg, PA.
29. Cantor, J. M. (2014, September). *Understanding neuroimaging of pedophilia: Current status and implications.* Invited lecture presented to the Mental Health and Addition Rounds, St. Joseph's Healthcare, Hamilton, Ontario, Canada.
30. Cantor, J. M. (2014, June). *An evening with Dr. James Cantor.* Invited lecture presented to the Ontario Medical Association, District 11 Doctors' Lounge Program, Toronto, Ontario, Canada.
31. Cantor, J. M. (2014, April). *Pedophilia and the brain.* Invited lecture presented to the University of Toronto Medical Students lunchtime lecture. Toronto, Ontario, Canada.
32. Cantor, J. M. (2014, February). *Pedophilia and the brain: Recap and update.* Workshop presented at the 2014 annual meeting of the Washington State Association for the Treatment of Sexual Abusers, Cle Elum, WA.

33. Cantor, J. M., Lafaille, S., Hannah, J., Kucyi, A., Soh, D., Girard, T. A., & Mikulis, D. M. (2014, February). *Functional connectivity in pedophilia.* Neuropsychiatry Rounds, Toronto Western Hospital, Toronto, Ontario, Canada.
34. Cantor, J. M. (2013, November). *Understanding pedophilia and the brain: The basics, the current status, and their implications.* Invited lecture to the Forensic Psychology Research Centre, Carleton University, Ottawa, Canada.
35. Cantor, J. M. (2013, November). *Mistaking puberty, mistaking hebephilia.* Keynote address presented to the 32nd annual meeting of the Association for the Treatment of Sexual Abusers, Chicago, IL.
36. Cantor, J. M. (2013, October). *Understanding pedophilia and the brain: A recap and update.* Invited workshop presented at the 32nd annual meeting of the Association for the Treatment of Sexual Abusers, Chicago, IL.
37. Cantor, J. M. (2013, October). *Compulsive-hyper-sex-addiction: I don't care what we all it, what can we* do*?* Invited address presented to the Board of Examiners of Sex Therapists and Counselors of Ontario, Toronto, Ontario, Canada.
38. Cantor, J. M. (2013, September). *Neuroimaging of pedophilia: Current status and implications.* McGill University Health Centre, Department of Psychiatry Grand Rounds presentation, Montréal, Québec, Canada.
39. Cantor, J. M. (2013, April). *Understanding pedophilia and the brain.* Invited workshop presented at the 2013 meeting of the Minnesota Association for the Treatment of Sexual Abusers, Minneapolis, MN.
40. Cantor, J. M. (2013, April). *The neurobiology of pedophilia and its implications for assessment, treatment, and public policy.* Invited lecture at the 38th annual meeting of the Society for Sex Therapy and Research, Baltimore, MD.
41. Cantor, J. M. (2013, April). *Sex offenders: Relating research to policy.* Invited roundtable presentation at the annual meeting of the Academy of Criminal Justice Sciences, Dallas, TX.
42. Cantor, J. M. (2013, March). *Pedophilia and brain research: From the basics to the state-of-the-art.* Invited workshop presented to the annual meeting of the Forensic Mental Health Association of California, Monterey, CA.
43. Cantor, J. M. (2013, January). *Pedophilia and child molestation.* Invited lecture presented to the Canadian Border Services Agency, Toronto, Ontario, Canada.
44. Cantor, J. M. (2012, November). *Understanding pedophilia and sexual offenders against children: Neuroimaging and its implications for public safety.* Invited guest lecture to University of New Mexico School of Medicine Health Sciences Center, Albuquerque, NM.
45. Cantor, J. M. (2012, November). *Pedophilia and brain research.* Invited guest lecture to the annual meeting of the Circles of Support and Accountability, Toronto, Ontario, Canada.
46. Cantor, J. M. (2012, January). *Current findings on pedophilia brain research.* Invited workshop at the San Diego International Conference on Child and Family Maltreatment, San Diego, CA.
47. Cantor, J. M. (2012, January). *Pedophilia and the risk to re-offend.* Invited lecture to the Ontario Court of Justice Judicial Development Institute, Toronto, Ontario, Canada.
48. Cantor, J. M. (2011, November). *Pedophilia and the brain: What it means for assessment, treatment, and policy.* Plenary Lecture presented at the Association for the Treatment of Sexual Abusers, Toronto, Ontario, Canada.

49. Cantor, J. M. (2011, July). *Towards understanding contradictory findings in the neuroimaging of pedophilic men.* Keynote address to 7th annual conference on Research in Forensic Psychiatry, Regensberg, Germany.
50. Cantor, J. M. (2011, March). *Understanding sexual offending and the brain: Brain basics to the state of the art.* Workshop presented at the winter conference of the Oregon Association for the Treatment of Sexual Abusers, Oregon City, OR.
51. Cantor, J. M. (2010, October). *Manuscript publishing for students.* Workshop presented at the 29th annual meeting of the Association for the Treatment of Sexual Abusers, Phoenix, AZ.
52. Cantor, J. M. (2010, August). *Is sexual orientation a paraphilia?* Invited lecture at the International Behavioral Development Symposium, Lethbridge, Alberta, Canada.
53. Cantor, J. M. (2010, March). *Understanding sexual offending and the brain: From the basics to the state of the art.* Workshop presented at the annual meeting of the Washington State Association for the Treatment of Sexual Abusers, Blaine, WA.
54. Cantor, J. M. (2009, January). *Brain structure and function of pedophilia men.* Neuropsychiatry Rounds, Toronto Western Hospital, Toronto, Ontario.
55. Cantor, J. M. (2008, April). *Is pedophilia caused by brain dysfunction?* Invited address to the University-wide Science Day Lecture Series, SUNY Oswego, Oswego, NY.
56. Cantor, J. M., Kabani, N., Christensen, B. K., Zipursky, R. B., Barbaree, H. E., Dickey, R., Klassen, P. E., Mikulis, D. J., Kuban, M. E., Blak, T., Richards, B. A., Hanratty, M. K., & Blanchard, R. (2006, September). *MRIs of pedophilic men.* Invited presentation at the 25th annual meeting of the Association for the Treatment of Sexual Abusers, Chicago.
57. Cantor, J. M., Blanchard, R., & Christensen, B. K. (2003, March). *Findings in and implications of neuropsychology and epidemiology of pedophilia.* Invited lecture at the 28th annual meeting of the Society for Sex Therapy and Research, Miami.
58. Cantor, J. M., Christensen, B. K., Klassen, P. E., Dickey, R., & Blanchard, R. (2001, July). *Neuropsychological functioning in pedophiles.* Invited lecture presented at the 27th annual meeting of the International Academy of Sex Research, Bromont, Canada.
59. Cantor, J. M., Blanchard, R., Christensen, B., Klassen, P., & Dickey, R. (2001, February). *First glance at IQ, memory functioning and handedness in sex offenders.* Lecture presented at the Forensic Lecture Series, Centre for Addiction and Mental Health, Toronto, Ontario, Canada.
60. Cantor, J. M. (1999, November). *Reversal of SSRI-induced male sexual dysfunction: Suggestions from an animal model.* Grand Rounds presentation at the Allan Memorial Institute, Royal Victoria Hospital, Montréal, Canada.

PAPER PRESENTATIONS AND SYMPOSIA

1. Cantor, J. M. (2020, April). "I'd rather have a trans kid than a dead kid": Critical assessment of reported rates of suicidality in trans kids. *Paper presented at the annual meeting of the Society for the Sex Therapy and Research.* Online in lieu of in person meeting.
2. Stephens, S., Lalumière, M., Seto, M. C., & Cantor, J. M. (2017, October). *The relationship between sexual responsiveness and sexual exclusivity in phallometric profiles.* Paper presented at the annual meeting of the Canadian Sex Research Forum, Fredericton, New Brunswick, Canada.
3. Stephens, S., Cantor, J. M., & Seto, M. C. (2017, March). *Can the SSPI-2 detect hebephilic sexual interest?* Paper presented at the annual meeting of the American-Psychology Law Society Annual Meeting, Seattle, WA.
4. Stephens, S., Seto, M. C., Goodwill, A. M., & Cantor, J. M. (2015, October). *Victim choice polymorphism and recidivism.* Symposium Presentation. Paper presented at the 34th annual meeting of the Association for the Treatment of Sexual Abusers, Montréal, Canada.
5. McPhail, I. V., Hermann, C. A., Fernane, S. Fernandez, Y., Cantor, J. M., & Nunes, K. L. (2014, October). *Sexual deviance in sexual offenders against children: A meta-analytic review of phallometric research.* Paper presented at the 33rd annual meeting of the Association for the Treatment of Sexual Abusers, San Diego, CA.
6. Stephens, S., Seto, M. C., Cantor, J. M., & Goodwill, A. M. (2014, October). *Is hebephilic sexual interest a criminogenic need?: A large scale recidivism study.* Paper presented at the 33rd annual meeting of the Association for the Treatment of Sexual Abusers, San Diego, CA.
7. Stephens, S., Seto, M. C., Cantor, J. M., & Lalumière, M. (2014, October). *Development and validation of the Revised Screening Scale for Pedophilic Interests (SSPI–2).* Paper presented at the 33rd annual meeting of the Association for the Treatment of Sexual Abusers, San Diego, CA.
8. Cantor, J. M., Lafaille, S., Hannah, J., Kucyi, A., Soh, D., Girard, T. A., & Mikulis, D. M. (2014, September). *Pedophilia and the brain: White matter differences detected with DTI.* Paper presented at the 13th annual meeting of the International Association for the Treatment of Sexual Abusers, Porto, Portugal.
9. Stephens, S., Seto, M., Cantor, J. M., Goodwill, A. M., & Kuban, M. (2014, March). *The role of hebephilic sexual interests in sexual victim choice.* Paper presented at the annual meeting of the American Psychology and Law Society, New Orleans, LA.
10. McPhail, I. V., Fernane, S. A., Hermann, C. A., Fernandez, Y. M., Nunes, K. L., & Cantor, J. M. (2013, November). *Sexual deviance and sexual recidivism in sexual offenders against children: A meta-analysis.* Paper presented at the 32nd annual meeting of the Association for the Treatment of Sexual Abusers, Chicago, IL.
11. Cantor, J. M. (2013, September). *Pedophilia and the brain: Current MRI research and its implications.* Paper presented at the 21st annual World Congress for Sexual Health, Porto Alegre, Brazil. [Featured among Best Abstracts, top 10 of 500.]
12. Cantor, J. M. (Chair). (2012, March). *Innovations in sex research.* Symposium conducted at the 37th annual meeting of the Society for Sex Therapy and Research, Chicago.
13. Cantor, J. M., & Blanchard, R. (2011, August). fMRI versus phallometry in the diagnosis of pedophilia and hebephilia. In J. M. Cantor (Chair), *Neuroimaging of men's object*

preferences. Symposium presented at the 37th annual meeting of the International Academy of Sex Research, Los Angeles, USA.

14. Cantor, J. M. (Chair). (2011, August). *Neuroimaging of men's object preferences.* Symposium conducted at the 37th annual meeting of the International Academy of Sex Research, Los Angeles.
15. Cantor, J. M. (2010, October). A meta-analysis of neuroimaging studies of male sexual arousal. In S. Stolerú (Chair), *Brain processing of sexual stimuli in pedophilia: An application of functional neuroimaging.* Symposium presented at the 29th annual meeting of the Association for the Treatment of Sexual Abusers, Phoenix, AZ.
16. Chivers, M. L., Seto, M. C., Cantor, J. C., Grimbos, T., & Roy, C. (April, 2010). *Psychophysiological assessment of sexual activity preferences in women.* Paper presented at the 35th annual meeting of the Society for Sex Therapy and Research, Boston, USA.
17. Cantor, J. M., Girard, T. A., & Lovett-Barron, M. (2008, November). *The brain regions that respond to erotica: Sexual neuroscience for dummies.* Paper presented at the 51st annual meeting of the Society for the Scientific Study of Sexuality, San Juan, Puerto Rico.
18. Barbaree, H., Langton, C., Blanchard, R., & Cantor, J. M. (2007, October). *The role of age-at-release in the evaluation of recidivism risk of sexual offenders.* Paper presented at the 26th annual meetingof the Association for the Treatment of Sexual Abusers, San Diego.
19. Cantor, J. M., Kabani, N., Christensen, B. K., Zipursky, R. B., Barbaree, H. E., Dickey, R., Klassen, P. E., Mikulis, D. J., Kuban, M. E., Blak, T., Richards, B. A., Hanratty, M. K., & Blanchard, R. (2006, July). *Pedophilia and brain morphology.* Abstract and paper presented at the 32nd annual meeting of the International Academy of Sex Research, Amsterdam, Netherlands.
20. Seto, M. C., Cantor, J. M., & Blanchard, R. (2006, March). *Child pornography offending is a diagnostic indicator of pedophilia*. Paper presented at the 2006 annual meeting of the American Psychology-Law Society Conference, St. Petersburg, Florida.
21. Blanchard, R., Cantor, J. M., Bogaert, A. F., Breedlove, S. M., & Ellis, L. (2005, August). *Interaction of fraternal birth order and handedness in the development of male homosexuality.* Abstract and paper presented at the International Behavioral Development Symposium, Minot, North Dakota.
22. Cantor, J. M., & Blanchard, R. (2005, July). *Quantitative reanalysis of aggregate data on IQ in sexual offenders.* Abstract and poster presented at the 31st annual meeting of the International Academy of Sex Research, Ottawa, Canada.
23. Cantor, J. M. (2003, August). *Sex reassignment on demand: The clinician's dilemma.* Paper presented at the 111th annual meeting of the American Psychological Association, Toronto, Canada.
24. Cantor, J. M. (2003, June). *Meta-analysis of VIQ–PIQ differences in male sex offenders.* Paper presented at the Harvey Stancer Research Day, Toronto, Ontario, Canada.
25. Cantor, J. M. (2002, August). *Gender role in autogynephilic transsexuals: The more things change…* Paper presented at the 110th annual meeting of the American Psychological Association, Chicago.

26. Cantor, J. M., Christensen, B. K., Klassen, P. E., Dickey, R., & Blanchard, R. (2001, June). *IQ, memory functioning, and handedness in male sex offenders.* Paper presented at the Harvey Stancer Research Day, Toronto, Ontario, Canada.
27. Cantor, J. M. (1998, August). *Convention orientation for lesbian, gay, and bisexual students*. Papers presented at the 106th annual meeting of the American Psychological Association.
28. Cantor, J. M. (1997, August). *Discussion hour for lesbian, gay, and bisexual students*. Presented at the 105th annual meeting of the American Psychological Association.
29. Cantor, J. M. (1997, August). *Convention orientation for lesbian, gay, and bisexual students*. Paper presented at the 105th annual meeting of the American Psychological Association.
30. Cantor, J. M. (1996, August). *Discussion hour for lesbian, gay, and bisexual students*. Presented at the 104th annual meeting of the American Psychological Association.
31. Cantor, J. M. (1996, August). *Symposium: Question of inclusion: Lesbian and gay psychologists and accreditation*. Paper presented at the 104th annual meeting of the American Psychological Association, Toronto.
32. Cantor, J. M. (1996, August). *Convention orientation for lesbian, gay, and bisexual students*. Papers presented at the 104th annual meeting of the American Psychological Association.
33. Cantor, J. M. (1995, August). *Discussion hour for lesbian, gay, and bisexual students*. Presented at the 103rd annual meeting of the American Psychological Association.
34. Cantor, J. M. (1995, August). *Convention orientation for lesbian, gay, and bisexual students*. Papers presented at the 103rd annual meeting of the American Psychological Association.
35. Cantor, J. M. (1994, August). *Discussion hour for lesbian, gay, and bisexual students*. Presented at the 102nd annual meeting of the American Psychological Association.
36. Cantor, J. M. (1994, August). *Convention orientation for lesbian, gay, and bisexual students*. Papers presented at the 102nd annual meeting of the American Psychological Association.
37. Cantor, J. M., & Pilkington, N. W. (1992, August). *Homophobia in psychology programs: A survey of graduate students.* Paper presented at the Centennial Convention of the American Psychological Association, Washington, DC. (ERIC Document Reproduction Service No. ED 351 618)
38. Cantor, J. M. (1991, August). *Being gay and being a graduate student: Double the memberships, four times the problems*. Paper presented at the 99th annual meeting of the American Psychological Association, San Francisco.

POSTER PRESENTATIONS

1. Klein, L., Stephens, S., Goodwill, A. M., Cantor, J. M., & Seto, M. C. (2015, October). *The psychological propensities of risk in undetected sexual offenders.* Poster presented at the 34th annual meeting of the Association for the Treatment of Sexual Abusers, Montréal, Canada.
2. Pullman, L. E., Stephens, S., Seto, M. C., Goodwill, A. M., & Cantor, J. M. (2015, October). *Why are incest offenders less likely to recidivate?* Poster presented at the 34th annual meeting of the Association for the Treatment of Sexual Abusers, Montréal, Canada.
3. Seto, M. C., Stephens, S. M., Cantor, J. M., Lalumiere, M. L., Sandler, J. C., & Freeman, N. A. (2015, August). *The development and validation of the Revised Screening Scale for Pedophilic Interests (SSPI-2).* Poster presentation at the 41st annual meeting of the International Academy of Sex Research. Toronto, Canada.
4. Soh, D. W., & Cantor, J. M. (2015, August). *A peek inside a furry convention.* Poster presentation at the 41st annual meeting of the International Academy of Sex Research. Toronto, Canada.
5. VanderLaan, D. P., Lobaugh, N. J., Chakravarty, M. M., Patel, R., Chavez, S. Stojanovski, S. O., Takagi, A., Hughes, S. K., Wasserman, L., Bain, J., Cantor, J. M., & Zucker, K. J. (2015, August). *The neurohormonal hypothesis of gender dysphoria: Preliminary evidence of cortical surface area differences in adolescent natal females.* Poster presentation at the 31st annual meeting of the International Academy of Sex Research. Toronto, Canada.
6. Cantor, J. M., Lafaille, S. J., Moayedi, M., Mikulis, D. M., & Girard, T. A. (2015, June). *Diffusion tensor imaging (DTI) of the brain in pedohebephilic men: Preliminary analyses.* Harvey Stancer Research Day, Toronto, Ontario Canada.
7. Newman, J. E., Stephens, S., Seto, M. C., & Cantor, J. M. (2014, October). *The validity of the Static-99 in sexual offenders with low intellectual abilities.* Poster presentation at the 33rd annual meeting of the Association for the Treatment of Sexual Abusers, San Diego, CA.
8. Lykins, A. D., Walton, M. T., & Cantor, J. M. (2014, June). *An online assessment of personality, psychological, and sexuality trait variables associated with self-reported hypersexual behavior.* Poster presentation at the 30th annual meeting of the International Academy of Sex Research, Dubrovnik, Croatia.
9. Stephens, S., Seto, M. C., Cantor, J. M., Goodwill, A. M., & Kuban, M. (2013, November). *The utility of phallometry in the assessment of hebephilia.* Poster presented at the 32nd annual meeting of the Association for the Treatment of Sexual Abusers, Chicago.
10. Stephens, S., Seto, M. C., Cantor, J. M., Goodwill, A. M., & Kuban, M. (2013, October). *The role of hebephilic sexual interests in sexual victim choice.* Poster presented at the 32nd annual meeting of the Association for the Treatment of Sexual Abusers, Chicago.
11. Fazio, R. L., & Cantor, J. M. (2013, October). *Analysis of the Fazio Laterality Inventory (FLI) in a population with established atypical handedness.* Poster presented at the 33rd annual meeting of the National Academy of Neuropsychology, San Diego.
12. Lafaille, S., Hannah, J., Soh, D., Kucyi, A., Girard, T. A., Mikulis, D. M., & Cantor, J. M. (2013, August). *Investigating resting state networks in pedohebephiles.* Poster presented at the 29th annual meeting of the International Academy of Sex Research, Chicago.

13. McPhail, I. V., Lykins, A. D., Robinson, J. J., LeBlanc, S., & Cantor, J. M. (2013, August). *Effects of prescription medication on volumetric phallometry output.* Poster presented at the 29th annual meeting of the International Academy of Sex Research, Chicago.
14. Murray, M. E., Dyshniku, F., Fazio, R. L., & Cantor, J. M. (2013, August). *Minor physical anomalies as a window into the prenatal origins of pedophilia.* Poster presented at the 29th annual meeting of the International Academy of Sex Research, Chicago.
15. Sutton, K. S., Stephens, S., Dyshniku, F., Tulloch, T., & Cantor, J. M. (2013, August). *Pilot group treatment for "procrasturbation."* Poster presented at 39th annual meeting of the International Academy of Sex Research, Chicago.
16. Sutton, K. S., Pytyck, J., Stratton, N., Sylva, D., Kolla, N., & Cantor, J. M. (2013, August). *Client characteristics by type of hypersexuality referral: A quantitative chart review.* Poster presented at the 39th annual meeting of the International Academy of Sex Research, Chicago.
17. Fazio, R. L., & Cantor, J. M. (2013, June). *A replication and extension of the psychometric properties of the Digit Vigilance Test.* Poster presented at the 11th annual meeting of the American Academy of Clinical Neuropsychology, Chicago.
18. Lafaille, S., Moayedi, M., Mikulis, D. M., Girard, T. A., Kuban, M., Blak, T., & Cantor, J. M. (2012, July). *Diffusion Tensor Imaging (DTI) of the brain in pedohebephilic men: Preliminary analyses.* Poster presented at the 38th annual meeting of the International Academy of Sex Research, Lisbon, Portugal.
19. Lykins, A. D., Cantor, J. M., Kuban, M. E., Blak, T., Dickey, R., Klassen, P. E., & Blanchard, R. (2010, July). *Sexual arousal to female children in gynephilic men.* Poster presented at the 38th annual meeting of the International Academy of Sex Research, Prague, Czech Republic.
20. Cantor, J. M., Girard, T. A., Lovett-Barron, M., & Blak, T. (2008, July). *Brain regions responding to visual sexual stimuli: Meta-analysis of PET and fMRI studies.* Abstract and poster presented at the 34th annual meeting of the International Academy of Sex Research, Leuven, Belgium.
21. Lykins, A. D., Blanchard, R., Cantor, J. M., Blak, T., & Kuban, M. E. (2008, July). *Diagnosing sexual attraction to children: Considerations for DSM-V.* Poster presented at the 34th annual meeting of the International Academy of Sex Research, Leuven, Belgium.
22. Cantor, J. M., Blak, T., Kuban, M. E., Klassen, P. E., Dickey, R. and Blanchard, R. (2007, October). *Physical height in pedophilia and hebephilia.* Poster presented at the 26th annual meeting of the Association for the Treatment of Sexual Abusers, San Diego.
23. Cantor, J. M., Blak, T., Kuban, M. E., Klassen, P. E., Dickey, R. and Blanchard, R. (2007, August). *Physical height in pedophilia and hebephilia.* Abstract and poster presented at the 33rd annual meeting of the International Academy of Sex Research, Vancouver, Canada.
24. Puts, D. A., Blanchard, R., Cardenas, R., Cantor, J., Jordan, C. L., & Breedlove, S. M. (2007, August). *Earlier puberty predicts superior performance on male-biased visuospatial tasks in men but not women.* Abstract and poster presented at the 33rd annual meeting of the International Academy of Sex Research, Vancouver, Canada.
25. Seto, M. C., Cantor, J. M., & Blanchard, R. (2005, November). *Possession of child pornography is a diagnostic indicator of pedophilia.* Poster presented at the 24th annual meeting of the Association for the Treatment of Sexual Abusers, New Orleans.

26. Blanchard, R., Cantor, J. M., Bogaert, A. F., Breedlove. S. M., & Ellis, L. (2005, July). *Interaction of fraternal birth order and handedness in the development of male homosexuality.* Abstract and poster presented at the 31st annual meeting of the International Academy of Sex Research, Ottawa, Canada.
27. Cantor, J. M., & Blanchard, R. (2003, July). *The reported VIQ–PIQ differences in male sex offenders are artifactual?* Abstract and poster presented at the 29th annual meeting of the International Academy of Sex Research, Bloomington, Indiana.
28. Christensen, B. K., Cantor, J. M., Millikin, C., & Blanchard, R. (2002, February). *Factor analysis of two brief memory tests: Preliminary evidence for modality-specific measurement.* Poster presented at the 30th annual meeting of the International Neuropsychological Society, Toronto, Ontario, Canada.
29. Cantor, J. M., Blanchard, R., Paterson, A., Bogaert, A. (2000, June). *How many gay men owe their sexual orientation to fraternal birth order?* Abstract and poster presented at the International Behavioral Development Symposium, Minot, North Dakota.
30. Cantor, J. M., Binik, Y., & Pfaus, J. G. (1996, November). *Fluoxetine inhibition of male rat sexual behavior: Reversal by oxytocin*. Poster presented at the 26th annual meeting of the Society for Neurosciences, Washington, DC.
31. Cantor, J. M., Binik, Y., & Pfaus, J. G. (1996, June). *An animal model of fluoxetine-induced sexual dysfunction: Dose dependence and time course*. Poster presented at the 28th annual Conference on Reproductive Behavior, Montréal, Canada.
32. Cantor, J. M., O'Connor, M. G., Kaplan, B., & Cermak, L. S. (1993, June). *Transient events test of retrograde memory: Performance of amnestic and unimpaired populations*. Poster presented at the 2nd annual science symposium of the Massachusetts Neuropsychological Society, Cambridge, MA.

EDITORIAL AND PEER-REVIEWING ACTIVITIES

Editor-in-Chief

Sexual Abuse: A Journal of Research and Treatment	Jan., 2010–Dec., 2014

Editorial Board Memberships

Journal of Sexual Aggression	Jan., 2010–Dec., 2021
Journal of Sex Research, The	Jan., 2008–Aug., 2020
Sexual Abuse: A Journal of Research and Treatment	Jan., 2006–Dec., 2019
Archives of Sexual Behavior	Jan., 2004–Present
The Clinical Psychologist	Jan., 2004–Dec., 2005

Ad hoc Journal Reviewer Activity

American Journal of Psychiatry
Annual Review of Sex Research
Archives of General Psychiatry
Assessment
Biological Psychiatry
BMC Psychiatry
Brain Structure and Function
British Journal of Psychiatry
British Medical Journal
Canadian Journal of Behavioural Science
Canadian Journal of Psychiatry
Cerebral Cortex
Clinical Case Studies
Comprehensive Psychiatry
Developmental Psychology
European Psychologist
Frontiers in Human Neuroscience
Human Brain Mapping
International Journal of Epidemiology
International Journal of Impotence Research
International Journal of Sexual Health
International Journal of Transgenderism
Journal of Abnormal Psychology
Journal of Clinical Psychology
Journal of Consulting and Clinical Psychology
Journal of Forensic Psychology Practice
Journal for the Scientific Study of Religion
Journal of Sexual Aggression
Journal of Sexual Medicine
Journal of Psychiatric Research
Nature Neuroscience
Neurobiology Reviews
Neuroscience & Biobehavioral Reviews
Neuroscience Letters
Proceedings of the Royal Society B (Biological Sciences)
Psychological Assessment
Psychological Medicine
Psychological Science
Psychology of Men & Masculinity
Sex Roles
Sexual and Marital Therapy
Sexual and Relationship Therapy
Sexuality & Culture
Sexuality Research and Social Policy
The Clinical Psychologist
Traumatology
World Journal of Biological Psychiatry

GRANT REVIEW PANELS

2017–2021 Member, College of Reviewers, *Canadian Institutes of Health Research,* Canada.

2017 Committee Member, Peer Review Committee—Doctoral Research Awards A. *Canadian Institutes of Health Research*, Canada.

2017 Member, International Review Board, Research collaborations on behavioural disorders related to violence, neglect, maltreatment and abuse in childhood and adolescence. *Bundesministerium für Bildung und Forschung [Ministry of Education and Research],* Germany.

2016 Reviewer. National Science Center [*Narodowe Centrum Nauki*], Poland.

2016 Committee Member, Peer Review Committee—Doctoral Research Awards A. *Canadian Institutes of Health Research*, Canada.

2015 Assessor (Peer Reviewer). Discovery Grants Program. *Australian Research Council,* Australia.

2015 Reviewer. *Czech Science Foundation,* Czech Republic.

2015 Reviewer, "Off the beaten track" grant scheme. *Volkswagen Foundation,* Germany.

2015 External Reviewer, Discovery Grants program—Biological Systems and Functions. *National Sciences and Engineering Research Council of Canada*, Canada

2015 Committee Member, Peer Review Committee—Doctoral Research Awards A. *Canadian Institutes of Health Research*, Canada.

2014 Assessor (Peer Reviewer). Discovery Grants Program. *Australian Research Council,* Australia.

2014 External Reviewer, Discovery Grants program—Biological Systems and Functions. *National Sciences and Engineering Research Council of Canada*, Canada.

2014 Panel Member, Dean's Fund—Clinical Science Panel. *University of Toronto Faculty of Medicine*, Canada.

2014 Committee Member, Peer Review Committee—Doctoral Research Awards A. *Canadian Institutes of Health Research*, Canada.

2013 Panel Member, Grant Miller Cancer Research Grant Panel. *University of Toronto Faculty of Medicine*, Canada.

2013 Panel Member, Dean of Medicine Fund New Faculty Grant Clinical Science Panel. *University of Toronto Faculty of Medicine,* Canada.

2012 Board Member, International Review Board, Research collaborations on behavioural disorders related to violence, neglect, maltreatment and abuse in childhood and adolescence (2nd round). *Bundesministerium für Bildung und Forschung [Ministry of Education and Research],* Germany.

2012 External Reviewer, University of Ottawa Medical Research Fund. *University of Ottawa Department of Psychiatry*, Canada.

2012 External Reviewer, Behavioural Sciences—B. *Canadian Institutes of Health Research*, Canada.

2011 Board Member, International Review Board, Research collaborations on behavioural disorders related to violence, neglect, maltreatment and abuse in childhood and adolescence. *Bundesministerium für Bildung und Forschung [Ministry of Education and Research],* Germany.

TEACHING AND TRAINING

PostDoctoral Research Supervision
Law & Mental Health Program, Centre for Addiction and Mental Health, Toronto, Canada

Dr. Katherine S. Sutton	Sept., 2012–Dec., 2013
Dr. Rachel Fazio	Sept., 2012–Aug., 2013
Dr. Amy Lykins	Sept., 2008–Nov., 2009

Doctoral Research Supervision
Centre for Addiction and Mental Health, Toronto, Canada

Michael Walton • University of New England, Australia	Sept., 2017–Aug., 2018
Debra Soh • York University	May, 2013–Aug, 2017
Skye Stephens • Ryerson University	April, 2012–June, 2016

Masters Research Supervision
Centre for Addiction and Mental Health, Toronto, Canada

Nicole Cormier • Ryerson University	June, 2012–present
Debra Soh • Ryerson University	May, 2009–April, 2010

Undergraduate Research Supervision
Centre for Addiction and Mental Health, Toronto, Canada

Kylie Reale • Ryerson University	Spring, 2014
Jarrett Hannah • University of Rochester	Summer, 2013
Michael Humeniuk • University of Toronto	Summer, 2012

Clinical Supervision (Doctoral Internship)
Clinical Internship Program, Centre for Addiction and Mental Health, Toronto, Canada

Katherine S. Sutton • Queen's University	2011–2012
David Sylva • Northwestern University	2011–2012
Jordan Rullo • University of Utah	2010–2011
Lea Thaler • University of Nevada, Las Vegas	2010–2011
Carolin Klein • University of British Columbia	2009–2010
Bobby R. Walling • University of Manitoba	2009–2010

TEACHING AND TRAINING

Clinical Supervision (Doctoral- and Masters- level practica)
Centre for Addiction and Mental Health, Toronto, Canada

Tyler Tulloch • Ryerson University	2013–2014
Natalie Stratton • Ryerson University	Summer, 2013
Fiona Dyshniku • University of Windsor	Summer, 2013
Mackenzie Becker • McMaster University	Summer, 2013
Skye Stephens • Ryerson University	2012–2013
Vivian Nyantakyi • Capella University	2010–2011
Cailey Hartwick • University of Guelph	Fall, 2010
Tricia Teeft • Humber College	Summer, 2010
Allison Reeves • Ontario Institute for Studies in Education/Univ. of Toronto	2009–2010
Helen Bailey • Ryerson University	Summer, 2009
Edna Aryee • Ontario Institute for Studies in Education/Univ. of Toronto	2008–2009
Iryna Ivanova • Ontario Institute for Studies in Education/Univ. of Toronto	2008–2009
Jennifer Robinson • Ontario Institute for Studies in Education/Univ. of Toronto	2008–2009
Zoë Laksman • Adler School of Professional Psychology	2005–2006
Diana Mandelew • Adler School of Professional Psychology	2005–2006
Susan Wnuk • York University	2004–2005
Hiten Lad • Adler School of Professional Psychology	2004–2005
Natasha Williams • Adler School of Professional Psychology	2003–2004
Lisa Couperthwaite • Ontario Institute for Studies in Education/Univ. of Toronto	2003–2004
Lori Gray, née Robichaud • University of Windsor	Summer, 2003
Sandra Belfry • Ontario Institute for Studies in Education/Univ. of Toronto	2002–2003
Althea Monteiro • York University	Summer, 2002
Samantha Dworsky • York University	2001–2002
Kerry Collins • University of Windsor	Summer, 2001
Jennifer Fogarty • Waterloo University	2000–2001
Emily Cripps • Waterloo University	Summer, 2000
Lee Beckstead • University of Utah	2000

PROFESSIONAL SOCIETY ACTIVITIES

OFFICES HELD

2018–2019	Local Host. Society for Sex Therapy and Research.
2015	Member, International Scientific Committee, World Association for Sexual Health.
2015	Member, Program Planning and Conference Committee, Association for the Treatment of Sexual Abusers
2012–2013	Chair, Student Research Awards Committee, Society for Sex Therapy & Research
2012–2013	Member, Program Planning and Conference Committee, Association for the Treatment of Sexual Abusers
2011–2012	Chair, Student Research Awards Committee, Society for Sex Therapy & Research
2010–2011	Scientific Program Committee, International Academy of Sex Research
2002–2004	Membership Committee • APA Division 12 (Clinical Psychology)
2002–2003	Chair, Committee on Science Issues, APA Division 44
2002	Observer, Grant Review Committee • Canadian Institutes of Health Research Behavioural Sciences (B)
2001–2009	Reviewer • APA Division 44 Convention Program Committee
2001, 2002	Reviewer • APA Malyon-Smith Scholarship Committee
2000–2005	Task Force on Transgender Issues, APA Division 44
1998–1999	Consultant, APA Board of Directors Working Group on Psychology Marketplace
1997	Student Representative • APA Board of Professional Affairs' Institute on TeleHealth
1997–1998	Founder and Chair • APA/APAGS Task Force on New Psychologists' Concerns
1997–1999	Student Representative • APA/CAPP Sub-Committee for a National Strategy for Prescription Privileges
1997–1999	Liaison • APA Committee for the Advancement of Professional Practice
1997–1998	Liaison • APA Board of Professional Affairs
1993–1997	Founder and Chair • APA/APAGS Committee on LGB Concerns

PROFESSIONAL SOCIETY ACTIVITIES

MEMBERSHIPS

2017–2021 Member • *Canadian Sex Research Forum*

2009–Present Member • *Society for Sex Therapy and Research*

2007–Present Fellow • *Association for the Treatment and Prevention of Sexual Abuse*

2006–Present Full Member (elected) • *International Academy of Sex Research*

2006–Present Research and Clinical Member • *Association for the Treatment and Prevention of Sexual Abuse*

2003–2006 Associate Member (elected) • *International Academy of Sex Research*

2002 Founding Member • CPA Section on Sexual Orientation and Gender Identity

2001–2013 Member • *Canadian Psychological Association* (CPA)

2000–2015 Member • *American Association for the Advancement of Science*

2000–2015 Member • *American Psychological Association* (APA)

APA Division 12 (Clinical Psychology)

APA Division 44 (Society for the Psychological Study of LGB Issues)

2000–2020 Member • *Society for the Scientific Study of Sexuality*

1995–2000 Student Member • *Society for the Scientific Study of Sexuality*

1993–2000 Student Affiliate • *American Psychological Association*

1990–1999 Member, American Psychological Association of Graduate Students (APAGS)

CLINICAL LICENSURE/REGISTRATION

Certificate of Registration, Number 3793
College of Psychologists of Ontario, Ontario, Canada

AWARDS AND HONORS

2022 Distinguished Contribution Award
Association for the Treatment and Prevention of Sexual Abuse (ATSA)

2011 Howard E. Barbaree Award for Excellence in Research
Centre for Addiction and Mental Health, Law and Mental Health Program

2004 fMRI Visiting Fellowship Program at Massachusetts General Hospital
American Psychological Association Advanced Training Institute and NIH

1999–2001 CAMH Post-Doctoral Research Fellowship
Centre for Addiction and Mental Health Foundation and Ontario Ministry of Health

1998 Award for Distinguished Contribution by a Student
American Psychological Association, Division 44

1995 Dissertation Research Grant
Society for the Scientific Study of Sexuality

1994–1996 McGill University Doctoral Scholarship

1994 Award for Outstanding Contribution to Undergraduate Teaching
"TA of the Year Award," from the McGill Psychology Undergraduate Student Association

MAJOR MEDIA

(Complete list available upon request.)

Feature-length Documentaries

Vice Canada Reports. *Age of Consent.* 14 Jan 2017.
Canadian Broadcasting Company. *I, Pedophile.* Firsthand documentaries. 10 Mar 2016.

Appearances and Interviews

11 Mar 2020. Ibbitson, John. It is crucial that Parliament gets the conversion-therapy ban right. *The Globe & Mail.*
25 Jan 2020. Ook de hulpvaardige buurman kan verzamelaar van kinderporno zin. *De Morgen.*
3 Nov 2019. Village of the damned. *60 Minutes Australia.*
1 Nov 2019. HÅKON F. HØYDAL. Norsk nettovergriper: – Jeg hater meg selv: Nordmannen laster ned overgrepsmateriale fra nettet – og oppfordrer politiet til å gi amnesti for slike som ham.
10 Oct 2019. Smith, T. Growing efforts are looking at how—or if—#MeToo offenders can be reformed. *National Public Radio.*
29 Sep 2019. Carey, B. Preying on Children: The Emerging Psychology of Pedophiles. *New York Times.*
29 Apr 2019. Mathieu, Isabelle. La poupée qui a troublé les Terre-Neuviens. *La Tribune.*
21 Mar 2019. Pope Francis wants psychological testing to prevent problem priests. But can it really do that? *The Washington Post.*
12 Dec 2018. Child sex dolls: Illegal in Canada, and dozens seized at the border. Ontario Today with Rita Celli. *CBC.*
12 Dec 2018. Celli, R. & Harris, K. Dozens of child sex dolls seized by Canadian border agents. *CBC News.*
27 Apr 2018. Rogers, Brook A. The online 'incel' culture is real–and dangerous. *New York Post.*
25 Apr 2018. Yang, J. Number cited in cryptic Facebook post matches Alek Minassian's military ID: Source. *Toronto Star.*
24 Ap 2018 Understanding 'incel'. *CTV News.*
27 Nov 2017. Carey, B. Therapy for Sexual Misconduct? It's Mostly Unproven. *New York Times.*
14 Nov 2017. Tremonti, A. M. The Current. *CBC.*
9 Nov2017. Christensen, J. Why men use masturbation to harass women. *CNN.* http://www.cnn.com/2017/11/09/health/masturbation-sexual-harassment/index.html
7 Nov 2017. Nazaryan, A. Why is the alt-right obsessed with pedophilia? *Newsweek.*
15 Oct 2017. Ouatik, B. Déscouvre. Pédophilie et science. *CBC Radio Canada.*
12 Oct 2017. Ouatik, B. Peut-on guérir la pédophilie? *CBC Radio Canada.*
11 Sep 2017. Burns, C. The young paedophiles who say they don't abuse children. *BBC News.*
18 Aug 2017. Interview. *National Post Radio.* Sirius XM Canada.
16 Aug 2017. Blackwell, Tom. Man says he was cured of pedophilia at Ottawa clinic: 'It's like a weight that's been lifted': But skeptics worry about the impact of sending pedophiles into the world convinced their curse has been vanquished. *National Post.*
26 Apr 2017. Zalkind, S. Prep schools hid sex abuse just like the catholic church. *VICE.*
24 Apr 2017. Sastre, P. Pédophilie: une panique morale jamais n'abolira un crime. *Slate France.*
12 Feb 2017. Payette, G. Child sex doll trial opens Pandora's box of questions. *CBC News.*
26 Nov 2016. Det morke uvettet ["The unknown darkness]". *Fedrelandsvennen.*
13 July 2016. Paedophilia: Shedding light on the dark field. *The Economist.*

1 Jul 2016. Debusschere, B. Niet iedereen die kinderporno kijkt, is een pedofiel: De mythes rond pedofilie ontkracht. *De Morgen.*
12 Apr 2016. O'Connor, R. Terence Martin: The Tasmanian MP whose medication 'turned him into a paedophile'. *The Independent.*
8 Mar 2016. Bielski, Z. 'The most viscerally hated group on earth': Documentary explores how intervention can stop pedophiles. *The Globe and Mail.*
1 Mar 2016. Elmhirst, S. What should we do about paedophiles? *The Guardian.*
24 Feb 2016. The man whose brain tumour 'turned him into a paedophile'. *The Independent.*
24 Nov 2015. Byron, T. The truth about child sex abuse. *BBC Two.*
20 Aug 2015. The Jared Fogle case: Why we understand so little about abuse. *Washington Post.*
19 Aug 2015. Blackwell, T. Treat sex offenders for impotence—to keep them out of trouble, Canadian psychiatrist says. *National Post.*
2 Aug 2015. Menendez, J. BBC News Hour. *BBC World Service.*
13 Jul 2015. The nature of pedophilia. *BBC Radio 4.*
9 Jul 2015. The sex-offender test: How a computerized assessment can help determine the fate of men who've been accused of sexually abusing children. *The Atlantic.*
10 Apr 2015. NWT failed to prevent sex offender from abusing stepdaughter again. *CBC News.*
10 Feb 2015. Savage, D. "The ethical sadist." In Savage Love. *The Stranger.*
31 Jan 2015. Begrip voor/van pedofilie [Understanding pedophilia]. *de Volkskrant.*
9 Dec 2014. Carey, B. When a rapist's weapon is a pill. *New York Times*.
1 Dec 2014. Singal, J. Can virtual reality help pedophiles? *New York Magazine.*
17 Nov2014. Say pedófile, busco aydua. *El Pais.*
4 Sep 2014. Born that way? *Ideas, with Paul Kennedy.* CBC Radio One.
27 Aug 2014. Interrogating the statistics for the prevalence of paedophilia. BBC.
25 Jul 2014. Stephenson, W. The prevalence of paedophilia. *BBC World Service.*
21 Jul 2014. Hildebrandt, A. Virtuous Pedophiles group gives support therapy cannot. *CBC.*
26 Jan 2014. Paedophilia a result of faulty wiring, scientists suggest. *Daily Mail.*
22 Dec 2013. Kane, L. Is pedophilia a sexual orientation? *Toronto Star.*
21 Jul 2013. Miller, L. The turn-on switch: Fetish theory, post-Freud. *New York Magazine.*
1 Jul 2013. Morin, H. Pédophilie: la difficile quête d'une origine biologique. *Le Monde.*
2 Jun 2013. Malcolm, L. The psychology of paedophilia. *Australian National Radio.*
1 Mar 2013. Kay, J. The mobbing of Tom Flanagan is unwarranted and cruel. *National Post.*
6 Feb 2013. Boy Scouts board delays vote on lifting ban on gays. *L.A. Times.*
31 Aug 2012. CNN Newsroom interview with Ashleigh Banfield. *CNN.*
24 Jun 2012. CNN Newsroom interview with Don Lemon. *CNN.*

EXPERT WITNESS TESTIMONY

2010

In Re the detention of William G. Dutcher
Case No 08-2-38259-1 SEA
Superior Court, King County, Seattle, WA

2015

State of Florida vs Jon Herb
Case No 11-2013-CF-001958-AXXX-XX

2017

In re Commitment of Nicholas Bauer (Frye Hearing)
Case No. 2-18-0905; Appeal No. 2009-MR-64
Appellate Court of Illinois, Lee County, Second District

U.S. vs. William Hutcheson Leford (Presentencing Hearing)
Case No. 3:16-CR-00012-1
Southern District of Georgia, Dublin Division

2018

NY State Office Mental Health/Dept. of Corrections & Comm Superv vs. Fernando Little
Index# CA2016-002179; RJI No 32-16-7108; Consec No. 290430
Application for discharge from Central NY Psychiatric Center
Utica, New York

2019

John Fitzpatrick v Her Majesty the Queen
Ontario Superior Court of Justice, Canada

Re Commitment of Steven Casper (Frye Hearing)
Case No. 09 MR 135, IDOC No. B23461; DHS No. 887057
Kendall County, Illinois

Re Commitment of Ian Inger (Frye Hearing)
Poughkeepsie, NY

Helen Spiegel v. Keeley Savoie
Docket No HS14D0435 DR
Probate & Family Court, Hampshire Division, Massachusetts

Southern District of New York vs. Peter Bright
Case No. 1:19 Cr -00521 PKC
U.S. District Court, New York, Southern District

2021

State of Arizona vs Franklin Arnett Clifton
IR# JWID 14-70629; Cr2017-150114-001
Maricopa County, Arizona

B.P.J. v West Virginia
Civil Action No. 2:21-cv-00316
US District Court, Southern District, Charleston Division

Cross, et al. v Loudoun School Board
Case No. CL21-3254
Circuit Court, County of Loudoun, VA

Re Commitment of Michael Hughes (Frye Hearing)
Case No. 10-CR-80013
Circuit Court, Cook County, Chicago, Illinois

In the Matter of Alexander Aurora Cox
Cause number 48C02-215-JC-000143
Madison Circuit Court 2, Indiana

Josephson v University of Kentucky
Case No: 3:19-cv-00230-RGJ
Kentucky Western District, Louisville Division

2022

A.M. v. Indianapolis Public Schools, et al.
Cause No. 1:22-cv-01705-JMS-DLP
U.S. District Court, Southern District of Indiana

Boe et al, USA v Marshall
Civil Action No. 2:22-cv-00184- LCB
U.S. District Court, Middle District of Alabama, Northern Div

Bridge, et al. v Oklahoma State Department of Education, et al.
Case No. CIV-22-787-JD
Oklahoma, Western District Court

Dekker, et al. v Florida Agency for Health Care Admin.
Case 4:22-cv-00325-RH-MAF
Florida, Northern District Court

Doe, et al. v Abbott, et al.
Case No. D-1-GN-22-000977
Texas, Travis County

Xavier Hersom and John Doe v West Virginia

Civil Action No. 2:21-cv-00450
US District Court, Southern District, Charleston Division

NY v Frederick B. (Re: Commitment of Frederick B.)
Index No. 001141/2022
New York Supreme Court

Pamela Ricard v USD 475 Geary County School Board
Case No. 5:22-cv-04015
US District Court, District of Kansas

Roe, et al. v. Utah High School Activities Association, et al.
Case No. 220903262
Salt Lake County, Utah Third Judicial District Court

Voe, PFLAG, et al. v Abbott
NO. D-1-GN-22-002569
Texas, Travis County District Court

2023

Doe, et al. v. Thornbury, et al.
Civil No. 3:23CV-230-RGJ
U.S. District Court, Western District of Kentucky

Doe, et al. v. Horne, et al.
Case No. 4:23-cv-00185-JGZ
District of Arizona, Tucson Division

K.C., et al. v. Medical Licensing Board of Indiana, et al.
Case No. 1:23-CV-595
Southern District of Indiana, Indianapolis Division

L.W., et al. v. Skrmetti, et al.
Case No. 3:23-cv-00376
Middle District of Tennessee, Nashville Division

Poe, et al., v. Drummond, et al.
Case No. 23-CV-00177-JFH-SH
Northern District of Oklahoma

Koe, et al., v. Noggle, et al.
Civil Action No. 1:23-cv-02904-SEG
U.S. District Court, Northern District of Georgia, Atlanta Div

Poe, et al., v. Labrador
Case No. 1:23-cv-00269-CWD
U.S. District Court, District of Idaho, Southern Division

Roe, et al., v. Critchfield, et al.
Case No. 1:23-cv-00315-DCN
U.S. District Court, District of Idaho

Lazaro Loe v Texas
Cause No. D-1-GN-23-003616
201st Judicial District, Travis County, Texas

Noe, et al., v. Parson, et al.
Case No 23AC-CC04530
Circuit Court of Cole County, State of Missouri

Van Garderen, et al. v. Montana, et al.
Cause No. DV 2023–0541
Montana Fourth Judicial District Court, Missoula County

B.C. College of Nurses and Midwives v Amy HAMM
Citation issued under Health Professional Act

Voe, et al. v Mansfield, et al.
Civil No. 1:23-cv-864
U.S. District Court, North Carolina, Middle District, Durham Div.

TD, et al. v Wrigley, et al.
Case No. 08-2023-CV-2189
District Court, South Central Judicial District, North Dakota

EXHIBIT 4

SUBMITTED UNDER SEAL

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

BRIANNA BOE, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
UNITED STATES OF AMERICA,	)	
	)	
Intervenor Plaintiff,	)	
	)	
v.	)	Civil Action No. 2:22-cv-184-LCB
	)	
HON. STEVE MARSHALL, in his Official capacity as Attorney General, of the State of Alabama, *et al.*,	)	
	)	
Defendants.	)	

EXPERT REPORT OF
PAUL W. HRUZ, M.D., PH.D.

TABLE OF CONTENTS

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 CV is attached as Exhibit A to this report.

2. I am an Associate Professor of Pediatrics in the Division of Pediatric Endocrinology and Diabetes at Washington University School of Medicine. I also have a secondary appointment as Associate Professor of Cellular Biology and Physiology in the Division of Biology and Biological Sciences at Washington University School of Medicine. I served as Chief of the Division of Pediatric Endocrinology and Diabetes at Washington University from 2012-2017. I served as the Director of the Pediatric Endocrinology Fellowship Program at Washington University from 2008-2016. I am currently serving as Associate Fellowship Program Director at Washington University in St. Louis.

3. Related to the litigation of issues of sex and gender, I have been designated as an expert witness in *Carcaño v. Cooper* (United States District Court for the Middle District of North Carolina, Case No. 1:16-cv-236); *Doe v. Board of Education of the Highland School District* (United States District Court for the Southern District of Ohio, Eastern Division, Case No. 2:16-CV-524); *Whitaker v. Kenosha*

Unified School District (United States District Court for the Eastern District of Wisconsin, Case No. 2:16-cv-00943), *Bruce v. South Dakota* (United States District Court for the District of South Dakota, Western Division, Case No. 17-5080); *Kadel v. Falwell* (United States District Court for the Middle District of North Carolina, Case No. 1:19-cv-272-LCB-LPA); *Brandt v. Rutledge* (United States District Court for the Eastern District of Arkansas, Central Division, Case No. 4:21-CV-00450-JM); *D.H. v. Snyder* (United States District Court for the District of Arizona, Case No. 4:20-cv-00335-SHR), Cause DF-15-09887-SD of the 255th Judicial Circuit of Dallas County, TX regarding the dispute between J.A. D.Y. and J.U. D.Y., Children; and *Dekker v. Weida* (United States District Court for the Northern District of Florida, Tallahassee Division, Case No. 4:22-cv-00325-RH-MAF). I have also served as a science consultant or submitted written testimony for court cases in Canada (B.C. Supreme Court File No. E190334) and Great Britain (*Bell v. Tavistock*).

4. I am being compensated at an hourly rate for actual time devoted, at the rate of $400 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. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

5. My opinions as detailed in this report are based upon my:

   a. knowledge, training, and clinical experience in caring for thousands of patients over many years;

b. detailed methodological reviews of hundreds of relevant peer-reviewed science publications;
c. consults, discussions, and team analyses with colleagues and other experts in the field, including attendance and participation in various professional conferences;
d. publications in peer-reviewed scientific journals;
e. editorial work for peer-reviewed scientific journals; and
f. peer-reviewed research grant receipt and review work.

In addition, I have reviewed the expert reports in this case of Dr. Armand Antommaria, Dr. Daniel Shumer, Dr. Meredithe McNamara, Dr. Aron Janssen, and Dr. Morissa Ladinsky. I have also reviewed certain medical records of the individual Plaintiffs in this case, and I discuss these records in a separate report. The materials that I have relied upon are the same types of materials that other experts in my field of clinical practice rely upon when forming opinions on the subject.

6. My opinions and hypotheses in this matter are — as all expert reports are — subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, and the limitations of social, biological, and medical science. I have not met with, or personally interviewed, anyone in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. In my opinion, a key

role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information.

BACKGROUND

7. I received my Doctor of Philosophy degree from the Medical College of Wisconsin in 1993. I received my Medical Degree from the Medical College of Wisconsin in 1994.

8. I am board certified in Pediatrics and Pediatric Endocrinology. I have been licensed to practice medicine in Missouri since 2000. My professional memberships include the American Diabetes Association, the Pediatric Endocrine Society, and the Endocrine Society.

9. I have published 62 scholarly articles over my academic career spanning over two decades. This includes peer-reviewed publications in the leading journals in the fields of metabolism, cardiology, HIV, and ethics. Those journals include Gastroenterology, Circulation, Diabetes, Science Signaling, the Journal of Biological Chemistry, and FASEB Journal. See Exhibit A.

10. I have served as a Reviewer for a number of leading science journals in relevant fields including the Journal of Clinical Endocrinology and Metabolism, the Journal of Biological Chemistry, Diabetes, Scientific Reports, and PLOS ONE, assessing the quality of evidence that is put forward for publication. I have also been

involved in the evaluation of clinical trials with colleagues. I have received over $4.6 million in governmental and non-governmental funding for scientific research, including grants from the National Institutes of Health, the American Diabetes Association, The American Heart Association, the March of Dimes, and the Harrington Discovery Institute. I am a member of the Alpha Omega Alpha Medical Honor Society and have received the Armond J. Quick Award for Excellence in Biochemistry, the Eli Lilly Award for Outstanding Contribution to Drug Discovery, and the Julio V. Santiago Distinguished Scholar in Pediatrics Award.

11. During the more than 22 years that I have been in clinical practice, I have participated in the care of hundreds of infants and children, including adolescents, with disorders of sexual development. I was a founding member of the multidisciplinary Disorders of Sexual Development (DSD) program at Washington University. I continue to contribute to the discussion of complex cases and the advancement of research priorities in this field. In the care of these patients, I have acquired expertise in the understanding and management of associated difficulties in gender identification and gender transitioning treatment issues. I have trained and/or supervised hundreds of medical students, residents, and clinical fellows in the practice of medicine.

12. In my role as a scientist and as the Director of the Division of Pediatric Endocrinology at Washington University, I extensively studied the existing scientific research literature related to the incidence, potential etiology, and treatment of gender dysphoria as efforts were made to develop a Transgender Medicine Clinic at Saint Louis Children's Hospital. I have participated in local, national, and international meetings where the endocrine care of children with gender dysphoria has been discussed in detail and debated in depth. I have met individually and consulted with several pediatric endocrinologists (including Dr. Norman Spack) and other professionals specializing in sexual health (including Eli Coleman) who have developed and led transgender programs in the United States. I have also consulted with, met with, and had detailed discussions with dozens of parents of children with gender dysphoria to understand the unique difficulties experienced by this patient population. I continue to evaluate the ongoing experimental investigation of this condition. I am frequently consulted by other medical professionals to help them understand the complex medical and ethical issues related to this emerging field of medicine.

13. In my 25 years of clinical practice, I have cared for children from birth to the completion of college in their early twenties who have a variety of hormone-related diseases. This includes disorders of growth, puberty (both precocious and delayed), glucose homeostasis (both hypoglycemia and diabetes mellitus), adrenal function (both adrenal insufficiency and steroid excess), thyroid function, skeletal

abnormalities, gonadal dysfunction (including polycystic ovarian syndrome and ovarian failure), hypopituitarism, and disorders of sexual development. Pediatric patients referred to our practice for the evaluation and treatment of gender dysphoria are cared for by an interdisciplinary team of providers that includes a psychologist and pediatric endocrinologist who have been specifically chosen for this role based upon a special interest in this patient population.

BACKGROUND ON SEX AND GENDER

14. Sex is an objective biological trait intrinsically oriented toward specific roles in the conception and development of new members of a species. Both males and females contribute genetic information in distinct yet complementary ways. Males have the role of delivering sperm produced by testes and the unique paternal DNA contained therein to a female. Females have the role of receiving this male genetic information to join with the maternal genetic information contained in ova produced by ovaries. Sex is not "assigned at birth"; it is permanently determined by biology at conception. This remains the standard definition that has been accepted by the relevant scientific community and used worldwide by scientists, medical personnel, and society in general for decades.

15. The scientific and clinical measurement of sex is done with highly reliable and valid objective methodologies. Visual medical examination of the appear-

ance of the external genitalia is the primary methodology used by clinicians to recognize sex. In cases where genital ambiguity is present, additional testing modalities including chromosomal analysis, measurement of hormone levels, radiographic imaging of internal sexual anatomy and biological response to provocative testing are utilized. The measurement and assessment of biological sex has been documented by valid and reliable research published in credible journals, and is accepted by the relevant scientific community. Medical recognition of an individual as male or female is correctly made at birth in nearly 99.98% of cases according to external phenotypic expression of primary sexual traits (i.e., the presence of a penis for males and presence of labia and vagina for females).

16. For members of the human species (and virtually all mammals), sex is normatively aligned in a binary fashion (i.e., either male or female) in relation to biologic purpose. The presence of individuals with disorders of sexual development (along the range of the established Prader scale) does not alter this fundamental reality.

17. Due to genetic and hormonal variation in the developing fetus, normative development of the external genitalia in any individual differs with respect to size and appearance while maintaining an ability to function with respect to biologic purpose (i.e., reproduction). Internal structures (e.g., gonad, uterus, vas deferens)

normatively align in more than 99.9%+ of mammals with external genitalia, including humans.

18. Due to the complexity of the biological processes that are involved in normal sexual development, it is not surprising that a very small number of individuals are born with defects in this process (1 in 5,000 births).[1] Defects can occur through either inherited or *de novo* mutations in genes that are involved in sexual determination or through environmental insults during critical states of sexual development. Persons who are born with such abnormalities are considered to have a disorder of sexual development (DSD). Most often, this is first detected as ambiguity in the appearance of the external genitalia. Such detection measurements are reliable and valid and accepted by the relevant scientific community.

19. The medical care of persons with DSDs is primarily directed toward identification of the etiology of the defect and treatment of any associated complications. Similar to the diagnosis of other diseases, objective diagnostic tools such as the Prader scale are used to assess, measure, and assign a "stage" to the severity of the deviation from normal. In children with DSDs, characterization based upon phenotype alone does not reliably predict the sex chromosomes present, nor does it

[1] See L. Sax, How common is Intersex? A response to Anne Fausto-Sterling, 39 J. Sex Rsch. 174 (2002).

necessarily correlate with potential for biological sexual function. Decisions on initial sex assignment in these very rare cases require detailed assessment of objective, reliable medical evidence by a team of expert medical providers. In previous years, the general practice was to make a definitive sex assignment shortly after birth, the belief being that this would allow patients with a disorder of sexual development to best conform to the assigned sex and parents-caregivers to help socialize the child to the assigned sex. Current practice is to defer sex assignment until the etiology of the disorder is determined and, if possible, a reliable prediction can be made on likely biologic and psychologic outcomes. When this cannot be done with confidence, a presumptive sex assignment is made. Factors used in making such decisions include karyotype (46XX, 46XY, or other), phenotypic appearance of the external genitalia, and parental desires. The availability of new information can, in rare circumstances, lead to a change in sex determination. Decisions on whether to surgically alter the external genitalia to align with sex are generally deferred until the patient is able to provide consent.[2]

20. "Gender," a term that had traditionally been reserved for grammatical purposes, is currently used to describe the psychological and cultural characteristics of a person in relation to biological sex. Gender in such new definitions would

[2] See P. A. Lee et al., Global Disorders of Sex Development Update since 2006: Perceptions, Approach and Care, 85 Horm. Rsch. Paediatr. 158 (2016).

therefore exist only in reference to subjective personal perceptions and feelings and societal expectations, not biology. The reliability and validity of various usages of the term "gender" is currently controversial. The dangers of incorrectly using the term "gender" in place of "sex" have been acknowledged by the Endocrine Society.[3]

21. "Gender identity" refers to a person's individual experience and perception and unverified verbal patient reports of how they experience being male or female or a combination of these or other categories. The term "gender identity" is controversial. There is no current worldwide definition of "gender identity" accepted by the relevant clinical communities. The measurement error rate for non-biological "gender identity" is unknown.

22. People who identify as "transgender" transiently or persistently experience a sex-discordant gender identity.[4]

PUBERTY

23. Puberty is "the morphological and physiological changes that occur in the growing boy or girl as the gonads change from the infantile to the adult state. These changes involve nearly all the organs and structures of the body but they do not begin at the same age nor take the same length of time to reach completion in all

[3] See A. Bhargava et al., Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Scientific Statement, 42 Endocrine Revs. 219 (2021).
[4] American Psychological Association, The Diagnostic and Statistical Manual of Mental Disorders, (DSM-5), 451 (2013).

individuals. Puberty is not complete until the individual has the physical capacity to conceive and successfully rear children."[5]

24. The principal manifestations of puberty are:

- The adolescent growth spurt; i.e., an acceleration followed by a deceleration of growth in most skeletal dimensions and in many internal organs.
- The development of the gonads.
- The development of the secondary reproductive organs and the secondary sex characters.
- Changes in body composition, i.e., in the quantity and distribution of fat in association with growth of the skeleton and musculature.
- Development of the circulatory and respiratory systems leading, particularly in boys, to an increase in strength and endurance.[6]

25. The ability to physically conceive children is made possible by the maturation of the primary sex characteristics, the organs and structures that are involved directly in reproduction. In boys, these organs and structures include the scrotum, testes, and penis while in girls they include the ovaries, uterus, and vagina. In addition to these primary sex characteristics, secondary sex characteristics also develop

[5] W. A. Marshall et al., Puberty, in F. Falkner et al. eds., 2 Human Growth: A Comprehensive Treatise, 2nd ed., (New York: Springer, 1986), 171.
[6] *Id.* at 171-72.

during puberty — the distinctive physical features of the two sexes that are not directly involved in reproduction. Secondary sex characteristics that develop in girls include "the growth of breasts and the widening of the pelvis," while in boys they include "the appearance of facial hair and the broadening of shoulders." Other patterns of body hair and changes in voice and skin occur during puberty in both girls and boys.[7]

26. Physicians characterize the progress of puberty by marking the onset of different developmental milestones. The earliest visible event, the initial growth of pubic hair, is known as "pubarche;" it occurs between roughly ages 8 and 13 in girls, and between ages 9.5 and 13.5 in boys.[8] In girls, the onset of breast development, known as "thelarche," occurs around the same time as pubarche.[9] "Menarche" is another manifestation of sexual maturation in females, referring to the onset of menstruation, which typically occurs at around 13 years of age and is generally a sign of the ability to conceive.[10] Roughly corresponding to menarche in girls is "spermarche" in boys; this refers to the initial presence of viable sperm in semen, which also typically occurs around 13.[11] (The "-arche" in the terms for these milestones

[7] R. V. Kail et al., Human Development: A Life-Span View 276 (7th ed. 2016).
[8] J. Stang et al., Adolescent Growth and Development 1, 2-3 in J. Stang et al. eds., Guidelines for Adolescent Nutrition Services, (2005), available at http://demoiselle2femme.org/wp-content/uploads/Adolescent-Growth-and-Development.pdf (last visited Apr. 29, 2023).
[9] *Id.* at 2.
[10] Marshall et al., Puberty, at 191-92.
[11] *Id.* at 185.

comes from the Greek for beginning or origin). Pubarche and thelarche correspond to the transition from Tanner Stage 1 to Tanner Stage 2 of sexual development. Spermarche and menarche generally occur at Tanner Stage 4 to Tanner Stage 5.

27. Scientists distinguish three main biological processes involved in puberty: adrenal maturation, gonadal maturation, and somatic growth acceleration. "Adrenarche" — the beginning of adrenal maturation — begins between ages 6 and 9 in girls, and ages 7 and 10 in boys. The hormones produced by the adrenal glands during adrenarche are relatively weak forms of androgens (masculinizing hormones) known as dehydroepiandrosterone and dehydroepiandrosterone sulfate. These hormones are responsible for signs of puberty shared by both sexes: oily skin, acne, body odor, and the growth of axillary (underarm) and pubic hair.[12]

28. "Gonadarche" — the beginning of the process of gonadal maturation — normally occurs in girls between ages 8 and 13 and in boys between ages 9 and 14.[13] The process begins in the brain, where specialized neurons in the hypothalamus secrete gonadotropin-releasing hormone (GnRH).[14] This hormone is secreted in a cyclical or "pulsatile" manner — the hypothalamus releases bursts of GnRH,

[12] S. E. Oberfield et al., Approach to the Girl with Early Onset of Pubic Hair, 96 J. Clin. Endocrinol. & Metabol. 1610 (2011).
[13] S. F. Witchel et al., Puberty: Gonadarche and Adrenarche, in J. F. Strauss III et al. eds., Yen and Jaffe's Reproductive Endocrinology, 6th ed., 395, 395-446.e16 (2009).
[14] A. E. Herbison, Control of Puberty Onset and Fertility by Gonadotropin-Releasing Hormone Neurons, 12 Nature Revs. Endocrinol. 452 (2016).

and when the pituitary gland is exposed to these bursts, it responds by secreting two other hormones.[15] These are luteinizing hormone (LH) and follicle-stimulating hormone (FSH), which stimulate the growth of the gonads (ovaries in females and testes in males).[16] (The "follicles" that the latter hormone stimulates are not hair follicles but ovarian follicles, the structures in the ovaries that contain immature egg cells.) In addition to regulating the maturation of the gonads and the production of sex hormones, these two hormones also play an important role in regulating aspects of human fertility.[17]

29. As the gonadal cells mature under the influence of LH and FSH, they begin to secrete androgens (masculinizing sex hormones like testosterone) and estrogens (feminizing sex hormones).[18] These hormones contribute to the further development of the primary sex characteristics (the uterus in girls and the penis and scrotum in boys) and to the development of secondary sex characteristics (including breasts and wider hips in girls, and wider shoulders, breaking voices, and increased muscle mass in boys). The ovaries and testes both secrete androgens as well as

[15] *Id.* at 453.
[16] *Id.* at 454.
[17] *Id.* at 452.
[18] M. A. Preece, Prepubertal and Pubertal Endocrinology, in F. Falkner et al. eds., 2 Human Growth: A Comprehensive Treatise, 211, 212 (1986).

estrogens, however the testes secrete more androgens and the ovaries more estrogens.[19]

30. The gonads and the adrenal glands are involved in two separate but interrelated pathways (or "axes") of hormone signaling. These are the hypothalamic-pituitary-gonadal (HPG) axis and the hypothalamic-pituitary-adrenal (HPA) axis.[20] Though both play essential roles in puberty, it is, as just noted, the HPG axis that results in the development of the basic reproductive capacity and the external sex characteristics that distinguish the sexes.[21]

31. The third significant process that occurs with puberty, the somatic growth spurt, is mediated by increased production and secretion of human growth hormone, which is influenced by sex hormones secreted by the gonads (both testosterone and estrogen). Similar to the way that the secretion of GnRH by the hypothalamus induces the pituitary gland to secrete FSH and LH, in this case short pulses of a hormone released by the hypothalamus cause the pituitary gland to release human growth hormone.[22] This process is augmented by testosterone and estrogen.

[19] R. A. Hess, Estrogen in the adult male reproductive tract: A review, 1 Reproductive Biol. and Endocrinol. 1, (2003); H. G. Burger, Androgen Production in Women, 77 (Suppl.) Fertility and Sterility, S3-5 (2002).
[20] R. D. Romeo, Neuroendocrine and Behavioral Development during Puberty: A Tale of Two Axes, 71 Vitamins and Hormones 1, 1-25 (2005).
[21] M. E. Wierman et al., Neuroendocrine Control of the Onset of Puberty, 2 Human Growth 225 (1986).
[22] M. A. Preece, Prepubertal and Pubertal Endocrinology, at 218-19.

Growth hormone acts directly to stimulate growth in certain tissues, and also stimulates the liver to produce a substance called "insulin-like growth factor 1," which has growth-stimulating effects on muscle.[23]

32. The neurological and psychological changes occurring in puberty are less well understood than are the physiological changes. Men and women have distinct neurological features that may account for some of the psychological differences between the sexes, though the extent to which neurological differences account for psychological differences, and the extent to which neurological differences are caused by biological factors like hormones and genes (as opposed to environmental factors like social conditioning), are all matters of debate.

33. Scientists distinguish between two types of effects hormones can have on the brain: organizational effects and activational effects. Organizational effects are the ways in which hormones cause highly stable changes in the basic architecture of different brain regions. Activational effects are the more immediate and temporary effects of hormones on the brain's activity. During puberty, androgens and estrogens primarily have activating effects, but long before then they have organizational effects in the brains of developing infants and fetuses.[24]

[23] U. J. Meinhardt et al., Modulation of growth hormone action by sex steroids, 65 Clin. Endocrinol. 413, 414 (2006).
[24] M. M. Herting et al., Puberty and structural brain development in humans, 44 Frontiers in Neuroendocrinol. 122 (2017); J. Hornung et al., Sex hormones and human brain function, 195 Handb. Clin. Neurol. 175 (2020).

34. In sum: Puberty involves a myriad of complex, related, and overlapping physical processes, occurring at various points and lasting for various durations. During this period of life, adrenarche and changes in the secretion of growth hormone contribute to the child's growth and development. With gonadarche, the maturation of sex organs begins and with normal maturation will lead to the emergence of reproductive capacity, as well as the development of the other biological characteristics that distinguish males and females.

PEDIATRIC ENDOCRINE DISORDERS AND TREATMENTS

35. The field of endocrinology is directed toward the care of hormone-related diseases. Pediatric endocrine diseases include disorders of glucose regulation (hypoglycemia and diabetes mellitus), disorders of thyroid function (hyper and hypothyroidism), disorders of growth (e.g., short stature, acromegaly, obesity, and poor weight gain), disorders of sexual development and function (e.g., genital ambiguity, precocious and delayed puberty, hypogonadism, polycystic ovarian syndrome), disorders of adrenal function (e.g., adrenal insufficiency and Cushing's syndrome), disorders of pituitary function, lipid disorders, and disorders of bone and mineral metabolism. For all of these conditions, there are objective physical and biochemical criteria for diagnosis and treatment with well-established normal reference ranges for hormones and metabolites.

I. Using GnRH Analogues — "Puberty Blockers" — to Treat Precocious Puberty and Other Conditions

36. Hormone interventions to suppress puberty were not developed for the purpose of treating children with gender dysphoria. Rather, they were first used as a way to normalize puberty for children who undergo puberty too early, a condition known as "precocious puberty."

37. For females, precocious puberty is defined by the onset of puberty before age 8, while for males it is defined as the onset of puberty before age 9.[25] Premature thelarche (the appearance of breast development) is usually the first clinical sign of precocious puberty in girls. For males, precocious puberty is marked by premature testicular enlargement.[26] In addition to the psychological and social consequences that a child might be expected to suffer, precocious puberty can also lead to reduced adult height, since the early onset of puberty interferes with later bone growth.[27]

[25] K. O. Klein, Precocious Puberty: Who Has It? Who Should Be Treated?, 84 J. Clin. Endocrinol. & Metabol. 411 (1999). See also F. M. Biro et al., Onset of Breast Development in a Longitudinal Cohort, 132 Pediatrics 1019 (2013); C.-J. Partsch et al., Pathogenesis and epidemiology of precocious puberty. Effects of exogenous oestrogens, 7 Human Reproduction Update 292, 293 (2001).
[26] A. Parent et al., The Timing of Normal Puberty and the Age Limits of Sexual Precocity: Variations around the World, Secular Trends, and Changes after Migration, 24 Endocrine Revs. 675 (2011).
[27] J.-C. Carel et al., Precocious puberty and statural growth, 10 Human Reproduction Update 135 (2004).

38. Precocious puberty is divided into two types, central precocious puberty (sometimes labeled "true precocious puberty") and peripheral precocious puberty (sometimes labeled "precocious pseudopuberty").[28] Central precocious puberty is caused by the early activation of the gonadal hormone pathway by GnRH, and is amenable to treatment by physicians. Peripheral precocious puberty, which is caused by secretion of sex hormones by the gonads or adrenal glands independent of signals from the pituitary gland, is less amenable to treatment. Effects of androgen or estrogen hypersecretion can be reduced by administration of drugs that block the activity of the sex hormone receptors. If a tumor is causing the disorder, surgical removal may be necessary.

39. Precocious puberty is rare, especially in boys. A recent Spanish study of central precocious puberty estimated the overall prevalence to be 19 in 100,000 (37 in 100,000 girls affected, and 0.46 in 100,000 boys).[29] A Danish study of precocious puberty (not limited to central precocious puberty) found the prevalence to be between 20 to 23 per 10,000 in girls and less than 5 in 10,000 in boys.[30]

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[28] C.-J. Partsch et al., Pathogenesis and epidemiology of precocious puberty. Effects of exogenous oestrogens, at 294-95.

[29] L. Soriano-Guillén et al., Central Precocious Puberty in Children Living in Spain: Incidence, Prevalence, and Influence of Adoption and Immigration, 95 J. Clin. Endocrinol. & Metabol., 4305, 4307 (2011). In some cases, peripheral precocious puberty is caused by an underlying condition, such as a tumor, that can be treated.

[30] G. Teilmann et al., Prevalence and Incidence of Precocious Pubertal Development in Denmark: An Epidemiologic Study Based on National Registries, 116 Pedriatics 1323 (2005).

40. To diagnose central precocious puberty, hormones from the pituitary gland, LH and FSH, are objectively measured. This can sometimes be done by measurement of baseline levels[31] but often requires assessment after transient stimulation with GnRH. As discussed, these are two hormones that are made in the pituitary gland that signal to the gonads. In males, they lead to production of testosterone. In females, they lead to the production of estrogen. LH and FSH signaling are essential for normal sperm production and ovarian maturation in males and females, respectively.

41. Also subject to objective measurement when diagnosing and treating central precocious puberty are sex steroid hormones, either testosterone or estrogen, and bone growth.

42. Treatment for precocious puberty is somewhat counterintuitive. Rather than stopping the production of GnRH, physicians actually provide patients more constant levels of synthetic GnRH (called GnRH analogues or GnRH agonists).[32] As discussed above, when produced endogenously (that is, by the body naturally), GnRH stimulates the pituitary gland to release gonad-stimulating hormones (gonad-

[31] S. Heo et al., Basal Serum Luteinizing Hormone Value as the Screening Biomarker in Female Central Precocious Puberty, 24 Annals of Pediatr. Endocrinol. & Metabol., 164, 164-71 (2019).
[32] W. F. Crowley, Jr. et al., Therapeutic use of pituitary desensitization with a long-acting LHRH agonist: a potential new treatment for idiopathic precocious puberty, 52 J. Clin. Endocrinol. & Metabol., 370, 370-72 (1981) (LHRH refers to "lutenizing hormone releasing hormone," another term for GnRH.).

otropins, LH and FSH). When added exogenously, the additional GnRH "desensitizes" the pituitary, leading to a decrease in the secretion of gonadotropins, which in turn leads to the decreased maturation of and secretion of sex hormones by the gonads (ovaries and testes). The intent and effect of giving puberty blockers is identical when it is given to a male as when it is given to a female in this context: suppressing the secretion of gonadotropin hormones. Even the dosing is the same for males and females, and depends on the person's weight.

43. The first publication describing the use of GnRH analogues in children for precocious puberty appeared in 1981.[33] In the time since GnRH analogues were first proposed, they have become fairly well accepted as a treatment of precocious puberty, with one prominent GnRH analogue, Lupron, approved for that use by the FDA in 1993.[34] However, there remain some questions concerning the effectiveness of treatment with GnRH analogues. A 2009 consensus statement of pediatric endocrinologists concluded that GnRH analogues are an effective way to improve the height of girls with onset of puberty at less than 6 years of age, and also recommended the treatment be considered for boys with onset of precocious puberty who

[33] *Id.*

[34] "Full Prescribing Information" for Lupron Depot-Ped, FDA.gov (undated), https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020263s036lbl.pdf (last visited April 6, 2023).

have compromised height potential.[35] Regarding the negative psychological and social outcomes associated with precocious puberty, the authors found that the available data were unconvincing, and that additional studies are needed.[36] Puberty blockers have recently been recognized to carry a risk of increased brain pressure that can adversely affect vision and cause severe headaches.[37]

44. When used to treat precocious puberty, the process of desensitization of the pituitary gland by synthetic GnRH is not permanent. After a patient stops taking the GnRH analogues, the pituitary will resume its normal response to the pulsatile secretion of GnRH by the hypothalamus, as evidenced by the fact that children treated for precocious puberty using GnRH analogues will resume normal pubertal development, usually about a year after they withdraw from treatment.[38]

45. The goal of treating precocious puberty is to allow the child to have pubertal development enter the normal quiescence that is present at that age. This treatment helps to preserve their final adult height, by slowing the rate of bone age advancement. The goal is *not* to delay puberty beyond other children, as delaying

[35] J.-C. Carel et al., Consensus Statement on the Use of Gonadotropin-Releasing Hormone Analogs in Children, 123 Pediatrics e752, e753 (2009).
[36] *Id.*
[37] Risk of pseudotumor cerebri added to labeling for gonadotropin-releasing hormone agonists, AAP News, July 1, 2022, https://publications.aap.org/aapnews/news/20636/Risk-of-pseudotumor-cerebri-added-to-labeling-for?autologincheck=redirected (last visited April 7, 2023).
[38] M. M. Fisher et al., Resumption of Puberty in Girls and Boys Following Removal of the Histrelin Implant, 164 J. Pediatrics 912, 912-16 (2014).

too long can lead to adverse effects, including reduced bone marrow density, as discussed below.

46. In addition to being prescribed for children with precocious puberty, GnRH analogues have also been used in adults for a variety of indications, including hormone-sensitive tumors.[39] GnRH analogues have also been given to post-pubertal adolescents undergoing chemotherapy with drugs that can have toxic effects on the gonads.[40]

II. Using Sex Steroids Such as Testosterone and Estrogen to Treat Disorders of Normal Gonadal Function

47. Sex steroids such as testosterone and estrogen are frequently used in the treatment of disorders of normal gonadal function. This includes hypogonadotropic hypogonadism, primary gonadal failure, and delayed puberty.[41] In each of these conditions, there are objective laboratory tests that are used to diagnose these condi-

[39] See P. Kumar et al., Gonadotropin-releasing hormone analogs: Understanding advantages and limitations, 7 J. Human Reproductive Scis. 170 (2014).
[40] M. Meli et al., Triptorelin for Fertility Preservation in Adolescents Treated With Chemotherapy for Cancer, 40 J. Pediatr. Hematol./Oncol. 269 (2018).
[41] P. Kumar et al., Male hypogonadism: Symptoms and treatment, 1 J. Advanced Pharmaceutical Technology & Research 297 (2010); K. Voutsadaki et al., Hypogonadism in adolescent girls: treatment and long-term effects, 93 Acta Biomedica Atenei Parmensis e2022317 *1 (2022).

tions and monitor response to treatment. Deficiency of sex steroids has bodily effects that extend beyond sexual function.[42] This includes significant effect on bone density, lean body mass, metabolism, immunity, and neural function.

48. There are major and highly significant differences between male and female responses to sex hormones.[43] Giving estrogen to a biological male is not equivalent to giving the same hormone to a biological female. Likewise, giving testosterone to a biological female is not equivalent to giving the same hormone to a biological male.[44] Differences are not limited to pharmacokinetic effect (i.e., how drugs are absorbed, distributed throughout the body, and metabolized) but are present even at the cellular level.[45] Sex steroids act by altering the expression of the genetic information present in all nucleated cells of the body. Epigenetic differences (i.e., chemical changes to DNA structure) result in sex-differential expression of over 6,500 genes in the body.[46] Consequences of a failure to recognize these differences can result in drug overdose, lack of treatment response, or serious side effects.

[42] M. Alemany, The Roles of Androgens in Humans: Biology, Metabolic Regulation and Health. 23 Int'l. J. Molecular Scis. 11952 (2022); S. Patel et al., Estrogen: The necessary evil for human health, and ways to tame it, 102 Biomed. & Pharmacother. 403 (2018).
[43] See C. Madla et al., Let's talk about sex: Differences in drug therapy in males and females, 175 Advanced Drug Delivery Revs. 113804 (2021).
[44] See O. P. Soldin et al., Sex Differences in Pharmacokinetics and Pharmacodynamics, 48 Clin. Pharmacokinetics 143 (2009); S. Pogun et al., Sex Differences in Drug Effects, in Encyclopedia of Psychopharmacology, 1210, 1210-16 (I. P. Stolerman, ed., 2010).
[45] See, e.g., C. J. Walker et al., Matters of the heart: Cellular sex differences, 160 J. Molecular and Cellular Cardiol. 42 (2021).
[46] M. Gershoni et al., The landscape of sex-differential transcriptome and its consequent selection in human adults, 15 BMC Biol. 7 (2017).

49. Several conditions in male minors may indicate a need for endocrinologic treatment with testosterone. For instance, primary hypogonadism from gonadal failure is caused by damage or impaired function of the male testes. Secondary hypogonadism is caused by abnormalities in pituitary structure or function. Hypogonadism can be objectively diagnosed by measurement of testosterone (or its derivatives) and gonadotropin (LH and FSH) levels. When used for the treatment of affected males with hypogonadism, testosterone is administered to achieve levels that are normal for males of the patient's age. For young adult Tanner Stage 5 males, normal testosterone levels range from 300-900 ng/dL.[47] Achievement of appropriate testosterone levels requires careful monitoring, as excess levels can have serious adverse effects, including elevations of red blood cell counts, changes in blood pressure, and brain changes.[48]

50. Testosterone may also be used in males to treat delayed puberty. To treat the condition of constitutional delay (where the person has means to progress through puberty, but onset was delayed), the male would normally be given low

[47] T. G. Travison et al., Harmonized Reference Ranges for Circulating Testosterone Levels in Men of Four Cohort Studies in the United States and Europe, 102 J. Clin. Endocrinol. & Metabol., 1161 (2017).

[48] S. J. Ohlander et al., Erythrocytosis Following Testosterone Therapy, 6 Sexual Medicine Revs. 77 (2018); T. Kienitz et al., Testosterone and Blood Pressure Regulation, 31 Kidney and Blood Press. Rsch. 71 (2008); M. Scarth et al., Androgen abuse and the brain, 28 Curr. Op. in Endocrinol., Diabetes & Obes. 604 (2021).

doses of testosterone for 3-4 months to "prime the pump" for normal puberty. Assessment of this condition includes measuring levels of LH, FSH, and testosterone, as well as observation of testicular size. Once puberty has been initiated and is progressing, there is no need to administer ongoing testosterone therapy. Normal gonadotropin (LH and FSH) signaling from the pituitary gland will allow continued maturation of the testes, leading to reproductive capacity.

51. Continuing to give external testosterone to a male in normal puberty would suppress the normal function of the testes and can lead to infertility — a result contrary to the goal of endocrinology, which is to restore health. Thus, for instance, a male adolescent undergoing normal puberty who simply desired increased lean body mass (i.e., higher muscle mass) should not normally be given testosterone for that purpose, both because it is considered medically unnecessary and because of the adverse effects of extra testosterone. Among other reasons, these effects explain why testosterone is a controlled substance.

52. Outside the context of gender dysphoria, testosterone is not an indicated treatment for a female child or adolescent. Testosterone, or any androgen, would

lead to virilization, which can come with serious adverse effects. This includes impaired fertility, alopecia (hair loss), disfiguring acne, and metabolic changes that increase risk of heart disease and diabetes.[49]

53. Estrogen can be given to young females to treat the same conditions testosterone treats in young males: constitutional delay and hypogonadism, either primary or secondary. Primary hypogonadism is caused by a defect in the presence or function of the ovaries. Secondary hypogonadism is caused by a defect in the structure or function of the pituitary gland. A female can experience premature ovarian insufficiency where the ovaries become inactive over time, both genetically and through environmental incidents. To diagnose these conditions, hormone levels can be objectively measured. This includes LH, FSH, estradiol, and other levels. (Estradiol is a form of estrogen, and generally the main hormone followed and measured in female endocrinologic practice.) Female estrogen levels will vary throughout the menstrual cycle but are normally 30-400 pg/mL.[50] The physical response to the intervention can also be measured.

54. Estrogen treatments carry risks, including stroke, elevated blood pressure, and changes to bone development. Males are not generally prescribed estrogen

[49] R. Yang et al., Effects of hyperandrogenism on metabolic abnormalities in patients with polycystic ovary syndrome: a meta-analysis, 14 Reproductive Biol. and Endocrinol. 67 (2016).
[50] S. Verdonk et al., Estradiol reference intervals in women during the menstrual cycle, postmenopausal women and men using an LC-MS/MS method, 495 Clinica Chimica Acta 198, 198-204 (2019).

(again, outside the context of gender dysphoria), and there is concern that the risks of estrogen are even higher in males.

GENDER DYSPHORIA AND TREATMENTS

I. Diagnosis

55. In contrast to the conditions discussed above, gender dysphoria is not an endocrine disorder. Instead, it is a diagnostic term for "the distress that may accompany the incongruence between one's experienced or expressed gender and one's" biological sex.[51] Gender dysphoria is associated with high rates of comorbidity, including suicidal ideation, depression, anxiety, poverty, homelessness, eating disorders, and HIV infection.[52] Gender dysphoria as a psychiatric disorder should be distinguished from identifying as transgender or transsexual. As noted, people who identify as transgender "transiently or persistently identify with a gender different from their natal gender." In this definition, "natal gender" refers to sex. Transsexual has an even more specific meaning; it "denotes an individual who seeks, or has undergone, a social transition from male to female or female to male, which in many, but not all, cases also involves a somatic transition by cross-sex hormone treatment and genital surgery."[53]

[51] DSM-5, at 451.
[52] M. D. Connolly et al., The Mental Health of Transgender Youth: Advances in Understanding, 59 J. Adolesc. Health 489 (2016); F. Pinna et al., Mental health in transgender individuals: a systematic review, 34 Int'l Rev. of Psychiatry 292 (2022).
[53] DSM-5, at 451.

56. The clinical assessment methodology in sex discordant gender medicine is currently limited to self-reported information from patients without objective scientific markers or medical tests. There are no reliable radiological, genetic, physical, hormonal, or biomarker tests that can establish gender identity or reliably predict treatment outcomes.

57. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions. While the contributors to sex-discordant gender identity remain to be fully identified and characterized, differences both in kind and degree within individuals and across varied populations create challenges in establishing specific approaches to alleviate associated suffering. For example, data from adults cannot be assumed to apply equally to children. Nor can data from children who present with sex-discordant gender pre-pubertally be presumed to apply to the growing number of post-pubertal adolescent females presenting with this condition.

58. Although gender perceptions, feelings, and "identity" usually align with biological sex, some individuals report experiencing discordance in these distinct traits. Specifically, for example, biological females may report experiencing that they identify as men and biological males may report experiencing that they identify as women. As gender by definition is distinct from biological sex, one's gender identity does not change a person's biological sex. There is currently no

known reliable and valid methodology for assessing the accuracy or nature of unverified, verbal reports of discordant "identity," nor whether that discordant identity will persist or resolve over time. There is thus no known "error rate" for relying upon such reports to engage in hormonal and surgical treatments.

II. Treatments

59. Moving from diagnosis to treatment, two broad approaches are generally used to treat children with gender dysphoria.[54]

A. Watchful Waiting and Exploratory Therapy

60. The first approach, sometimes called "watchful waiting," motivated by an understanding of the natural history of transgender identification in children, is to neither encourage nor discourage transgender identification, recognizing that existing evidence (discussed next) shows that the vast majority of affected children are likely to eventually realign their reports of gender identification with their sex. This realignment of expressed gender identity to be concordant with sex is sometimes called "desistance."

61. The "watchful waiting" approach does not advocate doing nothing. Rather, it focuses on affirming the inherent dignity of affected people and supporting them in other aspects of their lives, including the diagnosis and treatment of any

[54] See K. J. Zucker, On the "Natural History" of Gender Identity Disorder in Children, 47 J. Am. Acad. Child & Adolesc. Psychiatry 1361 (2008).

comorbidities, as individuals proceed through the various stages of physical and psychological development. For instance, the approach may include the use of scientifically validated treatments (e.g., cognitive behavioral therapy) to treat the patient's anxiety, depression, social skills deficits, or other issues.[55] It may also use exploratory therapy to explore potential causes of the dysphoria, which may be linked to trauma, developmental issues, or psychological comorbidities.

62. Despite differences in country, culture, decade, follow-up length, and method, multiple studies have come to a remarkably similar conclusion: Very few gender dysphoric children still want to transition by the time they reach adulthood. Many turn out to have been struggling with sexual orientation issues rather than gender discordant "transgender" identity. The exact number of children who experience realignment of gender identity with biological sex by early adult life varies by study. Estimates within the peer-reviewed published literature range from 50-98%, with most reporting desistance in approximately 85% of children before the widespread adoption of the "affirming" model discussed below.[56] In 2018, for instance, studies found that 67% of children meeting the diagnostic criteria for gender

[55] See J. S. van Bentum et al., Cognitive therapy and interpersonal psychotherapy reduce suicidal ideation independent from their effect on depression, 38 Depression and Anxiety 940 (2021).
[56] T. D. Steensma et al., Factors Associated With Desistence and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study, 52 J. Am. Acad. of Child & Adolesc. Psychiatry 582 (2013); K. D. Drummond et al., A Follow-up Study of Girls with Gender Identity Disorder, 44 Dev. Psychol. 34 (2008); M. S. Wallien et al., Psychosexual Outcome of Gender-Dysphoric Chil-

dysphoria no longer had the diagnosis as adults, with an even higher rate (93%) of natural resolution of gender-related distress for the less significantly impacted cases.[57] A March 2021 study, with one of the largest samples in the relevant literature, suggests that most young gender dysphoric children grow out of the condition without medical interventions.[58] Thus, desistance (i.e., the child accepting their natal, biological sex identity and declining "transitioning" treatments) is the outcome for the vast majority of affected children who are not actively encouraged to proceed with sex-discordant gender affirmation.

63. Decades of peer-reviewed, published scientific research have supported the efficacy of the psychological approaches for the majority of patients experiencing gender dysphoria.[59] Cognitive therapy and interpersonal psychotherapy have been found to reduce suicidal ideation independent of their effect on depression.[60]

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dren, 47 J. Am. Acad. Child & Adolesc. Psychiatry 1413 (2008); K. J. Zucker et al., Gender Identity Disorder and Psychosexual Problem in Children and Adolescents (New York: Guilford Press., 1995) (ISBN 10: 0898622662; ISBN 13: 9780898622669); D. Singh, A Follow-Up Study of Boys With Gender Identity Disorder, i-ii, 103-07 (Ph.D. thesis, University of Toronto 2012), available at https://tspace.library.utoronto.ca/bitstream/1807/34926/1/Singh_Devita_201211_PhD_Thesis.pdf (last visited May 9, 2023).

[57] See, e.g., K. J. Zucker, The myth of persistence: Response to "A critical commentary on follow-up studies and 'desistance' theories about transgender and gender non-conforming children" by T. Newhook et al. (2018), 19 Int'l. J. Transgenderism 231 (2018).

[58] See D. Singh et al., A Follow-Up Study of Boys With Gender Identity Disorder, 12 Frontiers in Psychiatry 632784 (2021).

[59] See K. J. Zucker (2008), On the "Natural History," 47 J. Am. Acad. Child & Adolesc. Psychiatry, at 1361, 1361-63; S. J. Bradley et al., Gender Identity Disorder: A Review of the Past 10 Years, 36 J. Am. Acad. Child & Adolesc. Psychiatry 872-80 (1997).

[60] J. S. van Bentum et al. (2021), Cognitive therapy and interpersonal psychotherapy, 38 Depression and Anxiety at 940 (2021); M. W. Gallagher et al., Trajectories of change in well-being during

Within the "watchful waiting" model, these data support the investigative use of modern psychotherapeutic approaches to address suicidal ideation in children with gender dysphoria (as well as to treat other psychological ailments).

B. Gender Affirming

64. The second, so-called "gender affirming," approach is to affirm the child's present gender identity. This affirmation may have social, medical, legal, and behavioral dimensions. Typically, the "affirming" approach encourages children to embrace transgender identity with social transitioning followed by puberty blockade and hormonal therapy (cross-sex hormones), and potential surgical interventions.[61] This approach is considered below.

65. The first stage of this approach is social affirmation. Included interventions include allowance of name change, use of preferred pronouns, wearing of sex-stereotyped clothing, and access to sex-segregated facilities (bathrooms and locker rooms) corresponding to the child's gender identification. While often presented as a neutral intervention, there is concern that social affirmation will alter the rate of spontaneous desistance. As noted by Steensma et al., "one may wonder whether a childhood transition has an effect by itself and influences the cognitive

cognitive behavioral therapies for anxiety disorders: Quantifying the impact and covariation with improvements in anxiety, 57 Psychotherapy 379 (2020).

[61] See A. Walch et al., Proper Care of Transgender and Gender Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective, 106 J. Clin. Endocrinol. & Metabol. 305 (2021).

gender identity representation of the child and/or their future development"; this "hypothesized link between social transitioning and the cognitive representation of the self [may] influence the future rates of persistence."[62] For this reason, in the original Dutch protocol social transition of pre-pubertal children was discouraged. The Dutch protocol authors reference the prior work of Wallien and Cohen-Kettenis[63] in asserting that "because most gender dysphoric children will not remain gender dysphoric through adolescence, we recommend that young children not yet make a complete social transition (different clothing, a different given name, referring to a boy as 'her' instead of 'him') before the very early stages of puberty."[64] In the initial 2009 Endocrine Society guidelines, it was stated that "given the high rate of remission of GID [gender identity disorder] after the onset of puberty, we recommend against a complete social role change and hormone treatment in prepubertal children with GID."[65] Current data validate this concern. In the 2022 study by Olson et al., 94% of children who were socially affirmed persisted with sex-discordant

[62] T. D. Steensma et al., Factors Associated with Desistence and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-up Study, Chapter 6 in T. D. Steensma, From Gender Variance to Gender Dysphoria: Psychosexual development of gender atypical children and adolescents, 97, 115 (Ph.D. thesis, Vrije Universiteit Amsterdam, 2013), available at https://research.vu.nl/ws/files/42117780/hoofdstuk%2006.pdf (last visited May 1, 2023).
[63] M. S. C. Wallien et al. (2008), Psychosexual Outcome of Gender-Dysphoric Children, 47 J. Am. Acad. Child & Adolesc. Psychiatry, at 1413 (2008).
[64] A. L. C. de Vries et al., Clinical management of gender dysphoria in children and adolescents: the Dutch approach, 59 J. Homosex. 301 (2012).
[65] W. C. Hembree et al., Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline, 94 J. Clin. Endocrinol. & Metabol. 3132, 3132-33 (2009).

gender identity.[66] This is in sharp contrast to the low rates of persistence prior to adoption of social affirmation in pre-pubertal children with sex-discordant gender identity.[67]

66. Before analyzing gender affirmative medical interventions, it is important to understand that underlying biology is not changed by altering bodily features to appear as the opposite sex, and such alterations do not change disease vulnerabilities associated with genetically defined sex. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by genetic makeup, normatively by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally-defined sex.[68] For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. It is possible for some adolescents and adults to pass unnoticed as the

[66] K. R. Olson et al., Gender Identity 5 Years After Social Transition, 150 Pediatrics e2021056082. (2022).
[67] M. S. C. Wallien et al. (2008), Psychosexual Outcome of Gender-Dysphoric Children, 47 J. Am. Acad. Child & Adolesc. Psychiatry, at 1413-23. The rate of persistence in this study was 27%. *Id.* at 1413, 1416, 1420.
[68] See Exploring the biological contributions to human health: does sex matter?, (Institute of Medicine (U.S.), T. M. Wizemann, & M. L. Pardue eds., 2001) (hardcover edition); Exploring the Biological Contributions to Human Health: Does Sex Matter?, (2001), http://www.nap.edu/catalog/10028 (last visited Apr 8, 2023) (electronic editions).

opposite gender that they aspire to be — but with limitations, costs, and risks.[69] And their underlying biology does not change.

1. Puberty Blockers

67. Only in the 1990s did GnRH analogues begin being used to suppress puberty in children who identify as the opposite sex. In 1998, Peggy Cohen-Kettenis and Stephanie van Goozen, psychologists at a Dutch gender clinic, described the case of a 13-year-old female gender-dysphoria patient, on whom a GnRH analogue was used to suppress puberty before the patient received a definitive diagnosis of gender identity disorder at age 16. At age 18, the patient underwent sex-reassignment surgery.[70]

68. The clinic's scientists developed an influential protocol, often referred to as the "Dutch protocol," which involved puberty suppression followed by cross-sex hormones and potential surgical interventions.[71] In many clinics that adhere to the gender affirmation model, the ages for initiating sex-discordant, gender-affirming, sex-steroid hormones has deviated substantially from the original Dutch

[69] See S. B. Levine, Informed Consent for Transgendered Patients, 45 J. Sex & Marital Therapy, 218 at *6 (2018) ("Informed Consent"); S. B. Levine, Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, 44 J. Am. Acad. Psychiatry & L. 236, 238 (2016) ("Reflections on Legal Battles").

[70] P. T. Cohen-Kettenis et al., Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent, 7 Eur. Child & Adolesc. Psychiatry 246 (1998). See also P, T. Cohen-Kettenis et al., Treatment of Adolescents With Gender Dysphoria in the Netherlands, 20 Child and Adolesc. Psychiatric Clinics of N. Am. 689 (2011).

[71] M. Biggs, The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence, J. Sex & Marital Therapy, 1 (Sept.19, 2022).

protocol. The typical protocol is to initiate puberty blockers (GnRH analogs) as soon as puberty begins (Tanner Stage 2), which can occur as early as 8 years in females and 9 years in males. While in the Dutch protocol, cross-sex hormones started at 16 years, the Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (SOC-8), the latest guidelines published by the World Professional Association for Transgender Health (WPATH), made no recommendations on specific ages for initiation of gender-affirming medical interventions, stating that decisions need to be made on an individual basis with the possibility of there being compelling reasons to start interventions earlier.[72] Gender-affirming surgery in the Dutch model was reserved to (and originally required for) patients 18 years or older. Again, WPATH discusses surgery for minors, noting that "[c]hest masculinization surgery can be considered in minors when clinically and developmentally appropriate," and suggesting that "there may be a benefit for some adolescents to having [vaginoplasties] performed before the age of 18."[73] GnRH analogs are discontinued after gonadectomy is performed as this medication is no longer needed to suppress gonads that are no longer present. Due to the suppressive effect of exogenous sex-steroids on gonadal function, GnRH analogs are often

[72] E. Coleman et al., Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, 23 Int'l. J. Transgender Health, 51-5258, 556-66, S1, S65-66 (Sept. 6, 2022) ("SOC-8").
[73] *Id.* at 566.

stopped after gender-affirming hormone administration has been titrated to maximal doses required to achieve the desired change in secondary sex characteristics.

69. This gender "affirming" model, with its reliance on hormones and surgical interventions, would make gender dysphoria unique among psychiatric conditions: sex reassignment surgery "for Gender Dysphoria is symptom based. It does not correct a biological abnormality.[74] The same is true for hormone-based interventions.

70. These scientists, along with others (such as Dr. Ladinsky at p. 9 of her report), have claimed that puberty suppression is "fully reversible."[75] On this view, puberty suppression "give[s] adolescents, together with the attending health professional, more time to explore their gender identity, without the distress of the developing secondary sex characteristics. The precision of the diagnosis, it is claimed, may thus be improved."[76]

71. This assertion appears to presume that natural sex characteristics interfere with the "exploration" of gender identity, when one would expect that the development of natural sex characteristics might contribute to the natural consolidation of one's gender identity. It is based upon an untested scientific

[74] S. B. Levine (2016), Reflections on Legal Battles, 44 J. Am. Acad. Psychiatry & L., at 240.
[75] H. A. Delemarre-van de Waal et al., Clinical management of gender identity disorder in adolescents: a protocol on psychological and paediatric endocrinology aspects, 155 Eur. J. of Endocrinol., S131, S133 (Nov. 1, 2006).
[76] P. T. Cohen-Kettenis et al., The Treatment of Adolescent Transsexuals: Changing Insights, 5 J. Sexual Med. 1892, 1894 (2008).

premise that interfering with the development of natural sex characteristics can allow for a more accurate diagnosis of the gender identity of the child. Given that nearly all gender dysphoric adolescents who begin puberty blockers proceed to cross-sex hormones,[77] it seems more plausible that the interference with normal pubertal development will influence the gender identity of the child by reducing the prospects for developing a gender identity corresponding to his or her biological sex.

72. Given their potential importance in the lives of the affected children, claims about reversibility require careful examination. In developmental biology, it makes little sense to describe anything as "reversible." If a child does not develop certain characteristics at age 12 because of a medical intervention, then his or her developing those characteristics at age 18 is not a "reversal," since the sequence of development has already been disrupted. This is especially important since there is a complex relationship between physiological and psychosocial development during adolescence. Gender identity is shaped during puberty and adolescence as young people's bodies become more sexually differentiated and mature. Given how little we understand about gender identity and how it is formed and consolidated, we should be cautious about interfering with the normal process of sexual maturation.

[77] M. A. T. C. van der Loos et al., Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence: a cohort study in the Netherlands, 6 Lancet Child & Adolesc. Health 869 (2022).

73. A more relevant question is whether the physiological and psychosocial development that occurs during puberty can resume in something resembling a normal way after puberty-suppressing treatments are withdrawn. In children with precocious puberty, this does appear to be the case. Puberty-suppressing hormones are typically withdrawn around the average age for the normal onset of gonadarche, at about age 12, and normal hormone levels and pubertal development gradually resume. For one common method of treating precocious puberty, girls reached menarche approximately a year after their hormone treatments ended, at an average age of approximately 13, essentially the same average age as the general population.[78] The evidence for the safety and efficacy of puberty suppression in boys is less robust, chiefly since precocious puberty is much rarer in boys. Although the risks are speculative and based on limited evidence, boys who undergo puberty suppression may be at greater risk for the development of testicular microcalcifications, which may be associated with an increased risk of testicular cancer, and puberty suppression in boys may also be associated with obesity.[79]

[78] M. M. Fisher et al., Resumption of Puberty in Girls and Boys Following Removal of the Histrelin Implant, 164 J. Pediatrics 912, 912-16 (2014).
[79] S. Bertelloni, Treatment of central precocious puberty by GnRH analogs: long-term outcome in men, 10 Asian J. Androl. 525, 531 (2008).

74. Unlike children affected by precocious puberty, adolescents with gender dysphoria do not have any physiological disorders of puberty that are being corrected by the puberty-suppressing drugs. The fact that children with suppressed precocious puberty between ages 8 and 12 resume puberty at age 13 does not mean that adolescents suffering from gender dysphoria whose puberty is suppressed beginning at age 12 will simply resume normal pubertal development later if they choose to withdraw from the puberty-suppressing treatment and choose not to undergo other sex-reassignment procedures. Interrupting puberty in this manner may have significant effects on final stature and bone density.[80]

75. After an extended period of pubertal suppression one cannot "turn back the clock" and reverse changes in the normal coordinated pattern of adolescent psychological development and puberty.[81] Once puberty is blocked, even if eventually unblocked (and assuming signaling from the pituitary gland resumes), the person cannot "buy back" the time when the physical process of puberty has been disrupted

[80] T. Joseph et al., The effect of GnRH analogue treatment on bone mineral density in young adolescents with gender dysphoria: findings from a large national cohort, 32 J. Pediatric Endocrinol. and Metabol. 1077, 1077-81 (2019); D, Klink et al., Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria, 100 J. Clin. Endocrinol. & Metabol., E270-E275 (2015).

[81] See P. W. Hruz et al., Growing Pains, 52 The New Atlantis: A Journal of Technology and Society, 3 (Spring 2017). See also N. Vijayakumar et al., Puberty and the human brain: Insights into adolescent development, 92 Neurosci. & Biobehav. Revs 417 (2018); S. Choudhury, Culturing the adolescent brain: what can neuroscience learn from anthropology?, 5 Social Cognitive and Affective Neurosci. 159 (2010).

at the time when it would normally occur with complementary psychological processes in that stage in the person's life.

76. A possible effect of blocking normally timed puberty is alteration of normal adolescent brain maturation.[82]

77. Another troubling question that has been largely uninvestigated is what psychological consequences there might be for children with gender dysphoria whose puberty has been suppressed and who later come to identify as their biological sex.

78. In addition to the reasons to suspect that puberty suppression may have side effects on physiological, psychological, and brain development, the evidence that something like normal puberty will resume for these patients after puberty-suppressing drugs are removed is very weak. Data obtained from the treatment of precocious puberty cannot be assumed to apply equally to the disruption of puberty that begins after 8 years of age in females and after 9 years of age in males.

79. In addressing the concern of puberty blockers on bone density, Dr. Ladinsky's declaration references the paper by Van der Loos[83] without discussing that

[82] See M. Arain et al., Maturation of the adolescent brain, 9 Neuropsychiatric Disease and Treatment, 449 (2013).
[83] M. A. T. C. van der Loos et al., Development of Hip Bone Geometry During Gender-Affirming Hormone Therapy in Transgender Adolescents Resembles That of the Experienced Gender When Pubertal Suspension Is Started in Early Puberty, 86 J. Bone and Mineral Rsch. 931 (2021).

this study examined bone geometry, not bone density. Since bone density is normally increasing during the teenage years, observing an increase in bone density measurement does not indicate lack of adverse effect.[84] The relevant parameter is the bone density in relation to mean bone density in age and size matched controls. This is generally assessed as a "z-score." In both the Klink and Vlot studies referenced in footnote 21 of Dr. Ladinsky's report, it was observed that there was a failure to regain pre-treatment z-scores for bone density. This supports the concern that interruption of normally timed puberty adversely affects bone density.

80. In Dr. Shumer's declaration (page 22, ¶ 16) he correctly acknowledges that it is necessary "to complete puberty to produce viable eggs or sperm." However, he fails to present the existing evidence that nearly all patients who are placed on puberty blockers will proceed to cross-sex hormones.[85] As discussed next, it is this later drug exposure that is of concern for irreversible sterility. There are no existing data to demonstrate that the exposure of immature gonads to sex-hormones corresponding to the opposite sex is "safe and reversible." The concern for irreversible

[84] L. K. Bachrach, Acquisition of optimal bone mass in childhood and adolescence, 12 Trends in Endocrinol. & Metabol. 22 (2001).
[85] M. A. T. C. van der Loos et al. (2022), Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence, 6 Lancet Child & Adolesc. Health, at 869-75.

effects on fertility is the basis for recommendations to cryopreserve sperm or eggs prior to initiation of this intervention.[86]

2. Cross-Sex Hormones

81. Rather than resuming biologically normal puberty, adolescents treated on the "affirming" model overwhelmingly go from suppressed puberty to medically conditioned cross-sex puberty, when they are administered cross-sex hormones.[87] Specifically, exogenous estrogen is administered to biological men to induce gynecomastia (i.e., the enlargement of breast tissues), and testosterone is administered to biological women to induce virilization (i.e., the development of facial hair and other desired male features) and to interfere with normal ovarian function.

82. Along with (and often before) estrogen is administered to biological males in this treatment, spironolactone may be used as an androgen blocker. Spironolactone is primarily used for the treatment of blood pressure and heart failure. It is a mineralocorticoid antagonist, meaning that it blocks the function of proteins in the kidney that regulate salt retention. But it also has effects in blocking the action of androgens. As discussed, androgens are masculinizing hormones that lead to virilization. Testosterone is a prime androgen, but other androgens are also made in

[86] P, J. Cheng et al., Fertility concerns of the transgender patient, 8 Translational Androl. and Urol. 209 (2019).
[87] M. A. T. C. van der Loos et al. (2022), Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence, 6 Lancet Child & Adolesc. Health, at 869-75.

the gonads and adrenal gland. Spironolactone is sometimes used in the treatment of polycystic ovarian syndrome, in which females will undergo virilization due to excess androgen production in the ovaries. This syndrome can have adverse effects on fertility, metabolic health, and cardiovascular health.[88] The diagnosis of polycystic ovarian syndrome is a clinical diagnosis based upon the physical evidence of virilization or androgen effects, insulin resistance, and irregular periods. There are objective biological measures to assess those androgen levels, most notably elevated free testosterone levels. And there are objective measures of dysregulation of relevant signals from the pituitary gland, the LH and the FSH, to complement the clinical diagnosis by looking at the degree of virilization that is present in the patient.

83. Spironolactone would not be prescribed to male patients for an endocrinologic purpose related to androgen production. Once again, this reflects a fundamental biological difference between males and females. Though spironolactone can be used to regulate the levels of potassium and sodium in the body, such treatment would be based on objective markers of those levels.

84. Likewise, the administration of the sex steroid hormones differ by the sex of the individual. It is not identical to give testosterone to a male as it is to give it to a female, nor is it the same treatment to give estrogen to a male versus female.

[88] M. H. Hunter et al., Polycystic Ovary Syndrome: It's Not Just Infertility, 62 Am. Fam. Physician 1079, 1079-88 (2000).

This difference has an established scientific basis. The differences between males and females occurs in every nucleated cell of the body, for males and females have different genetic programming. This is a process known as epigenetics, meaning that there are modifications of the DNA itself that alter the expression of genes when exposed to the same stimulus. As noted above, there are over 6,000 sex-differentially expressed genes. So, if one gives testosterone to a male, the physiologic effects of that treatment, even in the measurement at which genes are turned on and turned off, will be different than if one gives testosterone to a female.[89]

85. In congenital or acquired conditions where there is a defect in the ability to produce endogenous sex-steroid hormones, the goal of administering testosterone or estrogen is to restore the body to its natural state had the defect not been present. For example, females with Turner syndrome have premature ovarian failure and are therefore given estrogen to preserve bone health and allow normal pubertal maturation. Males with Klinefelter syndrome have primary hypogonadism and are therefore given testosterone to achieve normal lean body mass, bone density, hematocrit, and other androgen mediated bodily changes. Importantly, sex-steroid hormone doses are adjusted to maintain levels within the normal range for the sex of that individual.

[89] M. Gershoni et al., The landscape of sex-differential transcriptome and its consequent selection in human adults, 15 BMC Biol. 7 (2017)

86. While the normal range for testosterone levels in a male adolescent who has completed puberty is 300-900 ng/dL, testosterone levels for a female adolescent are 15-70 ng/dL. Testosterone levels can be elevated in females with pathologic conditions such as polycystic ovarian syndrome, but levels generally are less than 150 ng/dL. Levels above 200 ng/dL would generally necessitate evaluation for an adrenal or ovarian tumor.

87. When a patient with gender dysphoria is placed on cross-sex hormones, per the Dutch protocol, puberty-suppressing GnRH analogues continue to be administered until exogenous administration of cross-sex hormones (i.e., sex hormones normally produced by the gonads of the opposite sex) leads to sufficient suppression of endogenous sex hormone production, or the gonads are surgically removed. With pubertal blockade, sex hormones that are normally secreted by the maturing gonads are not produced. This means that adolescents undergoing cross-sex hormone treatment circumvent the most fundamental form of sexual maturation — the maturation of their reproductive organs.

88. For males who are being medically transitioned, exogenously administered estrogen will suppress testosterone production through feedback inhibition of pituitary LH and FSH secretion. Without pubertal blockade, this reduction of endogenous testosterone production is usually not sufficient to fully prevent viriliza-

tion, and it is therefore necessary to add anti-androgenic medications such as spironolactone. For females being medically transitioned, exogenously administered testosterone will usually result in the cessation of menses and lead to the expected effect of virilization.

89. Patients undergoing gender affirming surgery discontinue GnRH treatment after having their gonads removed, since the secretion of sex hormones that the treatment is ultimately intended to prevent will no longer be possible. These patients are then sterile, as loss or alteration of primary sexual organs leads directly to impairment of reproductive potential.

90. Although the long-term effect of exposing immature gonads to cross-sex hormones is currently unknown, it is generally accepted, even by advocates of transgender hormone therapy, that hormonal treatment impairs fertility, which may be irreversible.[90] Specifically, estrogen administration to males who identify as women results in impaired spermatogenesis and an absence of Leydig cells in the testis.[91] Exogenous testosterone administration to females who identify as men causes ovarian stromal hyperplasia and follicular atresia.[92] Recognition of these

[90] See L. Nahata et al., Low Fertility Preservation Utilization Among Transgender Youth, 61 J. Adolesc. Health 40 (2017).
[91] C. Schulze, Response of the human testis to long-term estrogen treatment: Morphology of Sertoli cells, Leydig cells and spermatogonial stem cells, 251 Cell and Tissue Rsch. 31 (1988).
[92] T. D. Pache et al., Ovarian morphology in long-term androgen-treated female to male transsexuals. A human model for the study of polycystic ovarian syndrome?, 19 Histopathol. 445 (1991);

consequences is the basis for the development of new areas of medical practice where there is an attempt to restore fertility that has been intentionally destroyed.[93]

91. Gametes (sperm and ova) require natural puberty to mature to the point that they are viable for reproduction.[94] While it is expected that the exposure of immature gonads to cross-sex hormones will lead to infertility, whether affected individuals have permanent sterility has not been established. Much of the uncertainty arises from the novelty of this intervention and the lack of long term follow up. There are limited reports of successful pregnancies after cross-sex hormones, but all of the subjects started gender-affirming hormones as adults after completing puberty.[95] While Dr. Shumer's report in this case implies that it is possible for an adult patient who was previously treated with GnRHa followed by hormone therapy to achieve fertility by withdrawing hormones (pages 24-25), he does not provide any published data to support this assertion. I am not aware of any reports that show this for children who were exposed to puberty blockers before completing puberty followed by cross-sex hormones.

K. Ikeda et al., Excessive androgen exposure in female-to-male transsexual persons of reproductive age induces hyperplasia of the ovarian cortex and stroma but not polycystic ovary morphology 28 Human Reproduction 453 (2013).

[93] See, e.g., A. J. Ainsworth et al., Fertility Preservation for Transgender Individuals: A Review, 95 Mayo Clinic Proceedings 784, 784-92 (2020).

[94] H. E. Kuhn et al., The Onset of Sperm Production in Pubertal Boys: Relationship to Gonadotropin Excretion, 143 Am. J. Diseases in Children 190 (1989).

[95] I. de Nie et al., Successful restoration of spermatogenesis following gender-affirming hormone therapy in transgender women, 4 Cell Reports Med. 100858 (2023).

92. There are many other known risks to puberty suppression followed by cross-sex hormones beyond fertility concerns. As noted, emerging data show that treated patients have lower bone density, which may lead to increased fracture risk later in life.[96] Other potential adverse effects include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease.[97] In addition, non-physiological levels of estrogen in males has been shown to increase the risk of thromboembolic stroke above the incidence observed in females.[98]

93. In her declaration, Dr. Ladinksy, similar to Dr. Shumer, makes misleading or erroneous statements about the potential or known adverse effects of interrupting normally timed puberty with GnRH analogues and the administration of "gender-affirming" sex-steroid hormones. This includes appeal to data on the safety of using these drugs in treating precocious puberty, where the effect of the intervention is to restore the patient to the normal phase of quiescence of the

[96] See D. Klink et al. (2015), Bone Mass in Young Adulthood, 100 J. Clin. Endocrinol. & Metabol., at E270-E275.

[97] See L. J. Seal, A review of the physical and metabolic effects of cross-sex hormonal therapy in the treatment of gender dysphoria, 53 Annals Clin. Biochem. 10 (2016); K. Banks et al., Blood Pressure Effects of Gender-Affirming Hormone Therapy in Transgender and Gender-Diverse Adults, 77 Hypertension 2066, 2066-74 (2021); D. Getahun et al., Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study, 169 Annals of Internal Med. 205 (2018); S. Maraka et al., Sex Steroids and Cardiovascular Outcomes in Transgender Individuals: A Systematic Review and Meta-Analysis, 102 J. Clin. Endocrinol. & Metabol., 3914, 3914-23 (2017).

[98] See, e.g. D. Getahun et al. (2018), Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons, 169 Annals of Internal Med., at 205, *6-*8.

pituitary-gonadal axis. Further assertions that such treatments are the same as those used to treat conditions that are associated with infertility (e.g., Turner syndrome and Klinefelter syndrome) ignore the striking differences in both physiological attributes and goal of intervention. Assertions made based upon "personal experience" fall far short of the standard necessary to establish proportionate benefit relative to treatment risk. Some potential adverse effects can only be ascertained with directed testing that goes beyond what is normally performed as screening tests done in medical clinics. Cancer and cardiovascular and metabolic risks often take decades to manifest. The failure to observe patients with myocardial infarction (heart attack), thromboembolic events (stroke), or cancer in adolescent patients exposed to testosterone or estrogen at levels at or exceeding those observed in known disease states (e.g., polycystic ovarian syndrome or hormone-secreting tumors) does not mitigate concerns with these interventions in youth who experience sex-discordant gender identity.

ENDOCRINE SOCIETY AND WPATH GUIDELINES

94. A reasonable understanding of relative risk versus benefit for medical products or procedures is a fundamental obligation in providing appropriate clinical care. This is the bedrock standard of "evidence-based medical practice." When considering clinical practice guidelines, it is essential that physicians recognize the relative risks and benefits of such documents. If done properly, they can distill large

data sets into actionable clinical recommendations. However, there is a long history of clinical practice guidelines that have later been found to be deficient, resulting in wasted medical resources, failure to achieve desired benefits, and, at times, substantial harm to patients.[99]

95. As detailed throughout this report, this foundational standard of "evidence-based medical practice" has never been met as to so-called gender affirming care. The field of "affirming care" is characterized by a poor quality of evidence regarding safety and efficacy, as well as attempts to silence standard scientific discussion and consideration of alternative hypotheses; failures to acknowledge existing data showing persistence of suicidality after intervening; the intentional impairment and destruction of normally formed and functioning male and female sexual organs to address psychological-psychiatric distress; the manipulation of language from standard medical definitions; and widespread failures to properly report research data related to gender transitioning.

96. Despite the dangers of confirmation bias, existing guidelines base recommendations for "affirming" medical interventions on uncorroborated patient self-reports, assessed by mental health professionals with no methodology for discerning

[99] See S. H. Woolf et al., Clinical guidelines: potential benefits, limitations, and harms of clinical guidelines, 318 BMJ 527 (1999).

accurate patient reports, no alternative treatments offered, and no alternative explanations (e.g., social contagion) explored. There is no biological test to verify the diagnosis.

I. Endocrine Society

97. In 2009, the Endocrine Society published clinical guidelines for the treatment of patients with persistent gender dysphoria.[100] The recommendations include temporary suppression of pubertal development of children with GnRH agonists followed by hormonal treatments to induce the development of secondary sexual traits consistent with one's gender identity. In developing these guidelines, the authors assessed the quality of evidence supporting the recommendations made with use of the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) system for rating clinical guidelines. As stated in the Endocrine Society publication, "the strength of recommendations and the quality of evidence was low or very low."[101] According to the GRADE system, low recommendations indicate that "[f]urther research is very likely to have an important impact on our confidence

[100] See W. C. Hembree et al. (2009), Endocrine Treatment of Transsexual Persons, 94 J. Clin. Endocrinol. & Metabol. at 3132, 3132-54.
[101] *Id.* at 3132.

in the estimate of effect and is likely to change the estimate."[102] Very low recommendations mean that "any estimate of effect is very uncertain."[103]

98. The Endocrine Society published an updated set of guidelines in September 2017.[104] Those guidelines show that all recommendations as to "affirming" treatment of adolescents are supported by low or very low-quality evidence.[105] Despite this low-quality evidence in this document, strong recommendations are frequently made on the basis of the "values and preferences" of either the Endocrine Society or the patient.[106] For instance, the Endocrine Society's recommendations expressly place "a lower value on avoiding potential harm from early pubertal suppression."[107]

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[102] G. H. Guyatt et al., GRADE: an emerging consensus on rating quality of evidence and strength of recommendations, 336 BMJ 924, 926 (2008).
[103] *Id.*
[104] See W. C. Hembree et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, 102 J. Clin. Endocrinol. & Metabol., 3869, 3869-3903 (2017). See also Corrigendum for "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," 103 J. Clin. Endocrinol. & Metabol. 2758 (July 2018) ("Endocrine Society Clinical Practice Guideline"); Corrigendum for "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline," 103 J. Clin. Endocrinol. & Metabol. 699 (Feb. 2018).
[105] J. Block, Gender dysphoria in young people is rising — and so is professional disagreement, 380 BMJ 382, at *2 (2023). See also W. C. Hembree et al. (2017), Endocrine Society Clinical Practice Guideline, 102 J. Clin. Endocrinol. & Metab. at 3869-3903.
[106] See, e.g., W. C. Hembree et al. (2017), Endocrine Society Clinical Practice Guideline, 102 J. Clin. Endocrinol. & Metab., at 3872-73, 3881, 3894.
[107] *Id.* at 3881.

99. Dr. Guyatt, a co-developer of the GRADE system, "found 'serious problems' with the Endocrine Society guidelines, noting that the systematic reviews didn't look at the effect of the interventions on gender dysphoria itself, arguably 'the most important outcome.'"[108] He also criticized the Endocrine Society guidelines for pairing strong recommendations with weak evidence, explaining that such practice is discouraged "except under very specific circumstances."[109] He states that except under very specific circumstances, such practice is discouraged.[110]

100. The Endocrine Society guidelines state that "[w]eak recommendations require more careful consideration of the person's circumstances, values, and preferences to determine the best course of action."[111] These values and preferences include the desire of the individual seeking gender-affirming medical interventions, who may be operating under an *a priori* presumption (encouraged by the Endocrine Society's "strong recommendations") that these will lead to improved mental health. As detailed throughout this declaration, the existing data do not support this presumption. Instead, the existing data substantiate Dr. Guyatt's concerns as summarized by J. Block:

> For Guyatt, claims of certainty represent both the success and failure of the evidence based medicine movement. "Everybody now has to claim

[108] J. Block (2023), Gender dysphoria in young people is rising, 380 BMJ 382, at *2-*3.
[109] *Id.* at *3.
[110] *Id.*
[111] W. C. Hembree et al. (2017), Endocrine Society Clinical Practice Guideline, 102 J. Clin. Endocrinol. & Metab., at 3872-73, 3885.

> to be evidence based" in order to be taken seriously, he says—that's the success. But people "don't particularly adhere to the standard of what is evidence based medicine—that's the failure." When there's been a rigorous systematic review of the evidence and the bottom line is that "we don't know,'" he says, then "anybody who then claims they do know is not being evidence based."[112]

101. The assertion by Dr. Antommaria that reliance on low-quality evidence to recommend gender-affirming medical interventions for adolescents who experience gender dysphoria is justified by comparison to other clinical practice guidelines issued by the Endocrine Society (Obesity and Congenital Adrenal Hyperplasia) fails to address fundamental differences in potential risk versus purported benefit in these different conditions. The three recommendations in the Gender Dysphoria guidelines supported by moderate-level evidence refer to the need to make an accurate diagnosis, the need to address medical conditions that could be exacerbated by hormonal treatment, and the need for fertility preservation efforts. All other recommendations in the Gender Dysphoria guidelines are based upon low or very low level of evidence. In the Obesity Guidelines listed in Exhibit C, Table 1 of Dr. Antommaria's report, strong recommendations made with weak evidence are generally in reference to interventions such as reducing screen time, getting more exercise, or changing diet. The potential risks of these interventions are very low and can be justified with limited evidence. This is vastly different than recommendations for initiation of

[112] J. Block (2023), Gender dysphoria in young people is rising, 380 BMJ 382, at *4.

pubertal blockade with a GnRH analogue or referral for gender-affirming surgery. The higher the risk, the greater the requirement for strong evidence of safety and efficacy.

102. It is highly misleading to imply that the current Endocrine Society guidelines[113] represent the opinions of the Society's 18,000 members. The committee that drafted these guidelines was composed of *less than a dozen* members. The guidelines were never submitted to the entire Endocrine Society membership for comment and approval prior to publication. They also did not undergo external review. Such methodologies are common in association "statements" and "endorsement;" they are not scientific or generally reliable.

103. The panel that drafted the Endocrine Society guidelines was heavily composed of individuals who have significant associations with WPATH. Specifically, all but one of the committee members were leaders in WPATH. Two of the authors served as WPATH's president (Walter J. Meyer and Vin Tangpricha);[114] at

[113] W. C. Hembree et al. (2017), Endocrine Society Clinical Practice Guideline, 102 J. Clin. Endocrinol. & Metab., at 3872.

[114] A. Devor, History, WPATH World Professional Association for Transgender Health, https://www.wpath.org/about/history (last visited Apr 12, 2023) (Walter Meyer III, M.D. (President, 2003-2005)); Profile, Vin Tangpricha MD/PHD, Emory School of Medicine, https://med.emory.edu/departments/medicine/divisions/endocrinology/profile/?u=VTANGPR (last visited Apr 12, 2023).

least five have served, or are serving, on WPATH's Board of Directors (Peggy Cohen-Kettenis, Louis Gooren, Stephen Rosenthal, Joshua Safer, Guy T'Sjoen);[115] and at least four (Stephen Rosenthal, Joshua Safer, Vin Tangpricha, and Guy T'Sjoen) were authors of WPATH SOC-8[116]. Three (Peggy Cohen-Kettenis, Walter Meyer, and Vin Tangpricha) were authors of WPATH SOC-7.[117]

II. WPATH

104. The World Professional Association for Transgender Health (WPATH) has also issued several iterations of guidelines. The first set of clinical practice guidelines was published in 1979. WPATH published its latest version of their "Standards of Care for the Health of Transgender and Gender Diverse People" (SOC-8) in September 2022.[118] While this document has been presented as "authoritative" and "evidence-based," numerous concerns have been raised about the updated recommendations. Changes in SOC-8 include removal of age limits for initiation of cross-sex hormones and gender-affirming surgery,[119] recommendations with

[115] A. Devor, History, WPATH (Peggy Cohen-Kettenis (Board of Directors, 2003-2005), Louis J. G. Gooren, MD (Board of Directors, 1999-2003)); WPATH, Executive Committee and Board of Director, WPATH World Professional Association for Transgender Health, https://www.wpath.org/about/EC-BOD (last visited Apr 12, 2023) (Stephen Rosenthal, MD (Board of Directors, Member-at-Large, 2020-2024), Joshua Safer, MD (Board of Directors, Member-at-Large, 2022-2026), Guy G. R. T'Sjoen, MD, PhD (EPATH Representative — Term Determined by Board of Directors)).
[116] E. Coleman et al. (2022), SOC-8, 23 Int'l. J. Transgender Health, at 51-5258.
[117] E. Coleman et al., Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7, 13 Int'l. J. Transgenderism 165 (2012) ("SOC-7").
[118] E. Coleman et al. (2022), SOC-8, 23 Int'l. J. Transgender Health, at 51-5258, S1-259.
[119] See, e.g., J. Block (2023), Gender dysphoria in young people is rising, 380 BMJ 382, at *1.

language sufficiently flexible to encourage the exclusion of parents from the decision-making process if they question or challenge medical interventions,[120] elimination of safeguards for addressing underlying mental health illness before the start of gender-affirming medical interventions,[121] and the addition of a section on "eunuch-identified" people.[122] Many of the recommendations made reflect WPATH's acknowledged agenda as an advocacy group. In SOC-8, WPATH specifically states, "Health is promoted through public policies and legal reforms that advance tolerance and equity for gender diversity and that eliminate prejudice, discrimination, and stigma. WPATH is committed to advocacy for these policy and legal changes."[123] Despite the claim that the SOC-8 guidelines are based upon solid scientific evidence, such recommendations represent ideological positions devoid of rigorous scientific evidence.[124] Scientific data on long-term outcomes in adolescents who are exposed to the U.S. affirmation model simply do not exist.

[120] See, e.g., E. Coleman et al. (2022), SOC-8, 23 Int'l. J. Transgender Health, at 5548 and Recommendation 6.11 ("We recommend when gender-affirming medical or surgical treatments are indicated for adolescents, health care professionals working with transgender and gender diverse adolescents involve parent(s)/guardian(s) in the assessment and treatment process, unless their involvement is determined to be harmful to the adolescent *or not feasible*." (emphasis added)).
[121] P. Toro, 7 takeaways for HR from the new transgender guidelines, HR Executive (2022), https://hrexecutive.com/7-takeaways-for-hr-from-the-new-transgender-guidelines/ (last visited Apr 29, 2023) ("Operationally, this means that TGD individuals do not require a mental health evaluation in order to obtain medical or surgical services. This is quite different from the prior guideline, which required mental health sign-off from one or two mental health providers in order to obtain gender-affirming surgery.").
[122] E. Coleman et al. (2022), SOC-8, 23 Int'l. J. Transgender Health, at 51-5258, S1-259.
[123] *Id.* at 55.
[124] See, e.g., J. Block (2023), Gender dysphoria in young people is rising, 380 BMJ 382, at *1-*3.

105. In sum, clinical guidelines or standards of care should provide practitioners with evidence-based standards by which they may reliably inform the patient of projected outcomes, and do so with a known error rate. Such data is the starting point for obtaining informed consent. This information is not provided by either WPATH or Endocrine Society's guidelines.

INFORMED CONSENT

106. The fundamental purpose of the practice of medicine is to treat disease and alleviate suffering. An essential tenet of medical practice is to avoid doing harm in the process. As discussed above, relying on clear, valid, reliable, and definitive evidence on how to best accomplish treatment goals is the essential ethical, professional, scientific, and clinical goals of physicians. Using "affirming" treatments on minors violates this essential principle by using experimental treatments on vulnerable populations without properly informing them of the actual risks and limitations of the treatments.[125]

107. It is now universally agreed that medical and psychotherapy patients have a right to proper informed consent. Professional ethics codes, licensing rules and regulations, hospital rules and regulations, state and federal laws, and biomedi-

[125] See A. R. Jonsen et al., Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine (4th ed. 1998).

cal conventions and declarations all protect patients' right to informed consent discussions of the risks and benefits of proposed treatments and alternative treatments including no treatment.[126]

108. Essential requirements for informed consent include the ability of the patient or study subject to understand the proposed procedure, full disclosure of known and potential risks and benefits, discussion of alternative treatments, and freedom to act voluntarily. This information is presented verbally and in written form with allowance of sufficient time for the patient to ask questions and for the provider to assess adequate comprehension by the patient. It is well recognized that the signing of a formal consent form does not guarantee that informed consent has been obtained.

109. Several aspects of the care of individuals with gender dysphoria may substantially interfere with proper application of these foundational principles.[127] For adolescent children seeking medical gender affirmation, well-established limitations in decision-making ability raise serious concerns about their ability to consent to hormonal and surgical interventions. Adolescents have a known tendency to

[126] See *id.* ("Informed consent is defined as the willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the nature of the intervention, its risks, and benefits, as well as of alternatives with their risks and benefits."). See also A. L. Katz et al., Informed Consent in Decision-Making in Pediatric Practice, 138 Pediatrics e20161485 (2016) (reaffirmed in AAP Publications Reaffirmed, 151 Pediatrics e2023061452 (2023)).

[127] P. S. Appelbaum et al., Assessing Patients' Capacities to Consent to Treatment, 319 N. Engl. J. Med. 1635 (1988) (correction issued in Correction, 320 N. Engl. J. Med. 748 (1989)).

engage in risky behaviors, exercise poor impulse control, and show frequent failure to appreciate long-term consequences of current choices.[128]

110. For example, the ability of a child to understand implications for future fertility while still developmentally immature can pose a significant barrier to meeting the criterion of appreciating decision consequence. Children are often unlikely to be capable of giving truly informed consent, particularly when it comes to hormonal or surgical treatments that can result in lifelong sterility.[129] Adolescents' inability to adequately weigh potential short-term benefits against long-term risks seems supported by the observation that few adolescents express concern over loss of fertility even when directly told of the potential sterilizing effect of medical intervention.[130]

111. Similarly, 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.[131]

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[128] Neuroscientists have found that the adolescent brain is too immature to make reliably rational decisions. S-J. Blakemore et al., Decision-Making in the Adolescent Brain, 15 Nature Neurosci. 1184 (2012); B. J. Casey et al., The Adolescent Brain 1124 Annals N.Y. Acad. Scis. 111 (2008).

[129] See C. F. Geier, Adolescent cognitive control and reward processing: Implications for risk taking and substance use, 64 Hormones and Behavior 333 (2013).

[130] L. Nahata et al. (2017), Low Fertility Preservation Utilization, 61 J. Adolesc. Health, at 40.

[131] H. Helmchen, Ethics of Clinical Research with Mentally Ill Persons, 262 Eur. Archs. Psychiatry and Clin. Neurosci. 441 (2012).

112. In addition, a study subject's underlying belief that he or she was born in the wrong body is the primary reason for seeking medical intervention. Thus, any challenge to this underlying premise is seen as a threat to the affected individual. Under such conditions, an individual will find it difficult, if not impossible, to give truly informed consent.

113. A model relying on parental consent with child assenting to affirmative medical interventions does not remove concerns about the difficulty in obtaining truly informed consent. Since many of the long-term outcomes of gender-affirming interventions are unknown, prospective patients are being asked to consent without sufficient knowledge of inherent risk versus benefit. Without understanding that nearly all adolescents who are put on puberty blockers will proceed to cross-sex hormones, with many subsequently opting for gender-affirming surgeries, focus on gaining consent for this first stage of the affirmative model is difficult if not impossible.

114. Parents are often told by gender affirmation activists or providers that the failure to allow a gender dysphoric child to medically transition will result in suicide. These "threats" ignore data that challenge this biased assumption.[132]

[132] See D'Angelo et al., One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria, 50 Archs. Sex. Behav. 7 (2021).

115. While any cases of suicide are of utmost concern, suicide rates in children with sex-discordant gender identity must be put in context of overall suicidality in the pediatric population independent of gender dysphoria. When considered in this context, the rates of suicidal ideation and attempt in transgender adolescents are similar to those found in adolescents without gender dysphoria who present for psychological care.[133] Furthermore, it is necessary to critically assess, with rigorous scientific data, whether gender affirming medical interventions succeed in preventing suicides. While long-term data are not available for pediatric patients, the adult literature consistently reports continued elevated suicidality after undergoing gender affirming medical interventions.[134] In considering the population-based study in Sweden by Dhejne and colleagues,[135] it is not possible to draw conclusions on the effect of gender affirming interventions on suicide outcome since it was not a controlled study. Nevertheless, the observation that completed suicide rates following such interventions were 19-fold above the background population clearly demonstrates that gender affirming medical care did not fix the problem of suicide.

[133] M. Aitken et al., Self-Harm and Suicidality in Children Referred for Gender Dysphoria, 55 J. Am. Acad. Child & Adolesc. Psychiatry, 513 (2016).
[134] N. Adams et al., Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature, 2 Transgender Health 60 (2017).
[135] C. Dhejne et al., Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden, 6 PLOS ONE e16885 (2011).

116. Researchers have noted that in the "affirming" context, "the informed consent process rarely adequately discloses" either "the uncertain permanence of a child's or an adolescent's gender identity" or "the uncertain long-term physical and psychological health outcomes of gender transition."[136] Levine et al. recently noted the following major deficiencies in the informed consent process under existing "affirming" guidelines and approaches:

- "High rate of desistance/natural resolution of gender dysphoria in children is not disclosed";
- "Implications of very low-quality evidence that underlies the practice of pediatric gender transition are not explained"; and
- "The question of suicide is inappropriately handled."[137]

As discussed above, the informed consent process for "affirming" treatments is further "limited by" "erroneous professional assumptions" and "poor quality of the initial evaluations."[138]

117. Using experimental procedures on uninformed, vulnerable patients is unethical and improper. Some of the most tragic chapters in the history of medicine include violations of informed consent and improper experimentation on patients using methods and procedures that have not been tested and validated by methodologically sound science — such is the case with the gender transition industry. The

[136] S. B. Levine et al., Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults, 48 J. Sex & Marital Therapy 706 (2022).
[137] *Id.* at 711, 712, 713.
[138] *Id.* at 706 (Abstract).

infamous Tuskegee studies, Nazi and Imperial Japanese wartime experiments, lobotomies (e.g., Dr. Egas Moniz received the 1949 Nobel Prize in Medicine for inventing lobotomies as a "treatment" for schizophrenia[139]), recovered memory therapy, multiple personality disorders, rebirthing therapy,[140] coercive holding therapy,[141] and other tragic examples should serve as a stark warning to medical providers to properly protect the rights of patients and their families to a proper informed consent process and to not be subjected to experimental, unproven interventions.

118. Contrary to the *ipse dixit* assertion by Dr. Shumer on page 35 of his declaration, personal experience in talking to patients about "expected effects, risks and benefits to patients and families in an age-appropriate and culturally competent way," even if repeated multiple times, does not demonstrate that informed consent is obtained.

EXISTING LITERATURE AND ITS LIMITATIONS

119. Before turning to the existing literature on gender dysphoria and its treatments, it is important to understand the varying types of studies conducted in

[139] See Bengt Jansson, Egas Moniz: Controversial Psychosurgery Resulted in a Nobel Prize, NobelPrize.org (Oct. 29, 1998), https://www.nobelprize.org/prizes/medicine/1949/moniz/article/ (last visited Apr 11, 2023).

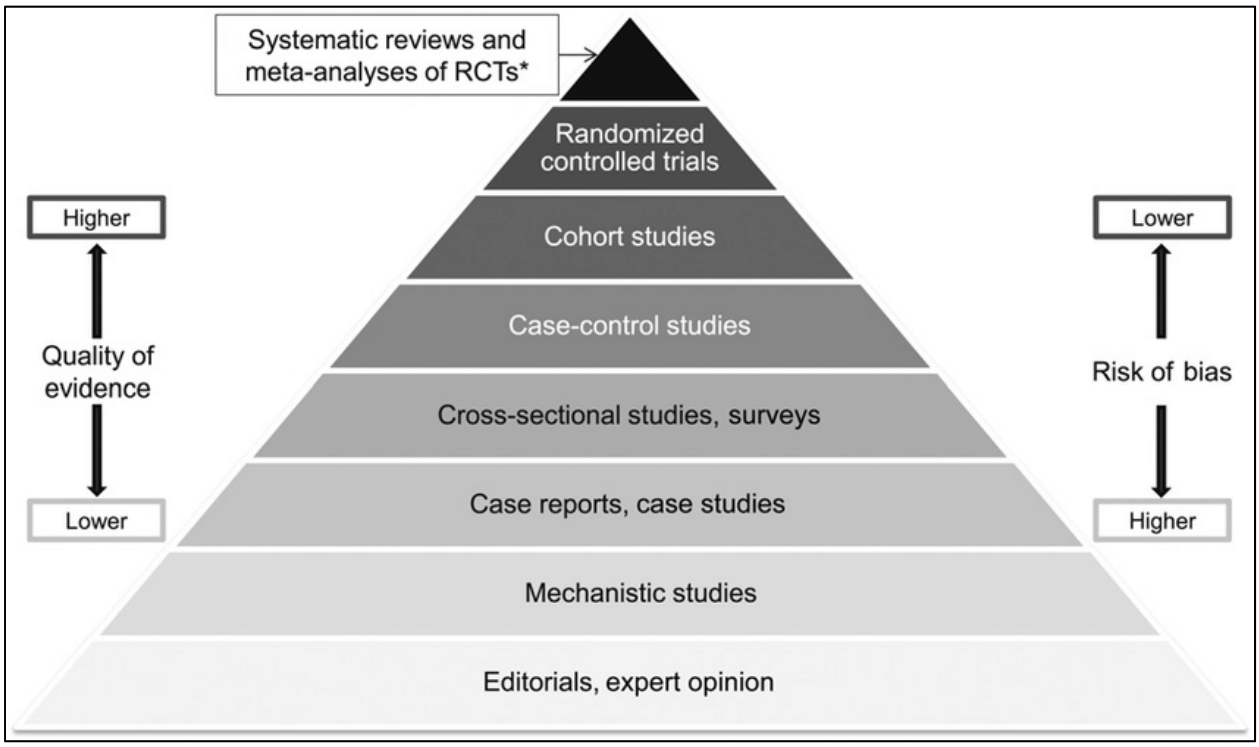
[140] See, e.g., M. Janofsky, Girl's Death Brings Ban on a Kind of Therapy, The New York Times, Apr. 18, 2001, https://www.nytimes.com/2001/04/18/us/girl-s-death-brings-ban-on-a-kind-of-therapy.html (last visited Apr 11, 2023); see also P. Lowe, Rebirthing team convicted: Two therapists face mandatory terms of 16 to 48 years in jail, Rocky Mountain News, Apr. 21, 2001.

[141] See J. Hyde, Holding therapy appears finished, Deseret News (Feb. 23, 2005), https://www.deseret.com/2005/2/13/19877054/holding-therapy-appears-finished (last visited Apr 11, 2023).

this and other medical fields, as well as the general approach to scientific testing. Appropriate testing of medical and other scientific hypothesis requires proper study design. First, the researcher formulates a hypothesis as to whether there is a difference — a cause and effect relationship — from the studied intervention. The study starts by assuming the "null hypothesis" — there is no difference — and then one looks for evidence sufficient to disprove the null hypothesis. When conducting the study, statistical significance is of central importance, for it states the likelihood that the observation would exist if the null hypothesis were true. Only if there is a very small likelihood that the null hypothesis is true is it generally appropriate to treat a study as providing evidence that the null hypothesis is, in fact, false. Accordingly, if a study finding does not reach statistical significance, it would be improper to use the finding as a rejection of the null hypothesis.

120. Case reports or experts' opinions are recognized as the lowest level of evidence. Those are based upon general experiences, not scientific testing. They can be useful for generating novel hypotheses, which can then be tested through experimental testing to establish if there are cause/effect relationships. Next up on the pyramid of quality of evidence would be, for example, cross-sectional studies that are done where one looks at a condition at one point in time. One can merely infer associations from these types of studies. Randomized longitudinal studies can permit, to some extent, the elimination of unrecognized variables that may distort the

results. The highest part of the evidence-based pyramid (for individual studies) is randomized controlled trials, in which the investigator attempts to control all aspects of the study with the exception of the independent variable that is being tested. When done properly, this type of study can provide strong evidence of causation. The following illustrates this pyramid:[142]



121. Since the "affirming" model of treating transgender children — as summarized by the WPATH and Endocrine Society guidelines discussed above — are

[142] Image available at https://www.researchgate.net/figure/Hierarchy-of-evidence-pyramid-The-pyramidal-shape-qualitatively-integrates-the-amount-of_fig1_311504831. For original source, see E. A Yetley et al., Options for basing Dietary Reference Intakes (DRIs) on chronic disease endpoints: report from a joint US-/Canadian-sponsored working group, 105 Am. J. Clin. Nutrition 249S, 259S (2017).

relatively new, long-term outcomes are unknown. Evidence presented as support for short-term reductions in psychological distress following social transition in a "gender-affirming" environment remains inconclusive. Multiple potential confounders are evident. The most notable deficiencies of existing research are the absence of proper control subjects and lack of randomization in study design.[143] No randomized control trials have been performed, and the existing longitudinal studies have serious limitations — most significantly, that they follow cohorts of patients in a non-controlled, unrandomized manner. This design severely limits any conclusions that can be drawn.

122. Moreover, many studies find no improvement — or negative effects — from "affirming" care. For instance, a 2020 British study (Carmichael et al.[144]) found "no evidence of change in psychological function with GnRHa treatment as indi-

[143] See P. W. Hruz, Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria, 87 Linacre Quarterly 34 (2020).

[144] P. Carmichael et al., Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK, 16 PLOS ONE e0243894, *1, *19 (2021). The acronyms CBCL and YSR refer to Child Behavior CheckList and Youth Self-Report, respectively. *Id.* at Abstract. See also H. Cass, The Cass Review, Independent review of gender identity services for children and young people: Interim report, Feb. 2022, at 31 and n.27, https://cass.independent-review.uk/wp-content/uploads/2022/03/Cass-Review-Interim-Report-Final-Web-Accessible.pdf.

cated by parent report (CBCL) or self-report (YSR) of overall problems, internalising or externalising problems or self-harm."[145] Puberty blockers used to treat children aged 12 to 15 who had severe and persistent gender dysphoria had no significant effect on their psychological function, thoughts of self-harm, or body image.[146] However, as expected, the children experienced reduced growth in height and bone strength by the time they finished their treatment at age 16.[147]

123. The widely respected Cochrane Review examined hormonal treatment outcomes for male-to-female transitioners over 16 years.[148] They found "insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition."[149] Thus, decades after the first transitioned male-to-female patient, quality evidence for the benefit of transitioning remains lacking.

124. Although appropriate caution is warranted in extrapolating the outcomes observed from prior studies with current treatments, adults who have under-

[145] P. Carmichael et al. (2020), Short-term outcomes of pubertal suppression, 16 PLOS ONE e0243894, at *19.
[146] *Id.* at *18, *19.
[147] *Id.*
[148] See C. Haupt et al., Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 2020 Cochrane Database of Systematic Revs., Issue 11, Art. No. CD013138 (2020).
[149] *Id.* at 2.

gone social transition with or without surgical modification of external genitalia continue to have rates of depression, anxiety, substance abuse, and suicide far above the background population.[150]

125. Given the low quality of scientific evidence currently available regarding the relative risk versus benefit of gender-affirming medical interventions, existing evidence that suicidality remains markedly elevated after engaging in this therapeutic approach, and a general failure to directly test the benefits of psychological intervention to alleviate suffering in people who experience sex-discordant gender identity, before offering gender affirming care as a standard treatment there is an ethical imperative to conduct clinical trials to assess the validity of alternate hypotheses for effective treatment. Thus, contrary to the assertion of Dr. Antommaria, clinical equipoise does indeed exist. His dismissal of randomized controlled trials rests upon an erroneous portrayal of clinical trial design. While it may be true that prospective research subjects would reject enrollment in a trial comparing affirmative care with no care, proper discussion of the inherent risk of gender affirming interventions, the lack of data showing long term resolution of suicidal ideation, and the goal of alleviating dysphoria through alternate means can provide reasonable expectation of enrolling a sufficient number of study subjects.

[150] See N. Adams et al., Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature, 2 Transgender Health 60, 60-75 (2017). See also C. Dhejne et al. (2011), Long-Term Follow-Up of Transsexual Persons, 6 PLOS ONE e16885.

126. The 2015 study by Costa et al.,[151] cited by Dr. McNamara in her declaration in a misleading manner (pages 9-11), provides preliminary evidence that psychotherapy alone is associated with improved mental health. It is important to note that in this study comparing subjects that received psychological support alone versus those who received psychological support together with pubertal blockade, both study groups had significantly improved psychosocial function (CGAS) from baseline. Importantly, there was no statistical difference in CGAS scores between the two study groups throughout the study.[152] With such data, it is simply bad science to make an inference that there are meaningful differences in experimental groups masked by lack of statistical power from low sample size. A lack of significant difference means that one cannot reject the null hypothesis because any observed differences could be due to random chance. Both groups had final CGAS scores in the 61-70 range, which reflects "some difficulty in a single area but generally functioning well."[153] The magnitude of difference between the CGAS scores at the end

[151] R. Costa et al., Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria, 12 J. Sexual Med. 2206 (2015) (using the Utrecht Gender Dysphoria Scale (UGDS) and the Children's Global Assessment Scale (CGAS) as main outcome measures).
[152] *Id.* at 2206.
[153] D. Shaffer, A Children's Global Assessment Scale (CGAS), 40 Archs. Gen. Psychiatry 1228 (1983).

of the study was 5 points on a 100-point scale.[154] Of high interest would be an attempt to replicate this study in a randomized manner to better ascertain a causal relationship between psychotherapy and mental health.

I. Change in Patient Population

127. One important (and contentious) issue requiring more study is the recent trend of adolescent female to male gender discordant patients. In the United Kingdom, where centralized medical care provides data to track health care phenomenon, the number of adolescent girls seeking sex transitioning exploded over 4,000% in the last decade. Similarly, in the United States, where we lack the same kinds of centralized health care data, it has been reported that, in 2018, 2% of high school students identified on surveys as "transgender" — this is 200 times greater response, a 20,000% increase — over reports during past decades which showed a rate of only .01%.[155]

128. Along with this increase in transgender patients and identifiers has come a radical and recent transformation of the patient population from early onset males to rapid onset adolescent girls. Currently the majority of new patients with sex-gender discordance are not males with a long, stable history of gender dysphoria

[154] R. Costa et al. (2015), Psychological Support, Puberty Suppression, and Psychological Functioning, 12 J. Sexual Med. at 2212 (Table 2).
[155] See M. M. Johns et al., Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students — 19 States and Large Urban School Districts, 2017, 68 MMWR Morb. Mortal. Wkly. Rep. 67 (2019).

since early childhood — as they were for decades, and under the Dutch protocols — but instead adolescent females with no documented long-term history of gender dysphoria. One might say, as Dr. Lisa Littman has theorized,[156] that these females experienced "rapid onset" transgender identification.

129. This recent change in the typical patient raises questions about our understanding of the origins of transgender identity. For instance, a genetics or "immutable" theory of transgender identity cannot explain the rapid expansion of new gender dysphoria cases (a 4,000% to 20,000% increase), given that our genome is simply not changing that fast. Nor can that theory explain the explosion of adolescent females presenting with gender dysphoria. A "brain structures" theory has only weak medical evidence, and it also cannot explain the rapid expansion of new gender dysphoria cases. As for the theory that increased social acceptance is leading many people who were transgender all along to identify as such to their medical providers, this theory fails to explain why the rate of increase in males and older women transitioning has not kept pace with that for adolescent females. It also does not explain why many adolescent females are found transitioning along with their "social peer group clusters."

[156] See L. Littman, Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria, 13 PLOS ONE e0202330 (2018); Erratum in L. Littman, Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria, 14 PLOS ONE e0214157 (2019).

II. Methodological Problems with "Affirming" Literature

130. The published literature relied on to advocate for the use of puberty blockers, cross-sex hormones, and gender-affirming surgeries in minors consists almost entirely of studies with major methodological limitations.[157] As detailed next, these include:

- Significant recruitment biases, including internet-based convenience sampling;
- Relatively small sample sizes for addressing a condition that is likely to be multifactorial;
- Short-term follow-up;
- Lack of randomization to different treatment arms;
- Failure to consider alternate hypotheses;
- Failure to include proper control groups;
- Reliance on cross sectional sampling that may identify associations, but cannot establish causal relationships between intervention and outcome;
- A high rate of patients lost to follow up in longitudinal analyses, which is relevant to questions of regret, desistance, and completed suicide;
- Biased interpretation of study findings with a goal of validating *a priori* conclusions rather than seeking evidence to disprove the null hypothesis; and
- Ignoring starkly contradictory research documenting the lack of effectiveness of "transitioning" procedures, the low quality of research in this area, and the ongoing contentions and disagreements over this highly controversial, experimental medical field.

131. Some or all of these methodological and statistical flaws are present in the following studies, which are commonly relied on by advocates of "affirming" treatments. This list is not exhaustive but is rather presented to demonstrate the

[157] See generally P. W. Hruz (2020), Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria, 87 Linacre Quarterly, at 34.

serious scientific deficiencies in the published literature related to the care of individuals who experience sex-discordant gender identity.

The Bränström Long-Term Treatment Outcome Study: The historic Bränström study[158] is a long-term treatment outcome research investigation testing the effects of hormonal and surgical "transitioning" treatments on patients. Ultimately, but only after the authors' initial findings had come under public scrutiny,[159] this study found no reliable benefits from these treatments.[160] In addition, the study suggested *increased* suicide attempts and anxiety disorders following the "gender transitioning" treatments.[161]

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[158] R. Bränström et al., Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study, 177 Am. J. Psychiatry 727 (2020). See also Correction to Bränström and Pachankis, 177 Am. J. Psychiatry 734 (2020).

[159] N. H. Kalin, Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process, 177 Am. J. Psychiatry 764 (2020) (writing on behalf of the Journal to announce a correction and an addendum published as a result of additional research requested and undertaken in response to the criticism of the Bränström study). See, e.g., A. Van Mol et al., Gender-Affirmation Surgery Conclusion Lacks Evidence, 177 Am. J. Psychiatry 765 (2020) (Letter to the Editor); A. Van Mol et al., Correction: Transgender Surgery Provides No Mental Health Benefit, Public Discourse, Sept. 13, 2020, https://www.thepublicdiscourse.com/2020/09/71296/ (last visited Apr 11, 2023). See also S. B. Levine, Reflections on the Clinician's Role with Individuals Who Self-identify as Transgender, 50 Archs. Sex Behav. 3527, 3530 (2021).

[160] See A. van Mol et al. (2020), Gender-Affirmation Surgery Conclusion Lacks Evidence, 177 Am. J. Psychiatry at 765 (Letter to the Editor). See also N. H. Kalin (2020), Reassessing: A Comment by the Editor on the Process, 177 Am. J. Psychiatry at 764; SEGM, Correction of a Key Study: No Evidence of "Gender-Affirming" Surgeries Improving Mental Health, https://segm.org/ajp_correction_2020 (Aug. 30, 2020).

[161] See, e.g., H. Anckarsäter et al., Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery, 177 Am. J. Psychiatry 764 (2020) (Letter to the Editor); A. van Mol et al., Gender-Affirmation Surgery Conclusion Lacks Evidence, 177 Am. J. Psychiatry 765 (2020)

Of note, significant research errors suggested that the authors had initially attempted to manipulate and misreport the findings of the study.[162] After publication of the original article in October 2019, "letters containing questions on the statistical methodology employed in the study led the [American Journal of Psychiatry] to seek statistical consultations."[163] According to the Journal, "[t]he results of these consultations were presented to the study authors," who on request "reanalyzed the data."[164] That reanalysis led the authors to recant their initial misreporting, as "the results demonstrated no advantage of surgery in relation to subsequent mood or anxiety

(Letter to the Editor); W. J. Malone et al., Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological Distress, 177 Am. J. Psychiatry 766 (2020) (Letter to the Editor); M. Landén, The Effect of Gender-Affirming Treatment on Psychiatric Morbidity Is Still Undecided, 177 Am. J. Psychiatry 767, 767-68 (2020) (Letter to the Editor); A. Wold, Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article, 177 Am. J. Psychiatry 768 (2020) (Letter to the Editor) (noting that "among the individuals examined in the study, the risk of being hospitalized for a suicide attempt was 2.4 times higher if they had undergone gender-corrective surgery than if they had not.").

[162] See, e.g., H. Anckarsäter et al. (2020) Methodological Shortcomings, 177 Am. J. Psychiatry at 764-65); D. Curtis, Study of Transgender Patients: Conclusions Are Not Supported by Findings, 177 Am. J. Psychiatry 766 (2020); A. van Mol et al. (2020), Gender-Affirmation Surgery Conclusion Lacks Evidence, 177 Am. J. Psychiatry at 765-66. See also A. Ring et al., Confounding Effects on Mental Health Observations After Sex Reassignment Surgery, 177 Am. J. Psychiatry 768, 768-69 (2020) (Letter to the Editor) (noting that "the same data [used in the Bränström study] may be modeled in a way that leads to the opposite conclusion" of that reached by Bränström study.).

[163] Correction to Bränström and Pachankis, 177 Am. J. Psychiatry 734 (2020).

[164] *Id.*

disorder-related health care visits or prescriptions or hospitalizations following suicide attempts."[165] And the Bränström study at no point showed any advantages from hormonal treatments in improving mental health outcomes.[166]

Thus, the Bränström study is devoid of any solid indication that medical interventions would objectively improve medical or mental health outcomes for transgender persons. Furthermore, because neither the original study nor the subsequent correction provide any statistically significant support for hormone treatment, the Bränström study has done nothing to close any of what the Cass Review has described as existing "gaps in the evidence base for hormone treatment" of minors.[167] Meanwhile, as discussed later in this report, several factors, including increased caution among some care providers, are resulting in a profound collapse of support for these experimental procedures across Europe, most notably in clinics providing treatment for minors.[168]

A 2011 Dutch study by De Vries et al.[169] is often cited to support longitudinal evidence of benefit from pubertal blockade. Although the study found slight

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[165] *Id.*
[166] R. Bränström et al. (2020), Reduction in Mental Health Treatment Utilization, 177 Am. J. Psychiatry at 727. See also D. Curtis, Study of Transgender Patients: Conclusions Are Not Supported by Findings, 177 Am. J. Psychiatry 766 (2020) (Letter to the Editor) (stating that the Bränström study "does not demonstrate that either hormonal treatment or surgery has any effect on this morbidity.").
[167] H. Cass (2022), The Cass Review — Interim Report, at 23.
[168] See, e.g., infra International Responses, ¶¶ 134 et seq.
[169] A. L. C. de Vries et al., Puberty Suppression in Adolescents With Gender Identity Disorder: A Prospective Follow-Up Study, 8 J. Sexual Med. 2276 (2011).

improvements in mood and the risk of behavioral disorders with pubertal blockade over baseline, the study included no control group, and all 70 participants received ongoing psychological support. Thus, the authors were unable to determine the basis of the limited observed improvement. The authors acknowledge that psychological support or other reasons may have contributed to (or wholly caused) this observation. By the very nature of the trial, at best the study can provide a rationale for doing further studies that could show whether "affirming" interventions provide a benefit. The study does not (and cannot) answer the central question: whether the administration of puberty blockers is the solution to the problem and whether alternative approaches that do not carry the same risks relative to purported benefits (e.g., psychological interventions) may have the same or superior benefits.

Moreover, there remain questions about the extent to which the protocol used in these early Dutch studies may be relevant to the patient population presenting today. For decades transgender patients were mostly older adults or very young boys. As noted, over the last few years, a tsunami of teenaged girls has flipped the demographics of transgender patients — now up to 7 to 1 teen girls. The newly presenting cases are vastly overrepresented by adolescent females, the majority of

whom also have significant mental health problems and neurocognitive comorbidities such as autism-spectrum disorder or ADHD.[170] Furthermore, estimates of gender-dysphoria transgenderism are rocketing upwards from 1 in 10,000 to, in youth, "as high as 9%."[171] This unexplained, radical transformation of patient demographics raises questions about the applicability even of the limited existing literature on this issue, particularly as to the Dutch protocol. Dr. Thomas Steensma, a prominent investigator of the Dutch protocol — the original model for transitioning treatments — has recently noted that "[w]e don't know whether studies we have done in the past can still be applied to this time,"[172] specifically because of the unexplained surge in female adolescents reporting gender dysphoria. "Many more children are registering, but also of a different type . . . Suddenly there are many more girls applying who feel like a boy."[173] He concluded with the warning that

[170] See N. M. de Graaf et al., Reflections on emerging trends in clinical work with gender diverse children and adolescents, 24 Clin. Child Psychol. and Psychiatry 353 (2019).
[171] See K. M. Kidd et al., Prevalence of Gender-Diverse Youth in an Urban School District, 147 Pediatrics e2020049823 (2021).
[172] See B. Tetelepta, More research is urgently needed into transgender care for young people: "Where does the large increase of children come from?," Voorzij, Feb. 26, 2021, available at https://www.voorzij.nl/more-research-is-urgently-needed-into-transgender-care-for-young-people-where-does-the-large-increase-of-children-come-from/ (last visited Apr 11, 2023) (translation from B. Tetelepta, Dringend meer onderzoek nodig naar transgenderzorg aan jongeren: 'Waar komt de grote stroom kinderen vandaan?,' Algemeen Dagblad, Feb. 27, 2021, available at https://www.ad.nl/nijmegen/dringend-meer-onderzoek-nodig-naar-transgenderzorg-aan-jongeren-waar-komt-de-grote-stroom-kinderen-vandaan~aec79d00/ (last visited Apr 11, 2023)).
[173] *Id.*

"[w]e conduct structural research in the Netherlands. But the rest of the world is blindly adopting our research."[174]

A 2014 follow-up study by De Vries et al.[175] encompassed 55 of the original 70 patients; 15 were lost to follow-up or not included. It has the same limitations that were present in assessing the original 2011 study, including a carefully selected patient population that is not representative of the broader population, especially now. Having a longer study does not obviate the limitations of the study design in making a conclusion that can be applied to the gender clinics that are operating in the United States.

In addition to the concerns of the Dutch studies already exposed, "[t]he linch-pin result of the Dutch studies is the reported *resolution of gender dysphoria*, as measured by the Utrecht Gender Dysphoria Scale (UGDS)."[176] Yet, as several researchers (E. Abbruzzese et al.) recently explained, the observed "drop was an artifact of switching the scale from 'female' to 'male' versions (and vice versa) before and after treatment, prompting a problematic reversal in the scoring."[177] "The *same*

[174] *Id.*
[175] A. L. C. de Vries et al., Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment, 134 Pediatrics 696 (2014).
[176] E. Abbruzzese et al., The Myth of "Reliable Research" in Pediatric Gender Medicine: A critical evaluation of the Dutch Studies—and research that has followed, J. Sex & Marital Therapy, Jan. 2, 2023, at 1, 7-8.
[177] *Id.* at 1, 8.

gender dysphoric individual, effectively answering the *same* question (albeit linguistically inverted)" — e.g., "Every time someone treats me like a girl [or boy] I feel hurt" — "results in either the maximum or the minimum 'gender dysphoria' score — depending on which sexed version of the scale was used."[178] Thus, because researchers used different scales of the UGDS before and after treatment, "it is impossible to determine if [the result shows] a real difference in gender dysphoria between groups or if this is an artifact of measurement error."[179] Indeed, if anything, "[t]he fact that after gender reassignment, the UGDS scores were low on the opposite-sex scale indicates that the subjects would have scored high on the natal sex scale, which corresponds to a *persistence in transgender identity*."[180] This, of course, is the opposite result purportedly reached by the 2014 De Vries study.

The 2018 paper by Wiepjes et al.[181] is a retrospective review of records from all patients of the Center of Expertise on Gender Dysphoria gender clinic in Amsterdam from 1972-2015. While the study appears to report on the regret rates among a large cohort of adolescents (812) and children (548),[182] regret is only reported for children and adolescents who had undergone gonadectomy once over

[178] *Id.* at 8.
[179] *Id.* at 9 (internal quotation and citation omitted).
[180] *Id.* at 10 (emphasis in original).
[181] C. M. Wiepjes et al., The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets, 15 J. Sexual Med. 582 (2018).
[182] *Id.* at 584 (Table 1).

18 years of age.[183] Of the adolescents, 41% started puberty suppression. Of those who started GnRH agonists, only 2% stopped this intervention (meaning that 98% of those who started puberty suppression progressed to cross-sex hormone therapy).[184] An additional 32%, having already completed puberty, started cross-sex hormone therapy without use of a GnRH agonist.[185] Classification of regret was very stringent, requiring physician documentation of patient verbalized regret after gonadectomy and start of sex-concordant hormones to treat the iatrogenic hypogonadism.[186] This means there are significant limitations to the conclusions that can be drawn from this paper. There is no discussion in the paper regarding adolescent regret of use of puberty blockers, cross-sex hormones, or mastectomies. Importantly, 36% of patients were lost to follow up.[187] This is notable given that gonadectomy iatrogenically induces the pathologic state of primary hypogonadism. Affected patients have a lifelong dependency for exogenously administered sex-steroid hormones, and thus an acute need for ongoing follow-up. Their failure to return to the physicians who provided gender-affirming interventions raises serious questions about their outcome. It is reasonable to hypothesize that some may have

[183] *Id.* at 585, 587. See also *id.* at 582 (Abstract).
[184] *Id.* at 585 ("Of adolescents, 41.0% started PS, whereas only 1.9% of these adolescents stopped PS and did not start HT (Table 1).").
[185] *Id.*
[186] *Id.* at 583-84, 587 (with columns in Table 4 indicating the type of detransitions for each patient listed and the specific reversal treatments undertaken for each patient listed).
[187] *Id.* at 589.

experienced regret or completed suicide. Yet due to missing data, their fate remains unknown. It is also significant that the average time to regret was 130 months.[188] The authors themselves acknowledge that it may be too early to predict regret in patients who started hormone therapy in the past 10 years.[189]

The 2018 Olson-Kennedy et al. paper[190] presents the results of a survey of biologically female patients with male gender identity at the lead author's institution using a novel rating system for "chest dysphoria" created by the study authors.[191] There were an equal number (68) of nonsurgical and post-surgical subjects surveyed.[192] Those who had undergone bilateral mastectomies were reported to have less chest dysphoria than those who did not receive this intervention.[193] Limitations of this study include convenience sampling of nonsurgical study subjects with high potential for selection bias, cross-sectional design, lack of validation of the primary outcome measure, and short follow-up time (about 2 years). Test validation is particularly relevant in assessing adolescent questionnaires due to a variety of cognitive

[188] *Id.* at 589.
[189] *Id.* at 589.
[190] J. Olson-Kennedy et al., Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts, 172 JAMA Pediatrics 431 (2018).
[191] *Id.* at 432.
[192] *Id.* at 431.
[193] *Id.* at 431 (Abstract).

and situational factors in this population.[194] Rigorous validation methods have been previously used in several other established questionnaires addressing adolescent self-perception.[195] As previously noted, this study cannot provide information about a causal relationship between the intervention and outcomes observed.

A 2019 study by Allen et al.[196] considered suicidality after cross-sex hormones. It was limited by a very small patient population (47), had no control group, had a short follow-up period (mean < 1 year), and again ignored that patients receiving the interventions also received psychological support.

A 2019-2020 study by Turban et al. in JAMA Psychiatry[197] aimed to consider "recalled exposure to gender identity conversion efforts [GICE] (ie, psychological interventions that attempt to change one's gender identity from transgender to cisgender) associated with adverse mental health outcomes in adulthood."[198] However, this paper has been repeatedly and pointedly criticized for a number of

[194] See N. D. Brener et al., Assessment of factors affecting the validity of self-reported health-risk behavior among adolescents: evidence from the scientific literature, 33 J. Adolesc. Health 436 (2003).
[195] See N. Palenzuela-Luis et al., Questionnaires Assessing Adolescents' Self-Concept, Self-Perception, Physical Activity and Lifestyle: A Systematic Review, 9 Children 91 (2022).
[196] L. R. Allen et al., Well-being and suicidality among transgender youth after gender-affirming hormones, 7 Clin. Practice in Pediatric Psychol. 302 (2019).
[197] J. L. Turban et al., Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults, 77 JAMA Psychiatry 68 (2020) (originally posted online on September 11, 2019).
[198] *Id.* at 68.

improper extrapolations and serious methodological defects,[199] several of which stem from its reliance on flawed data from the 2015 U.S. Transgender Survey (USTS).[200]

The USTS was an anonymous online survey conducted in the summer of 2015[201] and "is the largest survey examining the experiences of transgender people in the United States, with 27,715 respondents."[202] Anonymous surveys are not rigorous sources of evidence, and the data from this survey are compromised by numerous biases and irregularities. The 2015 USTS Report and Executive Summary

[199] See, e.g., D'Angelo et al. (2021), One Size Does Not Fit All, 50 Archs. Sex. Behav., at 7; R. Byng et al., Misinterpretation of the findings of this study may limit safe, ethical treatment options for gender-questioning and gender-diverse people, Comment on J. L. Turban et al., Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults, 77 JAMA Psychiatry 68 (2020), Comment posted on Oct. 8, 2019, available at https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2749479; H. Horvath, A deeply flawed analysis, Comment on J. L. Turban et al., Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults, 77 JAMA Psychiatry 68 (2020), Comment posted on Oct. 6, 2019, available at https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2749479; J. Mason, Not all therapy is conversion therapy, Comment on J. L. Turban et al., Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults, 77 JAMA Psychiatry 68 (2020), Comment posted on Sept. 27, 2019, available at https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2749479. These three Comments on Turban's article at JAMA Psychiatry, the comments by Byng et al., H. Horvath, and J. Mason, shall collectively be referred to as "Three Comments on J. L. Turban, Associations (2019-2020), at 77 JAMA Psychiatry 68."

[200] 2015 U.S. Transgender Survey Report, 2022 U.S. Trans Survey, https://www.ustranssurvey.org/reports (last visited Apr 25, 2023).

[201] S. E. James et al., The Report of the 2015 U.S. Transgender Survey, 4, Washington, DC: National Center for Transgender Equality (2016), available at https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf (last visited Apr. 25, 2023) ("USTS 2015 Report").

[202] *Id.*

were published by the National Coalition for Transgender Equality (NCTE).[203] Several authors of the USTS Report have been actively involved in policy work and legal advocacy at both the state and federal level, and in legislatures and courts.[204] More broadly, the USTS is currently supported by a coalition including several trans advocacy groups that, like the NCTE, are active in the realm of public policy.[205] In 2022, the USTS conducted another survey in partnership with several other trans advocacy organizations, and results are expected to be released later in 2023.[206] The current homepage for the USTS describes the 2022 survey as "the largest survey of trans people, by trans people, in the United States."[207]

The Turban et al. 2019-2020 JAMA Psychiatry study relying on the USTS survey tool has been criticized on account of several limitations and weaknesses of

[203] S. E. James et al., USTS 2015 Report; S. E. James et al., Executive Summary of the Report of the 2015 U.S. Transgender Survey, 16, Washington, DC: National Center for Transgender Equality (2016), available at https://transequality.org/sites/default/files/docs/usts/USTS-Executive-Summary-Dec17.pdf (last visited Apr. 25, 2023).
[204] S.E. James et al. (2015), USTS 2015 Report, at 241-42.
[205] See 2022 U.S. Trans Survey, USTS Homepage (featuring logos from and hyperlinks to BTAC, the Black Trans Advocacy Coalition; the TransLatin@ Coalition; and NQAPIA, the National Queer Asian Pacific Islander Alliance).
[206] 2022 U.S. Trans Survey, 2022 U.S. Trans Survey, https://www.ustranssurvey.org (last visited Apr 25, 2023) (USTS Homepage); FAQ's, 2022 U.S. Trans Survey, https://www.ustranssurvey.org/faq (last visited Apr 28, 2023) (Who Conducts the USTS?).
[207] *Id.*

that survey tool — and resulting data — such as convenience sampling[208] and recruitment of patients through transgender advocacy organizations.[209] Furthermore, the USTS "sampling method's inadequacy"[210] renders it highly unlikely that the survey tool (and thus the Turban 2019-2020 study data) captures or adequately accounts for populations integral to this study and its conclusions, such as "the population whose earlier gender dysphoria was alleviated through cognitive behavioral therapy or other standard approaches,"[211] or "individuals exposed to GICE who subsequently adopted a gender identity concordant with their biological sex."[212] Another crucial defect is the failure of Turban et al. to "control for comorbid psychiatric illness, the greatest single predictor of suicidality."[213]

In their comment, Byng et al. concluded:

> [T]he authors underplay the serious methodological weaknesses, particularly the likely confounding effects of co-existing mental health

[208] See, e.g., Three Comments on J. L. Turban, Associations (2019-2020), at 77 JAMA Psychiatry 68.
[209] Three Comments on J. L. Turban, Associations (2019-2020), at 77 JAMA Psychiatry 68.
[210] H. Horvath, A deeply flawed analysis, Comment on J. L. Turban et al. (2019-2020), 77 JAMA Psychiatry 68.
[211] *Id.*
[212] R. Byng et al., Misinterpretation of the findings, Comment on J.T. Turban et al. (2019-2020), 77 JAMA Psychiatry at 68.
[213] R. Byng et al., Misinterpretation of the findings, Comment on J.T. Turban et al. (2019-2020), 77 JAMA Psychiatry at 68. See also J. Mason, Not all therapy is conversion therapy, Comment on J. L. Turban et al. (2019-2020), 77 JAMA Psychiatry 68 ("Turban et al allowed a number of study limitations — including convenience sampling and failure to control for mental illness, a key predictor of suicidality — which should make any savvy reader wary of accepting the study conclusions about the harms of therapy aimed at alleviating GD.").

> problems. They then take this association and in the abstract and conclusion seek to imply causation. Hence, the findings could mislead frontline clinicians and public policymakers alike. [214]

D'Angelo et al.,[215] in their response to the Turban et al. 2019-2020 JAMA Psychiatry study, highlighted further limitations of the USTS survey tool.[216] These include demand bias (i.e., the good subject effect[217]), a high number of respondents who reported having not transitioned medically or socially (and reported no desire to do so in the future), and several data irregularities.[218] One notable data irregularity was that a high number of USTS respondents reported that their age was exactly 18 years.[219] Another was that "information about treatments received does not appear to be accurate, as a number of [USTS] respondents reported the initiation of puberty blockers after the age of 18 years, which is highly improbable."[220] These irregularities raise serious questions about the reliability of the USTS data and therefore the reliability of conclusions based on that data.[221] Because the 2019-2020 Turban study

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[214] R. Byng et al., Misinterpretation of the findings, Comment on J.T. Turban et al. (2019-2020), 77 JAMA Psychiatry at 68. See also H. Horvath, A deeply flawed analysis, Comment on J.T. Turban et al. (2019-2020), 77 JAMA Psychiatry at 68 ("It is surprising that so eminent a scholar as Dr. Turban did not perceive the methodological errors to which he was evidently susceptible in preparing his recent analysis of suicidality in transgender persons.").
[215] *Id.*
[216] *Id.* at 7. See J. L. Turban et al., Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults, 77 JAMA Psychiatry 68 (2020).
[217] A. L. Nichols et al., The Good-Subject Effect: Investigating Participant Demand Characteristics, 135 J. Gen. Psychol. 151 (2008).
[218] R. D'Angelo et al. (2021), One Size Does Not Fit All, 50 Archs. Sex. Behav., at 8.
[219] *Id.*
[220] *Id.* at 8 (internal citation omitted).
[221] See generally *id.* at 7-16.

in JAMA Psychiatry is founded on a data set from an anonymous survey replete with flaws such as bias and convenience sampling, and because the study fails to control for multiple population gaps in the survey data and multiple key variables (such as co-morbid psychological illness), its conclusions are unreliable and potentially misleading.

Additional flaws and limitations of the USTS 2015 Survey data are set forth below in this report's summaries of the Turban et al. 2020 Pediatrics study, the Almazan et al. 2021 study, and the 2022 Turban et al. study, all papers which relied substantially on the USTS data.[222]

Another 2020 study by Turban et al. in Pediatrics[223] is often cited as proof that pubertal blockade prevents suicide in transgender youth. But this study also used the same unreliable, biased sampling methodology, the 2015 USTS.[224] As stated in the paper, the authors considered "a cross-sectional online survey of 20,619

[222] See infra discussion of the 2022 Turban et al. study. Also, further caution is warranted in evaluating the literature as the flawed data from the 2015 USTS may appear in other studies, including studies that have yet to be published. Upon request, the USTS makes the raw data from the 2015 survey available to researchers through the Inter-University Consortium for Political and Social Research (ICPSR). See Data Requests, 2022 U.S. Trans Survey, https://www.ustranssurvey.org/data-requests (last visited Apr 25, 2023). See also ICPSR, 2015 U.S. Transgender Survey (USTS) (ICPSR 37229), Version Date: May 22, 2019, https://www.icpsr.umich.edu/web/RCMD/studies/37229 (last visited Apr. 29, 2023).

[223] J. L. Turban et al., Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145 Pediatrics e20191725 (2020). See also Erratum for TURBAN 2019-1725, 147 Pediatrics e2020049767 (2021).

[224] *Id.* at *2-*3 and n.6.

transgender adults aged 18 to 36 years" from the 2015 U.S. Transgender Survey.[225] In addition to the defects in the 2015 USTS anonymous online survey discussed above, there is no evidence of study subject identities, no way to assess for potential false subjects, and no medical diagnosis for entry into the survey. Also, the patient sample was compromised by ascertainment bias.[226] It is impossible for deceased persons, including those who have succumbed to suicide, to respond to an online survey necessary for their inclusion into the data set. No causation can be determined from this retrospective, cross-sectional design. Furthermore, the study apparently failed to even assess individuals who may have desisted or regretted transitions.[227] Thus, the study "does not include outcomes for people who may have initiated pubertal suppression and subsequently no longer identify as transgender."[228]

Turban's misleading claim of lower suicidal ideation for treated patients is based upon "lifetime suicidality."[229] It fails to recognize or acknowledge that the decision to provide puberty blockers was likely influenced by the mental health of

[225] *Id.* at *1, *2-*3.
[226] P. W. Hruz, Suicidality in Gender Dysphoric Youth Offered Pubertal Blockade Remains Alarmingly High, Comment on Comment on J. L. Turban, Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145 Pediatrics e20191725, Comment published on Jan. 26, 2020, available at https://publications.aap.org/pediatrics/article/145/2/e20191725/68259/Pubertal-Suppression-for-Transgender-Youth-and?autologincheck=redirected (last visited April 24, 2023).
[227] J. L. Turban et al. (2020), Pubertal Suppression, 145 Pediatrics e20191725, at *1-*8.
[228] *Id.* at *7.
[229] *Id.* at *4.

the subjects at the time of presentation.[230] Specifically, the most seriously mentally ill patients would have been denied puberty blockers.[231] The study can only be understood in light of these limitations and confounding issues.

According to the study, those who received treatment with pubertal suppression, when compared with those who wanted pubertal suppression but did not receive it, had lower odds of lifetime suicidal ideation (adjusted odds ratio = 0.3; 95% confidence interval = 0.2-0.6).[232] In Table 3 of the paper, under "Suicidality (past 12 months)" reductions for suppressed group versus non-suppressed were seen for ideation (50.6% v 64.8%) and "ideation with plan" (55.6% v 58.2%).[233] However, it is important to note that differences in suicidal "ideation with plan and suicide attempt" and "attempt resulting for inpatient care" did not reach statistical significance.[234] When discussing the results of their study, the authors fail to mention this lack of statistical significance in two of the most serious measures and, instead, ref-

[230] M. Biggs, Comment on J. L. Turban, Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145 Pediatrics e20191725, Comment published on Jan. 30, 2020, available at https://publications.aap.org/pediatrics/article/145/2/e20191725/68259/Pubertal-Suppression-for-Transgender-Youth-and?autologincheck=redirected (last visited April 24, 2023).
[231] *Id.*
[232] J. L. Turban et al. (2020), Pubertal Suppression, 145 Pediatrics e20191725, at *1.
[233] *Id.* at *5.
[234] *Id.* at *5 and Table 2 (indicated by lack of an asterisks next to the P column for the Univariate Analyses). See also use of the asterisks in Table 1, at *4.

erence only suicidal ideation. It would be reasonable to be concerned from an observation of over 40% attempted suicide in the treated group that the intervention was unsuccessful in improving health.[235]

Thus, much like the previously discussed Turban et al. 2019-2020 JAMA Psychiatry study, this Turban et al. 2020 Pediatrics study is severely compromised by unsound methodology, flawed and biased data from the 2015 USTS, and improper or weak extrapolations.

A 2020 study by Van der Miesen et al.[236] was a cross-sectional Dutch study that measured some patients who received puberty blockers and some who did not. The study had three populations of subjects: One was patients presenting to the gender clinic who had not received any intervention, the second was patients who had received puberty blocker, and the third was adolescents from the general population.[237] Because of this study's cross-sectional nature, it cannot establish a causal

[235] See generally M. Biggs, Comment on J. L. Turban, Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, 145 Pediatrics e20191725, Comment published on Jan. 30, 2020, available at https://publications.aap.org/pediatrics/article/145/2/e20191725/68259/Pubertal-Suppression-for-Transgender-Youth-and?autologincheck=redirected (last visited April 24, 2023), and the multiple Letters to the Editor that criticized the multiple methodological errors in this study, https://pediatrics.aappublications.org/content/145/2/e20191725/tab-e-letters#re-pubertal-suppression-for-transgender-youth-and-risk-of-suicidal-ideation. See also M. Biggs, Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria, 49 Archs. Sex. Behav. 2227 (2020).

[236] A. I. R. van der Miesen et al., Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared With Cisgender General Population Peers, 66 J. Adolesc. Health 699 (2020).

[237] *Id.* at 700.

relationship between intervention and effect. It also represents a non-probability sample with potential for significant biases in subject recruitment. In addition, the subjects assessed before and after treatment are different populations. Among the differences between these groups is patient age (mean of 14.5 and 16.8 years before and after treatment, respectively).[238] This two-year age difference is important as developmental progress during adolescence is known to influence psychological well-being.[239] There was also the same limitation noted in the 2011 de Vries study, that the treated population also received psychological support.[240]

A 2021 study by Bustos et al.[241] attempts to provide a systematic review of 27 observational or interventional studies that report on regret or detransition following gender-transition surgeries. A total of 7,928 subjects were included in their meta-analysis.[242] The authors concluded that only 1% or less of those who had gender-transition surgeries expressed regret.[243] It is important to understand the serious

[238] *Id.*
[239] J. He et al., Meta-analysis of gender differences in body appreciation, 33 Body Image 90 (2020).
[240] A. I. R. van der Miesen et al. (2020), Psychological Functioning, 66 J. Adolesc. Health, at 703.
[241] V. P. Bustos et al., Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence, 9 Plastic and Reconstructive Surg. – Global Open e3477 (2021); Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence—Erratum, 10 Plastic and Reconstructive Surg. – Global Open e4340 (2022) ("The systematic review was re-conducted, and the meta-analysis was re-run with the updated numbers with no significant or major changes. The updated tables and figures are included below.").0
[242] V. P. Bustos et al. (2021), Regret after Gender-affirmation Surgery, 9 Plastic and Reconstructive Surg. – Global Open e3477, at *1.
[243] *Id.*

methodological limitations and high risk of bias contained within this study's analysis.[244] This includes failure to include major relevant studies addressing this question,[245] inaccurate analysis within one of the studies considered,[246] and the general lack of controlled studies, incomplete and generally short-term follow-up, large numbers of lost subjects, and lack of valid assessment measures in the published literature addressing this question.[247] As noted by Expósito-Campos and D'Angelo (2021), moderate to high risk of bias was present in 23 of the 27 studies included in the analysis.[248] Furthermore, 97% of subjects analyzed were found within studies deemed to be of fair to poor scientific quality.[249] Thus, this study cannot be used as strong support for the contention that regret is rare.

The 2021 study by Narayan et al.[250] examines anonymous survey results from 154 surgeons affiliated with WPATH. The response rate for this survey was

[244] See P. Expósito-Campos et al., Letter to the Editor: Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence, 9 Plastic and Reconstructive Surg. – Global Open e3951 (2021).
[245] *Id.* See, e.g., C. Dhejne et al., An Analysis of All Applications for Sex Reassignment Surgery in Sweden, 1960-2010: Prevalence, Incidence, and Regrets, 43 Archs. Sex. Behav. 1535 (2014).
[246] C. M. Wiepjes et al., The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets, 15 J. Sexual Med. 582 (2018).
[247] P. Expósito-Campos et al. (2021), Letter to the Editor regarding Bustos et al., Regret after Gender-affirmation Surgery, (2021), 9 Plastic and Reconstructive Surg., at *1.
[248] *Id.*
[249] *Id.*
[250] S. K. Narayan et al., Guiding the conversation—types of regret after gender-affirming surgery and their associated etiologies, 9 Annals of Translational Med. 605 (2021).

30%.[251] Of the respondents, 57% had encountered patients with surgical regret.[252] It is important to recognize that this study was specifically directed toward patients who had undergone surgical transition. Acknowledged biases of this study include selection bias, recall bias, and response bias.[253] This type of study cannot accurately identify the prevalence in the transgender population as a whole, and is particularly limited in the ability to assess potential for regret in the pediatric population.

The 2021 Almazan et al. study is "a secondary analysis of data from the 2015 US Transgender Survey" (USTS).[254] As a secondary analysis that is entirely reliant on the highly flawed and bias 2015 USTS data set, this study is subject to the resulting deficiencies already discussed above in the summaries of the 2019-2020 Turban et al. JAMA Psychiatry study and the 2020 Turban et al. Pediatrics study.

In addition, the Almazan study itself has come under even more direct critique. In a Comment in response to the study, D. Curtis noted that the two groups the study compared are too dissimilar to one another to draw meaningful conclusions

[251] *Id.*
[252] *Id.*
[253] *Id.* at 9.
[254] A. N. Almazan et al., Association Between Gender-Affirming Surgeries and Mental Health Outcomes, 156 JAMA Surg. 611 (2021).

and that the authors failed to adequately highlight the magnitude of several differences.[255] Curtis lists a number of these differences — including significant differences in age, education (degree-status), employment status, gender identification, household income, and sexual orientation. — and then concludes:

> The two groups are so radically different that we really cannot assume that the multivariate analyses carried out allow us to conclude that differences in psychopathology are likely the result of surgical intervention. . . . We cannot agree that the results provide strong evidence that gender-affirming surgery is causally associated with improved mental health outcomes.[256]

In short, the Almazan study is discredited by both unreliable data and improper comparisons.

The 2022 Van der Loos study[257] is a Dutch cohort study that investigates the continuation rate of gender affirming interventions in people who began puberty blockers and gender affirming hormones during adolescence. The authors claim that the study provides evidence against desistance after receiving gender-affirming hormones. While the paper gives the impression that subjects represent a period of

[255] D. Curtis, Unrecognized confounding may explain differences in mental health outcomes, Comment on A. N. Almazan et al., Association Between Gender-Affirming Surgeries and Mental Health Outcomes, 156 JAMA Surg. 611 (2021), available at https://jamanetwork.com/journals/jamasurgery/fullarticle/2779429.
[256] *Id.*
[257] M. A. T. C. van der Loos et al. (2022), Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence, 6 Lancet Child & Adolesc. Health at 869-75.

study extending from 1972 to 2018, the majority of subjects recently started hormone interventions. The length of time for follow-up (mean of 3.5 years for males and 2.3 years for females) and the average age at follow-up (20.2 years for males and 19.3 years for females) are inadequate to support the authors' claim. Notably, research from these same investigators has suggested that the average time to detransition is over 10 years.[258] Thus, it would be necessary for the study to assess patients at least a decade after starting gender-affirming hormones to make any meaningful conclusions on desistance. Furthermore, as a retrospective cohort study without a control group, the study design cannot determine the effect of gender affirming therapy on whether the intervention influences the rate of desistance that would have occurred without the provision of gender-affirming hormones.

The 2022 Nos et al. study[259] is a retrospective cohort study that reports on the likelihood of starting on gender-affirming hormones (GAH) based upon whether or not subjects were treated with puberty blockers. While the title and abstract give the impression that puberty blocker use is not linked to subsequent GAH, the data fail to support this conclusion. Since nearly all of the patients in this study who did not receive GnRHa were given GAH, it is not possible to determine whether GnRHa

[258] C. M. Wiepjes et al. (2018), The Amsterdam Cohort of Gender Dysphoria Study (1972-2015), 15 J. Sexual Med., at 582-90.
[259] A. L. Nos et al., Association of Gonadotropin-Releasing Hormone Analogue Use With Subsequent Use of Gender-Affirming Hormones Among Transgender Adolescents, 5 JAMA Netw. Open e2239758 (2022).

could increase this outcome. The comparison groups differed by age at time of initial presentation (age 10-13 years versus 14-17 years). GnRHa use was higher among the younger patients owing to the fact that they had not completed puberty at the time of first visit. A lag in progression to GAH use in this group is heavily influenced by the difference in age at time of initial presentation. The older group was eligible to start GAH at the time of study entry while those in the younger group were not. When adjusted for age, the rates of progression to GAH use is nearly identical. Importantly, among the patients who received GnRHa, 94% (64 out of 70) went on to take gender affirming hormones. Thus, the study further confirms that, rather than serving as a "pause button" for gender dysphoric adolescents, GnRHa use is an intervention that will lead to progression to gender affirming hormones.

The 2022 Green at al. study[260] purported to measure suicide attempts and access to cross-sex hormones. Though this study had a large cohort of patients,[261] it suffered many biases in patient recruitment — which was done over the Internet[262] and provided a cross-sectional analysis[263] which can, at best, demonstrate correlation but not causation. Similar to other studies, it did not assess the effect of psychiatric

[260] A. E. Green et al., Association of Gender-Affirming Hormone Therapy With Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth, 70 J. Adolesc. Health 643 (2022).
[261] *Id.* at 644.
[262] *Id.*
[263] *Id.* at 647.

medications or psychotherapy on outcomes. It also failed to include variables to assess at what age youth began puberty blockers or the duration which they had received gender-affirming hormones.

The 2022 Turban et al. study[264] is a retrospective cross-sectional investigation to assess whether there is an association between adolescent access to gender-affirming hormones and mental health. By nature of its retrospective cross-sectional design, the study is not able to make any conclusions regarding a causal relationship between GAH access and mental health. Like the Almazan et al. study and the two prior studies from Turban discussed above, this 2022 Turban study rests entirely on data from the USTS[265] and therefore suffers from similar defects.[266] Caution is warranted in evaluating any and all studies that either use or conduct further analysis of the USTS data because those studies would naturally be subject to any limitations, flaws, biases, irregularities, or anomalies in this source data.

The authors of the Turban 2022 study claim that there is an association between getting gender-affirming hormones and favorable mental health outcomes compared to those who desired but did not receive this intervention.[267] However,

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[264] J. L. Turban et al., Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults, 17 PLOS ONE e0261039 (2022).
[265] *Id.* at *3.
[266] See supra discussion of Alamazan et al., USTS, R. D'Angelo et al, and D. Curtis comment on Almazan et al.
[267] J. L. Turban et al. (2022), Access to gender-affirming hormones, 17 PLOS ONE e0261039, at *1, *1.

since the methodology used is similar to the author's 2020 study on the effects of access to puberty blockers on lifetime suicidality, already discussed above, and used the same 2015 U.S. Transgender Survey (USTS), it is subject to all of the associated limitations and biases.[268] Participants in the USTS were recruited through transgender advocacy organizations and subjects were asked to "pledge" to promote the survey among friends and family.[269] Thus, there are serious concerns of selection bias.[270] It also suffers from recall bias[271] and an inability to verify the veracity of the claims of treatments given to the study respondents.

Review of the data contained within the paper leads to conclusions that are far different than those stated by the study authors regarding mental health of the study participants. While the odds ratio for past-year suicidal ideation was statistically different between those who did and those who did not get GAH, there was no difference in those who had a suicide plan, actually attempted suicide, or were hospitalized for a suicide attempt.[272] This is important since the rationale for accepting the attendant risks of gender-affirming hormones is to prevent suicide. As pointed

[268] R. D'Angelo et al. (2021), One Size Does Not Fit All, 50 Archs. Sex. Behav. at 7-16.
[269] *Id.* at 8.
[270] S. Tyrer et al., Sampling in epidemiological research: issues, hazards and pitfalls, 40 BJPsych Bull. 57 (2016).
[271] See generally S. S. Coughlin, Recall bias in epidemiologic studies, 43 J. Clin. Epidemiol. 87 (1990).
[272] J. L. Turban et al. (2022), Access to gender-affirming hormones, 17 PLOS ONE e0261039, at *5-*8 ("We detected no difference for other mental health variables measured.").

out by Michael Biggs in a commentary on this article,[273] the data presented in this study negate the purported significance of effects of puberty blocker access on mental health as reported in Turban's 2020 Pediatrics article. As with many of the other studies considered in this report, the Turban et al. 2022 study is also discredited both by deficient data-sampling techniques and by flawed reasoning and unsound methodology overall.

The 2022 Tordoff study[274] is a prospective observational cohort study that assessed the mental health of patients presenting to the Seattle Children's gender clinic over a one-year period of follow-up. The authors claimed that access to gender-affirming care had significantly improved mental health with lower odds ratios of depression and suicidality. This purported finding was widely publicized by the University of Washington and was featured on several news media sites.[275] A

[273] M. Biggs, Estrogen is associated with greater suicidality among transgender males, and puberty suppression is not associated with better mental health outcomes for either sex, Comment on J. L. Turban et al., Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults, 17 PLOS ONE e0261039 (2022), Comment posted on Jan. 19, 2022, available at https://journals.plos.org/plosone/article/comment?id=10.1371/annotation/dcc6a58e-592a-49d4-9b65-ff65df2aa8f6 ("Conversely, a previous article by Turban et al. claimed to find a positive association between puberty suppression (using a Gonadotropin-Releasing Hormone agonist) and mental health--but this did not control for cross-sex hormones." (citing J. L. Turban et al. 2020, Pubertal suppression, 145 Pediatrics e20191725)).

[274] D. M. Tordoff et al., Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care, 5 JAMA Netw. Open e220978 (2022). For errata, see Data Errors in eTables 2 and 3, 5 JAMA Netw. Open e2229031 (2022).

[275] See, e.g., Teens who received gender-affirming care had 60% lower odds of depression, UW study finds, king5.com, Published Mar. 12, 2022, Updated Sept. 7, 2022, https://www.king5.com/article/news/health/gender-affirming-care-reduces-depression-university-of-washington-study-transgender-nonbinary/281-bcfece1b-a7cb-4c95-80d0-3f02c597d783

detailed critique of the paper's data and flawed conclusions has been posted online.[276] Contrary to the authors' claims, data contained in the paper did not show improvement in mental health over the one-year study period. At entry into the study, 57% of the subjects who reported receiving treatment with puberty blockers or gender-affirming hormones (PB/GAH) had moderate to severe depression.[277] At the end of the study, 56% of the subjects who reported receiving PB/GAH had moderate to severe depression.[278] Rates for moderate to severe anxiety were 57% and 51% at baseline and 12 months, respectively, for subjects who reported receiving PB/GAH.[279] Self-harm or suicidal thoughts were 43% and 37% at baseline and 12 months, respectively for subjects who reported receiving PB/GAH.[280] These are alarmingly high numbers for an intervention that is touted to be lifesaving. J. Singal notes that "[a]mong the kids who went on hormones, there isn't genuine statistical

(last visited Apr 30, 2023); Medical treatments cut risks for depression, suicide among transgender youth, UPI, https://www.upi.com/Health_News/2022/03/01/medical-treatments-transgender-youth/3211646078081/ (last visited Apr 30, 2023).

[276] See J. Singal, Researchers Found Puberty Blockers And Hormones Didn't Improve Trans Kids' Mental Health At Their Clinic. Then They Published A Study Claiming The Opposite. (Updated), Singal-Minded (Apr. 6, 2022), https://jessesingal.substack.com/p/researchers-found-puberty-blockers (last visited Apr 13, 2023). See also Jesse Singal, Authors, Macmillan, https://us.macmillan.com/author/jessesingal (last visited Apr 30, 2023).

[277] D. M. Tordoff et al. (2022), Mental Health Outcomes, 5 JAMA Netw. Open e220978, at Online Supplementary Materials (Tordoff Supplement) and eTable 3 (at *4).

[278] *Id.*

[279] *Id.*

[280] *Id.*

improvement here from baseline to the final wave of data collection.[281] Singal contacted one of the authors to ask about the data in eTable 3 and to confirm that there was, in fact, no improvement within the group of participants that had received puberty-blocking or hormonal interventions. Singal writes:

> [The authors] reference "improvements" twice . . . but offer no statistical demonstration anywhere in the paper or the supplemental material. I wanted to double-check this to be sure, so I reached out to one of the study authors. They wanted to stay on background, but they confirmed to me that there was no improvement over time among the kids who went on hormones or blockers.[282]

The reported statistical difference in odds ratios were comparisons between those who started on puberty blockers and cross-sex hormones and those who did not receive hormones. Importantly, there was a marked difference in the number of drop-out subjects in the treated and non-treated groups (17.4% versus 80%, respectively).[283] It is reasonable to speculate that the small number of subjects who remained in the study but did not receive hormones had significant co-morbidities that

[281] J. Singal (2022), Research Found Puberty Blockers And Hormones Didn't Improve Trans Kids' Mental Health, https://jessesingal.substack.com/p/researchers-found-puberty-blockers (last visited Apr 30, 2023).
[282] J. Singal (2022), Research Found Puberty Blockers And Hormones Didn't Improve Trans Kids' Mental Health, https://jessesingal.substack.com/p/researchers-found-puberty-blockers (last visited Apr 30, 2023) (linking at the phrase "on background" to J. Bender et al., Levels of Attribution, in J. Bender et al., Writing & Reporting for the Media, 11th ed., Oxford University Press (2016), available at https://global.oup.com/us/companion.websites/9780190200886/student/chapter10/gline/level/#:~:text=%E2%80%9COn%20background%2C%E2%80%9D%20which%20is,the%20source%20by%20her%20position. (last visited May 1, 2023)).
[283] D. M. Tordoff et al. (2022), Mental Health Outcomes, 5 JAMA Netw. Open e220978, at 1, and Tordoff Supplement at eTable2 (*4), eTable3 (*4). See also J. Singal (2022), Research Found Puberty Blockers And Hormones Didn't Improve Trans Kids' Mental Health, at nn.3-4.

prevented them from accessing this intervention. In any event, the actual data from this study demonstrates that access to puberty blockers and gender affirming hormones did not improve mental health over the first year of treatment. This is drastically different from what the authors and the media claimed.

The 2023 Chen et al. study[284] is a longitudinal observational study of patients receiving care at four gender centers in the United States. The primary conclusion made by the authors is that "GAH improved appearance congruence and psychosocial functioning."[285] However, there are major limitations and weaknesses in the data that limit the conclusions that can be made. The most glaring problem is that the study was observational and did not include a control group. Thus, there is no ability to draw causal conclusions. At best, the authors can find associations. A revealing critique of the paper by De Vries and Hannema that was published alongside this article exposes some of these concerns.[286] Akin to many of the other papers in this field, there is no way to determine whether any of the changes were contributed by or due solely to psychiatric interventions.[287] It is also notable that even though the study was designed to recruit only subjects with good mental health at

[284] D. Chen et al., Psychosocial Functioning in Transgender Youth after 2 Years of Hormones, 388 N. Engl. J. Med. 240 (2023).
[285] *Id.* at 240.
[286] A. L. C. De Vries et al., Growing Evidence and Remaining Questions in Adolescent Transgender Care, 388 N. Engl. J. Med. 275, (2023).
[287] *Id.* at 276.

baseline, 48 of the 307[288] study subjects (15.6%) were described as having severe or moderate depression at this time point.[289] At the end of the two-year follow-up, 30 of the 219 remaining subjects (13.7%) were reported to have major depression. Furthermore, two patients committed suicide during the two-year observation period, "one after 6 months of follow-up and the other after 12 months of follow-up."[290] This is an outcome that in most other situations would lead to a halt in study and detailed inquiry by an institutional review board.[291] The paper claims to present two-year follow-up data in this cohort. However, only about half of the study participants were assessed at all five of the study time points,[292] and 30% did not have 24-month data collected.[293] Even if one accepted the follow-up period, this is likely not long enough to make firm conclusions about long-term efficacy. Several key outcomes

[288] While 315 participants enrolled in the Chen study, only 307 participants remained at the conclusion of the study. D. Chen et al. (2023), Psychosocial Functioning, 388 N. Engl. J. Med. at 243.
[289] *Id.* at 243.
[290] *Id.* at 243.
[291] NIH Guide: Guidance on Reporting Adverse Events to Institutional Review Boards for NIH-Supported Multicenter Clinical Trials, NOT-99-107, June 11, 1999, available at https://grants.nih.gov/grants/guide/notice-files/NOT99-107.html (last visited Apr 13, 2023) (also accessible through NIH Funding Opportunities and Notices for The Week Ending 06-11-99, available at https://grants.nih.gov/grants/guide/WeeklyIndex.cfm?WeekEnding=06-11-99 (last visited Apr 13, 2023)). See also NIH Grant Policy Statement, § 4.1.15.6 Data and Safety Monitoring (U.S. Department of Health and Human Services, National Institutes of Health, December 2022) available at https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf (last visited April 13, 2022) (setting planning standards for reporting of adverse events to institutional review boards in NIH grant-funded clinical trials).
[292] D. Chen et al. (2023), Psychosocial Functioning, 388 N. Engl. J. Med. at 240.
[293] D. Chen et al. (2023), Psychosocial Functioning, 388 N. Engl. J. Med. at 240, Supplementary Appendix at 8 (Table S2. Coverage for Key Variables).

that according to the original study protocol were to be measured (gender dysphoria, trauma symptoms, self-injury, suicidality, body esteem, and quality of life) are not reported in this paper.[294] The reason for these omissions is not apparent in the published manuscript. The study authors failed to report on robust measures of psychological well-being such as the number on antidepressants and other psychotropic medications.[295] The study effects for many of the measures reported was very modest at best and, even when statistically significant, do not have any meaningful clinical significance. For example, the depression scores showed little change over two years in the highest severity group.[296] There is also significant heterogeneity in responses with some subjects showing improvement, some no change, and others worsening.[297] Consequently, these data do not alleviate the serious concerns raised regarding the safety and efficacy of gender-affirming medical interventions.

132. Many conclusions in the above studies are drawn or characterized in fundamentally unscientific ways without apparent regard to the scientific process of disproving a null hypothesis. Instead, these studies — along with the comments, responses, and professional criticism they have received — suggest that the authors began with a conclusion and then looked for data to support that conclusion. That

[294] D. Chen et al. (2023), Psychosocial Functioning, 388 N. Engl. J. Med. at 240-50.
[295] *Id.*
[296] D. Chen et al. (2023), Psychosocial Functioning, 388 N. Engl. J. Med. at 240, Supplementary Appendix at 13 (Table S6. Proportions of Youth Scoring in the Clinical Range for Depression and Anxiety at Each Timepoint).
[297] D. Chen et al. (2023), Psychosocial Functioning, 388 N. Engl. J. Med. at 240-50.

is a vastly unsound way of doing science, and patients will not be aware of these methodological limitations and distortions when informed of these purported conclusions.

133. There remains a significant and unmet need to improve our understanding of the biological, psychological, and environmental basis for the manifestation of patient reports of discordance of gender identity and biological sex in affected individuals, as well as the long-term effects of "affirming" interventions.[298] In particular, there is a concerning lack of randomized controlled trials or adequately controlled longitudinal studies comparing outcomes of youth with gender dysphoria who received psychological support, were encouraged to socially transition, or were put on medical interventions, and how these differential treatments affect the usual and natural progression to resolution of gender dysphoria and other variables. Such studies can be ethically designed and executed with provisions for other dignity-affirming measures to all treatment groups.[299] But they have not been performed in the existing literature, leaving that literature in a state insufficient to enable sound conclusions about the efficacy of "affirming" treatments.

[298] J. Olson-Kennedy et al., Research priorities for gender nonconforming/transgender youth: gender identity development and biopsychosocial outcomes, 23 Current Op. in Endocrinol., Diabetes & Obesity 172, 172-79 (2016).
[299] See generally J. Sugarman, Ethics in the Design and Conduct of Clinical Trials, 24 Epidemiologic Reviews 54, 54-58 (2002).

INTERNATIONAL RESPONSES

134. Recognizing the paucity of evidence supporting "affirming" treatments, along with the proven risks of those treatments, other countries are increasingly limiting use of those treatments.

135. **Finland**: The National Science Review in Finland carefully examined all relevant science and suspended transition treatments for minors under age 16.[300] The review determined that "[t]he first-line treatment for gender dysphoria is psychosocial support and, as necessary, psychotherapy and treatment of possible comorbid psychiatric disorders."[301] According to the review, "[c]ross-sex identification in childhood, even in extreme cases, generally disappears during puberty."[302] The review also found: "Potential risks of GnRH therapy include disruption in bone mineralization and the as yet unknown effects on the central nervous system";[303] "there are no medical treatment[s] [for transitioning] that can be considered evidence-based";[304] and, "[t]he reliability of the existing studies with no control groups is

[300] See 2020 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, Palveluvalikoima, Nov. 6, 2020, available at https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf. See also Recommendations - Choices in health care, Palveluvalikoimaneuvosto, https://palveluvalikoima.fi/en/recommendations (last visited Apr 13, 2023).
[301] PALKO / COHERE Finland, Recommendation, Nov. 6, 2020 (unofficial translation), at 5.
[302] *Id.*
[303] *Id.* at 6.
[304] *Id.*

highly uncertain."[305] Thus, "because of this uncertainty, no decisions should be made that can permanently alter a still-maturing minor's mental and physical development,"[306] and "[n]o gender confirmation surgeries are performed on minors."[307] "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. For children and adolescents, these factors are key reasons for postponing any interventions until adulthood. . . . In light of available evidence, gender reassignment of minors is an experimental practice."[308]

136. **Sweden**: The world-renowned Karolinska Hospital reviewed the current research and suspended pediatric gender transitions for patients under 16 outside of experimental, monitored clinical trials settings as of May 2021.[309] Treatment will

[305] *Id.* at 7.
[306] *Id.*
[307] *Id.*
[308] *Id.* at 7-8.
[309] Karolinska Universitetssjukhuset — Astrid Lindgrens Barnsjukhus, English, unofficial translation, Guideline Regarding Hormonal Treatment of Minors with Gender Dysphoria at Tema Barn - Astrid Lindgren Children's Hospital (ALB), K2021-4144, Apr. 2021, at 2, available at https://segm.org/sites/default/files/Karolinska%20Guideline%20K2021-4144%20April%202021%20%28English%2C%20unofficial%20translation%29.pdf; Karolinska Universitetssjukhuset — Astrid Lindgrens Barnsjukhus, English, unofficial translation, Policy Change Regarding Hormonal Treatment of Minors with Gender Dysphoria at Tema Barn - Astrid Lindgren Children's Hospital, K2021-3343, Mar. 2021, at 1-2, available at https://segm.org/sites/default/files/Karolinska%20Policy%20Change%20K2021-3343%20March%202021%20%28English%2C%20unofficial%20translation%29.pdf. See also

focus on psychotherapy and assessment.[310] The "Dutch protocol" for treating gender-dysphoric minors has been discontinued over concerns of medical harm and uncertain benefits.[311]

Moreover, in a national policy review, a report commissioned by the Swedish government concluded that:

- We have not found any scientific studies which explains the increase in incidence in children and adolescents who seek the heath care because of gender dysphoria.
- We have not found any studies on changes in prevalence of gender dysphoria over calendar time, nor any studies on factors that can affect the societal acceptance of seeking for gender dysphoria.
- There are few studies on gender affirming surgery in general in children and adolescents and only single studies on gender affirming genital surgery.
- Studies on long-term effects of gender affirming treatment in children and adolescents are few, especially for the groups that have appeared during the recent decennium. . . .

Karolinska Universitetssjukhuset — Astrid Lindgrens Barnsjukhus, Riktlinje gällande hormonell behandling till minderariga patienter med könsdysfori inom Tema Barn, K2021-4144, Apr. 2021, available at https://segm.org/sites/default/files/Karolinska%20Riktlinje%20K2021-4144%20April%202021%20%28Swedish%29.pdf (Swedish-language document); Karolinska Universitetssjukhuset — Astrid Lindgrens Barnsjukhus, Policyförändring gällande hormonell behandling till minderariga patienter med könsdysfori inom Tema Barn - Astrid Lindgrens Barnsjukhus, K2021-3343, Mar. 2021, available at https://segm.org/sites/default/files/Karolinska%20Policyförändring%20K2021-3343%20March%202021%20%28Swedish%29.pdf (Swedish-language document).

[310] See Society for Evidence-Based Medicine, Sweden's Karolinska Ends All Use of Puberty Blockers and Cross-Sex Hormones for Minors Outside of Clinical Studies, SEGM.org, May 5, 2021, https://segm.org/Sweden_ends_use_of_Dutch_protocol ((featuring links to PDF copies of the Karolinska Policy and Guidelines documents, along with unofficial English translations, at the bottom of the page).

[311] *Id.*

- . . . No relevant randomized controlled trials in children and adolescents were found.[312]

From these findings, the Swedish National Board of Heath in December of 2022 issued updated guidelines for the care of adolescents and children with gender dysphoria.[313] This medical board concluded that "the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatments."[314] Noting that there is uncertainty about the cause for the rapid rise in number of people being diagnosed with gender dysphoria, documented evidence of detransitioning young adults with uncertainty regarding the prevalence of this outcome, and lack of uniformity in experience-based knowledge among providers,

[312] See Sweden Policy Review, Gender dysphoria in children and adolescents: an inventory of the literature, SBU Policy Support no 307, 2019, https://www.sbu.se/307e.

[313] Socialstyrelsen —The National Board of Health and Welfare, Vård av barn och ungdomar med könsdysfori Nationellt kunskapsstöd med rekommendationer till profession och beslutsfattare (2022), https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-12-8302.pdf (full report in Swedish, PDF format). See also Uppdaterat kunskapsstöd för vård vid könsdysfori hos unga, Socialstyrelsen (2022), https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/uppdaterat-kunskapsstod-for-vard-vid-konsdysfori-hos-unga/ (last visited Apr 14, 2023) (announcing and publishing the full Swedish report); Socialstyrelsen —The National Board of Health and Welfare, Care of children and adolescents with gender dysphoria Summary of national guidelines, December 2022, https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf (English-language Summary from Socialstyrelsen).

[314] Socialstyrelsen —The National Board of Health and Welfare, Care of children and adolescents with gender dysphoria Summary of national guidelines, December 2022, at 3, https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf (English-language Summary from Socialstyrelsen). See also J. Block (2023), Gender dysphoria in young people is rising-and so is professional disagreement, 380 BMJ 382, at *2, *3.

GnRH analogues, gender-affirming hormones and mastectomy should be provided only in exceptional cases and ideally as part of an experimental trial.[315]

The results of the Swedish systematic review of the current published literature related to hormone treatment of gender dysphoric youth that served as the basis for this policy change were published on April 17, 2023 in the peer-reviewed journal Acta Paediatrica.[316] The authors of this systematic review identified 9,934 abstracts related to hormone administration to childen with gender dysphoria among the English language literature as of November 9, 2022.[317] The authors crafted a series of exclusion criteria to ensure that only an appropriate, relevant sample remained for analysis.[318] From the 9,934 abstracts, 36 studies passed through to the final stage of the winnowing process.[319] Twelve of these studies were assessed to have a high risk of bias and were therefore excluded from analysis, leaving 24 studies that met the rigorous inclusion criteria.[320] These remaining 24 studies were assessed for findings relevant to the inclusion criteria. This included 21 studies in which adolescents were given GnRH analogues (i.e., puberty blockers) and 3 studies where

[315] *Id.* at 3-4.
[316] J. F. Ludvigsson et al., A systematic review of hormone treatment for children with gender dysphoria and recommendations for research, Acta Paediatrica, Apr. 17, 2023, available at https://onlinelibrary.wiley.com/doi/10.1111/apa.16791 (Early View: Online Version of Record before inclusion in an issue).
[317] *Id.* at *2-*3.
[318] *Id.* at *1-*3, *4.
[319] *Id.* at *3, *4.
[320] *Id.* at *3, *4.

cross-sex hormones were administered without prior GnRHa treatment.[321] Among the studies, the authors did not find any randomized controlled trials addressing the psychosocial effects, bone health, body composition and metabolism, or persistence in children with gender dyshporia undergoing treatment with GnRHa medications.[322] The authors of this study found serious methodological weaknesses in each of the the three longitudinal observational studies assessed.[323] These weaknesses included small sample size and high attrition rates.[324] And these deficiencies prevented any verifiable conclusions regarding the long-term effects of hormone therapy on psychological health from being drawn.[325] Moreover, GnRHa therapy was found to delay bone maturation and bone mineral density gain, a delay that was only partially recovered by cross-sex hormone administration when studied at age 22 years.[326] Among the key findings of this published peer-reviewed study were that the long long-term effects of hormone therapy on psychosocial health are unknown, GnRHa treatment delays bone maturation and gain in bone mineral density, and GnRHa

[321] *Id.* at *1.
[322] *Id.* at *1, *9, See also, *id.* at *10 (stating generally that "randomized controlled trials are lacking in gender dysphoria research").
[323] *Id.* at *9-*10.
[324] *Id.* at *9-*10.
[325] See, e.g., *id.* at *4 ("Because these studies were hampered by small number of participants and substantial risk of selection bias, the long-term effects of hormone treatment on psychosocial health could not be evaluated. Of note, [these] studies do not allow separation of potential effects of psychological intervention independent of hormonal effects."). See also *id.* at *8 and Table 2.
[326] *Id.* at *1, *8-*9 and Table 3, *12.

treatment in children with gender dysphoria should be considered experimental treatment of individual cases rather than standard procedure.[327]

137. **United Kingdom**: The British official medical review office, National Institute of Health and Care Excellence (NICE), published reports on the use of both puberty blockers and hormones for transitioning purposes.[328] The assessment of the evidence into the drugs was commissioned by the National Health Service England (NHS). The review found that the evidence for using puberty-blocking drugs to treat young people struggling with their gender identity is "very low certainty."[329] The review on GnRH analogues found only "small, uncontrolled observational studies, which are subject to bias and confounding, and all the results are of very low certainty using modified GRADE. They all reported physical and mental health comorbidities and concomitant treatments very poorly."[330]

NICE also reviewed the evidence base for cross-sex hormones.[331] This review found the evidence of clinical effectiveness and safety of cross-sex hormones was

[327] *Id.* at *2 (Key Notes), *8 and Table 2 (columns for 'Certainty of evidence" and Deduction in GRADE), *9 and Table 3 (columns for "Certainty of evidence" and Deduction in GRADE), and *10 and Table 4 (columns for "Certainty of evidence and Deduction in GRADE).
[328] Nice Evidence Reviews — Cass Review, https://cass.independent-review.uk/nice-evidence-reviews/ (last visited Apr. 29, 2023).
[329] NICE, Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria, (Oct. 2020), https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_GnRH-analogues_For-upload_Final.pdf.
[330] *Id.* at 11-12.
[331] NICE, Evidence review: Gender-affirming hormones for children and adolescents with gender dysphoria, (Oct. 2020), https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_Gender-affirming-hormones_For-upload_Final.pdf.

also of "very low" quality.[332] The review concluded: "Any potential benefits of gender-affirming hormones must be weighed against the largely unknown long-term safety profile of these treatments in children and adolescents with gender dysphoria."[333]

A recent independent review of gender identity services in the United Kingdom, by Dr. Hilary Cass, concluded that "Evidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and internationally."[334] In summarizing a few of the key points and context from the Interim Report, the Cass Review stated, "There is lack of consensus and open discussion about the nature of gender dysphoria and therefore about the appropriate clinical response."[335]

Following the Cass Review, the NHS ordered the closure of the Tavistock clinic, the UK's only dedicated gender identity clinic for children and young people.[336] As the BBC summarized, the Cass Review found that "the current model of care was leaving young people 'at considerable risk' of poor mental health and distress, and having one

[332] See, e.g., *id.* at 7, 47.
[333] *Id.* at 14.
[334] H. Cass (2022), The Cass Review — Interim Report, at 18.
[335] The Cass Review, Interim report — Cass Review, Publications, https://cass.independent-review.uk/publications/interim-report/ (last visited Apr 14, 2023) (announcing the submission of the Interim Report to NHS and summarizing some key findings).
[336] J. Andersson et al., NHS to close Tavistock child gender identity clinic, BBC News, Jul. 28, 2022, https://www.bbc.com/news/uk-62335665.

clinic was not 'a safe or viable long-term option.'"[337] The Tavistock will be replaced by a new regional hospital-based service where related services for mental health and autism can be provided by clinicians who have expertise in safeguarding and supporting children.[338] Thus, gender-related distress will be addressed "within a broader child and adolescent health context."[339]

This new model is in sharp contrast to recommendations made by WPATH in SOC-8. (Indeed, WPATH criticizes the UK's recent approach.[340]) Differences in approach include the prioritization of parent versus child expectations for care, recommendations against social affirmation of pre-pubertal youth, the provision of puberty blockers within the experimental setting, initial focus on exploration and treatment of mental health problems, and use of psychological support as a primary intervention.[341]

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[337] *Id.*

[338] Letter from Dr. Hilary Cass, Chair, Independent Review of Gender Identity Services for Children and Young People, to John Stewart, National Director Specialised Commissioning, NHS England, (Jul. 19, 2022), at 2, https://cass.independent-review.uk/wp-content/uploads/2022/07/Cass-Review-Letter-to-NHSE_19-July-2022.pdf.

[339] *Id.*

[340] WPATH, WPATH, ASIAPATH, EPATH, PATHA, and USPATH Response to NHS England in the United Kingdom (UK) Statement regarding the Interim Service Specification for the Specialist Service for Children and Young People with Gender Dysphoria (Phase 1 Providers) by NHS England, (2022), https://www.wpath.org/media/cms/Documents/Public%20Policies/2022/25.11.22%20AUSPATH%20Statement%20reworked%20for%20WPATH%20Final%20ASIAPATH.EPATH.PATHA.USPATH.pdf?_t=1669428978#:~:text=the%20specialist%20service.-,WPATH%2C%20ASIAPATH%2C%20EPATH%2C%20PATHA%2C%20and%20USPATH%20believe%20that,to%20puberty%20suppression%20and%20gender%2D.

[341] See generally, E. Coleman et al. (2022), SOC-8, 23 Int'l. J. Transgender Health, at 51-5258; H. Cass (2022), The Cass Review – Interim Report.

CONCLUSIONS

138. There are no long-term, peer-reviewed, published, reliable, and valid research studies documenting the reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

139. There are no long-term, peer-reviewed, published, reliable, and valid research studies documenting any valid and reliable biological, medical, surgical, radiological, psychological, or other objective assessment of gender identity or gender dysphoria.

140. A large percentage of children (over 80% in some studies) who questioned their gender identity will, if not affirmed in a sex-discordant gender identity, develop an acceptance of their natal (biological) sex.

141. A currently unknown percentage and number of patients reporting gender dysphoria suffer from mental illness(es) that complicate and may distort their judgments and perceptions of gender identity.

142. A currently unknown percentage and number of patients reporting gender dysphoria may be manipulated by a social contagion and social pressure processes, including peer group, social media, YouTube role modeling, and parental pressures.

143. There are no long-term, peer-reviewed, published, reliable, and valid research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are helped by such procedures.

144. There are no long-term, peer-reviewed, published, reliable, and valid research studies documenting the number or percentage of patients receiving gender-affirming medical interventions who are injured or harmed by such procedures.

145. "Affirming" treatments have no known, peer-reviewed, and published error rates.

146. The gender-affirming approach has limited, very weak scientific support for short-term alleviation of dysphoria and no long-term outcomes data demonstrating superiority over the other approaches.

147. Because of the major methodological limitations and weaknesses of the extant published literature in the field of gender dysphoria, one cannot make a conclusion that "affirming" treatments are justified as a safe and effective long-term solution to gender dysphoria in consideration of the significant risks and unsubstantiated long-term benefits.

148. With the limited and poor-quality data currently available about the purported efficacy of blocking normally timed puberty, administering cross-sex hormones, and gender-affirming surgeries in alleviating psychological morbidity for youth who experience sex-discordant gender identity and the serious medical risks

associated with these interventions, it cannot be concluded that this approach is "medically necessary." Use of such medical interventions remains a largely experimental approach.

149. Experimentation on gender-discordant youths is especially likely to cause harm to patients from historically marginalized communities. That is because children in such communities are disproportionally affected by gender discordance. These include:

- children with a history of psychiatric illness;[342]
- children of color;[343]
- children with mental developmental disabilities;[344]
- children on the autistic spectrum;[345] and
- children residing in foster care homes and adopted children.[346]

150. Patients suffering from gender dysphoria or related issues have a right to be protected from experimental, potentially harmful treatments lacking reliable,

[342] See, e.g., R. Kaltiala-Heino et al., Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development, 9 Child Adolesc. Psychiatry Mental Health 9 (2015).
[343] See, e.g., G. N. Rider et al., Health and Care Utilization of Transgender and Gender Nonconforming Youth: A Population-Based Study, 141 Pediatrics e20171683 (2018).
[344] See, e.g., C. Bedard et al., Gender Identity and Sexual Orientation in People with Developmental Disabilities, 28 Sexuality and Disability 165 (2010).
[345] See, e.g., A. L. C. De Vries et al., Autism Spectrum Disorders in Gender Dysphoric Children and Adolescents, 40 J. Autism Dev. Disord. 930 (2010).
[346] See, e.g., D. E. Shumer et al., Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic, 2 Transgender Health 76 (2017).

valid, peer-reviewed, published, long-term scientific evidence of safety and effectiveness.

151. The treatment protocols and recommendations of politically influenced, non-science associations like WPATH and the American Academy of Pediatrics that engage in consensus-seeking methodologies by vote rather than science are not based on competent, credible, methodologically sound science, and have no known or published error rate.

152. The committee that developed the Endocrine Society gender-dysphoria guidelines relied on low-quality scientific evidence in making strong treatment recommendations and failed to adequately review the scientific evidence pertaining to long-term risk of medical interventions to affirm sex-discordant gender identity

153. Administering hormones to a child whose gender dysphoria is highly likely to resolve is risky, unscientific, and unethical. Iatrogenic damages from these interventions, including infertility, stunted growth, increased heart attack risk, and many more, are often irreversible.

154. Because of these concerns about the safety, efficacy, and scientific validity of controversial, unproven, and experimental treatment paradigms, I have not personally engaged in the delivery of gender-affirming medical interventions to children with gender dysphoria. Given the unproven long-term benefits and the well-documented risks and harms of "transitioning" children, I decline to participate in

such experimental treatments until the science has proven that the relative risks and benefits of this approach warrant such procedures.

155. My decision is strengthened by the knowledge that the vast majority of children who report gender dysphoria will, if not affirmed in their sex-discordant gender identity grow out of the problem — a natural coping-developmental process — and willingly accept their biological sex. Since there are no reliable assessment methods for identifying the small percentage of children with persisting sex-gender identity discordance from the vast majority who will accept their biological sex, and since puberty blocking treatments, hormone transition treatments, and surgical transition treatments are all known to have potentially life-long devastating, negative effects on patients, I and many colleagues view it as unethical to treat children with an unknown future by using experimental, aggressive, and intrusive gender affirming medical interventions.

Dated: May 19, 2023

Paul W. Hruz, MD, PhD

Curriculum Vitae

Date: 3/19/2023
Name: Paul W. Hruz, M.D., Ph.D.

Contact Information

Office:	Phone: 314-286-2797 Fax: 314-286-2892
Mail:	Washington University in St. Louis School of Medicine Department of Pediatrics Endocrinology and Diabetes 660 South Euclid Avenue St Louis MO 63110
Email:	Office: hruz_p@wustl.edu

Present Position

Associate Professor of Pediatrics, Endocrinology and Diabetes
Associate Professor of Pediatrics, Cell Biology & Physiology

Education

1987	BS, Chemistry, Marquette University, Milwaukee, WI
1993	PhD, Biochemistry, Medical College of Wisconsin, Milwaukee, WI Elucidation of Structural, Mechanistic, and Regulatory Elements in 3-Hydroxy-3-Methlyglutaryl-Coenzyme A Lyase, Henry Miziorko
1994	MD, Medicine, Medical College of Wisconsin, Milwaukee, WI
1994 - 1997	Pediatric Residency, University of Washington, Seattle, Washington
1997 - 2000	Pediatric Endocrinology Fellowship, Washington University, Saint Louis, MO
2017	Certification in Healthcare Ethics, National Catholic Bioethics Center, Philadelphia, PA

Academic Positions / Employment

1996 - 1997	Locum Tenens Physician, Group Health of Puget Sound Eastside Hospital, Group Health of Puget Sound Eastside Hospital, Seattle , WA
2000 - 2003	Instructor in Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2003 - 2011	Assistant Professor of Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2004 - 2011	Assistant Professor of Pediatrics, Cell Biology & Physiology, Washington University in St. Louis, St. Louis, MO
2011 - Pres	Associate Professor of Pediatrics, Cell Biology & Physiology, Washington University in St. Louis, St. Louis, MO

2011 - Pres	Associate Professor of Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2012 - 2017	Division Chief, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO

Clinical Title and Responsibilities

	General Pediatrician, General Pediatric Ward Attending: 2-4 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Endocrinology Night Telephone Consult Service: Average of 2-6 weeks/per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Inpatient Endocrinology Consult Service: 3-6 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Outpatient Endocrinology Clinic: Approximately 150 patient visits per month, St. Louis Children's Hospital

Teaching Title and Responsibilities

2009 - Pres	Lecturer, Markey Course-Diabetes Module
2008 – 2016	Fellowship Program Director- Pediatric Endocrinology and Diabetes
2020 - 2020	Facilitator, Reading Elective-Interdisciplinary/Miscellaneous Course #M80-800, Washington University School of Medicine
2019 – Pres	Associate Fellowship Program Director- Pediatric Endocrinology and Diabetes

University, School of Medicine and Hospital Appointments and Committees

University

2012 - 2020	Disorders of Sexual Development Multidisciplinary Care Program

School of Medicine

2013 - 2020	Molecular Cell Biology Graduate Student Admissions Committee
2014 - Pres	Research Consultant, ICTS Research Forum - Child Health

Hospital

2000 - Pres	Attending Physician, St. Louis Children's Hospital

Medical Licensure and Certifications

1997 - Pres	Board Certified in General Pediatrics
2000 - Pres	MO Stae License #2000155004
2001 - Pres	Board Certified in Pediatric Endocrinology & Metabolism

Honors and Awards

1987	National Institute of Chemists Research and Recognition Award
1987	Phi Beta Kappa
1987	Phi Lambda Upsilon (Honorary Chemical Society)
1988	American Heart Association Predoctoral Fellowship Award

1994	Alpha Omega Alpha
1994	Armond J. Quick Award for Excellence in Biochemistry
1994	NIDDK/Diabetes Branch Most Outstanding Resident
1998	Pfizer Postdoctoral Fellowship Award
2002	Scholar, Child Health Research Center of Excellence in Developmental Biology at Washington University
2013	Julio V Santiago, M.D. Scholar in Pediatrics
2017	Redemptor Hominis Award for Outstanding Contributions to the Study of Bioethics
2018	Eli Lilly Outstanding Contribution to Drug Discovery: Emerging Biology Award
2018	Scholar-Innovator Award, Harrington Discovery Institute
2021	Linacre Award

Editorial Responsibilities

Editorial Ad Hoc Reviews

	AIDS
	AIDS Research and Human Retroviruses
	American Journal of Pathology
	American Journal of Physiology
	British Journal of Pharmacology
	Circulation Research
	Clinical Pharmacology & Therapeutics
	Comparative Biochemistry and Physiology
	Diabetes
	Experimental Biology and Medicine
	Future Virology
	Journal of Antimicrobial Chemotherapy
	Journal of Clinical Endocrinology & Metabolism
	Journal of Molecular and Cellular Cardiology
	Obesity Research
2000 - Pres	Journal of Biological Chemistry
2013 - Pres	PlosOne
2016 - Pres	Scientific Reports
2018 - Pres	Nutrients

Editorial Boards

2014 - 2015	Endocrinology and Metabolism Clinics of North America

National Panels, Committees

2017 - Pres	Consultant, Catholic Health Association
2021 - Pres	Consulting Fellow, National Catholic Bioethics Center

National Boards

2020 - Pres	WU ICTS Clinical and Translational Research Funding Program (CTRFP) Review Committee

Professional Societies and Organizations

American Diabetes Association
Endocrine Society
Pediatric Endocrine Society

Major Invited Professorships and Lectures

2002	Pediatric Grand Rounds, St. Louis Children's Hospital, St Louis, MO
2004	National Disease Research Interchange, Human Islet Cell Research Conference, Philadelphia, PA
2004	NIDA-NIH Sponsored National Meeting on Hormones, Drug Abuse and Infections, Bethesda, MD
2005	Endocrine Grand Rounds, University of Indiana, Indianapolis, IN
2005	The Collaborative Institute of Virology, Complications Committee Meeting, Boston, MA
2006	Metabolic Syndrome Advisory Board Meeting, Bristol-Meyers Squibb, Pennington, NJ
2007	American Heart Association and American Academy of HIV Medicine State of the Science Conference: Initiative to Decrease Cardiovascular Risk and Increase Quality of Care for Patients Living with HIV/AIDS, Chicago, IL
2007	Minority Access to Research Careers Seminar, University of Arizona, Tucson, AZ
2007	MSTP Annual Visiting Alumnus Lecture, Medical College of Wisconsin , Milwaukee, WI
2007	Pediatric Grand Rounds, St Louis Children’s Hospital, St Louis, MO
2008	Division of Endocrinology, Diabetes and Nutrition Grand Rounds, Boston University, Boston, MA
2009	Pediatric Grand Rounds, St Louis Children's Hospital, St. Louis, MO
2010	American Diabetes Association Scientific Sessions, Symposium Lecture Orlando, FL
2010	School of Biological Sciences Conference Series, University of Missouri Kansas City, Kansas City, MO
2011	Life Cycle Management Advisory Board Meeting, Bristol-Myers Squibb,, Chicago, IL
2013	Pediatric Grand Rounds, St Louis Children's Hospital, ST LOUIS, MO
2013	Clinical Practice Update Lecture, St Louis Children's Hospital, St Louis, MO
2014	Pediatric Academic Societies Meeting,, Vancouver, Canada
2014	American Diabetes Association 74th Scientific Sessions, , San Francisco, CA
2017	Division of Pediatric Endocrinology Metabolism Rounds, University of Michigan, Ann Arbor, MI
2017	Catholic Medical Association National Conference, Denver, CO
2018	Obstetrics, Gynecology & Women's Health Grand Rounds, Saint Louis University, St. Louis, MO
2018	Medical Grand Rounds, Sindicato Médico del Uruguay, Montevideo, Uraquay
2018	Internal Medicine Grand Rounds, Texas Tech , Lubbock, TX
2019	Veritas Center for Ethics in Public Life Conference, Franciscan University, Steubenville, OH
2019	MaterCare International Conference, Rome, Italy
2019	Child Health Policy Forum, Notre Dame University, South Bend , IN

2021	Obstetrics & Gynecology Grand Rounds, University of Tennessee, Knoxville , TN
2022	The World Federation of Catholic Medical Associations (*FIAMC*), Rome, Italy

Consulting Relationships and Board Memberships

1996 - 2012	Consultant, Bristol Myers Squibb
1997 - 2012	Consultant, Gilead Sciences

Research Support

Completed Governmental Support

2001 - 2006	K-08 A149747, NIH Mechanism of GLUT4 Inhibition by HIV Protease Inhibitors Role: Principal Investigator
2007 - 2012	R01 Mechanisms for Altered Glucose Homeostasis During HAART Role: Principal Investigator Total cost: $800,000.00
2009 - 2011	R01 Student Supp Mechanisms for Altered Glucose Homeostasis During HAART Role: Principal Investigator Total cost: $25,128.00
2009 - 2014	R01 Direct Effects of Antiretroviral Therapy on Cardiac Energy Homeostasis Role: Principal Investigator Total cost: $1,250,000.00
2017 - 2019	R-21 1R21AI130584 , National Institutes of Health SELECTIVE INHIBITION OF THE P. FALCIPARUM GLUCOSE TRANSPORTER PFHT Role: Principal Investigator Total cost: $228,750.00

Completed Non-Governmental Support

2015	Novel HIV Protease Inhibitors and GLUT4 Role: Principal Investigator
2008 - 2011	II Insulin Resistance and Myocardial Glucose Metabolism in Pediatric Heart Failure Role: Co-Investigator PI: Hruz Total cost: $249,999.00
2009 - 2012	Research Program Regulation of GLUT4 Intrinsic Activity Role: Principal Investigator Total cost: $268,262.00
2010 - 2011	Protective Effect of Saxagliptin on a Progressive Deterioration of Cardiovascular Function Role: Principal Investigator
2012 - 2015	II Solution-State NMR Structure and Dynamics of Facilitative Glucose Transport Proteins Role: Principal Investigator Total cost: $375,000.00

2017 - 2020 Prevention And Treatment Of Hepatic Steatosis Through Selective Targeting Of GLUT8
Role: Co-Principal Investigator
PI: DeBosch
Total cost: $450,000.00

2017 - 2021 Matching Micro Grant
Novel Treatment of Fatty Liver Disease (CDD/LEAP)
Role: Principal Investigator
Total cost: $68,500.00

2018 - 2021 LEAP Innovator Challenge
Novel Treatment of Fatty Liver Disease
Role: Principal Investigator
Total cost: $68,500.00

2019 - 2021 Scholar-Innovator Award HDI2019-SI-4555 , Harrington Foundation
Novel Treatment of Non-Alcoholic Fatty Liver Disease
Role: Principal Investigator
Total cost: $379,000.00

Current Governmental Support

2021 - 2025 R-01 DK126622 (Co-investigator), 8/25/2021-7/31/2025, NIH-NIDDK, , NIH
Leveraging glucose transport and the adaptive fasting response to modulate hepatic metabolism
Role: Co-Investigator
PI: DeBosch

Trainee/Mentee/Sponsorship Record

2002 - 2002 Nishant Raj- Undergraduate Student, Other
Study area: Researcher

2002 - 2010 Joseph Koster, PhD, Postdoctoral Fellow
Study area: Researcher

2003 - 2004 Johann Hertel, Medical Student
Study area: Research
Present position: Assistant Professor, University of North Carolina, Chapel Hill, NC

2003 - 2003 John Paul Shen, Medical Student
Study area: Research

2004 - 2005 Carl Cassel- High School Student, Other
Study area: Research

2004 - 2004 Christopher Hawkins- Undergraduate Student, Other
Study area: Researcher

2004 - 2004 Kaiming Wu- High School Student, Other
Study area: Research

2005 - 2005 Helena Johnson, Graduate Student

2005 - 2005 Jeremy Etzkorn, Medical Student
Study area: Researcher

2005 - 2005 Dominic Doran, DSc, Postdoctoral Fellow
Study area: HIV Protease Inhibitor Effects on Exercize Tolerance

2006 - 2006 Ramon Jin, Graduate Student
Study area: Research

2006 - 2006 Taekyung Kim, Graduate Student
Study area: Research

2007 - 2007 Jan Freiss- Undergraduate Student, Other
Study area: Researcher

2007 - 2008 Kai-Chien Yang, Graduate Student
Study area: Research
Present position: Postdoctoral Research Associate, University of Chicago

2007 - 2007 Paul Buske, Graduate Student
Study area: Research

2007 - 2007 Randy Colvin, Medical Student
Study area: Researcher

2008 - 2011 Arpita Vyas, MD, Clinical Fellow
Study area: Research
Present position: Assistant Professor, Michigan State University, Lansing MI

2008 - 2009 Candace Reno, Graduate Student
Study area: Research
Present position: Research Associate, University of Utah

2008 - 2012 Dennis Woo- Undergraduate Student, Other
Study area: Researcher
Present position: MSTP Student, USC, Los Angeles CA

2008 - 2008 Temitope Aiyejorun, Graduate Student
Study area: Research

2009 - 2009 Anne-Sophie Stolle- Undergraduate Student, Other
Study area: Research

2009 - 2009 Matthew Hruz- High School Student, Other
Study area: Research
Present position: Computer Programmer, Consumer Affairs, Tulsa OK

2009 - 2009 Stephanie Scherer, Graduate Student
Study area: Research

2010 - 2014 Lauren Flessner, PhD, Postdoctoral Fellow
Present position: Instructor, Syracuse University

2010 - 2010 Constance Haufe- Undergraduate Student, Other
Study area: Researcher

2010 - 2011 Corinna Wilde- Undergraduate Student, Other
Study area: Researcher

2010 - 2010 Samuel Lite- High School Student, Other
Study area: Research

2011 - 2016 Thomas Kraft, Graduate Student
Study area: Glucose transporter structure/function
Present position: Postdoctoral Fellow, Roche, Penzberg, Germany

2011 - 2011 Amanda Koenig- High School Student, Other
Study area: Research

2011 - 2012 Lisa Becker- Undergraduate Student, Other

2011 - 2011 Melissa Al-Jaoude- High School Students, Other

2019 Ava Suda, Other, Pre-med

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C2. Chapters

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2. Paul W Hruz. Medical Approaches to Alleviating Gender Dysphoria In: Edward J Furton, eds. *Transgender Issues in Catholic Health Care* Philadelphia PA; 2021:1-42.
3. Cara Buskmiller and Paul Hruz. A Biological Understanding of Man and Woman In: John Finley, eds. *Sexual Identity: The Harmony of Philosophy, Science, and Revelation* Steubenville OH; 2022:Chapter 2, pp 65-103.

C4. Invited Publications

1. Grunfeld C, Kotler DP, Arnett DK, Falutz JM, Haffner SM, Hruz P, Masur H, Meigs JB, Mulligan K, Reiss P, Samaras K, Working Group 1. Contribution of metabolic and anthropometric abnormalities to cardiovascular disease risk factors. *Circulation*. 2008;118(2):e20-8. PMCID: PMC3170411 PMID: 18566314
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7. Hruz, PW. The Use of Cross-Sex Steroids in Treating Gender Dysphoria *Natl Cathol Bioeth Q*. 2018;17(4):1-11.
8. Hruz, PW. Experimental Approaches to Alleviating Gender Dysphoria in Children *Nat Cathol Bioeth Q*. 2019;19(1):89-104.

Expert Witness Testimony

2009 Rosas v. Astrazeneca

2012 O'Connor v. Stamford

2016 Carcaño et al. v. Patrick McCrory (United States District Court, M.D. North Carolina)

2016 Jane Doe v. Board of Education of the Highland School District (United States District Court For the Southern District of Ohio Eastern Division, Case No. 2:16-CV-, 524)

2017 Ward v. Janssen (Circuit Court of St Louis, Division 16, MO, Case No. 1522-CC00213-01)

2017 Adams v. St John's School Board (United States District Court For the Middle District of Florida, FL Civil Action No. 3:17-cv-00739-TJCJBT)

2017 Ashton Whitaker v. Kenosha Unified School District (United States District Court Eastern District of Wisconsin, Civ. Action No. 2:16-cv-00943)

2018 Terri Bruce v. State of South Dakota (The United States District Court District of South Dakota Western Division, Case No. 17-5080)

2019 Cause DF-15-09887-SD of the 255th Judicial Circuit of Dallas County, TX regarding the dispute between J.A. D.Y. and J.U. D.Y., Children

2021 Kadel vs. Falwell (The United States District Court For The Middle District Of North Carolina, Case No.: 1:19-cv-272-LCB-LPA)

2022 Brandt v Rutledge (The United States District Court Eastern District of Arkansas Central Division, Case No. 4:21-CV-00450-JM)

2022 Eknes-Tucker vs Ivey (United States District Court Middle District of Alabama Northern Division, Case 2:22-cv-00184-LCB-SRW)

2022 D.H. et al. v. Snyder (United States District Court For the District Court of Arizona, Case No. 4:20-cv-00335-SHR)

EXHIBIT 6

SUBMITTED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

BRIANNA BOE, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
UNITED STATES OF AMERICA,	)	
	)	
Intervenor Plaintiff,	)	
	)	
v.	)	Civil Action No. 2:22-cv-184-LCB
	)	
HON. STEVE MARSHALL, in his Official capacity as Attorney General, of the State of Alabama, *et al.*,	)	
	)	
Defendants.	)	

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

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

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

2. I am a board-certified endocrinologist. I received my medical degree from the University of Southern California in 2001. I completed my residency in internal medicine at Los Angeles County/University of Southern California Medical Center in 2004. I also completed a fellowship in endocrinology, diabetes and metabolism at Los Angeles County/University of Southern California Medical Center in 2006.

3. The information provided regarding my professional background is detailed in my curriculum vitae. A true and correct copy of my curriculum vitae is attached as Exhibit A.

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

5. I have been retained by Defendants in the above-captioned lawsuit to provide an expert opinion on the efficacy and safety of sex reassignment treatment, including the trustworthiness of proposed standards of care or treatment guidelines promulgated by medical organizations.

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

7. I am being compensated at an hourly rate of $450 per hour plus expenses for my time spent preparing this declaration, and to prepare for and provide testimony in this matter. I am being compensated at an hourly rate of $650 for testimony at depositions or trial. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

8. My opinions contained in this report are based on: (1) my clinical experience as an endocrinologist in particular dealing with hormone excess, hormone deficiency, and hormone balance; (2) my clinical experience evaluating individuals who have or have had gender incongruence including a detransitioner; (3) my knowledge of research and studies regarding the

treatment of gender dysphoria, including for minors and adults; (4) my review of the various declarations submitted by Plaintiffs; and (5) my first-hand personal experience in human research as a physician, having been involved in two studies, one involving magnesium and bone density and the other involving ultrasound use for detecting recurrent thyroid cancer.[1] I frequently review medical studies conducted by others and have experience assessing the strengths and weaknesses of such studies.

9. I was provided with and reviewed the following case-specific materials: The complaints and amended complaints; the expert reports disclosed by the Plaintiffs and the United States; and the Defendants' Response To Motion To Quash Subpoenas By AAP, WPATH, and the Endocrine Society; and the Minor Plaintiffs' medical records that were disclosed by the Plaintiffs.

10. A true and correct copy of my CV is attached to this declaration. In the previous four years, I have provided expert testimony in the following cases:

11. United States District Court for the Northern District of Florida Tallahassee Division, AUGUST DEKKER, et al., Plaintiffs, v. SIMONE MARSTILLER, et al., Defendants, Case No. 4:22-cv-00325-RHMAF, 2022-2023; C. P., by and through his parents, Patricia Pritchard and Nolle Pritchard; and PATRICIA PRITCHARD, Plaintiff, vs. BLUE CROSS BLUE SHIELD OF ILLINOIS, Defendants, Case No. 3:20-cv-06145-RJB, 2022; District Court of Travis County, Texas, 459th Judicial District, PFLAG, INC., ET AL., Plaintiffs, v. GREG ABBOTT, ET AL., Defendants. NO. D-1-GN-22-002569, 2022; JULIANA PAOLI v. JOSEPH HUDSON et al., Superior Court of State of California, County of Tulare, Case No. 279126. 2021; United States District Court for the District of Arizona, DH AND JOHN DOE, Plaintiffs, vs. JAMI SNYDER, Director of the Arizona Health Care Cost Containment System, in her official capacity, Defendant, Case No. 4:20-cv-00335-SHR. 2020; Supreme Court of British Columbia., File No. S2011599, Vancouver Registry, Between A.M., Plaintiff, and DR. F AND DANIEL MCKEE, Defendants, 11/23/20 & 11/25/20; and Court of Appeal File No. CA45940, Vancouver Registry, B.C. Canada, Supreme Court File No. E190334, between A.B., Respondent/Claimant, and C.D., Appellant/Respondent, and E.F. Respondent/Respondent, 24 Jun 2019.

[1] For the latter study I helped to design an Institutional Review Board ("IRB") approved protocol. Furthermore, I received certification in the required course "Understanding the Fundamentals: Responsibilities and Requirements for the Protection of Human Subjects in Research" at the University of Southern California in 2003.

12. In my professional opinion, treatment interventions on behalf of children and adults diagnosed with gender dysphoria must be held to the same scientific standards as other medical treatments. These interventions must be optimal, efficacious, and safe. Any treatment which alters biological development in children should be used with extreme caution. Except in the case of a fatal injury or disease, the minor will become an adult and present to the adult physician. The adult physician must be able to have a thorough understanding of any condition which alters the biological development of children and, in the case of the endocrinologist, be knowledgeable about the long-term effects of hormones on the human body, particularly when the hormones are being used in ways that alter development.

13. The following expresses my expert opinion regarding minors who present with a disparity between their biological sex and internal feeling about their gender, specifically with regard to the use of social transition, medications which block normal pubertal development, the applications of hormones of the opposite sex, and surgical procedures that alter the genitalia and/or breasts for those individuals.

I. Background

A. Biological Sex in Contrast to Gender Identity

14. A recognition and understanding of biological sex is critical to my practice as an endocrinologist because the endocrine physiology of men and women, boys and girls, differ.

15. Biological sex is the objective physical condition of having organs and body parts which correspond to a binary sex. There are only two physical sexes, male and female. The male is identified as having organs and tissues such as the penis, testicles and scrotum. The female sex is identified by having organs and tissues such as the labia, vagina, uterus, and ovaries. Biological sex is easily identified by physical observation such that adults and even young children can identify the biological sex of a newborn baby.

16. It is also noteworthy that the physical organs described above as representing biological sex have a physical genetic correlate. In other words, it is a well-established scientific fact that two X chromosomes identify the cells correlating to a female person, and an X and a Y chromosome correlate to a male person.

17. Dr. Shumer states, “Sex is comprised of several components, including, among others, internal reproductive organs, external genitalia, chromosomes, hormones, gender identity, and secondary sex characteristics (IOM, 2011)” (Shumer decl, p. 6, emphasis added). Dr. Shumer

is incorrect to include "gender identity" as a component of sex. What he states contradicts the Diagnostic and Statistical Manual of Mental Disorders (DSM-5 TR), which states that "sex and sexual refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and non-ambiguous internal and external genitalia" (DSM-5 TR, emphasis added). Note that gender identity is not a component of biological sex as defined by the DSM 5.

18. Gender identity in the DSM 5 is defined separately: "Gender identity is a category of social identity and refers to an individual's identification as male, female, or, occasionally, some category other than male or female" (DSM 5-TR). So we can see that gender identity is not a physical entity but is described as a social identity. It is a subjective identification known only once a patient makes it known. It cannot be identified by any physical means, cannot be confirmed by any outside observer, and can change over time.

19. Gender identity is a psychological concept. It has no correlate in the human body. In the letter to the editor I wrote with my colleagues, we wrote in our critique of the Endocrine Society Guidelines that "[t]here are no laboratory, imaging, or other objective tests to diagnose a 'true transgender' child" (Laidlaw et al., 2019).

20. For example, one cannot do imaging of the human brain to find the gender identity. Likewise, there is no other imaging, laboratory tests, biopsy of tissue, autopsy of the brain, genetic testing, or other biological markers that can identify the gender identity. There is no known gene that maps to gender identity or to gender dysphoria. In other words, there is no objective physical measure to identify either gender identity or gender dysphoria.

21. This is in contrast to endocrine disorders which have a measurable physical change in either hormone levels or gland structure which can be confirmed by physical testing. Therefore, gender dysphoria is a purely psychological phenomenon and not an endocrine disorder. But as my colleagues and I wrote in our letter to the editor, it becomes an endocrine condition through gender affirmative therapy: "Childhood gender dysphoria (GD) is not an endocrine condition, but it becomes one through iatrogenic puberty blockade (PB) and high-dose cross-sex (HDCS) hormones. The consequences of this gender-affirmative therapy (GAT) are not trivial and include potential sterility, sexual dysfunction, thromboembolic and cardiovascular disease, and malignancy" (Laidlaw et al. 2019).

22. Dr. Shumer goes on to say in p. 9 of his declaration: "Scientific research and medical literature across disciplines demonstrates that gender identity, like other components of sex, has a strong biological foundation...In one such study, the volume of the bed nucleus of the stria terminalis (a collection of cells in the central brain) in transgender women was equivalent to the volume found in cisgender women." The study that Dr. Shumer references, Chung et al., 2002, involved autopsies of 50 deceased persons brains to examine the tissue. This sort of examination obviously cannot be done on living persons and has not been validated in any way to confirm the gender identity. Likewise, there has been no imaging (such as an MRI or CT scan of the brain) to examine the nucleus of the stria terminalis that has been validated to confirm the gender identity of a patient. In any event, none of the plaintiffs have presented any evidence that a brain scan, blood tests, biopsy or other biological tests or markers were performed to confirm gender identity.

23. Dr. Shumer states that "[t]win studies have shown that if an identical twin is transgender, the other twin is much more likely to be transgender compared to fraternal twins, a finding which points to genetic underpinnings to gender identity development" (Shumer decl, p. 9). However, if gender identity is actually determined by genes, we would expect that identical twins would profess having the same gender identity nearly 100 percent of the time. This is not the case. In fact, the largest transexual twin study ever conducted included seventy-four pairs of identical twins (Diamond, 2013). They were studied to determine in how many cases both twins would grow up to identify as transgender. In only twenty-one of the seventy-four pairs (28 percent) did both identical twins identify as transgender. This is consistent with the fact that multiple factors play a role in determining gender identity, including psychological and social factors. This study suggests that those factors are more important than any potential genetic contribution. Furthermore, no genetic studies have ever identified a transgender gene or genes. And again, none of the five minor plaintiffs have presented evidence of genetic testing that was performed to verify the gender identity.

24. Sex is clearly identified in 99.98% of cases by chromosomal analysis (Sax, 2002). Sex is also clearly recognized at birth in 99.98% of cases (Id.). Therefore, sex is a clear provable objective reality that can be identified through advanced testing such as karyotyping, or simple genital identification at birth by any layperson. The other 0.02% of cases have some disorder of sexual development (DSD). DSDs do not represent an additional sex or sexes, but simply a disorder on the way to binary sex development (Chan et al., 2021).

25. Dr. Shumer states: "There is also ongoing research on how differences in fetal exposures to hormones may influence gender identity. This influence can be examined by studying a medical condition called congenital adrenal hyperplasia" (Shumer decl, p. 10). Congenital adrenal hyperplasia is a DSD. None of the plaintiffs have been diagnosed with congenital adrenal hyperplasia or any other DSD. Dr. Shumer also provides no evidence that any of the plaintiffs suffered from fetal exposure to opposite sex hormones.

26. Dr. McNamara states that "[t]he adolescent works with a mental health provider to confirm their gender identity" (McNamara decl, p. 12). But she offers no explanation as to what sort of testing procedures are performed to make the confirmation of an immutable gender identity.

B. Human Sexual Development

1. Embryologic Development

27. Another confirmation that there are only two biological sexes comes from what is known about embryologic development and fertilization. The biologic development of the human person begins with a gamete from a female termed an ovum or egg and a gamete from a biological male which is termed sperm. The fertilization of the egg by the sperm begins the process of human biological development. The cells of the fertilized ovum then multiply and the person undergoes the incredible changes of embryologic development.

28. It is noteworthy that the male sperm comes from the biological male and the female egg comes from the biological female. There is no other third or fourth or fifth type of gamete that exists to begin the development of the human person. This is consistent with the binary nature of human sex (Alberts et al., 2002).

29. The sex binary of the human embryo is further developed between roughly weeks 8 to 12 of human development. There are two primitive structures present within the developing embryo called the Wolffian duct and Mullerian ducts (Larsen et al., 2003). The Wolffian ducts develop into substructures of the genitalia including the vas deferens and epididymis which belong exclusively to the male sex. For the female, the Mullerian ducts go on to form the uterus, fallopian tubes, cervix and upper one third of the vagina which belong exclusively to the female sex (Id.)

30. Significantly once the male structures are developed from Wolffian ducts, the Mullerian ducts are obliterated. This means that throughout the rest of embryological development the Mullerian ducts will not form into biological female structures. Likewise, in the female, the

Wolffian ducts are destroyed by week 12 and will not form male structures at any point in the future (Id.).

31. Thus we can see in very early development that the sex binary is imprinted physically not only in the chromosomes, but also on the very organs that the body produces. Additionally, the potential to develop organs of the opposite sex is eliminated. Thus, in the human being there are only two physical tracts that one may progress along, the one being male and the other being female (Wilson and Bruno, 2022).

2. Pubertal Development

32. As mentioned previously, at the time of birth an infant's sex is easily identified through observation of the genitalia. Corresponding internal structures could also be confirmed through imaging if needed.

33. In early childhood, some low level of sex hormones are produced by the sex glands. The male testes produce testosterone. The female ovaries produce primarily the hormone estrogen. These sex glands remain quiescent for the most part, producing low levels of sex hormones until the time of pubertal development.

34. Dr. Shumer states that "[p]uberty is a process of maturation heralded by production of sex hormones—testosterone and estrogen—leading to the development of secondary sex characteristics" (Shumer, p. 18). Dr. Shumer presents a very limited view of puberty. Puberty is an essential part of human development. Its purpose is to achieve full adult sexual function and reproductive capacity.

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

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

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

3. Tanner Stages of Development

37. From a medical perspective it is important to know the stage of pubertal development of the developing adolescent. This can be determined through a physical examination of the body. The female will have changes in breast characteristics and pubic hair development. Similarly, the male will have changes in testicular size and pubic hair development. These findings can be compared to the Tanner staging system which will allow the stage of puberty to be known.

38. Tanner stages are divided into five. Stage 1 is the pre-pubertal state before pubertal development of the child begins. Stage 5 is full adult sexual maturity. Stages 2 through 4 are various phases of pubertal development (Greenspan and Gardner, 2004).

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

4. Biological Sex Cannot Be Changed

40. It is not possible for a person to change from one biological sex to the other, and there is no technology that allows a biological male to become a biological female or vice-versa. It is not technologically possible at this time to change sex chromosomes; these will remain in every cell throughout life. It is not technologically possible to transform sex glands from one to the other. In other words, there are no hormones or other means currently known to change an ovary into a testicle or a testicle into an ovary.

41. Furthermore, as noted earlier, several of the sex specific structures (such as the epididymis of the male or uterus of the female) are produced early in embryological development from around weeks 8 to 12. The primitive ducts which lead to these organs of the opposite sex are obliterated. There is no known way to resuscitate these ducts and continue development of opposite sex structures.

42. It is also not possible to produce gametes of the opposite sex. In other words, there is not any known way to induce the testicles to produce eggs. Nor is there any known way to induce

the ovaries to produce sperm. Therefore, creating conditions for a biological female to create sperm capable of fertilizing another ovum is impossible. The induction of opposite sex fertility is impossible.

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

C. Endocrine Disorders

44. Before discussing gender dysphoria and gender affirmative therapy from the perspective of an endocrinologist, it is helpful to discuss the background of endocrine diseases. This background demonstrates the difference in gender dysphoria, which is a psychological diagnosis, and other conditions treated by endocrinologists, which are physical diagnoses.

45. Endocrinology is the study of glands and hormones. Endocrine disorders can be divided into three main types: those that involve hormone excess, those that involve hormone deficiency, and those that involve structural abnormalities of the glands such as cancers.

46. It is important for the endocrinologist to determine the cause of hormone gland excess or deficiency in order to devise an appropriate treatment plan. The plan will generally be to help bring the hormones back into balance and thus bring the patient back to health.

47. To give an example of hormone excess, hyperthyroidism is a term which means overactivity of the thyroid gland. In this condition excess thyroid hormone is produced by the thyroid gland. This results in various physical and psychological changes for the afflicted patient. Examples of physical changes can include tachycardia or fast heart rate, hand tremors, and weight loss. Examples of psychological symptoms include anxiety, panic attacks, and sometimes even psychosis.

48. An endocrinologist can recognize thyroid hormone excess in part by signs and symptoms but can also confirm the diagnosis with laboratory testing that shows the thyroid hormones to be out of balance. Once this is determined and the degree of excess is known, then treatments can be given to bring these levels back into balance to benefit the patient's health and to prevent other disease effects caused by excess hormone.

49. To give another example, consider a deficiency of insulin. Insulin is a hormone which regulates blood glucose levels. If there is damage to the pancreas such that insulin levels are very low, then blood glucose levels will rise. If the glucose levels rise to a certain abnormally high level, then this is considered diabetes. In the case of type 1 diabetes, insulin levels are

abnormally low and therefore blood glucose levels are abnormally high leading to a variety of signs and symptoms. For example, the patient may have extreme thirst, frequent urination, muscle wasting, and weight loss. They may often experience lethargy and weakness.

50. In this case laboratory tests of glucose and insulin levels can confirm the diagnosis. Once diabetes is confirmed, the patient is then treated with insulin to help restore glucose balance in the body and prevent long-term complications of diabetes.

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

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

D. Gender Dysphoria is a Psychological Diagnosis

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

54. Drs. Shumer, Antommaria, McNamara, and Ladinsky advocate for the use of the Endocrine Society's Guideline (ESG) on gender dysphoria. The Guideline discusses the importance of a psychological evaluation by a qualified clinician. It states: "GD/gender incongruence may be accompanied with psychological or psychiatric problems. It is therefore necessary that clinicians who prescribe hormones and are involved in diagnosis and psychosocial assessment meet the following criteria: (1) are competent in using the DSM and/or the ICD for diagnostic purposes, (2) are able to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic

disorder), (3) are trained in diagnosing psychiatric conditions, (4) undertake or refer for appropriate treatment, (5) are able to do a psychosocial assessment of the patient's understanding, mental health, and social conditions that can impact gender affirming hormone therapy, and (6) regularly attend relevant professional meetings" (Hembree et al., 2017, citations omitted).

55. As a practicing endocrinologist and scientist, I have made a study of GD and its treatment for two reasons: 1) I want to be sure that my colleagues and I understand the science before we treat any patients with GD; and 2) I am concerned that the medical society that claims to speak for me and other endocrinologists has abandoned scientific principles in endorsing treatments for GD that have questionable scientific support. The opinions expressed in this report are the result of my own experience, studies, education, and review of the scientific literature related to GD.

II. Gender Affirmative Therapy

56. In the section that follows I discuss four interventions (social transition, blocking normal puberty, opposite sex hormones, and surgery) that some physicians are using to treat gender dysphoria. Each intervention can lead to iatrogenic harms to the patient. The term "iatrogenic" is used in medicine to describe harms or newly created medical conditions that are the result of a treatment. These harms will be described in detail below. I speak of these harms because it is important to understand that once a patient begins GAT it is more likely the patient will continue on to surgery (de Vries et al,, 2011; de Vries et al., 2014). Thus, GAT interrupts the natural desistance process and instead places the patient on a lifetime regimen of hormonal and surgical care. A good understanding of these harms is also critical to my practice as an endocrinologist: if I did not understand these harms, I could not advise patients of the risks associated with GAT.

57. There are three general approaches to treating gender dysphoria in minors. (Zucker, 2020). One is psychosocial treatment that helps the young person align their internal sense of gender with their physical sex. Another would be to "watch and wait" and allow time and maturity to help the young person align sex and gender through natural desistance, while providing psychological support and therapy as needed and addressing comorbidities. The third option, which is the focus of that which follows, is referred to as gender affirmative therapy.

58. Gender affirmative therapy of adults and minors consists of psychosocial, medical, and surgical interventions that attempt to psychologically and medically alter the patient so that they come to believe they may become similar to the physical sex which aligns with their gender

identity (but not their biological sex) and thereby reduce gender dysphoria. GAT consists of four main parts: 1) social transition, 2) blocking normal puberty or menstruation, 3) high dose opposite sex hormones, and 4) surgery of the genitalia and breasts.

59. The application of this medical therapy to minors[2] is a fairly new intervention and is associated with a number of harms both known and unknown. GAT suffers from a lack of a quality evidence-base, poorly performed studies, and ongoing unethical human experimentation. As discussed below, in my professional opinion as an endocrinologist, no child should be given these treatments.

A. Social transition

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

61. Social transition of the child has been noted by an expert researcher in the field of child gender dysphoria, Ken Zucker, to itself be a form of iatrogenic harm (Zucker, 2020). This is because the social transition process may solidify the young person's belief that they are in fact the sex opposite of their biological sex. The 2017 Endocrine Society Guideline states that "[s]ocial transition is associated with the persistence of GD/gender incongruence as a child progresses into adolescence" (Hembree et al., 2017). A recent study also supports the contention that children who

[2] "[T]he US Department of Health and the Food and Drug Administration reference approximate age ranges for these phases of life, which consist of the following: (1) infancy, between birth and 2 years of age; (2) childhood, from 2 to 12 years of age; and (3) adolescence, from 12 to 21 years of age. Additionally, *Bright Futures* guidelines from the American Academy of Pediatrics identify adolescence as 11 to 21 years of age, dividing the group into early (ages 11–14 years), middle (ages 15–17 years), and late (ages 18–21 years) adolescence. The American Academy of Pediatrics has previously published a statement on the age limit of pediatrics in 1988, which was reaffirmed in 2012 and identified the upper age limit as 21 years with a note that exceptions could be made when the pediatrician and family agree to an older age, particularly in the case of a child with special health care needs. Recent research has begun to shed more light on the progression of mental and emotional development as children progress through the adolescent years into young adulthood. It is increasingly clear that the age of 21 years is an arbitrary demarcation line for adolescence because there is increasing evidence that brain development has not reliably reached adult levels of functioning until well into the third decade of life." (Hardin, 2017) (footnotes omitted).

undergo social transition are more likely to have their gender dysphoria persist into adolescence. In the 2022 article "Gender Identity 5 Years After Social Transition," which studied 317 socially transitioned youths, the authors found that "most participants were living as binary transgender youth (94.0%)" (Olson et al., 2022).

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

63. Therefore, it would be quite frightening for a boy who believes he is a girl to be turning into a man with all of the adult features that accompany manhood. Vice versa, the girl who has become convinced that she is a boy will be frightened by the physical changes brought on by womanhood.

64. In fact, it would appear that in the minds of children and adolescents that they are anticipating a sort of disease state in the future by the hormone changes that will occur as a normal and natural part of human development. Until relatively recently in human history, it has not been possible to interfere with puberty through pharmaceutical means.

B. Medications That Block Pubertal Development

1. Background

65. A second stage of gender affirmative therapy may involve blocking normal pubertal development. This may be done with puberty blocking medications (PB) that act directly on the pituitary to cause the endocrine condition known as hypogonadotropic hypogonadism (HH).

66. In order to understand what is occurring in this process, it is helpful to be aware of normal hormone function during pubertal development. There is a small pea-sized gland in the brain called the pituitary. It is sometimes referred to as the "master gland," as it controls the function of several other glands. One key function for our purposes is the control of the sex glands. There are two specific hormones produced by the pituitary referred to as luteinizing hormone (LH) and follicle stimulating hormone (FSH). These are responsible for sex hormone production and fertility. The LH and FSH act as signals to tell the sex glands to begin or to continue their function.

67. In the adult male, the production of LH will cause adult levels of testosterone to be produced by the testicles. In the adult female, the production of LH will cause adult levels of estrogen to be produced by the ovaries.

68. In early childhood, prior to the beginning of puberty, the pituitary function with respect to the sex glands is quiescent. However, during pubertal development LH will signal the testicle to increase testosterone production and this carries the boy through the stages of pubertal development into manhood. Likewise for the female, the interaction of LH with the ovaries increases estrogen production and carries the girl through the stages of development into womanhood.

69. Hypogonadotropic hypogonadism is a medical condition in which the pituitary does not send the hormonal signals (LH and FSH) to the sex glands. Therefore, the sex glands are unable to make their sex specific hormones of testosterone or estrogen.

70. If this condition occurs during puberty, the effect will be to stop pubertal development. This is a disease state which is diagnosed and treated by the endocrinologist.

71. Medications such as GnRH analogues (sometimes called puberty blockers) act on the pituitary gland to lower the pituitary release of LH and FSH levels dramatically. The result is a blockage of the signaling of the pituitary to the testicles or ovaries and therefore underproduction of the sex hormones. This will stop normal menstrual function for the female and halt further pubertal development. For the male this will halt further pubertal development. If the male had already reached spermarche, then production of new sperm will stop.

2. GnRH Agonist Medication Effects Vary by Use Case

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

73. For example, the initial development of the medication called Lupron was for the treatment of prostate cancer, the idea being that blocking pituitary hormones will block the adult male's release of testosterone from the testicles. Since testosterone will promote the growth of prostate cancer, the idea is to lower testosterone levels to a very low amount and therefore prevent the growth and spread of prostate cancer. This is a labeled use of the medication. In other words, there is FDA approval for this use.

74. Another labeled use of GnRH agonist medication is for the treatment of central precocious puberty. In the disease state of central precocious puberty, pituitary signaling is

activated at an abnormally young age[3], say age four, to begin pubertal development. In order to halt puberty which has begun at an abnormally early time, a GnRH agonist may be used. Here the action of the medication on the pituitary will disrupt the signaling to the sex glands, stop early sex hormone production, and therefore stop abnormal pubertal development.

75. Then, at a more normal time of pubertal development, say age 11, the medication is stopped and puberty is allowed to proceed. The end result is to restore normal sex gland function and timing of puberty. This is a labeled use for a GnRH agonist medication.

76. What about the use of GnRH analogue medications such as Lupron in gender affirmative therapy? In these cases, we have physiologically normal children who are just beginning puberty or are somewhere in the process of pubertal development. They have healthy pituitary glands and sex organs. However, a puberty blocking medication is administered to stop normal pubertal development.

77. In this case the condition of hypogonadotropic hypogonadism described above (a medical disease) is induced by medication and is an iatrogenic effect of treating the psychological condition of gender dysphoria. GnRH analogue medications have not been FDA approved for this use. The use of GnRH analogue medication for this purpose in adolescents is experimental as there have been no randomized controlled trials for this specific use case.

78. Dr. Shumer states that "[t]he safety and efficacy of GnRHa in transgender adolescents are clearly outlined in longitudinal research studies outlined in this report and are not experimental" (Shumer, p. 30). However, he doesn't provide any evidence of which studies have longitudinal data for treatment of adolescents with gender dysphoria. He simply refers to the deeply flawed WPATH Standards of Care v. 8 ("SOC 8"), which will be discussed further below.

79. Dr. McNamara states that "[a] solid body of evidence documents that pubertal progression resumes after discontinuation of the medication," (McNamara decl., p. 13). To support her claim, she references six studies which are limited to the treatment of the medical condition of precocious puberty. She does not provide any evidence to support the very different, non-FDA approved use case of administering GnRHa to stop normal puberty.

80. Dr. McNamara states, "[p]uberty blockers have been prescribed for decades in … adolescents with cancer who need menstrual suppression as they undergo marrow-ablative

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

chemotherapy," (McNamara decl, p. 13). The use of GnRHa in conjunction with chemotherapy for a life-threatening cancer treatment is very different than its use in GAT. Such treatment for cancer is based on an objective and verifiable physical examination, typically the biopsy of a cancerous tumor. Again, no such objective validation of an immutable gender identity exists, making the underlying diagnosis uncertain. Her comparison is faulty.

81. In my opinion, there is not sufficient evidence to conclude that the use of puberty blockers to block natural puberty is safe when administered as part of gender affirming therapy. Nor is there sufficient evidence to conclude that the effects of puberty blockers when used in this manner are reversible.

3. Hypogonadotropic Hypogonadism

82. As described above, hypogonadotropic hypogonadism is a condition in which the pituitary fails to send signals to the gonads thereby preventing the testicle of the male from making testosterone or the ovary of the female from making estrogen.

83. As an endocrinologist I frequently evaluate patients to ascertain if they have the condition of hypogonadotropic hypogonadism. This is done by a laboratory evaluation. If the patient has this condition, I then determine the cause and the proper treatment.

84. The primary hormone of the pituitary which is abnormal in this condition is called luteinizing hormone or LH. In order to diagnose the condition, a laboratory test with reference ranges based on the person's sex and age is used to evaluate the blood sample.

85. For example, figure 1 shows the normal laboratory reference range for LH over the course of a month in an adult pre-menopausal female (0.5-76.3 mIU/mL) (Quest LH, 2023). A very low level of LH (red) with low estrogen levels indicates hypogonadotropic hypogonadism[4].

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

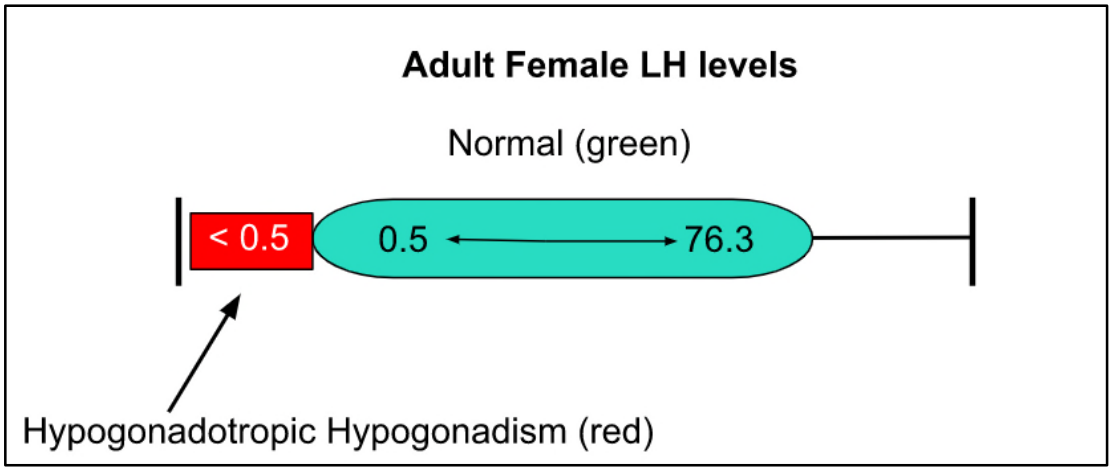

Figure 1.

86. As one can see, in hypogonadotropic hypogonadism the level of LH is below the reference range. In the female, this causes the cessation of estrogen production, and in the male it causes cessation of testosterone production. In adolescents of either sex, this will stop further pubertal development. For females in mid-puberty or beyond, this condition will also stop normal menstrual cycles and ovulation. For the male in mid-puberty or beyond, it will cause the cessation of normal sperm production.

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

88. What occurs to pituitary hormones and the sex hormones[5] when administering a GnRH analogue medication such as Lupron? The effect is identical to figure 1. Over time, the result of the medication is to cause very low LH levels (red) leading to low sex hormone levels thereby medically inducing the condition of hypogonadotropic hypogonadism.

89. In gender affirmative therapy, the medical condition of hypogonadotropic hypogonadism is being deliberately created by the use of medications called GnRH analogues, one of which is called Lupron.

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

4. Adverse Health Consequences of Blocking Normal Puberty

a. Infertility

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

91. Dr. Shumer states that "[i]n transgender youth, it is most typical to use GnRHa [puberty blockers] from the onset of puberty (Tanner Stage 2) until mid-adolescence" (Shumer decl, p. 21). This is correct. However, he also states "GnRHa have no long-term implications on fertility" (Id.). That statement is incorrect. As I explain below, GnRHa have profound implications for fertility.

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

93. If the patient remains blocked in an early pubertal stage, then even the addition of opposite sex hormones will not allow for the development of fertility. In fact, high doses of opposite sex hormones may permanently damage the immature sex organs leading to sterilization. Certainly, the removal of the gonads by surgery will ensure sterilization.

94. In a Dutch study by de Vries et al. that included seventy adolescents who took puberty blockers, all seventy decided to go on to hormones of the opposite sex (de Vries, et al. 2011). In a follow-up study by de Vries et al., the overwhelming majority went on to have sex reassignment surgery by either vaginoplasty for males or hysterectomy with ovariectomy for females (de Vries, et al. 2014). These surgeries resulted in sterilization[6]. This is why puberty blockers, rather than being a "pause" to consider aspects of mental health, are instead a pathway towards future sterilizing surgeries and potentially sterilizing hormonal treatments.

95. Dr. Antommaria writes that "The [Endocrine Society] guideline recommends that informed consent for pubertal blockers and gender-affirming hormones include a discussion of the implications for fertility and options for fertility preservation" (Antommaria decl, p. 28). However,

[6] The surgeries were consequential in another important way. One person who had a vaginoplasty died of post-surgical complications of necrotizing fasciitis, which is a rapidly progressive and very severe infection of the soft tissues beneath the skin and has a high rate of mortality (Id.).

even though procedures to preserve fertility are available for patients in late pubertal stages (Tanner 4 and 5), studies show that less than 5% of adolescents in North America receiving GAT even attempt fertility preservation (FP) (Nahata, 2017). Moreover, for those in early pubertal stages (Tanner 2 and 3), "ovarian tissue cryopreservation is still considered experimental in most centers and testicular tissue cryopreservation remains entirely experimental[7]. These experimental forms of FP would be the only options in children [with puberty] blocked prior to spermarche and menarche and are high in cost and limited to specialized centers. Even with FP there is no guarantee of having a child" (Laidlaw, Cretella, et al., 2019).

96. Dr. Antommaria states with respect to the treatment of precocious puberty and use in GAT that the "risks of and evidence for the use of puberty blockers in both conditions are comparable" (Antommaria decl, p. 33). This statement fails to recognize the very different effects of PB medication in early childhood versus during adolescence.

97. As an example, if a four-year-old child is diagnosed with precocious puberty, the abnormally early puberty may be halted by GnRH analogues (puberty blocking medication). The child will at a later time, say at age 12, have the puberty blocker discontinued and at that point normal pubertal development will be allowed to proceed. Therefore, when the child is no longer taking the medication, he or she will gain natural fertility.

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

b. Sexual Dysfunction

99. Another problem I would expect to find in youths who have HH and puberty stopped at an early stage is sexual dysfunction. The child will continue their chronological age progression toward adulthood and yet remain with undeveloped genitalia. This will lead to sexual

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

dysfunction, including potential erectile dysfunction and inability to ejaculate and orgasm for the male. For the female with undeveloped genitalia potential sexual dysfunction may include painful intercourse and impairment of orgasm.

100. The impairment of sexual function was evident in the TLC reality show "I am Jazz". In the show, Jazz, who was identified male at birth, had been given puberty blockers at an early pubertal stage. In an episode where Jazz visits a surgeon and has a discussion about sexual function, Jazz states: "I haven't experienced any sexual sensation." Regarding orgasm, Jazz says: "I don't know, I haven't experienced it"[8] (TLC, accessed 2022).

c. Negative Effects of Hypogonadotropic Hypogonadism on Bone Density

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

102. Any abnormal lowering of sex hormones occurring during this critical time will stop the rapid accumulation of bone and therefore lower ultimate adult bone density. If a person does not achieve peak bone density, they would be expected to be at future risk for osteoporosis and the potential for debilitating spine and hip fractures as adults. Hip fractures for the older patient very significantly increase the risk of major morbidity and death (Bentler, 2009). Allowing a "pause" in puberty for any period of time can lead to an inability to attain peak bone density.

103. DEXA scans are used to evaluate changes in bone density and to help evaluate risk for future fractures. In my practice I order and interpret DEXA scans for this purpose.

104. The Z-score of a DEXA scan is used to compare a patient's bone density to the same population based on age and sex. For example, a person who has a bone density similar to the average of the population would be at the 50th percentile. Those who have greater relative bone density would be above the 50th percentile. Those who have lower bone density would have a Z score below the 50th percentile.

105. Puberty blockers used in adolescence to cause HH will inhibit the normal accrual of bone density. This can be evaluated by DEXA scan. In a study in the UK, 44 patients aged 12-15 with gender dysphoria were given puberty blockers and tests of bone density were done at baseline, 12 months, 24 months and 36 months (Carmichael, 2021).

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

106. Figure 2 shows the Z-scores of the average age matched population percentile which is 50%. It shows the average baseline (before puberty blockers) Z-score percentile for the study participants. It also shows the bone density percentile at 12, 24, and 36 months. One can see that the average baseline z score was about 32% compared to peers of similar age and sex. At 12 months this had decreased to about 15%, and by 24 months it had declined further to about 5% compared to their peers and remained at this low level.

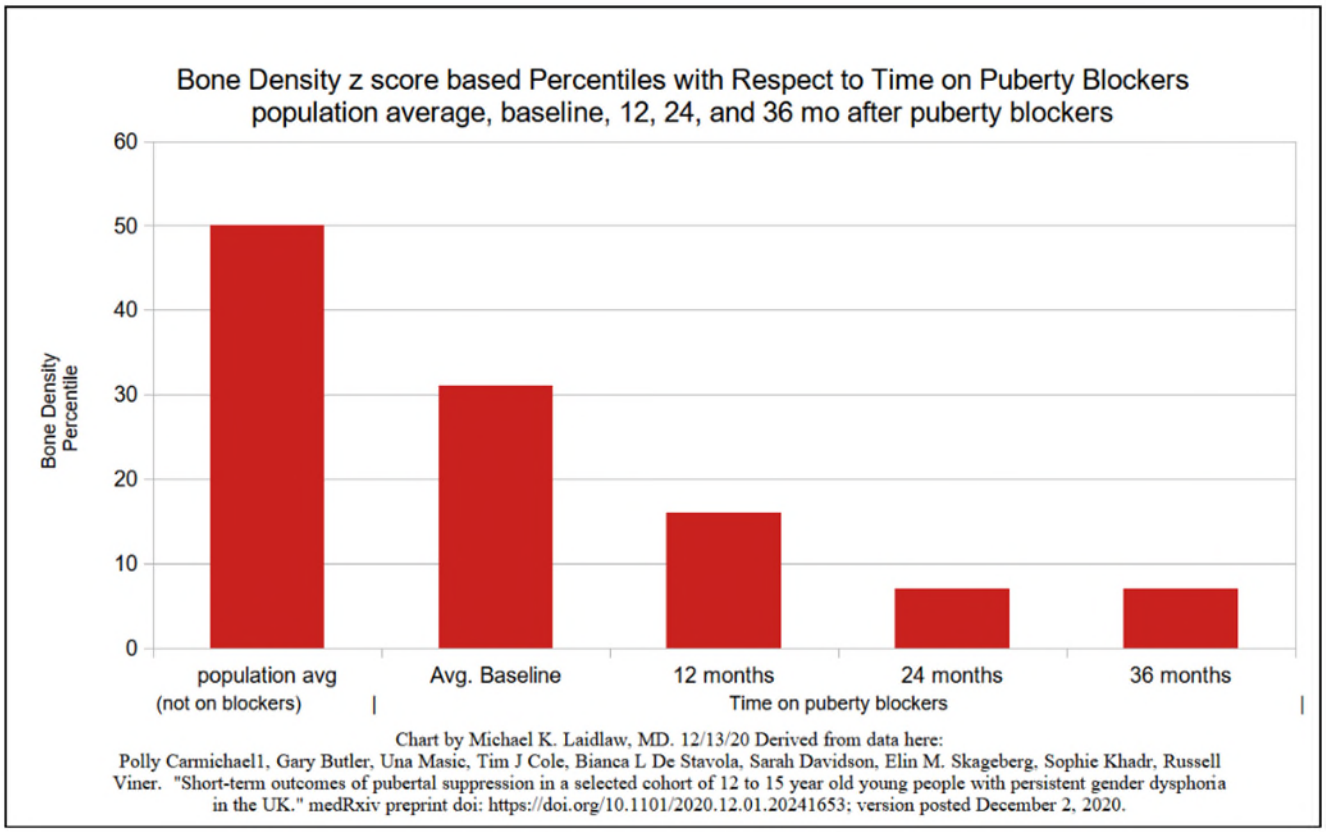

Figure 2

107. This is the same pattern of diminishing bone density compared to their peers that one would see in hypogonadotropic hypogonadism due to a pituitary injury. However, in these cases hypogonadotropic hypogonadism was caused by GnRH analogues (puberty blocking medication) that lead to greatly diminished bone density compared to their peers of the same age.

108. In natal females, hypogonadotropic hypogonadism leads to amenorrhea, meaning the absence of menstrual periods. Amenorrhea is detrimental to bone health: "In addition to this[9] important long-term consequence of amenorrhea, other problems, such as premature bone demineralization or inadequate bone formation, are likely to put amenorrheic women at high risk for osteoporosis and fracture" (Santoro, 2011, emphasis added).

109. Dr. Shumer states "The treatment [puberty blockade] works by pausing endogenous puberty at whatever stage it is at when the treatment begins, limiting the influence of a person's endogenous hormones on their body" (Shumer decl, p. 20). In actuality, allowing a "pause" in puberty for any period of time leads to an inability to attain peak bone density and puts the patient at future risk for osteoporosis and serious fractures as I have described.

110. Dr. Ladinsky states, "While lower bone density can sometimes occur while a young person is taking puberty blocking medication, that issue can be managed with the use of supplemental calcium and attention to weight bearing exercise" (Ladinsky, p. 27). However, Dr Ladinksy provides no evidence that supplemental calcium and weight bearing exercise alone can allow a developing adolescent's bone density to adequately recover from the harms of GnRHa described above.

111. Dr. Ladinsky goes on to say, "When these medications are stopped after a brief period of use of some 1-3 years (as is our practice), followed by a hormonal puberty, we know from excellent data that bone density catch-up ensues. This is well documented" (Ladinsky, p. 27 (emphasis added), citing van der Loos 2021). What Dr. Ladinsky calls "hormonal puberty" is the addition of opposite sex hormones in the referenced van der Loos study. None of the adolescents in the study "paused" puberty with GnRHa and then were allowed to have their normal, native puberty continue. The study group consisted solely of a cross sex hormone group, and (as is typical for these studies) no control group is available to compare bone density changes to those adolescents who resumed their normal, native puberty.

112. Dr. McNamara states, "[c]alcium supplementation has been shown to protect puberty blocker-treated patients from bone loss" (McNamara decl, p. 13). Once again, Dr. McNamara makes an incorrect comparison and uses a study of precocious puberty to support her

[9] "This" refers to cardiovascular disease: "Diagnosis and treatment of amenorrheic states is of increasing clinical importance because lifetime menstrual irregularities are known to be predictive of subsequent CVD in women."

claim. She does not provide evidence of a study examining calcium and GnRHa uses in normally timed puberty when large and rapid changes in bone growth and bone density are expected.

113. Another consideration is the effects of HH in adolescents and late teens on the maturation of the human brain. Much of what happens is actually unknown. However, "sex hormones including estrogen, progesterone, and testosterone can influence the development and maturation of the adolescent brain." (Arain, 2013). Therefore, there are unknown, but likely negative, consequences to blocking normal puberty with respect to brain development.

d. Psychosocial Development

114. A third major problem with blocking normal puberty involves psychosocial development. Adolescence is a critical time of physical, mental, and emotional changes for the adolescent. It is important that they develop socially in conjunction with their peers.

115. While I am not a psychologist, I am familiar with and rely upon the literature in this area for the rationale of the treatment of precocious puberty[10]. It is generally accepted in endocrinology that there are psychological benefits to adolescents who go through puberty around the same time as their peers, and this is why puberty blockers (GnRH analogues) in central precocious puberty are sometimes used to delay a child's abnormally early pubertal development to a more age-appropriate time.

116. The development of the adolescent along with their peers is also well recognized in the psychological literature: "For decades, scholars have pointed to peer relationships as one of the most important features of adolescence." (Brown, 2009). If one is left behind for several years under the impression that they are awaiting opposite sex puberty, they will miss important opportunities for socialization and psychological development. Psychosocial development will be necessarily stunted as they are not developing with their peers. This is a permanent harm as the time cannot be regained.

117. Aside from the multiple serious problems that are iatrogenically acquired by blocking normal puberty, there appear to be independent risks of the puberty blocking medication themselves. For example, one can read the labeling of a common puberty blocking medication called Lupron Depot-Ped and find under psychiatric disorders: "emotional lability, such as crying, irritability, impatience, anger, and aggression. Depression, including rare reports of suicidal

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

ideation and attempt. Many, but not all, of these patients had a history of psychiatric illness or other comorbidities with an increased risk of depression" (Lupron, 2022). This is particularly concerning given the high rate of psychiatric comorbidity with gender dysphoria (Kaltiala-Heino, 2015).

C. Opposite Sex Hormones

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

119. In GAT, what is termed "cross sex hormones" is the use of hormones of the opposite sex to attempt to create secondary sex characteristics. To do so, very high doses of these hormones are administered. When hormone levels climb above normal levels they are termed supraphysiologic.

1. Testosterone

120. Testosterone is an anabolic steroid of high potency. It is classified as a Schedule 3 controlled substance by the DEA: "Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence" (DEA, 2022). A licensed physician with a valid DEA registration is required to prescribe testosterone.

121. I prescribe testosterone to men for testosterone deficiency. The state of testosterone deficiency can cause various problems including problems of mood, sexual function, libido, and bone density. Prescription testosterone is given to correct the abnormally low levels and bring them back into balance. The dose of testosterone must be carefully considered and monitored to avoid excess levels in the male as there are a number of serious concerns when prescribing testosterone. The use of high dose testosterone in females is experimental.

122. Contrast the FDA approved use of testosterone in males versus its experimental use females. Testosterone is FDA approved for use in adult men as well as the pediatric male population aged 12 and older (Actavis, 2018). There is no FDA approved usage of testosterone for women or pediatric aged females.[11] The prescribing indications for adult males and pediatric males

[11] "Testosterone Cypionate Injection, USP is indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone" (Actavis, 2018, emphasis added).

are identical and are to treat the conditions of low testosterone caused by either primary hypogonadism or secondary hypogonadism (Id.). The intent of testosterone for women and pediatric aged females in GAT is to cause severe hyperandrogenism. In this case the purpose, effects, and ultimate outcome of the FDA approved usage of testosterone for males versus the experimental use for females in GAT are very different. Therefore, the low-quality evidence guidelines of the Endocrine Society/WPATH are not an acceptable substitute for proper scientific studies including randomized controlled trials (Malone et al., 2021; Hembree et al., 2017).

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

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

125. With regard to ultimate height, "[t]he following adverse reactions have been reported in male and female adolescents: premature closure of bony epiphyses with termination of growth" (Actavis Pharma, Inc., 2018). What this means is that testosterone applied to the adolescent will cause premature closure of the growth plates, stopping further gains in height in the growing individual, and ultimately making the person shorter than they otherwise would have been.

126. With respect to the cardiovascular system of men using ordinary doses, "Long-term clinical safety trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy in men" (Actavis Pharma, 2018). No clinical safety trials have been performed for women or adolescent girls to my knowledge.

127. "There have been postmarketing reports of venous thromboembolic events [blood clots], including deep vein thrombosis (DVT) [blood clot of the extremity such as the leg] and pulmonary embolism (PE) [blood clot of the lung which may be deadly], in patients using testosterone products, such as testosterone cypionate" (Actavis Pharma, 2018).

128. A very recently published study of adverse drug reactions (ADRs) as part of gender affirming hormone therapies in France states that "[o]ur data show a previously unreported, non-negligible proportion of cases indicating cardiovascular ADRs in transgender men younger than 40 years… In transgender men taking testosterone enanthate, all reported ADRs were cardiovascular events, with pulmonary embolism in 50% of cases" (Yelehe et al., 2022).

129. There are also serious concerns regarding liver dysfunction: "Prolonged use of high doses of androgens ... has been associated with development of hepatic adenomas [benign tumors], hepatocellular carcinoma [cancer], and peliosis hepatis [generation of blood-filled cavities in the liver that may rupture] —all potentially life-threatening complications" (Actavis Pharma, 2018).

a. Hyperandrogenism

130. Hyperandrogenism is a medical condition of elevated blood androgens such as testosterone. As an endocrinologist I frequently evaluate patients to determine if they have the condition of hyperandrogenism. Hyperandrogenism in the female or male is harmful and can lead to various maladies.

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

132. For example, for females aged 18 or older, the normal reference range is 2-45 ng/dL (Quest testosterone, 2023).[12] However, in female disease conditions these levels can be much higher. Levels above this normal reference range are considered hyperandrogenism (figure 3).

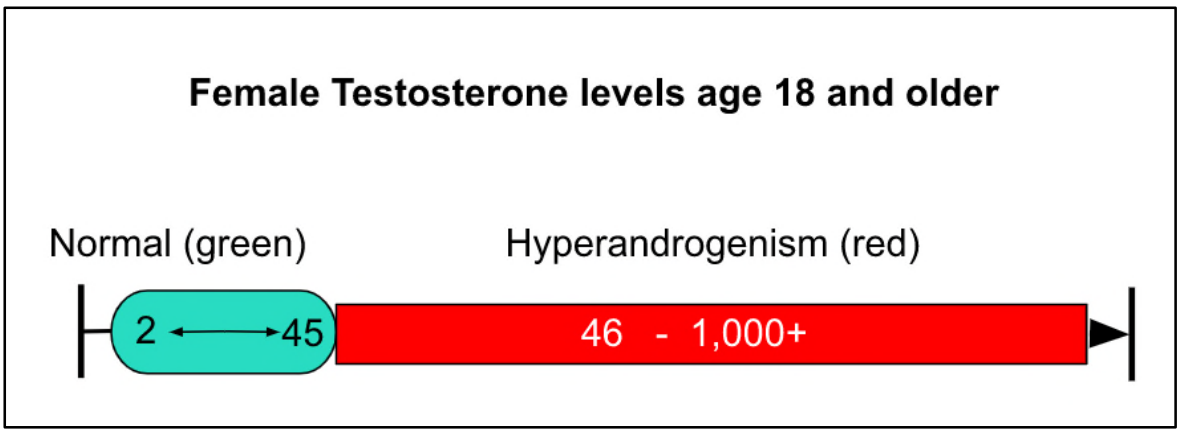

Figure 3

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

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

134. I frequently diagnose and treat the hyperandrogen condition called polycystic ovarian syndrome (PCOS). These patients have elevated testosterone levels. These levels are mildly to moderately elevated and may range from 50-150. Hyperandrogenism found in PCOS has been associated with insulin resistance (Dunaif, 1989), metabolic syndrome (Apridonidze, 2005) and diabetes (Joham, 2014).

135. I also evaluate patients to rule out rare androgen producing tumors that generate very high levels of testosterone. These rare endocrine tumors can cause severely elevated testosterone levels in the 300-1000 range. Once the cause of a hyperandrogen condition is identified, treatments may be put in place to help bring the testosterone levels down to the normal reference range.

136. Recommendations from the Endocrine Society's clinical guidelines related to GAT are to ultimately raise female levels of testosterone to 320 to 1000 ng/dL[13] which is on the same order as dangerous endocrine tumors for women as described above (Hembree, 2017). A simple calculation shows this level for the adult may be anywhere from 6 to 100 times higher than native female testosterone levels. In doing so they are inducing severe hyperandrogenism. These extraordinarily high levels of testosterone are associated with multiple risks to the physical and mental health of the patient.

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

[13] In the Endocrine Society's Guidelines there is no grading of evidence for the rationale of using such high supraphysiologic doses of opposite sex hormones for the female or male. There seems to be an underlying assumption that because the person believes to be the opposite sex then they acquire the sex specific laboratory ranges of the opposite sex. "The root cause of this flaw in thinking about diagnostic ranges was exemplified in a response letter by Rosenthal et al claiming that gender identity determines the ideal physiologic range of cross-sex hormone levels (5). Thus, a psychological construct, the 'gender identity', is imagined to affect physical reality and change a person's sex-specific laboratory reference ranges. This is clearly not the case, otherwise there would be no serious complications of high-dose androgen treatment in transgender males" (Laidlaw et al., 2021).

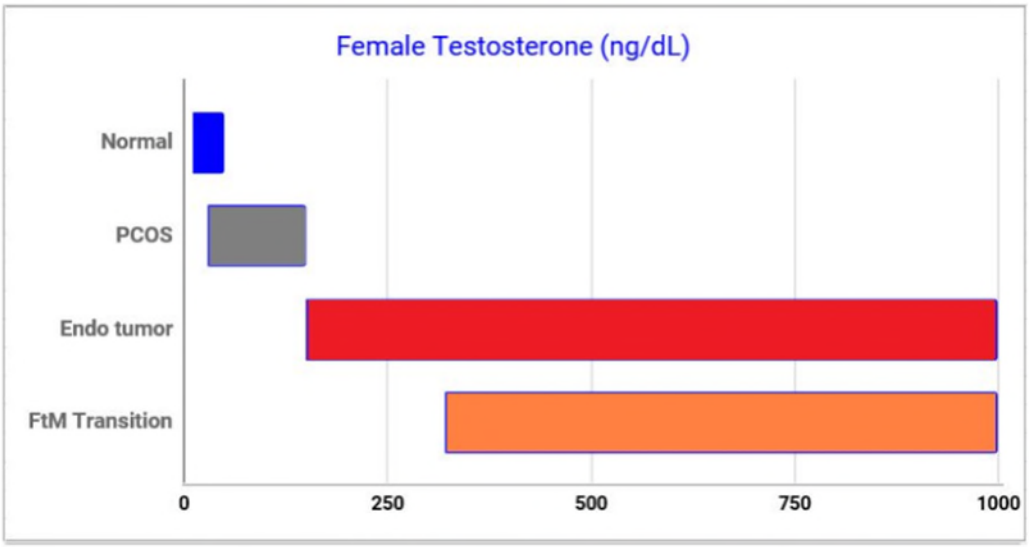

Image by Michael K Laidlaw. MD. Approximate total testosterone in ng/dL based on laboratory, etc. FtM transition from 2017 Endo Society Guidelines on Gender Dysphoria. With PCOS testosterone levels may be as high as 150. With endocrine tumors testosterone may be in the 150-1000 range. The recommendations of the Endocrine Society/WPATH are to bring levels into the 300-1000 range which is 6-100 times higher than normal endogenous adult female levels.

Figure 4.

b. Medical Problems Related to Hyperandrogenism

138. With respect to cardiovascular risk, "[s]tudies of transgender males taking testosterone have shown up to a nearly 5-fold increased risk of myocardial infarction relative to females not receiving testosterone" (Laidlaw et al.,2021; Alzahrani et al., 2019).

139. Permanent physical effects of testosterone therapy involve irreversible changes to the vocal cords. Abnormal amounts of hair growth which may occur on the face, chest, abdomen, back and other areas is known as hirsutism. Should the female eventually regret her decision to take testosterone, this body hair can be very difficult to remove. Male pattern balding of the scalp may also occur. I would expect these changes to occur to the plaintiffs taking testosterone to induce hyperandrogenism. Common sense suggests that changes of voice and hair growth could be psychologically troubling should a patient decide to detranstition and attempt to reintegrate into society as female.

140. Changes to the genitourinary system due to hyperandrogenism include polycystic ovaries, clitoromegaly and atrophy of the lining of the uterus and vagina (Hembree, 2017). The breasts have been shown to have an increase in fibrous breast tissue and a decrease in normal glandular tissue (Grynberg et al., 2010). Potential cancer risks from high dose testosterone include

ovarian and breast cancer (Hembree, 2017). I would expect some or all of these effects and risks to occur to the plaintiffs taking testosterone to induce hyperandrogenism.

141. Dr. McNamara erroneously states that "[t]he effects of cross-sex hormones can be reversible," (McNamara decl, p. 14). This is clearly incorrect as effects such as hirsutism, deepening of the voice, and clitoromegaly are permanent. The long-term effects of starting an adolescent on puberty blockers in early puberty (Tanner stage 2 or 3) and then adding opposite sex hormones on ultimate sterility are unknown in the sense that we do not have studies showing precisely what happens, but based on what we do know, it seems safe to say that opposite sex hormones are likely cytotoxic to the immature gonads.

142. According to research, anabolic steroid abuse[14] has been shown to predispose individuals towards mood disorders, psychosis, and psychiatric disorders. The "most prominent psychiatric features associated with AAS [anabolic androgenic steroids, i.e., testosterone] abuse are manic-like presentations defined by irritability, aggressiveness, euphoria, grandiose beliefs, hyperactivity, and reckless or dangerous behavior. Other psychiatric presentations include the development of acute psychoses, exacerbation of tics and depression, and the development of acute confusional/delirious states" (Hall, 2005). Moreover, "[s]tudies... of medium steroid use (between 300 and 1000 mg/week of any AAS) and high use (more than 1000 mg/week of any AAS) have demonstrated that 23% of subjects using these doses of steroids met the DSM-III-R criteria for a major mood syndrome (mania, hypomania, and major depression) and that 3.4% — 12% developed psychotic symptoms" (Hall, 2005).

c. Erythrocytosis as a Result of Hyperandrogenism

143. I regularly monitor patients who are receiving testosterone to evaluate for erythrocytosis. Erythrocytosis is a condition of high red blood cell counts. Prolonged hyperandrogenism such as occurs with the use of testosterone at supraphysiologic levels can cause erythrocytosis.

144. Males and females have different reference ranges for red blood cells (measured as hematocrit). For example, the normal range of hematocrit for females over age 18 is 35.0-45.0% and males 38.5-50.0% (Quest Hematocrit, 2023). Levels above this range signify erythrocytosis (see figure 5).

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

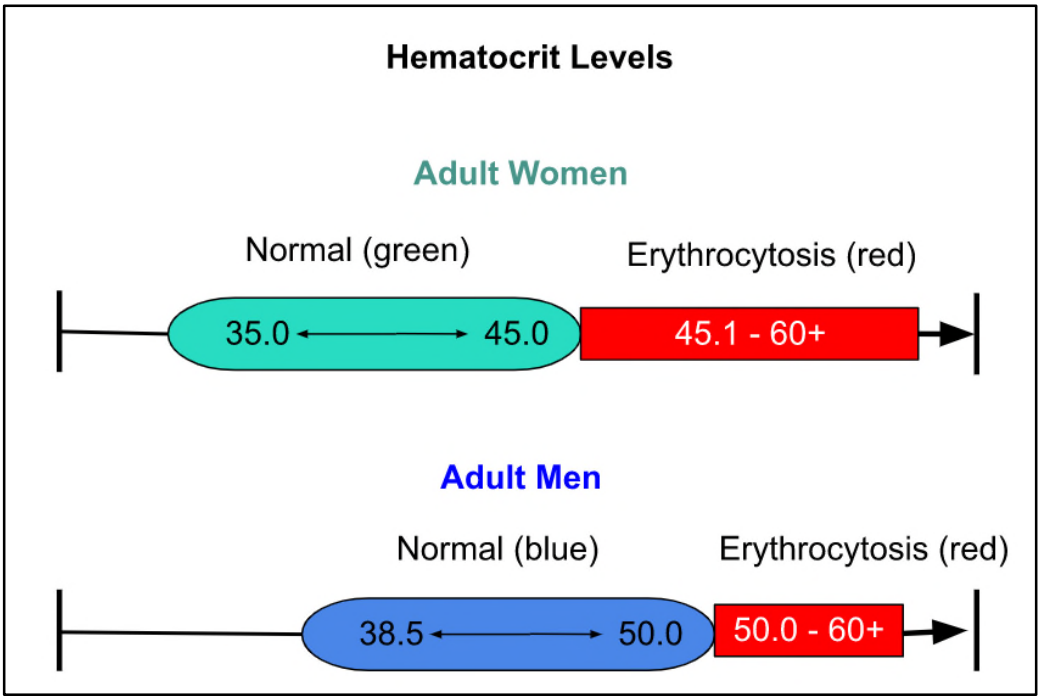

Figure 5.

145. As one can see, there is an overlap in the ranges of males and females such that levels between 45.1 and 50 are considered normal for the male. However, for the female these levels are considered erythroctotic. Levels above 50 for the male are considered erythrocytosis and for the female severe erythrocytosis.

146. The Madsen study was a "20-year follow-up study in [1,073] adult trans men who started testosterone therapy and had monitoring of hematocrit at our center" (Madsen, 2021). In this study, 24% of trans men had hematocrit levels 50% at some time which would be considered severe erythrocytosis. Unfortunately, they did not examine the hematocrit range of 45-50. However, one would presume that this would occur in at least the same percentage or higher as those who had developed severe erythrocytosis.

147. Any level of erythrocytosis in young women has been shown to be an independent risk factor for cardiovascular disease, coronary heart disease and death due to both (Gagnon, 1994).

2. Estrogen

148. Estrogen is the primary sex hormone of the female. Prescription estrogen may be used if a woman has low estrogen levels due to premature failure of her ovaries. Estrogen is prescribed to bring these levels back into a normal range for the patient's age. Another labeled use

of estrogen is to treat menopausal symptoms. The use of estrogen to treat pediatric age males is experimental.

149. Hyperestogenemia is a condition of elevated blood estrogens such as estradiol. I regularly evaluate patients for hyperestrogenemia in my practice. Hyperestrogenemia in the male is harmful and can lead to various maladies.

150. In order to diagnose hyperestrogenemia, a laboratory blood test of estrogen is performed. In hyperestrogenemia, one will find estrogen levels elevated above the reference range. For example, in an adult male the normal estrogen reference range is 60-190 pg/mL (Quest Estrogen, 2023). Levels above this range are consistent with hyperestrogenemia. See figure 6.

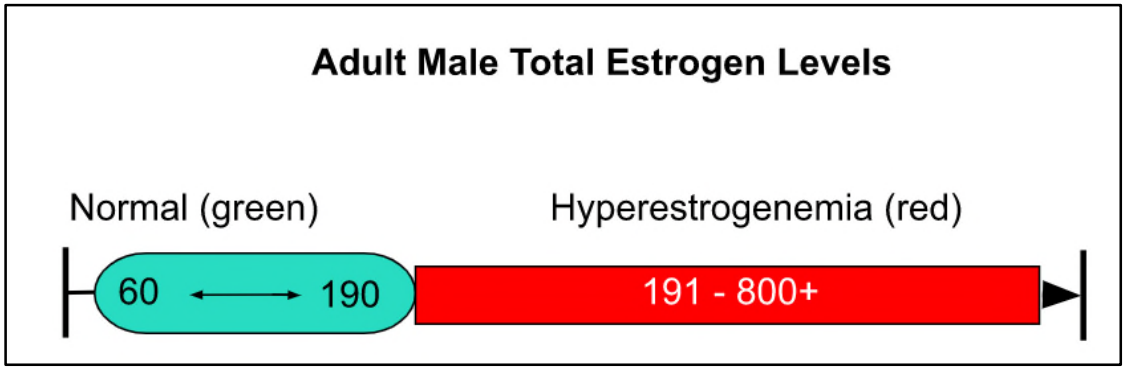

Figure 6.

151. There are medical conditions which can result in hyperestrogenemia. For example, "[t]he concentration of estrogen in cirrhotic patients is thought to increase by fourfold compared to individuals without cirrhosis" (Pagadala, 2023). Certain rare tumors for example of the adrenal gland can result in estrogen levels 3 to 10-fold higher than normal (Cavlan, 2010).

152. In gender affirmative therapy, the medical condition of hyperestrogenemia is being deliberately, medically induced by the off-label use of high doses of estrogen. The Endocrine Society guideline for treating gender dysphoria recommends raising estradiol levels to 2 to 43 times above the normal range.[15] The high doses are used in an attempt to primarily affect an increase of male breast tissue development known as gynecomastia. Gynecomastia is the abnormal

[15] Estradiol is a type of estrogen. The Endocrine Society Guideline recommends raising estradiol levels to 100-200 pg/mL (Hembree, 2017). The normal adult male estradiol range is 7.7-42.6 pg/mL (Labcorp Estadiol, 2023).

growth of breast tissue in the male. I evaluate and treat patients with gynceomastia. I have prescribed medication and have referred patients for surgery for this condition.

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

154. Long-term consequences of hyperestrogenemia include increased risk of myocardial infarction and death due to cardiovascular disease (Irwig, 2018). Also "[t]here is strong evidence that estrogen therapy for trans women increases their risk for venous thromboembolism[16] over 5 fold" (Irwig, 2018).

155. Breast cancer is a relatively uncommon problem of the male. However, the risk of a male developing breast cancer has been shown to be 46 times higher with high dose estrogen (Christel et al., 2019).

156. Sexual dysfunction, including decreased sexual desire and decreased spontaneous erections, is another adverse effect of hyperestrogenemia (Hembree, 2017).

3. Opposite Sex Hormones and Infertility/Sterility

157. Dr. Shumer introduces the unproven idea that those adolescents who received puberty blockers in early puberty and then take opposite sex hormones (which will lock them in early puberty) may be able at some point as adults stop the hormones and then advance through their normal physiologic puberty. He states, "If attempting fertility after previous treatment with GnRHa followed by hormone therapy is desired, an adult patient would withdraw from hormones and allow pubertal progression" (Shumer decl, p. 25). However, he provides no evidence that this is even possible. In fact, the evidence suggests that it is not.

158. Dr. McNamara erroneously states that "[t]he effects of cross-sex hormones can be reversible," (McNamara decl, p. 14). This is clearly incorrect as effects such as hirsutism, deepening of the voice, and clitoromegaly are permanent. The effects on ultimate fertility of starting an adolescent on puberty blockers in early puberty (Tanner stage 2 or 3), adding opposite sex hormones, and then stopping hormone treatment altogether are unknown at best. For example, there is no evidence so far that a male patient's testicles would continue to develop normally in

[16] Venous thromboembolism is a blood clot that develops in a deep vein and "can cause serious illness, disability, and in some cases, death" (CDC, 2022).

order to produce an ejaculate with healthy, mature sperm capable of fertilization under those circumstances.

159. Dr. McNamara claims otherwise, asserting that the "return of spermatogenesis typically occurs in patients who discontinue hormone treatment" (McNamara decl, p. 15). Ironically, in the study she uses to support her assertion, all of the subjects had their testicles removed by orchiectomy and were therefore sterilized (de Nie et al., 2022). The study also states that "[m]ature spermatozoa were encountered in 4.7% of orchiectomy specimens, all from transgender women who had initiated medical treatment in Tanner stage 4 or higher". Therefore, there were no mature spermatozoa in those patients whose puberty was blocked prior to Tanner stage 4. That finding is consistent with infertility and potential sterility caused by GAT.

D. Surgeries

160. The fourth stage of gender affirmative therapy is surgical alterations of the body of various kinds in an attempt to somehow mimic features of the opposite sex.

161. Dr. Shumer states that "The transition process in adolescence typically includes (i) social transition and/or (ii) medications, including puberty-delaying medication and hormone therapy" (Shumer decl, p. 18). However, Dr. Shumer neglects to describe surgeries as a part of the transition process. This is important to note because although endocrinologists like him and I do not typically perform surgery, we do refer patients for surgeries and need to be aware of the risks, benefits, complications, and long-term outcomes. This is also important to note because transition surgeries, in particular mastectomies, are being performed on minors throughout the country.

162. Individual surgical procedures can be a complex topic. It is helpful to first step back and consider conceptually what any surgery can and cannot accomplish.

163. In its basic form surgery is subtractive. In other words, a portion of tissue, an organ, or organs are removed in order to restore health. For example, a diseased gallbladder may be surgically removed to help the patient get back to wellness. An infected appendix may be surgically removed to prevent worsening infection or even death. In both of these cases an unhealthy body part is surgically removed in order to restore health.

164. In some cases a diseased tissue or organ is removed so that a foreign replacement part may be substituted for an unhealthy organ or tissue. For example, a diseased heart valve may be replaced with a pig valve or a prosthetic heart valve. Another example is a failed liver may be replaced by liver transplant.

165. Though modern surgical techniques and procedures are astounding, there are very noteworthy limitations. Importantly, surgery cannot de novo create new organs. If a person's kidneys fail, the surgeon has no scientific method for creating a new set of kidneys that can be implanted or grown within the patient. This conceptual background is helpful when considering various gender affirming surgeries.

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

1. Mastectomy

167. Mastectomies are the surgical removal of the breasts. The procedure is used in GAT in an attempt to make the chest appear more masculine. The surgery results in a permanent loss of the ability to breastfeed and significant scarring of 7 to 10 inches. The scars are prone to widening and thickening due to the stresses of breathing and arm movement. Other potential complications include the loss of normal nipple sensation and difficulties with wound healing (American Cancer Society, 2022).

168. It is important to note that this operation cannot be reversed. The female will never regain healthy breasts capable of producing milk to feed a child (Mayo Clinic, Top Surgery, 2022).

169. Another important consideration is that compared to the removal of an unhealthy gallbladder or appendix, in the case of gender dysphoria the breasts are perfectly healthy and there is no organic disease process such as a cancer warranting their removal.

2. GAT Surgeries on the Male

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

171. Potential surgical complications may include urethral strictures, infection, prolapse, fistulas and injury to the sensory nerves with partial or complete loss of erotic sensation (Mayo Clinic, Feminizing Surgery, 2022).

3. GAT Surgeries of the Female Pelvis and Genitalia

172. Other types of surgery for females include those of the genitalia and reproductive tract. For example, the ovaries, uterus, fallopian tubes, cervix and the vagina may be surgically removed. Removal of the ovaries results in sterilization.

173. Importantly, removing female body parts does not produce a male. Rather, the female has had sex-specific organs permanently destroyed with no hope of replacement, while remaining biologically female.

174. There have also been attempts to create a pseudo-penis. This procedure is known as phalloplasty. It is not possible to de novo create a new human penis. Instead, a roll of skin and subcutaneous tissue is removed from one area of the body, say the thigh or the forearm, and transplanted to the pelvis. An attempt is made to extend the urethra or urinary tract for urination through the structure. This transplanted tissue lacks the structures inherent in the male penis which allow for erection, therefore erectile devices such as rods or inflatable devices are placed within the tube of transplanted tissue in order to simulate erection (Hembree, 2017). The labia may also be expanded to create a simulated scrotum containing prosthetic objects to provide the appearance of testicles.

175. Complications may include urinary stricture, problems with blood supply to the transplanted roll of tissue, large scarring to the forearm or thigh, infections including peritonitis, and possible injury to the sensory nerve of the clitoris (Mayo Clinic, Masculinizing Surgery, 2022). A recent systematic review and meta-analysis of 1731 patients who underwent phalloplasty found very high rates of complications (76.5%) including a urethral fistula rate of 34.1% and urethral stricture rate of 25.4% (Wang, 2022).

III. The Lack of Evidence Supporting Gender-Affirming Therapy

176. There is not a medical consensus supporting the use of puberty blockers and cross-sex hormones for the treatment of gender dysphoria. In my opinion, there is insufficient evidence to conclude that any benefit of such treatment would outweigh the harm, particularly given the evidence of a rapid rise in cases of youth gender dysphoria, the high rates of coexisting mental health comorbidities, and naturally high rates of desistance.

A. The Endocrine Society, WPATH, and Other Pro-Affirmation Organizations

177. Dr. Shumer states, "Standards of care have been published by several long-standing and well-respected medical bodies," and he cites the WPATH Standards of Care and the Endocrine Society's 2017 Guideline (ESG) (Shumer decl, p. 15-16). I will address each in turn.

1. WPATH

178. WPATH has functioned primarily as an advocacy organization for promoting social and political activism rather than as a strictly scientific organization. Unlike a scientific organization that must allow for internal debate to clarify issues of uncertainty, WPATH has actively sought to stymie such debate. As an example, Dr. Kenneth Zucker, whom I cited earlier, is a psychologist who led the Child Youth and Family Gender Clinic in Toronto, which was "one of the most well-known clinics in the world for children and adolescents with gender dysphoria" (Singal, 2016). He also led the group which wrote the DSM's gender dysphoria section. (Id.)

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

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

181. As an example of WPATH's one-sided political advocacy, consider also the recent inflammatory message by WPATH president Marci Bowers, MD in a letter to members. Writing about laws like Alabama's that seek to protect vulnerable minors from experimental procedures, Bowers wrote: "Ultimately, what terrifies conservatives most is that gender diversity is a force of nature that can no longer be contained by religious conscription or enforcement of a gender binary." Bowers concluded: "Anti-trans legislation needs to be fought with every voice, every thought, every inclination by all who know it. We need to make anti-trans legislation a losing

political issue." (Bowers 2023). These statements are social-political advocacy statements and rallying cries, not scientific arguments. They reduce any disagreement or concern regarding the safety and efficacy of GAT for minors to "anti-trans" religious-based bigotry, and they leave no space for those who are concerned that, based on current scientific knowledge, the risks of GAT for minors outweigh their known benefits. In my experience, these statements are sadly indicative of WPATH's primary role as a political and social advocacy organization, not a scientific one.

182. As for WPATH's Standards of Care 8 (SOC 8), these were published Sep. 6, 2022 (Coleman et al., 2022) and are endorsed by Dr. Shumer as representing an "expert consensus for clinicians related to medical care for transgender people, based on the best available science and clinical experience" (Shumer decl, p. 16). However, there are multiple serious problems with this document such that any clinician who follows its recommendations puts the youth of Alabama at great risk.

183. In a correction to the SOC 8, all guidelines for minimum age of opposite sex hormones were removed (Correction IJTH, 2022). All guidelines for minimum age of surgery were also removed, meaning a minor of any age could be referred for any of the GAT surgeries listed previously (Id.).

184. The correction reads: "On page S258, the following text was removed:

'The following are suggested minimal ages when considering the factors unique to the adolescent treatment time frame for gender-affirming medical and surgical treatment for adolescents, who fulfil all of the other criteria listed above.

– Hormonal treatment: 14 years

– Chest masculinization: 15 years

– Breast augmentation, Facial Surgery: 16 years

– Metoidioplasty, Orchiectomy, Vaginoplasty,

– Hysterectomy, Fronto-orbital remodeling: 17 years

– Phalloplasty: 18 years'" (WPATH SOC 8 Correction, p. S261).

185. Of great concern is that the minimum age recommendations were retracted, it appears, in contradiction to the recommendation of their own expert consensus:

"On page S66, the following text was removed:

'Age recommendations for irreversible surgical procedures were determined by a review of existing literature and the expert consensus of mental health providers,

medical providers, and surgeons highly experienced in providing care to TGD adolescents.'" (WPATH SOC 8 Correction, p. S260, emphasis added).

186. Naturally, removing age limits for hormones and surgeries which have life altering physical consequences should only be done with the primary goal of obtaining the best possible health outcome for each patient. This should also be done with solid research and long-term studies justifying these treatments for young, developing persons.

187. However, WPATH's own statements show that liability and politics were their primary motivations. According to SOC8 author Dr. Tishleman the changes were made in order to help ensure that doctors would not be liable for malpractice suits if they deviated from their new standards (Davis 2022). Additionally, WPATH's president said that to "propose" surgeries at newly set lower age recommendations would necessitate a "better political climate" (Ghorayshi 2022).

188. Another concerning component of SOC 8 is a new chapter regarding eunuchs that gives recommendations for how to induce hypogonadism in men who have the eunuch "gender identity"[17] by either orchiectomy (testicle removal) or chemical castration such as with GnRH analogues (Coleman et al., 2022)[18].

189. The SOC8 also used an aberrant form of the GRADE approach for systematic reviews that removed the grading of quality of evidence (which should be categorized as very low, low, moderate, and high quality).[19] Instead any recommendation of "recommend" is automatically assigned as high quality of evidence. SOC 8 also failed to provide evidence profile tables which

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[17] The notion that there is a "eunuch gender identity" further invalidates the gender identity as a serious biological property of human beings: "Many eunuch individuals see their status as eunuch as their distinct gender identity with no other gender or transgender affiliation" (Coleman et al., 2022, p. S88).

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

- Hormone suppression to explore the effects of androgen deficiency for eunuch individuals wishing to become asexual, nonsexual, or androgynous;
- Orchiectomy [testicle removal] to stop testicular production of testosterone;
- Orchiectomy with or without penectomy to alter their body to match their self-image;
- Orchiectomy followed by hormone replacement with testosterone or estrogen. " (Id.)

[19] From SOC 8 "The [recommendation] statements were classified as:

- Strong recommendations ("we recommend") are for those interventions/therapy/strategies where:
- the evidence is of high quality" (Id., p. S250).

should include "an explicit judgment of each factor that determines the quality of evidence for each outcome" (Guyatt et al., 2021).

190. Such a modification of GRADE is explicitly recommended against in the referenced GRADE document[20] and in so doing, in my opinion, invalidates all of the SOC 8 recommendations as being evidence-based.

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

2. Endocrine Society

192. I have been a member in good standing of the Endocrine Society since 2006 and have attended meetings, presented an abstract, and received an Endocrine Society travel award. I have also been a long-time subscriber to their flagship journal, The Journal of Clinical Endocrinology and Metabolism, in which I have had two letters to the editor published.

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

194. It is also notable that nine out of ten authors of the Endocrine Society Guideline were members of WPATH or worked on WPATH's scientific committees. According to WPATH's website, seven of those nine had at some time been in WPATH leadership, including the WPATH presidency and board of directors.

195. Dr. Shumer states, "Options for treatment after the onset of puberty include the use of gonadotropin-releasing hormone agonists ('GnRHa') for purposes of preventing progression of pubertal development, and hormonal interventions such as testosterone and estrogen administration. These treatment options are based on robust research and clinical experience, which consistently demonstrate safety and efficacy" (Shumer decl, p. 15). However, he presents no evidence to support his claim of robust evidence.

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[20] From the GRADE guidelines: "Some organizations have used modified versions of the GRADE approach. We recommend against such modifications because the elements of the GRADE process are interlinked because modifications may confuse some users of evidence summaries and guidelines, and because such changes compromise the goal of a single system with which clinicians, policy makers, and patients can become familiar" (Guyatt et al., 2011).

196. In fact, with respect to the Endocrine Society's guidelines, the quality of evidence for the treatment of adolescents is rated "very low-quality evidence" and "low quality evidence". "The quality of evidence for [puberty blocking agents] is noted to be low. In fact, all of the evidence in the guidelines with regard to treating children/adolescents by [gender affirmative therapy] is low to very low because of the absence of proper studies" (Laidlaw et al., 2019).

197. Unlike some other recommendations for adolescent GAT, the Endocrine Society's guidelines do not include any grading of the quality of evidence specifically for their justification of laboratory ranges of testosterone or estrogen or for adolescent mastectomy or other surgeries.

198. Endocrinologists William Malone and Paul Hruz and other colleagues have written critically of the Endocrine Society's guidelines: "Unlike standards of care, which should be authoritative, unbiased consensus positions designed to produce optimal outcomes, practice guidelines are suggestions or recommendations to improve care that, depending on their sponsor, may be biased. In addition, the ES claim of effectiveness of these interventions is at odds with several systematic reviews, including a recent Cochrane review of evidence, and a now corrected population-based study that found no evidence that hormones or surgery improve long-term psychological well-being. Lastly, the claim of relative safety of these interventions ignores the growing body of evidence of adverse effects on bone growth, cardiovascular health, and fertility, as well as transition regret" (Malone et al., 2021) (footnotes omitted).

199. In June of 2022, the Endocrine Society published "Enhancing the Trustworthiness of the Endocrine Society's Clinical Practice Guidelines" (McCartney et al., 2022). It wrote: "In an effort to enhance the trustworthiness of its clinical practice guidelines, the Endocrine Society has recently adopted new policies and more rigorous methodologies for its guideline program." (Id.) The document relates that in 2019, the ECRI Guidelines Trust "asked the Society for permission to include its guidelines in the ECRI Guidelines Trust database". However, after an evaluation by ECRI, the guideline related to osteoporosis "was the only guideline for which all recommendations were based on verifiable systematic evidence review with explicit descriptions of search strategy, study selection, and evidence summaries" (Id.). It follows that the recommendations from the ESG 2017 on Gender Dysphoria/Gender Incongruence were not all recommendations "based on verifiable systematic evidence review with explicit descriptions of search strategy, study selection, and evidence summaries." Furthermore, these ESG 2017 were highly subject to conflicts of interest. As related earlier, nine out of the 10 authors were members or worked on the scientific

committees of the advocacy group WPATH. Additionally, WPATH was a cosponsoring organization of the 2017 Guideline. The "Enhancing Trustworthiness" article recommends the opposite composition of authors for guidelines: "A majority (>50%) of non-Chair GDP members must be free of relevant C/DOI [conflict/duality of interest]" (McCartney et al., 2022).

200. Further problems with the Endocrine Society's guidelines are highlighted in a recent BMJ Investigation article. It reads: "Guyatt, who co-developed GRADE, found 'serious problems' with the Endocrine Society guidelines, noting that the systematic reviews didn't look at the effect of the interventions on gender dysphoria itself, arguably 'the most important outcome.' He also noted that the Endocrine Society had at times paired strong recommendations—phrased as 'we recommend'—with weak evidence. In the adolescent section, the weaker phrasing 'we suggest' is used for pubertal hormone suppression when children 'first exhibit physical changes of puberty'; however, the stronger phrasing is used to 'recommend' GnRHa treatment. 'GRADE discourages strong recommendations with low or very low-quality evidence except under very specific circumstances,' Guyatt told the BMJ. Those exceptions are 'very few and far between'" (Block, 2023).

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

3. Social-Political Advocacy by Organizations Supporting Gender Affirmation

202. It is concerning that organizations purporting to establish medical guidelines and standards of care for gender dysphoria are often in the political advocacy role for numerous social positions that have little direct relation to the practice of medicine. For example, WPATH issued a statement on race relations.[21] The American Medical Association[22] has weighed in on affirmative

[21] "USPATH, WPATH, EPATH Joint Statement, Black Lives Matter – A Call to Action," June 18, 2020, https://www.wpath.org/media/cms/Documents/Public%20Policies/2020/FINAL%20WPATH%20USPATH%20EPATH%20BLM%20Statement%20Approved%20Jun%2018%202020.pdf

[22] The AMA is hardly representative of the majority of physicians of the United States. Business Insider wrote that "it counts fewer than 25 percent of practicing physicians as members, down from 75 percent in the 1950s." Graham, J. "'Like a slap in the face': Doctors no longer feel the nation's largest doctors group represent their interests." Dec. 22, 2016. https://www.businessinsider.com/doctors-american-medical-association-2016-12

action,[23] climate change,[24] immigration,[25] gun control,[26] nuclear weapons,[27] the conflict in Ukraine,[28] whether lifetime imprisonment for minor felons is cruel and unusual punishment,[29] and whether biological males should play on female sports teams.[30] The American Academy of

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[23] AMA. "Fisher v. University of Texas at Austin." https://searchltf.ama-assn.org/case/documentDownload?uri=%2Funstructured%2Fbinary%2Fcase%2FCase-Summary_Fisher-v-Univ-TX-Austin.pdf. AMA. "Students for Fair Admissions v. Harvard and UNC." https://searchltf.ama-assn.org/case/documentDownload?uri=%2Funstructured%2Fbinary%2Fcase%2FStudents_for_Fair_Admissions_v__Harvard_and_UNC.pdf

[24] AMA. "AMA adopts new policy declaring climate change a public health crisis." June 13, 2022. https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-policy-declaring-climate-change-public-health-crisis; Br. of Amici Curiae American Thoracic Society, American Medical Association, American Academy of Pediatrics, American College of Physicians, and Leaders of Public Health Schools, et al. in Support of Respondents, West Virginia v. U.S. EPA, No. 20-1530, https://www.supremecourt.gov/DocketPDF/20/20-1530/211345/20220125165209968_ELJC_WestVAvEPA_PublicHealthAmicus.pdf.

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

[26] AMA. "Webber v. Armslist, LLC." https://searchlf.ama-assn.org/case/documentDownload?uri=%2Funstructured%2Fbinary%2Fcase%2FWebber_v__Armslist_LLC.pdf; AMA. "New York State Rifle & Pistole Assn. v. Bruen." https://searchlf.ama-assn.org/case/documentDownload?uri=%2Funstructured%2Fbinary%2Fcase%2FNew_York_State_Rifle___Pistol_Assn__v__Bruen.pdf

[27] AMA. "AMA urges elimination of nuclear weapons." Nov. 18, 2015. https://www.ama-assn.org/delivering-care/public-health/ama-urges-elimination-nuclear-weapons

[28] AMA. "Senseless war in Ukraine sparks physician aid response." Mar. 22, 2022. https://www.ama-assn.org/delivering-care/public-health/senseless-war-ukraine-sparks-physician-aid-response

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

[30] AMA. "Hecox v. Little." https://searchlf.ama-assn.org/case/documentDownload?uri=%2Funstructured%2Fbinary%2Fcase%2FHecox_v__Little.pdf

Pediatrics has advocated on issues such as affirmative action,[31] climate change,[32] gun control,[33] immigration,[34] same-sex marriage,[35] and nuclear weapons.[36] And the Endocrine Society has issued statements on "eradicating racism"[37] and climate change.[38] Regardless of the specific views these organizations have taken and whether one might agree or disagree with those views, the organizations' advocacy concerning primarily political issues raises concerns that their views regarding gender affirming therapy may not be based on a full debate of the scientific evidence

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[31] Br. for Amici Curiae Association of Am. Medical Colleges et al. in support of Respondents. Students for Fair Admissions, Inc. v. President and Fellows of Harvard College. No. 20-1199 & 21-707. https://www.supremecourt.gov/DocketPDF/20/20-1199/232119/20220728171113348_20-1199%20and%2021-707%20Amicus%20Brief%20for%20Association%20of%20American%20Medical%20Colleges%20et%20al.pdf

[32] Paulson, J. et al. AAP Policy Statement: "Global Climate Change and Children's Health." Pediatrics (2015) 136 (5): 992-997. https://publications.aap.org/pediatrics/article/136/5/992/33836/Global-Climate-Change-and-Children-s-Health?autologincheck=redirected

[33] AAP. "Universal Background Checks for Gun Purchases." https://www.aap.org/en/advocacy/state-advocacy/universal-background-checks-for-gun-purchases/; AAP. "Waiting Periods for Firearms Purchases." https://www.aap.org/en/advocacy/state-advocacy/waiting-periods-for-firearms-purchases/

[34] AAP et al. "Leading Pediatric Medical Organizations Respond to Recent Executive Orders Impacting Immigrants and Refugees." Feb. 14, 2017. https://www.abp.org/sites/abp/files/pdf/immigration_eo_statement.pdf

[35] Pawelski, J., et al. "The Effects of Marriage, Civil Union, and Domestic Partnership Laws on the Health and Well-being of Children." Pediatrics (2006) 118 (1): 349-364. https://publications.aap.org/pediatrics/article/118/1/349/69577/The-Effects-of-Marriage-Civil-Union-and-Domestic; Committee on Psychosocial Aspects of Child and Family Health. "Promoting the Well-Being of Children Whose Parents are Gay or Lesbian." Pediatrics (2013) 131 (4): 827-830. https://publications.aap.org/pediatrics/article/131/4/827/31789/Promoting-the-Well-Being-of-Children-Whose-Parents

[36] Newman, T. "Taking a Stand Against Nuclear Proliferation: The Pediatricians' Role." Pediatrics (2008) 121 (5): e1430-e1433. https://publications.aap.org/pediatrics/article/121/5/e1430/73491/Taking-a-Stand-Against-Nuclear-Proliferation-The

[37] Dhaliwal, R., et al. "Eradicating Racism: An Endocrine Society Policy Perspective." The Journal of Clinical Endocrinology & Metabolism, Vol. 107, Issue 5 (May 2022), 1205-1215, https://academic.oup.com/jcem/article/107/5/1205/6505234?

[38] Stewart, P. et al. "Environmental Pollution, Climate Change, and a Critical Role for the Endocrinologist." The Journal of Clinical Endocrinology & Metabolism, Vol. 106, Issue 12 (Dec. 2021), 3381-3384. https://academic.oup.com/jcem/article/106/12/3381/6410138.

and may instead be influenced, perhaps unintentionally, by their desire to be on a particular side of another social issue of the day.

B. Dr. Antommaria's Faulty Comparison of GAT to CPR

203. Dr. Antommaria states that "[g]uidelines issued by other professional associations concerning pediatric medical care rely on similar quality evidence" and uses as an example "the American Heart Association's (AHA's) guideline for Pediatric Basic and Advanced Life Support" (Antommaria, p. 14).

204. Dr. Antommaria fails to recognize that the purpose and use of hormones and surgeries in GAT is fundamentally different than cardiopulmonary resuscitation for life support. Dr. Antommaria also fails to distinguish the experimental use of sex hormones in GAT for adolescents compared to the FDA approved usage of sex hormones as hormone replacement for hormone deficiencies (See also II.C.1).

205. The purpose of the American Heart Association's guideline is to restore normal "blood flow to vital organs" in order to "increase the likelihood of return of spontaneous circulation" (Topjian et al., 2020). In contrast to the restoration of normal function by the application of CPR, the purpose of the WPATH/Endocrine Society guideline for GAT is to intentionally disrupt normal endocrine function by generating the abnormal medical conditions of hypogonadotropic hypogonadism, hyperandrogenism, and hyperestrogenemia. It also advocates for the removal of healthy organs such as breasts, testicles, ovaries, penises, vaginas and uteruses in order to render these organs non-functional.

206. The purpose of chest compressions and the requirements of high-quality CPR are no different for adults compared to children and adolescents. The purpose of both are to "restore blood flow" to vital organs such as the heart and brain.[39] Likewise, what constitutes high-quality

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[39] Pediatric guideline:

> "High-quality CPR generates blood flow to vital organs and increases the likelihood of return of spontaneous circulation (ROSC). The 5 main components of high-quality CPR are (1) adequate chest compression depth, (2) optimal chest compression rate, (3) minimizing interruptions in CPR (ie, maximizing chest compression fraction or the proportion of time that chest compressions are provided for cardiac arrest), (4) allowing full chest recoil between compressions, and (5) avoiding excessive ventilation." (Topjian et al., 2020).

Adult guideline:

CPR (components such as proper rate and depth of chest compressions and avoiding overventilation) are the same in adults as they are in children and adolescents. Because the mechanisms of cardiopulmonary function are similar in adults and children it is logically inferred that the techniques used for CPR in adults will be fairly similar and have relatively similar effects in children and adolescents. Therefore guidelines of lower quality evidence in children and adolescents for CPR are acceptable because the purpose, what constitutes high quality CPR, and the ultimate outcomes are similar for both.

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

207. Dr. McNamara claims that "[t]he evidence shows that standard medical treatments for gender dysphoria improve mental health outcomes, including reducing rates of suicidal ideation and suicide attempts," (McNamara decl, p. 3, emphasis added). She goes on to say that "Defendants' experts have previously asserted that essential medical treatment for gender dysphoria causes suicide; however, no study has found a worsening of various mental health measures among recipients of essential medical treatment for gender dysphoria." (McNamara decl, p. 11). As shown below, Dr. McNamara is incorrect.

208. The most comprehensive study of GAT of its kind is from Sweden in 2011. The authors examined data over a 30-year time period (Dhejne, 2011). The Dhejne team made extensive use of numerous Swedish database registries and examined data from 324 patients in Sweden over 30 years who had taken opposite sex hormones and had undergone sex reassignment surgery. They used population controls matched by birth year, birth sex, and reassigned sex. When followed out beyond ten years, the sex-reassigned group had nineteen times the rate of completed suicides and nearly three times the rate of all-cause mortality and inpatient psychiatric care compared to the general population of Sweden.

209. The recent study published by Chen and Olson-Kennedy et al. confirms the inherent danger of gender affirmative therapy found in the Dhejne study. The New England Journal of Medicine recently published "Psychosocial Functioning in Transgender Youth after 2 Years of

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"For any cardiac arrest, rescuers are instructed to call for help, perform CPR to restore coronary and cerebral blood flow" (Panchal et al., 2020).

"A number of key components have been defined for high-quality CPR, including minimizing interruptions in chest compressions, providing compressions of adequate rate and depth, avoiding leaning on the chest between compressions, and avoiding excessive ventilation" (Id.).

Hormones," for which Dr. Johanna Olson-Kennedy is the principal investigator (Chen, Olson-Kennedy, et al., 2023). This arm of her study included 315 adolescents aged 12 to 20 years old who were taking high dose hormones of the opposite sex. The study was not randomized and had no control group. The authors report that 2 out 315 subjects died by suicide. The authors also report "The most common adverse event was suicidal ideation" in 11 subjects.

210. The death by suicide of 2 out of 315 subjects equates to approximately 317 suicide deaths per 100,000 patient-years. If we compare this figure to that of the UK's largest gender identity service, Tavistock, the "annual suicide rate is calculated as 13 per 100,000" patient-years (Biggs, 2021). The death-by-suicide rate was approximately 24 times higher in Dr. Olson-Kennedy's study compared to the much larger Tavistock Clinic. In fact, Professor Biggs reports that two of the four suicide deaths from the Tavistock data were of patients who were on the waiting list and "would not have obtained treatment" (Id.). This strongly suggests that the use of high dose opposite sex hormones in Dr. Olson-Kennedy's study was associated with a much higher death rate. NIH produced the consent forms related to this study pursuant to a FOIA request my colleague submitted. I have reviewed them and provided them to counsel for the Defendants. Unfortunately, of the many side effects of hormone therapy listed on the study's consent forms, death by suicide (or by any cause) is not listed and was not disclosed to participants.

211. Unfortunately, unlike the Dhejne study, the Olson-Kennedy study provides little other useful data about outcomes such as psychiatric hospitalizations, suicide attempts, or rates of comorbid psychiatric illness. These facts would be useful to know to determine how high-dose opposite hormones and gender affirmative therapy affect overall health and their association with death by suicide. All of the data collected to date in Dr. Olson-Kennedy's publicly funded study the "The Impact of Early Medical Treatment in Transgender Youth" should be released to the public so that other researchers and clinicians can determine how puberty blockers, opposite sex hormones, and mastectomy surgeries affect adolescent physical and mental health.

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

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

213. The initial reports of this study claimed that the authors found treatment benefits with surgery, and this was shared widely in the media. For example, ABC News posted an article titled "Transgender surgery linked with better long-term mental health, study shows" (Weitzer, 2019). An NBC news/Reuters headline reads: "Sex-reassignment surgery yields long-term mental health benefits, study finds" (Reuters, 2019).

214. However, after twelve authors from around the world (including our team) investigated the study in detail, a number of serious errors were exposed leading to a retraction (Kalin, 2020; Anckarsäter et al., 2020).

215. In our letter to the editor, which I co-wrote with former Chairman of Psychiatry at Johns Hopkins Medical School, Paul McHugh, MD, we noted key missing evidence in the original Branstrom report when compared to the previous body of knowledge yielded from the Swedish Dhejne study. We wrote that "[t]he study supports only weak conclusions about psychiatric medication usage and nothing decisive about suicidality. In overlooking so much available data, this study lacks the evidence to support its pro gender-affirmation surgery conclusion" (Van Mol, Laidlaw, et al., 2020).

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

217. In another letter to the editor, psychiatrist David Curtis noted that "[t]he study confirms the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex. However, the Branstrom study does not demonstrate that either hormonal treatment or surgery has any effect on this morbidity. It seems that the main message of this article is that the incidence of mental health problems and suicide attempts is especially high in the year after the completion of gender-affirming surgery" (Curtis, 2020).

218. In yet another critical letter, Dr. Agnes Wold stated that "[w]hether these factors involve a causal relationship (i.e., that surgery actually worsens the poor mental health in

individuals with gender dysphoria) cannot be determined from such a study. Nevertheless, the data presented in the article do not support the conclusion that such surgery is beneficial to mental health in individuals with gender dysphoria" (Wold, 2020).

219. While it is true that patients suffering from gender dysphoria have higher rates of suicidal ideation and completed suicide than the general population, studies have not shown that providing hormones reduces rates of suicide, and in fact those interventions may be associated with increased rates.

D. An Increase in Cases of Gender Dysphoria

220. Gender Dysphoria has been a relatively rare condition in children and adolescents. However there have been very significant increases in referrals for this condition noted around the globe.

221. For example, in the UK, "The number of referrals to GIDS [Gender Identity Development Service] has increased very significantly in recent years. In 2009, 97 children and young people were referred. In 2018 that number was 2519" (Bell v Tavistock Judgment, 2020). There is evidence that this increase may be in part due to social contagion and fueled by social media/internet use (Littman, 2018).

222. The French National Academy of Medicine wrote recently: "Parents addressing their children's questions about transgender identity or associated distress should remain vigilant regarding the addictive role of excessive engagement with social media, which is both harmful to the psychological development of young people and is responsible for a very significant part of the growing sense of gender incongruence" (SEGM, 2022).

223. In "a study of the Finnish gender identity service, '75% of adolescents [assessed] had been or were currently undergoing child and adolescent psychiatric treatment for reasons other than gender dysphoria' (Kaltiala-Heino, 2015). In fact, '68% had their first contact with psychiatric services due to other reasons than gender identity issues.' The same study also showed that 26% percent had an autistic spectrum disorder and that a disproportionate number of females (87%) were presenting to the gender clinics compared to the past" (Laidlaw in gdworkinggroup.org, 2018).

E. Desistance

224. Desistance is a term indicating that the child, adolescent, or adult who initially presented with gender incongruence has come to experience a realignment of their internal sense

of gender and their physical body. "Children with [gender dysphoria] will outgrow this condition in 61% to 98% of cases by adulthood. There is currently no way to predict who will desist and who will remain dysphoric" (Laidlaw et al., 2019; Ristori & Steensma, 2016).

225. Because there is no physical marker to diagnose gender dysphoria, and because it is not possible to predict which child or adolescent will desist, it is not possible to know which young person will remain transgender identified as adults. Also, because the rate of desistance is so high, gender affirmative therapy will necessarily cause serious and irreversible harm to many children and adolescents who would naturally outgrow the condition if not affirmed.

226. Dr. Shumer states "data and personal experience shows that children whose gender dysphoria persists into adolescence are highly likely to be transgender" (Shumer decl, p. 19). Similarly, Dr. McNamara states ""in contrast to prepubertal children, adolescents with gender dysphoria rarely find that their dysphoria resolves without [gender affirming] treatment" (McNamara decl, p. 22)." However, the statements of both physicians are contradicted by the evidence from the following studies.

227. Puberty, which pertains to the physical development of the reproductive tract, breasts, and associated secondary sex characteristics, can begin as early as age 8 in girls and age 9 in boys. The studies which have examined desistance involved adolescents and children aged twelve and under. For example, table 1 in Ristori and Steensma 2016 shows multiple studies involving minors. For the three most recent—Singh (2012), Wallien & Cohen-Kettenis (2008), and Drummond et al. (2008)—these involved age ranges from 3 to 12years old[40]. The desistance rate varied from 61 to 88%. Since the upper age was twelve this would include children in the age range of 8-12 years old, many of whom were already adolescents going through puberty based on

[40] "This study provided information on the natural histories of 25 girls with gender identity disorder (GID). Standardized assessment data in childhood (mean age, 8.88 years; range, 3-12 years)" (Drummond et al., 2008). "We studied 77 children who had been referred in childhood to our clinic because of gender dysphoria (59 boys, 18 girls; mean age 8.4 years, age range 5-12 years)" (Wallien et al., 2008). "Standardized assessment data in childhood (mean age, 7.49 years; range, 3–12 years) and at follow-up (mean age, 20.58 years; range, 13–39 years) were used to evaluate gender identity and sexual orientation outcome. At follow-up, 17 participants (12.2%) were judged to have persistent gender dysphoria" (Singh, 2012).

a knowledge of the ages of initiation of puberty and were therefore not pre-pubertal.[41] Therefore we can see that a high proportion of adolescents do in fact desist, contrary to what Drs. Shumer and McNamara have stated.

F. Mastectomy Surgery for Minors

228. Any serious look at long-term effects of surgical treatment would follow subjects out at least ten years. For example, an article was published recently examining patients who had mild calcium disorders due to a gland called the parathyroid. They compared a group of patients who had surgical removal of the parathyroid to a control group who had not. They examined data ten years after surgery was completed and concluded that parathyroid surgery in this group "did not appear to reduce morbidity or mortality" in that patient group (Pretorius, 2022).

229. To my knowledge there exists no comparable studies of minors with gender dysphoria comparing those who had mastectomy surgery to a control group who had not. There are also no known studies of minors followed for 10 years or more to determine the long-term risks and benefits of mastectomy for gender dysphoria.

230. Good quality studies specifically showing that mastectomy surgery is safe, effective, and optimal for treating minors with gender dysphoria do not exist. For example, there is a study titled "Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults Comparisons of Nonsurgical and Postsurgical Cohorts" (Olson-Kennedy, 2018). The study authors conclude that "[c]hest dysphoria was high among presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults." However, there are a number of problems with this study. First, the term "chest dysphoria" is a creation of the study authors and is not found as a diagnosis or even referenced in the DSM-5. Second the "chest dysphoria scale" is a measuring tool created by the authors, but which the authors state "is not yet validated." (*Id*., p. 435) Third, the mastectomies were performed on girls as young as 13 and 14 years old and who thereby lacked the maturity and capacity of good judgment for truly informed consent for this life altering procedure. For this reason, in my professional opinion, the research and surgeries performed were flawed and unethical.

[41] To my knowledge the desistance literature does not examine Tanner stages of puberty as part of their studies. However, one can infer based on the ages that many children had at least begun puberty (Tanner stage 2) or were at a more advanced stage of puberty.

231. There exists another poorly designed study which suffers from similar methodological and ethical problems as the Olson-Kennedy study. A 2021 study published in Pediatrics examined females aged 13-21 recruited from a gender clinic. Thirty young females had mastectomy procedures and sixteen had not. The average age at surgery was 16.4 years (Mehringer, 2021). The follow up time after surgery was only 19 months and no data is provided or analyzed about key psychiatric information such as comorbid psychological illnesses, self-harming behaviors, psychiatric hospitalizations, psychiatric medication use, or suicide attempts.

232. Information returned from the study surveys were all qualitative and included responses such as "[My chest dysphoria] made me feel like shit, honestly. It made me suicidal. I would have breakdowns". Another respondent stated, "I've been suicidal quite a few times over just looking at myself in the mirror and seeing [my chest]. That's not something that I should have been born with" (Mehringer, 2021). The omission of psychiatric data is a major flaw in the study and also irresponsible given the obviously dangerous psychological states that some of these young people were in.

233. Since such a high proportion of subjects were using testosterone (83%), some of the responses could be attributed to adverse effects of testosterone. For example, as related earlier, high dose testosterone can manifest in irritability and aggressiveness. One study subject responded, "I get tingly and stuff and it kind of makes me want to punch something" (Mehringer, 2022).

234. The testosterone labeling also indicates nausea and depression as adverse reactions which are described by another study subject "There's a feeling of hopelessness, of desperation, of—almost makes me feel physically sick" (Actavis Pharma, Inc., 2018; Mehringer, 2022).

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

G. Centers for Medicare and Medicaid Services

236. The Centers for Medicare and Medicaid Services ("CMS") has found "inconclusive" clinical evidence regarding gender reassignment surgery. Specifically, the CMS Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) (June 19, 2019) states: "The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population" (CMS.gov, 2016).

237. Dr. McNamara states that "the CMS did not reach any negative conclusion on the benefits of essential medical treatment for gender dysphoria for children and adolescents" (McNamara decl, p. 12). However, it does not make the converse true as Dr. McNamara seems to imply. In other words, the CMS review does not therefore mean that there is conclusive evidence of benefit and lack of harm for the under 65 population, including children and adolescents. On the contrary, evidence of benefit is lacking and the risks and harms due to GAT are very high as I have described.

H. Nations and States Question and Reverse Course on GAT

238. Dr. McNamara claims that "[i]nternational and national medical consensus supports the treatment of gender dysphoria" (McNamara decl, p. 2). The treatment she refers to is gender affirmative therapy as dictated by the "standards of care from WPATH and clinical practice guidelines from the Endocrine Society" (McNamara decl, p. 2).

239. However numerous nations are questioning and reversing course on the WPATH/Endocrine Society's low quality gender affirmative therapy guidelines. For example, in the *Bell v. Tavistock* Judgment in the UK, regarding puberty blockers in GAT, the court concluded that "there is real uncertainty over the short and long-term consequences of the treatment with very limited evidence as to its efficacy, or indeed quite what it is seeking to achieve. This means it is, in our view, properly described as experimental treatment" (*Bell v. Tavistock* Judgment, 2020, emphasis added). The case was appealed and although the medical decision making was returned to clinicians (rather than the courts), it was noted that great pains should be taken to ensure that the child and parents are properly informed before embarking on such treatments.

240. In the bulletin of the Royal College of Psychiatrists in 2021, in a reevaluation of the evidence, Griffin and co-authors write, "As there is evidence that many psychiatric disorders

persist despite positive affirmation and medical transition, it is puzzling why transition would come to be seen as a key goal rather than other outcomes, such as improved quality of life and reduced morbidity. When the phenomena related to identity disorders and the evidence base are uncertain, it might be wiser for the profession to admit the uncertainties. Taking a supportive, exploratory approach with gender-questioning patients should not be considered conversion therapy" (Griffin et al., 2021).

241. In 2020, Finland recognized that "[r]esearch data on the treatment of dysphoria due to gender identity conflicts in minors is limited," and recommended prioritizing psychotherapy for gender dysphoria and mental health comorbidities over medical gender affirmation (Council for Choices in Healthcare in Finland, 2020). Additionally, "[s]urgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors".

242. In 2021, Sweden's largest adolescent gender clinic announced that it would no longer prescribe puberty blockers or cross-sex hormones to youth under 18 years outside clinical trials (SEGM, 2021). "In December 2019, the SBU (Swedish Agency for Health Technology Assessment and Assessment of Social Services) published an overview of the knowledge base which showed a lack of evidence for both the long-term consequences of the treatments, and the reasons for the large influx of patients in recent years. These treatments are potentially fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis. This makes it challenging to assess the risk / benefit for the individual patient, and even more challenging for the minors or their guardians to be in a position of an informed stance regarding these treatments" (Gauffen and Norgren, 2021).

243. Dr. Hilary Cass "was appointed by NHS England and NHS Improvement to chair the Independent Review of Gender Identity Services for children and young people in late 2020" (The Cass Review website, 2022). In her interim report dated February 2022, it states that "[e]vidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and internationally" (Cass, 2022). This led to the shutting down of their Tavistock child gender identity clinic.

244. In the nation of Norway, a report from the Norwegian Healthcare Investigation Board (Ukom) was released in March of this year. The report found "there is insufficient evidence for the use of puberty blockers and cross sex hormone treatments in young people, especially for teenagers who are increasingly seeking health services and being referred to specialist healthcare.

Ukom defines such treatments as utprøvende behandling, or 'treatments under trial,' said Moen" (Block, "Norway", 2023).

245. In the State of Florida, effective March 6, 2023, the Florida Board of Medicine amended its "Standards of Practice for Medical Doctors" to include the following:

"64B8-9.019 Standards of Practice for the Treatment of Gender Dysphoria in Minors.

(1) The following therapies and procedures performed for the treatment of gender dysphoria in minors are prohibited.

(a) Sex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics.

(b) Puberty blocking, hormone, and hormone antagonist therapies."

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

VI. Conclusion

246. The gender affirmative therapy model suffers from serious deficiencies in logic and lacks scientific foundation. The deep error hidden in this model is that one cannot in fact change sex. One cannot acquire the deep characteristics of biological sex in order to gain the complete sexual and reproductive functions of the opposite sex. This is not technologically possible.

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

248. There are known risks from GAT for both adults and minors, some of which I have described above, including cardiovascular disease, cancer, deficiencies in ultimate bone density, harms to sexual function, infertility, and for some permanent sterility. The child or adolescent cannot consent (or assent) to these harms when they are not mature enough to fully comprehend what they mean. Long-term studies regarding the treatment effects specifically for minors with

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

249. WPATH's SOC 8 should not be followed by any physician, mental health care provider, or other medical professional.

250. For the reasons set forth above, in my professional opinion as an endocrinologist, no child or adolescent should receive puberty blockers to block normal puberty, nor should they receive supraphysiologic doses of opposite sex hormones to attempt to alter secondary sex characteristics, nor should they have surgeries to remove or alter the breasts, genitalia or reproductive tracts as part of GAT. There exists insufficient evidence of benefit, but serious concerns for risk of harm. Therefore, I believe that the Alabama Vulnerable Child Compassion and Protection Act is based on sound medical principles for the protection of minors.

Executed May 19, 2023

Michael K. Laidlaw, M.D.

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Endocrinology, Diabetes, and Metabolism
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Rocklin, CA 95677
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EMPLOYMENT

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

EDUCATION

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

LICENSURE

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

PROFESSIONAL AFFILIATIONS

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

HONORS AND RECOGNITION

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

RESEARCH AND PUBLICATIONS

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

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

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

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

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

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

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

2018 Publication – Laidlaw MK. "The Gender Identity Phantom". gdworkinggroup.org, 24 Oct 2018. http://gdworkinggroup.org/2018/10/24/the-gender-identity-phantom/

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

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

2011	Abstract – Poster presentation Nov 2011. Journal of Diabetes Science and Technology. A Video Game Teaching Tool for the Prevention of Type 2 Diabetes and Obesity in Children and Young Adults.
2011	Abstract – Journal of Diabetes Science and Technology. A Web-Based Clinical Software Tool to Assist in Meeting Diabetes Guidelines and Documenting Patient Encounters.
2008	Abstract - Accepted to Endocrine Society Annual Meeting 2008. Hypercalcemia with an elevated 1,25 dihydroxy-Vitamin D level and low PTH due to granulomatous disease.
2005-2006	Clinical Research - University of Southern California – Utility of Thyroid Ultrasound in the Detection of Thyroid Cancer. Study involving the use of color flow/power doppler ultrasound and ultrasound guided biopsy to detect the recurrence of thyroid cancer in patients with total thyroidectomies.
2005	Certification - Certification in Diagnostic Thyroid Ultrasound and Biopsy – AACE 2005
2003	Certification - Understanding the Fundamentals: Responsibilities and Requirements for the Protection of Human Subjects in Research. University of Southern California. 29 Sep 2003 - 29 Sep 2006
2002-2005	Clinical Research - University of Southern California - Determining the Role of Magnesium in Osteoporosis. Study involved collecting and analyzing patient data related to patient characteristics, laboratory results, bone mineral density exams, nutrition analysis, and genetic analysis in order to determine a link between magnesium deficiency and osteoporosis.
1996	Research Assistant - San Jose State University - Role of the suprachiasmatic nucleus pacemaker in antelope ground squirrels.
1995-1996	Research Assistant - San Jose State University/NASA. Acoustic tolerance test and paste diet study for space shuttle rats.

EXPERT WITNESS WORK AND AMICUS BRIEFS

2022-2023	Expert Witness – Laidlaw MK. United States District Court for the Northern District of Florida Tallahassee Division. AUGUST DEKKER, et al., Plaintiffs, v. SIMONE MARSTILLER, et al., Defendants. Case No. 4:22-cv-00325-RHMAF. Report October 3, 2022. Testified in court October 12, 2022. Expert Report February 17, 2023. Rebuttal March 10, 2023.
2022	Expert Witness Report – Laidlaw MK. C. P., by and through his parents, Patricia Pritchard and Nolle Pritchard; and PATRICIA PRITCHARD, Plaintiff, vs. BLUE CROSS BLUE SHIELD OF ILLINOIS, Defendants. Case No. 3:20-cv-06145-RJB

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

2022 Expert Witness Report #2 – Laidlaw MK. United States District Court for the District of Arizona. DH and John Doe, Plaintiffs, vs. Jami Snyder, Director of the Arizona Health Care Cost Containment System, in her official capacity, Defendant. Case No. 4:20-cv-00335-SHR. 24 Jun 2022. (Sealed under Protective Order).

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

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

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

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

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

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

2020 Expert Witness Report – Laidlaw MK. United States District Court for the District of Arizona. DH and John Doe, Plaintiffs, vs. Jami Snyder, Director of the Arizona Health Care Cost Containment System, in her official capacity, Defendant. Case No. 4:20-cv-00335-SHR. 27 Sep 2020.

EXHIBIT 7

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

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

PERSONAL

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

EXHIBIT 8

SUBMITTED UNDER SEAL

EXHIBIT 9

SUBMITTED UNDER SEAL

EXHIBIT 10

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

BRIANNA BOE, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
UNITED STATES OF AMERICA,	)	
	)	
Intervenor Plaintiff,	)	
	)	
v.	)	Civil Action No. 2:22-cv-184-LCB
	)	
HON. STEVE MARSHALL, in his Official capacity as Attorney General, of the State of Alabama, *et al.*,	)	
	)	
Defendants.	)	

EXPERT REPORT OF
ANGELA C.E. THOMPSON, M.D., MPH, FACOG

TABLE OF CONTENTS

1. My name is Angela C.E. Thompson. I am over the age of 19, I am qualified to give this declaration, and I have actual knowledge of the matters stated herein. I am a physician certified by the American Board of Obstetrics and Gynecology to practice within the specialty of Obstetrics and Gynecology. I am also a Fellow of the American College of Obstetrics and Gynecology. My professional background, experience, and publications are detailed in my curriculum vitae, which is attached to this report.

2. I have been retained by counsel for Defendants to provide an expert opinion on the fertility considerations of administering to minors gonadotropin releasing hormone agonists (GnRHa), colloquially known as "puberty blockers," followed by supraphysiological doses of cross-sex hormones. This report discusses (a) the medical evidence regarding the risks such treatment poses to healthy biological function; (b) whether children in early puberty can assent to such treatment; and (c) the prospects of experimental fertility preservation techniques in early pubertal children who undergo such treatment. I may wish to supplement my opinions or the bases for them as new research is published or in response to statements made in my area of expertise.

3. I have not provided expert testimony in the last four years.

4. If called to testify in this matter, I would testify truthfully and based on my expert opinion. I am being compensated at a rate of $350 per hour. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony that I provide.

I. Summary of Opinions

5. The prevailing literature describes "gender affirming care" in the following ways: 1) Gender affirming endocrine treatments (Hembree 2017 pg 3869); and 2) A process of intervention known as "gender affirmation" (Rafferty 2018 pg 5). It is my professional medical opinion that the current "gender affirming care" ("GAC") regimen, specifically the regimen that

administers Gonadotropin releasing hormone agonist (GnRHa) medication (colloquially termed "puberty blockers") at Tanner Stage 2 of puberty, followed directly by supraphysiologic cross sex hormones, creates an iatrogenic disease state in otherwise developmentally healthy children and young adolescents that continues into adulthood. ("Iatrogenesis" is defined as the creation of additional problems or complications resulting from treatment by a physician or surgeon (Dorland's 29th ed).) The iatrogenic risks of this regimen include: decreased bone density associated with a high risk of osteoporosis, loss of IQ and spatial memory that is not reversible, increased anxiety (seen in animal models (Biggs 2022 pg 11, 12)), and brain development (Bangalore Krishna 2019 pg 365) and fertility risks (Hembree 2017 pg 3880, Bangalore Krishna 2019 pg 365, WPATH 2022 16.1-16.), including permanent sterility (Harris 2020 pg 2454). The most severe risks include shortened life span as adults (de Blok 2021) and sterilization. In my professional opinion, the severe risks of this life-long iatrogenic disease state, for a condition with no physical locus within the body (Schwartz 2021, pg 1) are not outweighed by the regimen's unproven benefits (Byng 2019 pg 1, Griffin 2020 pg 5, Biggs 2022 LTE pg 668).

6. The purported benefits of GAC rely upon idiosyncratic views of "gender," which is not a medical term and has no agreed-upon meaning and is not observable in any clinical capacity. Gender has been used to describe social norms of male and female behavior, but it serves no physiologic function. As a result, the literature conflates phrases like gender dysphoria, gender incongruent, gender diverse, transgender, and gender questioning. Only gender dysphoria is a psychiatric diagnosis listed in the Diagnostic and Statistical Manual of Mental Disorders (DSM V). Simply identifying as transgender or any gender minority is not a pathological condition (i.e., it is not caused by or considered to be a disease).

7. Consequently, the GAC medicalized regimen creates actual physical pathology where none exists. Altering the body to such extremes has not been shown by any high-quality study or review of the literature to improve long-term mental health outcomes for vulnerable children and adolescents.[1] There is a well-recognized paucity of studies examining the use of puberty blockers and cross-sex hormones on children under 13.5 to 14 years of age (Hembree 2017 pg 3883), and even fewer studies involving children younger than 12 years of age (Olsen-Kennedy 2019 pg 3). This lack of data itself renders any assertion of GAC's benefits for these children highly speculative at best.

8. It is my professional opinion that children with gender dysphoria, gender incongruence, gender nonconformity, and those who identify as transgender, or any other gender

[1] Byng R, Bewley S (2019) *BMJ* 9;367:i6439 doi:10.1136/bmj.l6439; Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. *PLOS One* Feb 2021 https://doi.org/10.1371/journal.pone.023894;
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Pasternack I, Soderstrom I, Saijonkari M, Makela M. Medical Methods in the treatment of gender dysphoria related to gender variations. A systematic review. Helsinki 15.5.2019. www.summaryx.eu;
Council for Choices in Health Care in Finland (COHERE). Medical treatments for gender dysphoria that reduces functional capacity in transgender people-recommendation. 11 June 2020 www.palveluvalikoima.fi/en.

identity, should mature with their functional biological processes intact and without the introduction of iatrogenic risks to their capacity for healthy physiologic functioning, especially reproductive function. Gender dysphoria has no locus anywhere on the physical body, and GAC artificially *creates* a physical pathology where none existed, destroying the right of a child to develop with his or her functional bodily capacity intact. Moreover, because blocking puberty at the earliest signs of pubertal development (called Tanner stage 2) and then administering cross-sex hormones significantly risks future fertility (Klipstein 2020), GAC violates the child's right to an open future in which his or her future reproductive goals can be actualized (Harris 2020 pg 2259).

9. It is also my professional opinion that children and adolescents who undergo the current regimen of GAC do not have the developmental, intellectual, or emotional maturity to assent to the treatments. Nor do their parents have the ability to provide fully informed consent because there are no guidelines regarding fertility preservation for transgender individuals, and this confines the effectiveness of fertility counseling (Choi 2022 pg 10). Studies have shown that discussions surrounding fertility preservation even for children with cancer are underutilized and family satisfaction with the process is lacking (Klipstein 2020 pg 10); this also appears to be the case for fertility preservation counseling for children who are undergoing the medicalized GAC regimen. There are no clear guidelines or standard practices for fertility preservation counseling for transgender youth (Harris 2020 pg 2453). Fertility preservation counseling for transgender-identifying youth reveals varying degrees of understanding amongst parents and guardians (Harris et al. 2020 pg 2456), and less than 5% of transgender adolescents in one study accessed fertility preservation (Pang et al. 2020). Another study has shown that 35.9% of transgender and gender non-conforming adolescents were interested in biological parenthood, but that only 13.5% had

discussed effects of hormones on fertility (Cheng 2019 pg 12). The variance of what children and adolescents express about their future reproductive goals and actually receiving informed discussions about fertility and fertility preservation is very concerning, because it is well documented in the medical literature that potential risks of long-term exposure to hormones confers to the patient (or future offspring) are unknown (Cheng 2019).

10. All these data call into question how well the informed-consent process relays crucial facts about the permanent implications of GAC and the very limited, experimental options for "fertility preservation" available to young children and adolescents who undergo this regimen. There are *no* robust data that address fertility outcomes in these young patients for whom GAC began at Tanner stage 2. It is noted that "prepubertal transgender children may be forced to choose whether they want to experience permanent changes to their body associated with puberty or whether they want to transition and risk irreversible infertility" (Cheng 2019 pg 215). Up to 95% of transgender children undergoing medical treatment could experience permanent sterility (Harris 2020 pg 2462).

11. There are available, non-experimental fertility preservation technologies for use *after* natal pubertal transition is fully complete, and we do have some data regarding female patients who have taken testosterone *after* their female pubertal development was complete (Light et al. 2014). In contrast, the "fertility preservation" options for pre- and early pubertal children are still experimental. There have been only two live births *ever* reported for any female who underwent ovarian tissue cryopreservation prior to onset of menses. As for pre- or early pubertal males, any discussion regarding fertility preservation at Tanner stage 2 of puberty is purely theoretical, as the only data that currently exists regarding the possibility of achieving spermatogenesis from immature spermatogonal stem cells is from animal models (Ainsworth 2020

pg 786). Despite a long history of experimentation with trying to mature sperm from immature human testes cells or testicular tissue, this has not yet been developed in humans (Ibitsham 2020 pg 15). Because the GAC regimen at early pubertal development (Tanner stage 2) will almost certainly result in sterilization (there are no data providing any evidence to the contrary), and because the "fertility preservation" options for these children are inaccessible, experimental, and speculative, it is my opinion that any notion of informed consent to the risks of GAC at Tanner stage 2 is illusory.

12. In the absence of compelling data, the GAC regimen at early pubertal development (Tanner stage 2) constitutes a live experiment that significantly harms the physiologic functional capacity of healthy children and adolescents.

II. Qualifications

13. I received my medical degree from the University of Utah and my residency training in Obstetrics, Gynecology, and Women's Health at the University of Minnesota. I have a Master of Public Health degree from Yale University. I am Board Certified by the American Board of Obstetrics and Gynecology and am a Fellow of the American College of Obstetrics and Gynecology. My practice experience includes multispecialty group practice as well as academia. In addition to clinical care, I teach medical students and medical residents in the specialties of obstetrics and gynecology, family medicine, and emergency medicine.

14. I provide care, including medical and surgical care, for female patients at all areas of the reproductive life span, from early puberty to post-menopausal. My care has included: monitoring for gynecologic malignancies, endometriosis, painful menses (dysmenorrhea), abnormal uterine bleeding, uterine fibroids, endometrial polyps, pre-cancerous lesions of the cervix, menopausal symptoms, ovarian cysts, ovarian masses, infertility, polycystic ovary

syndrome, sexually transmitted infections, females with differences in sex development, and all aspects of pregnancy, birth, and postpartum care, including surgical care for gynecologic or obstetric emergencies. Currently, I concentrate my practice on caring for female patients in the hospitalized setting, providing care in the antepartum, intrapartum, and postpartum periods. I also perform surgical care for female patients with gynecologic or obstetrical emergencies. A significant proportion of the patients for whom I provide care do not have access to a personal physician/clinic for their obstetric or gynecologic care.

III. Medical Organizations Normally Treat Concerns of Sterilization Seriously—But Not When It Comes to Transgender Youth

A. ACOG

15. I have treated patients who identify as transgender in the context of pregnancy and birth. My experiences caring for pregnant patients who identified as transgender led me to seek guidance from the American College of Obstetrics and Gynecology (ACOG), as there is a dearth of literature on this specific subject. I have trusted ACOG since I was a medical student, and much of my practice is based on their clinical guidance. The time I began seeking this information also coincided with the reports from the UK, where the Gender Identity Development Service (GIDS) at the Tavistock and Portman NHS Trust was being sued by a young patient named Keira Bell (*Bell and Mrs. A v. The Tavistock and Portman NHS Foundation Trust*, 2020). I had not been aware that minors were allowed to undergo medicalization and surgery to alter their physical bodies in an attempt to provide aesthetic congruence to match the opposite sex. I read an interim board report from June 2015 and learned from the data that natal female patients actually had worse mental health after one year on puberty blockers than at baseline (an increase in the statement "I deliberately think about harming or killing myself") (The Tavistock and Portman

NHS Foundation Trust 2015). This shocked me because the justification for initiating this medicalized pathway was to improve psychological functioning.

16. At this same time, I read the ACOG Committee Opinion number 685, entitled "Care for Transgender Adolescents," which was published in January 2017 and reaffirmed in 2020 (ACOG Committee Opinion No. 685, withdrawn 2021). The document favorably discussed medicalization of transgender minors with gonadotropin releasing hormone agonists (GnRHa) and supraphysiologic doses of testosterone, even as it noted that "there is a concern that testosterone may cause future damage to ovaries and, thus, lead to infertility." It also recommended invasive, irreversible procedures such as bilateral mastectomies (which the document called "top surgery") and other procedures (labeled "bottom surgeries"), such as hysterectomies (removal of the uterus), oophorectomies (removal of the ovaries), and phalloplasties (the surgical creation of the facsimile of a penis from skin and soft tissue removed from either the forearm or the thigh of a female patient). (ACOG Committee Opinion No. 685, withdrawn 2021). ACOG's recommendation of these serious, life-altering procedures seemed to me to be at variance with the vast majority of ACOG documents published on surgical interventions, which recommend caution and safeguarding, especially in regard to fertility preservation in minors. As an example, a gynecologic pathologic condition with known physical locus is endometriosis, which is known to be the leading cause of secondary dysmenorrhea (pain during menstrual periods) in adolescents. According to ACOG, the goals of therapy for this condition include symptom relief, suppression of disease progression, and *protection* of future fertility, with the committee opinion specifically stating that "adolescents with endometriosis should not be treated with oophorectomy [removal of the ovaries] or hysterectomy [removal of the uterus]." (ACOG Committee Opinion No. 760, reaffirmed 2021).

17. ACOG has written extensively about the harms of medical abuse in the form of coercion and sterilization of vulnerable women. It was therefore alarming to read about the treatment of adolescents who identify as transgender involving invasive and often irreversible sterilizing interventions for a condition that does not carry a medical diagnosis. (The document did not mention gender dysphoria, and identifying as transgender is not a pathological condition.) The ACOG Committee Opinion "Sterilization of Women: Ethical Issues and Consideration" expressly and strongly cautions against treating sterilization lightly: "The suggestion that few protections are needed has been met with deep concern from many reproductive justice advocates, who remain worried about the potential for sterilization abuse of low-income women, women of color, or other disadvantaged women." (ACOG Committee Opinion No. 695, reaffirmed 2020). The opinion also emphasizes that full cognitive maturation, including the capacity to incorporate long-term goals into complex decisionmaking, is not reached until the mid-20s. Importantly, the opinion highlights concerns with the counseling process for *adult* women seeking permanent sterilization.

18. There is an egregious history in the United States of sterilizations being performed on disadvantaged and vulnerable women, and the counseling procedures for this intervention have been called into question. As recently as 2006-2010, 140 incarcerated women in California were sterilized; many of the women reported significant pressure from prison and hospital medical personnel to undergo the sterilization procedure (ACOG Committee Opinion No. 695, reaffirmed 2020).This occurred even *after* the US Department of Health, Education, and Welfare developed protective regulations in 1976 for Medicaid-funded women to prevent further coercive or non-consensual procedures by *prohibiting the sterilization of women younger than 21 years old* and of women with a mental disability. The regulations also required waiting periods before the consent is obtained and the procedure performed (ACOG Committee Opinion No. 695, reaffirmed 2020).

19. It is well established that sterilization for a woman under 30 years of age leads to a 20.3% probability of regret (measured to 14 years from the procedure), compared to a rate of 5.9% for women who are 30 or older when they are sterilized (ACOG Practice Bulletin No. 208, 2019). Women under age 30 are also up to 8 times more likely to undergo procedures to try to reverse sterilization compared to women 30 and older (ACOG Committee Opinion No. 695, reaffirmed 2020). The likelihood that women sterilized between the ages of 18-24 will request sterilization reversal is 40.4%. Males who undergo vasectomy at young ages are also more likely to have the procedure reversed than those who had the procedure performed at older ages (ACOG Practice Bulletin No. 208, 2019). These documents from ACOG do not even mention sterilization in anyone under 18 because it is uniformly not recommended in every clinical scenario—except, it now seemed, when it pertained to adolescents who identified as transgender.

20. Because of the stark contrasts between the Committee Opinion 685 and the other ACOG documents recommending safeguards around the procedure of sterilization, I communicated my concerns to ACOG Clinical members about this document in January 2021. On February 6, 2021, I submitted to ACOG the Board Papers from the Tavistock and Portman NHS trust from 2015, which on page 53 reveals the data that the mental health of young female adolescents worsened after administration of GnRHa. In March 2021, the ACOG Committee Opinion 685 document was withdrawn and replaced with a new one, Committee Opinion 823, "Health Care for Transgender and Gender Diverse Individuals," (ACOG Committee Opinion No. 823, 2021) which does not specifically address patients still in the developmental phase of adolescence.

B. WPATH and Endocrine Society

21. After this experience, I began to read the evidence base for gender affirming care to treat gender dysphoria in minors. The studies done by the Dutch and the British had used chronological age (minimum of age 12) to determine when to use puberty blockers (de Vries 2011 pg 2278, Table 1; Carmichael 2021), rather than stages of pubertal development. However, in 2017, the Endocrine Society issued guidelines to use Tanner stage 2 of pubertal development, rather than chronological age, as the determining factor to start puberty blockers (Hembree et al. 2017 section 2.2). The World Professional Association for Transgender Health (WPATH) standards of care (SOC 7) also recommended young people could start puberty blockers after they had reached at least Tanner stage 2 of pubertal development (WPATH 2012). The current WPATH guidelines, SOC 8, have *no* minimum age limit for hormonal or surgical interventions to transition a minor.

22. The shift from using chronological age (an average of 13 years in the Amsterdam Clinic study and 12 years in the Tavistock study) to Tanner stage 2 of pubertal development to time GnRHa administration concerned me because the gametes of both males and females are not fully mature at Tanner stage 2 of physiologic development. That means that the discussion about "fertility preservation" is largely academic, not a clinical reality, because the technological capacity for maturing gametes from a child or young adolescent at Tanner stage 2 is only available in experimental, highly specialized onco-fertility centers for females, and it has not been demonstrated in males outside of animal models.

23. Tanner stage 2 is when breast buds start to develop in females and when slight scrotal enlargement occurs in males; this can occur as young as age 8 in female children and 9 in male children (Olson-Kennedy et al. 2019). Gametes are usually mature (termed spermarche in

males and menarche in females, for whom the phase of development is manifested by menstruation) by Tanner stage 4 of clinical pubertal development (Emmanuel and Bokor 2022). Use of Tanner stage 2 belies the frequent claim that "children (as opposed to adolescents) are not treated with puberty blockers"; the American Academy of Pediatrics defines childhood as ages of 2-12 years. (Hardin et al. 2017).

24. Moreover, while puberty blockers are oft-cited as merely a "pause button," in clinical practice they seem to be a gateway to cross-sex hormone use by crystallizing gender dysphoria as a first step on a cascade of interventions (Griffin et al. 2020 pg 5), with suppression of puberty becoming a "self-fulfilling prophecy" (Biggs 2022 pg 5). This is also reflected in the data from the Dutch clinicians, as well as the experience of the Tavistock clinic in London. (Biggs 2022 pg. 5). Yet WPATH advocates beginning to transition 8 or 9 year-old children at the first signs of puberty, and the current WPATH document has no age limits to when medicalized or even surgical intervention might be able to occur.

IV. Biological Development: A Necessary Underpinning for Understanding How Fertility Preservation Techniques Work

25. Gender does not exist in the body or in any bodily structure or process; it is not assigned at birth. The phrase "gender assigned at birth" is a misnomer. This is in contrast to sex, which has observable characteristics that can readily be observed. The external phenotype correlates over 99.98% of the time with the individual's internal reproductive pathways and gametes (Sax 2002). What this means is a newborn infant observed to have a penis and scrotum is male; if there is a vulva, the baby is female. A physician is not needed to "assign" the sex of a newborn child; mothers easily observe the sex of their children at birth and have done so for centuries, before the medical establishment inserted itself into the birth process. Very rarely, there are differences in sex development observed; in such rare cases, the sex can generally be known

with use of chromosomal analysis and non-invasive imaging procedures. It is important to understand that individuals who are diagnosed with differences in sex development are still determined to be female sex or male sex.

26. The following discussion conveys the facts of human development and physiologic processes which are undermined at key pathways of healthy bodily function when the current regimen of GAC is administered at Tanner stage 2 of pubertal development. It is necessary to review physiologic development in order to explain how disruptions in this process by GnRHa and supraphysiologic exogenous sex steroid administration leads to a disease state[2] in the developing juvenile human in nearly every organ system, including the reproductive system, where it renders the juvenile human sterile. Especially for children younger than 12 (Olson-Kennedy et al 2019) there is a dearth of research (Mahfouda et al 2017) to inform evidence-based practice for use of puberty suppression; as such, this practice remains experimental.

27. *First*, I will discuss embryonic development and the process of sex differentiation. *Second*, I will discuss normal childhood and pubertal development and how the use of GnRHa as well as supraphysiologic hormone administration disrupts healthy biological processes by inducing a disease state in these children and adolescents. *Third*, I will discuss the realities about fertility preservation techniques and the significant limitations to implementation and practice. *Fourth*, I will respond to the claims made by Plaintiffs' experts. *Last*, I will discuss how attempts to represent GAC as the "standard of care" (Coleman et al. 2022) are disingenuous since GAC is based on poor evidence, violates a minor's right to an open future with reproductive potential, and constitutes a live experiment on vulnerable children and adolescents who are diagnosed with

[2] Disease is defined as any deviation from or interruption of the normal structure or function of a part, organ, or system of the body as manifested by characteristic symptoms and signs; the etiology, pathology, and prognosis may be known or unknown. (Dorland's 29th ed.)

gender dysphoria or otherwise identify as gender incongruent, gender non-conforming, transgender, nonbinary, or another gender minority.

A. Embryonic Development

28. Humans belong to the mammalian clade of the animal kingdom. Mammals reproduce sexually by internal fertilization and give birth to living progeny which use mammary glands for nutrition. The organization of mammalian species is divided between those with sessile, large gametes (female) and small mobile gametes (male). Reproduction in mammals is binary.

29. In order to generate a human embryo, fertilization must occur. Fertilization is the process by which a haploid (i.e., containing one set of unpaired chromosomes) female gamete (ovum, 23 X) is fused with a single male gamete (spermatozoan, 23 X or 23 Y); the two gametes exchange genetic material to restore the diploid (or complete, 46 XX or 46 XY) set of chromosomes, half from the male and half from the female. If this is successful, the fertilized ovum will undergo a series of divisions, the first of which is the zygote. The zygote contains its own unique combination of genetic material in equal parts from each parent; it is unique. It has the genetic potential for further development into a live birth so long as the combination is compatible with development into the zygotic stage and the later processes of embryonic and fetal development are not disrupted.

30. A series of mitotic divisions ("mitosis" is the division of one cell into two cells with the same genetic components) in the successfully created zygote continues to occur, and is now called a blastocyst. The multi-cellular blastocyst travels from the fallopian tube into the uterine cavity where it is able to implant. Implantation into the uterine cavity occurs approximately 6-12 days post fertilization. If any developmental process prevents implantation, the mammalian human embryo will not be able to survive and will cease to develop.

31. If the blastocyst implants successfully, further developmental processes of the embryo can continue—provided no interruption occurs. This period of embryonic development is known as organogenesis. In this stage of development, all the "blueprints" from the primordial germ cells have the potential to create the developmental pathways from which all organ systems develop.

32. Sex differentiation occurs during organogenesis. This process starts with germ cell migration. The germ cells that will differentiate into the gametes are found in the primitive endoderm within the yolk sac of the human embryo beginning at the 3rd week post fertilization. An embryo with the XX sex chromosome complement is female, and those with XY are male; this is determined at conception. The germ cells migrate along the dorsal mesentery of the hindgut arriving at the primitive gonads at the 5th week and invade the genital ridges in the 6th week of development (Langman's Embryology 8th ed 2000, Lippincott; Langman's Embryology 15th ed 2024, Wolters-Kluwer).

33. If the germ cells do not arrive at the site of the gonadal ridge, the gonads will not develop. These germ cells are the direct precursors to the gametes (spermatogonia in the genetic male embryo and the oogonia in the genetic female embryo). The gametes are unique from the rest of the somatic (body) cells, because they undergo a specialized type of cell division called "meiosis."

34. Meiosis is an intricately timed process and is unique to male and female gametes because the process allows the chromosomes from each parent to combine and generate a new human zygote once the developmental process of sexual maturity is reached. The function of this process is to ensure propagation of the species. In the female, the process of gametes undergoing meiosis starts well before birth; in the male, the gametes do not enter meiosis until the pubertal

transition. As I will detail in later sections, this process has extremely important implications for fertility and fertility preservation in both females and males.

1. Female Sex Developmental Pathway

35. Once the germ cells reach the gonad of the genetic female, they have an inductive influence on the development of the gonad into the ovary. The surface epithelium of the ovary continues to proliferate and penetrate the mesenchyme, and will eventually surround one or more germ cells. The germ cells will differentiate into oogonia, and the epithelial cells will become the follicular cells. By the end of the 3rd month post fertilization, the oogonia are arranged in clusters surrounded by a single layer of flat epithelial cells. The majority of the oogonia germ cells continue to divide by mitosis, but some will undergo meiosis.

36. By the end of the 7th month, nearly all of the oogonia that have entered meiosis have undergone natural degradation (atresia) except for a few near the ovary surface. The oogonia which start the process of meiosis are called the primary oocytes and are considered to be in meiosis prophase 1. The primary oocyte, surrounded by the flat epithelial cells, is called the primordial follicle.

37. Near the time of birth, the primary oocytes' DNA is "arrested" in a phase of meiosis prophase 1 known as "diplotene." The granulosa (follicular) cells surrounding the oocyte keep the oocyte in this arrested development phase until puberty by secreting a small protein called oocyte maturation inhibitor.

38. Once in the diplotene stage, the primary oocytes enter a long period of resting/quiescence before and beyond birth. The total number of primary oocytes present at birth are approximately 600,000-800,000. Approximately half of these primary oocytes are lost due to natural degeneration during childhood, leading to approximately 400,000 remaining at the start of

puberty. Only a small percentage of primary oocytes will be ovulated during the female's reproductive lifetime (Langman's 2000, 2024).

39. In females, primary oocytes have already started the process of meiosis (which is then arrested up until puberty) before birth; thus, they are *potentially* capable of maturation. Importantly, the surrounding follicular cells of the primary oocyte—which are essential for fertility—do not mature *until* the pubertal transition when menarche (also called menstruation) occurs. These facts have implications for fertility preservation techniques, which I will describe later in the report.

40. In the absence of the Y chromosome, the development of the female internal ductal development and external urogenital system continues into fetal development. By the beginning of the 4th month post fertilization, the Mullerian, (also called paramesonephric) internal ductal system (the uterus, fallopian tubes, cervix, and upper third of the vagina) are complete. By 20 weeks post fertilization the external labia, clitoris, and lower portion of the vagina are developed from the urogenital sinus, as is the vulva, which is observed at birth.

2. Male Sex Developmental Pathway

41. Embryos with XY chromosome complements have a similar timeline of sexual differentiation during the period of organogenesis, with a few key differences.

42. The germ cells invading the gonadal ridge will develop into testes if the SRY (testis determining factor) is present on the short arm of the Y chromosome. The gene product of the SRY gene is a transcription factor that helps express genes that encode for a protein called "MIS," or Mullerian inhibitory substance (also referred to as "anti-Mullerian hormone" or AMH), as well as the hormone testosterone (Langmans 2000, 2024). Cells supporting the germ cells in the male embryo are developed from the adjacent mesenchymal and epithelial cells. Fetal *Leydig* cells develop from the mesenchyme and the *Sertoli* cells develop from the surface epithelium. The

Leydig and Sertoli cells are very important for the development of the male in many ways. They ensure testosterone is present locally during the organogenesis of the genitourinary system in the male, and provide nutrition and support for the immature germ cells that will eventually become sperm in the male adult.

43. The fetal Leydig cells begin to secrete testosterone at eight weeks of embryonic development. The Sertoli cells secrete a hormone called androgen binding hormone. Testosterone in its active form, dihydrotestosterone, is required for the virilization of the external male genitalia (scrotum and penis). Localized testosterone produced by fetal Leydig cells as early as 8 weeks ensures virilization will continue throughout in utero development.

44. The sertoli cells secrete mullerian inhibitory substance (MIS), also known as anti-mullerian hormone (AMH). MIS/AMH hormone causes the regression of the paramesonephric ducts, meaning the female internal reproductive organs do not develop in the male embryo. The mesonephric ducts will then develop into the ducts that comprise the vas deferens and epididymis.[3]

45. The germ cells that migrate to the genital ridge in the male embryo become spermatogonia. They are present at birth in their immature form and will remain immature until puberty occurs. That is, they have not yet started the unique cellular division known as meiosis. This is in contrast to the oocytes in the female, which have already started the early stages of the part of cellular division called meiosis and are arrested at this developmental phase until ovulation occurs at puberty. Unlike the oocytes, the spermatogonia still must undergo a series of mitotic divisions before they are ready to undergo meiosis and thus before they are mature. The maturation of the diploid spermatogonia into the haploid mature spermatozoa is a very complex process and

[3] There are very rare genetic conditions in which there is incomplete expression of these genes responsible for sexual differentiation, but these children still develop along the male or female pathway depending on other factors important for the differentiation of the urogenital system.

it can only be confirmed with certainty to have occurred during male puberty at the period of spermarche. Spermarche is the male corollary to menarche in the female. These processes occur in late pubertal development, usually at Tanner stage 4 (Emmanuel & Bokor 2022). ***Thus, at Tanner stage 2 in the male, gametes are still not mature***. This fact has extremely important implications for fertility and fertility preservation, as discussed later in this report.

B. Childhood and Pubertal Transition

46. In the previous section, I outlined the embryonic developmental stages of development as it pertains to sexual differentiation in the male and female embryo, continuing into the fetal developmental stage. Once the fetus has delivered and is now in extrauterine life (i.e., is outside the uterus), further growth of the neonate into infancy, childhood, and during the pubertal transition is also susceptible to disruptions in physiological processes which can harm the developing human.

47. Once the separation from the maternal and placental estrogen and progesterone occurs at birth, the baby experiences a sudden decrease in maternal hormones. This sudden loss of the maternal hormones will prompt the hypothalamus of the baby to release GnRH. GnRH will cause the pituitary gland to release Luteinizing Hormone (LH) and Follicle Stimulating Hormone (FSH). These hormones will then cause the ovaries in the female baby to produce estradiol; in the male baby, these hormones will cause the testes to produce testosterone. The result of this process is a very short period of estradiol increase in the female infant and testosterone increase in the male infant. This transient rise in estradiol and testosterone in infants rapidly signals back to the hypothalamus in the brain to stop release of FSH/LH; that, in turn, reduces the estradiol (in the female) and testosterone (in the male) to very low levels until about 6-8 years in childhood. This period is not well understood but is postulated to 'set' the hypothalamic/pituitary/gonadal

communication that is important for later pubertal transition (Speroff & Fritz 2005). Once nighttime pulsatile secretion of GnRH starts to occur between ages 8-13 in females and 9-14 in males, the very earliest pubertal transition has begun.

48. Gonadotropin Releasing Hormone (GnRH) is a small protein hormone. It is known as a neurohormone because it is made in the part of the brain called the hypothalamus, connecting it to the hormone gland called the pituitary by a delicate network of blood vessels called the hypophyseal circulation. When GnRH is released by the hypothalamus, it lasts only 4-8 minutes before it undergoes degradation (its half-life is 2-4 minutes). Because of GnRH's short half-life and dilutional effects that the circulation has on GnRH's concentration once released, control of the reproductive cycle depends on a constant release of GnRH. To achieve this, the arcuate nucleus of the hypothalamus releases GnRH in a pulsatile fashion, the critical range of GnRH in the circulation being very narrow.

49. Once out in the hypophyseal circulation, GnRH reaches the anterior pituitary gland and binds to cells in the pituitary called gonadotropes. The immediate effect of this binding is the release of LH and FSH from the gonadotrope cells. LH and FSH are also released in a pulsatile fashion just like GnRH.

50. Once at the level of the ovary, the LH and FSH hormones (also referred to as gonadotropins) act on the Theca and Granulosa cells respectively, which are cells supporting the primary oocytes in the female ovary. At the level of the testes, gonadotropins act on the Leydig and Sertoli cells supporting the male immature spermatogonia. In females, these hormones cause the release of estradiol. In males, these hormones cause the release of testosterone. During early puberty, the communication between the hypothalamus, pituitary, and gonads starts to develop and mature; this process takes several years during pubertal transition.

51. Recall that primordial follicles in the human ovary are present before birth and consist of an oocyte ("arrested" in the diplotene stage of meiosis I) and a single layer of flat granulosa cells which support the oocyte. Primordial follicles that number in the millions during mid-gestation naturally reduce to approximately 400,000 at the beginning of puberty. The primordial follicles are in a consistent state of turnover and natural cell death called apoptosis, which continues throughout the entire lifespan of the female.

52. Once early pulsatile release of FSH occurs during puberty, the follicle destined to ovulate is "rescued" from natural cell death; the "fate" of the primordial follicle is apoptosis (natural cell death) unless it is able to be "rescued" from this natural process with the increase in FSH during puberty. The mechanism determining which primordial follicles will be "rescued," and thus progress to become the dominant follicle destined for ovulation, is not known. It is postulated that the follicle is "singled out" for this process by a combination of "readiness" in the microenvironment of the ovary, and appropriate levels of increased FSH in circulation (Speroff and Fritz, 2005).

53. The primordial follicle that first responds to the FSH "signal" to grow is the follicle destined to ovulate. In this process, the oocyte increases in size, and the granulosa cells surrounding the primary oocyte change from flat to cuboidal and increase in number. Intricate channels called gap junctions begin to develop between the granulosa cells and the oocyte. These gap junctions are very important, because they allow nutrients and molecular signals to "pass," which help grow and sustain the oocyte as well as mature the granulosa cells. The continued growth of the oocyte and the maturation of the granulosa cells are dependent upon the signals between these cells.

54. Under continued influence of FSH, the dominant follicle becomes surrounded by the fluid present in the spaces between the granulosa cells, and a fluid-filled cavity forms. The

granulosa cells surrounding the oocyte within this cavity are called the cumulus oophorus. The theca cells are adjacent to the granulosa cells in the ovary. The FSH receptors on the granulosa cells, and the LH receptors on the theca cells, allow these cells to respond to these hormones. The theca cells secrete androstenedione and testosterone (from the precursor cholesterol) which is then aromatized to estradiol by the granulosa cells. The amount of estradiol produced is dependent on the number of FSH receptors on the granulosa cells. Uterine blood flow rises sharply with elevated estrogens during this phase, providing evidence of a physiological role of estrogens in vasodilation, which help sustain the pregnancy if fertilization occurs by providing a physiologic mechanism by which the pregnancy receives adequate oxygenation and nutrition from placental circulation (Li Y et al 2021, Bai J et al 2020).

55. The increase in estradiol from the granulosa cells in response to FSH ultimately causes a large increase in LH several hours before the dominant follicle undergoes ovulation. The estradiol and progesterone levels are at their peak at this time (progesterone is secreted by the corpus luteum in the ovary), and organize the endometrium to prepare for pregnancy. If fertilization does not occur, the corpus luteum will fail to be "rescued" from programmed cells death, which in turn causes estrogen and progesterone levels to fall; uterine lining is then shed in response to the progesterone withdrawal, and the shedding of the endometrial lining of the uterus that ensues is recognized as menstruation. ***Notably, the maturation of the supporting follicular cells to create the cumulus oophorus, and thus the dominant follicle that is capable of being ovulated, only occurs during puberty.***

56. In males, the gametes themselves can mature only with puberty because the germ cells have not yet entered the cellular division of meiosis (unlike the primary oocytes); this process is dependent on LH and FSH release after GnRH signals the Leydig and Sertoli cells to mature the

spermatogonia into primary spermatocytes. Type A spermatogonia undergo mitosis and become primary spermatocytes; after a prolonged prophase of about 22 days, these cells will then enter, and rapidly complete, meiosis I and form secondary spermatocytes. Secondary spermatocytes complete meiosis II and form spermatids. Spermatids are now haploid and able to undergo spermiogenesis and mature spermatozoa. These mature spermatozoa enter the lumen of the seminiferous tubules and gain motility in the epididymis. The process of maturing a spermatogonia into a spermatozoan takes approximately 64 days.

57. In general, the first sign of puberty is an acceleration of growth followed by either breast budding (thelarche) in females or increase in scrotal size in males. Sometimes adrenarche (axillary and pubic hair) occurs prior to breast budding but often occurs two years after thelarche. Menarche (the onset of the shedding of the endometrial lining, or menstruation) is a late event in the pubertal transition in females, occurring after the peak of growth has passed—2 years on average after thelarche when breast development is Tanner stage 4. In the United States, the average age of menarche has been 12 years for over three decades.

58. Spermarche in males is the equivalent of menarche in females and occurs at Tanner stage 4 of physical pubertal development (Emmanuel and Bokor 2022). Tanner stage 2 of pubertal development occurs as early as age 8 in female children and age 9 in male children (Olson-Kennedy et al. 2019). The American Academy of Pediatrics defines childhood as between 2 and 12 years of age (Hardin et al. 2017).

V. Effects of Puberty Blockers on the Developing Child and Young Adolescent

59. The mechanism of action of GnRH agonists—"puberty blockers"—ultimately prevents the release of gonadotropin hormones LH and FSH from the pituitary gland, when administered continuously. This action prevents these hormones from acting in the ovaries in

females and the testes in males, ultimately preventing the release of estradiol and testosterone, respectively. ***If administered at Tanner stage 2, before gametes are mature, continuous administration of GnRHa makes the full maturation of the gametes impossible***.

60. A concern with the use of puberty blockers in female children before menstruation has begun is the fact that the menstrual cycle can be used as a "vital sign," and aberrations to the cycle can be a sign of underlying physiologic disease (ACOG Committee Opinion 651, reaffirmed 2020).This shows that there are other consequences to the healthy physiological development of female children when menstrual cycles are stopped before they even begin.[4]

61. There are also potential risks to children and young adolescents who have differences of sex development (DSD, also referred to by many as intersex) who receive GnRHa drugs. Such drugs can mask conditions that sometimes are diagnosed only during the pubertal transition.

62. GnRHa are used at times to alleviate symptoms due to physical gynecologic conditions in female adults, such as endometriosis and uterine myomas. Risks of GnRHa in adult females include hot flushes, headache, mood changes, vaginal dryness, joint and muscle stiffness, depression, and bone loss (Speroff & Fritz 2005). These same risks and side effects are present in a child taking this drug, in addition to other known and unknown risks.

63. Adult females using this medication for the aforementioned conditions are limited to 6 months duration of treatment. Importantly, during treatment with GnRHa adult women are prescribed either estrogen or progestogen (or both) to "add back" what the GnRHa medication has caused their body to stop producing physiologically. This "add back" hormone therapy is used to

[4] "It is imperative to communicate with patients and their caregivers the need for the first menstrual period as an indicator of typical pubertal development." (ACOG Clinical Consensus No 3 Sept 2022: General Approaches to Medical Management of Menstrual Suppression, pg 536.)

prevent cortical bone loss, for instance. The amount of bioavailable estrogen circulating in the blood is the most consistent predictor of bone density in men and women (Speroff and Fritz 2005, pg 369). Children receiving GnRHa for gender affirming care at Tanner stage 2 can potentially go years without receiving any hormonal support during the only time in their lives in which cortical bone mass would otherwise be maximized during physiologic development. Thus, this group of children is especially vulnerable to long term deficits in bone health, and knowledge gaps remain for this cohort (Klink 2015 pg 274).

64. While puberty blockers are often described as a "pause" that can be stopped at any time, in clinical practice, nearly all adolescents (98%) who begin GnRHa as part of gender-affirming care will go on to be prescribed cross-sex hormones (Carmichael 2021; de Vries 2011; Biggs 2022).

65. ***This pathway is significant because when the administration of GnRHa arrests gametes in normal pubertal development at Tanner stage 2, and then high-dose cross-sex hormones are administered (without a gap between administration of the GnRHa and cross-sex hormones), then, based on what we know of physiological development, there is no way for the gametes to ever mature***. In other words, if a child begins puberty blockers at Tanner stage 2, as recommended by WPATH and the Endocrine Society, and then moves on to cross-sex hormones without a gap in "care," he or she can risk permanent sterility.

66. Authors of several papers have indicated that the GAC regimen when initiated at Tanner stage 2 of puberty will lead to permanent sterility (Harris 2019; de Nie 2022). Regarding male children specifically, de Nie states on p. 298: "A complicating factor for contemporary fertility preservation in transgender female [i.e., natal male] adolescents is the requirement of complete spermatogenesis, which only develops from Tanner 3 onwards. ***If puberty suppression***

is started in Tanner stage 2, full spermatogenesis is usually not present yet and therefore preservation of spermatozoa is not possible." (Emphasis added.)

67. In females who identify as transgender men, there are isolated reports in the literature of adults who have carried pregnancies and given birth (Light et al. 2014); however, the regimen they received is not well known (Moravek et al. 2020). There are no fertility data I am aware of for females who received GnRHa at Tanner stage 2 of puberty, followed by cross sex hormones.

VI. Effects of Supraphysiologic Doses of Testosterone in Females

68. Total testosterone levels in reproductive age females typically range between 20-80 ng/dL (Speroff and Fritz, 2005). There are medical conditions in which the testosterone levels are higher than physiologic values. The most common condition of hyperandrogenism is a poorly understood condition called polycystic ovary syndrome (PCOS) (ACOG Practice Bulletin No. 194, 2018).

69. PCOS is a complex disorder characterized by hirsutism/hyperandrogenism, insulin resistance, and ovulatory dysfunction (most often clinically recognized as irregular periods of uterine bleeding due to the absence of ovulation, or even amenorrhea (the absence of menstruation, and infertility)). The etiology of this condition is unknown, and there is no universally accepted definition. Diagnostic criteria for this condition are not universally agreed upon, leading to varying reports of prevalence. Approximately 5-20% of the female population may have this condition (Liu et al. 2020). An elevated testosterone level is not required to make the diagnosis, only clinical evidence of hyperandrogenism (e.g., male-patterned hair growth, male pattern hair loss, and acne). The hyperpigmented, velvety appearance of the skin called acanthosis nigricans is due to hyperinsulinemia but is often seen in patients with androgen excess such as PCOS.

70. In adult women, PCOS has the potential to cause increased risks of impaired glucose tolerance, sleep apnea, mood disturbances, depression, increased risk of type 2 diabetes, dyslipidemia, non-alcoholic fatty liver disease, visceral obesity, cardiovascular disease, and increased risks for endometrial cancer (ACOG PCOS 2018, Liu et al 2020). The exact pathogenesis of PCOS has yet to be elucidated.

71. PCOS is not typically diagnosed in adolescence due to the immature hypothalamic-pituitary-gonadal axis and risk for over diagnosis. Administration of puberty blockers to young female adolescents or children for years, followed by cross-sex hormones, will mask the clinical diagnosis of PCOS in young females who may be at greater risk of this complex disease. Masking PCOS has deleterious effects because patients need to be closely medically monitored to avoid serious risks to their health.[5]

72. It has been postulated that gender incongruence may be elevated in females with PCOS (Liu et al. 2020) as well as reporting PCOS being more common in female transgender men (Moravek 2018). If PCOS is in fact more common in females who identify as transgender men, and these females already possess increased health risks baseline before starting exogenous

[5] It is recommended to avoid diagnosing PCOS in adolescents until at least 2-3 years post menarche (Goodman 2015 pg 1297). ACOG also encourages caution assigning the diagnosis prematurely (ACOG Committee Opinion No. 789). Even for female adolescents who use estrogen/progestin- or progestin-only hormonal management for dysmenorrhea or contraception, it is still a concern that the hormonal medication could hamper identification of menstrual patterns that, in turn, may delay potential health concerns for adulthood (although hormonal management has endometrial protective effects, reducing risk of endometrial hyperplasia and subsequent atypia, which decreases risk of endometrial cancer). Blocking puberty also poses potential significant risks to girls with differences in sex development who are not diagnosed until adolescence. The GAC regimen confers no such beneficial effects to the endometrium and may in fact exacerbate existing risk factors for endometrial hyperplasia/atypica/cancer with the increased aromatization of testosterone to estrogen.

testosterone administration, their health is placed at even greater risk by masking the effects of PCOS.

73. There are other conditions that cause hyperandrogenism in females. Affecting less than 1-2% of females, these conditions include congenital adrenal hyperplasia, androgen secreting ovarian or adrenal tumors, acromegaly, and Cushing's disease (a condition in which an adenoma called a corticotroph secretes the hormone ACTH which results in an excess of adrenal androgens and cortisol). The level of testosterone in these severely hyperandrogenic disease states can range from 100-300 ng/dL or more.

74. Excess androgens (including testosterone) in females is a serious risk to the healthy functioning of physiologic processes within the cardiovascular, endocrine, neurologic, pulmonary, and reproductive organ systems. Disease states can be caused by endogenous testosterone at levels orders of magnitude ***lower*** than the doses of exogenous testosterone administration in female sex individuals undergoing gender affirming care. The risks to the female body present within the conditions of endogenous hyperandrogenism would also be present in the healthy child or adolescent receiving supraphysiologic doses of exogenous testosterone (such as through gender affirming care). Numerous studies document that endogenously produced androgens leading to hyperandrogenism can contribute to significant health risks (Dubey et al. 2021, ACOG Practice Bulletin No. 194, 2018).

75. Gender affirming care suggests doses of exogenous testosterone in the female to match the normal physiologic male range (typically 320-1000 ng/dL) (ACOG Committee Opinion 823, 2021). These are ***extremely*** elevated androgen levels, the likes of which are not usually seen naturally except in cases of rare androgen-secreting tumors that comprise only about 1% of all

ovarian tumors. When diagnosed, such tumors are promptly surgically removed so that patients are not subjected to years of hyperandrogenism, which carries significant health risks.

76. Data are just now emerging with regard to the iatrogenic physiologic pathology that exogenous, supraphysiologic testosterone administration has to bodily function in females. There is growing evidence that this dose of "maintenance" testosterone therapy increases the risks of myocardial infarction in females who identify as transgender men compared to females who do not take exogenous testosterone (Aranda et al. 2021). A new study presented at the American College of Cardiology's Annual Scientific Session reported a substantially increased risk of serious cardiac events, including stroke, heart attack, and pulmonary embolism in individuals with gender dysphoria receiving GAC with supraphysiologic doses of estrogen or testosterone (American College of Cardiology News Release 2023). Androgens also appear to induce unfavorable responses in the female vascular system which can lead to endothelial dysfunction and mild hypertension; these responses persist as long as the female individual continues to take exogenous testosterone (Stone & Stachenfeld 2020). Endothelial dysfunction precedes clinically detectable atherosclerotic plaques, and it is important to be able to monitor this in females who are taking exogenous testosterone at young ages when their overall risk of cardiovascular events is still low (Gulanski et al 2020 pg 139). Flow mediated vasodilation in the brachial artery was monitored in females who were being administered exogenous testosterone at supraphysiologic female levels in order to affirm physical congruence to the opposite sex; it was found that, compared to females who did not receive these doses of testosterone, the magnitude of the vasodilatory response was attenuated in females who identified as transgender men. This study represents the first time physiological testosterone during testosterone administration for gender affirmation (a range of total testosterone of physiologic male levels in a female) impaired

endothelial function. This is in direct contrast to the effects that estrogen would have in a young female, as endogenous estrogen has beneficial effects, promoting vasodilation and endothelial cell growth and decreasing the development of atherosclerosis. This study directly demonstrates the detrimental effects of androgens on the female cardiovascular system when administered in such exogenously elevated doses to achieve levels more common with male sex.

77. High triglyceride levels appear to be a stronger predictor of increased cardiac risk in females compared to males. Non-HDL (total cholesterol minus HDL–or high-density lipoprotein) and also the ratio of total cholesterol/HDL are predictors of cardiovascular risk in females (Sallam & Watson 2013). In addition to decreased HDL and increased LDL (low density lipoprotein), testosterone administration in female transmen increases BMI and hypertension, with varying effects to triglyceride levels (Velho et al. 2017). All of these risks to the female cardiovascular system are exacerbated by supraphysiologic testosterone administered during gender affirming care. Even among studies which claim that testosterone administered in supraphysiologic doses not increase or exacerbate insulin resistance or markers for cardiovascular risk, such studies are quite small and use blood tests that are not usually measured to diagnose insulin resistance (Chan et al 2018); such findings have not been confirmed with larger studies. In fact, recent emerging data show either elevated cardiovascular risk for individuals who identify as transgender and who are receiving cross-sex estrogen (males) and testosterone (females) (Schutte et al 2022, Nota et al 2019) or inconclusive risk (Masumori et al 2023). These data show that it is too strong to conclude hormones do not "induce risk."

78. The risks of androgen abuse in the form of unmonitored supraphysiologic testosterone administration in females is well documented and includes depression, infertility, and mood instability (ACOG Committee Opinion No. 484, reaffirmed 2021). Testosterone is classified

as a schedule 3 controlled substance, meaning that it is a drug with a moderate to low potential for physical and psychological dependence (ACOG Committee Opinion No. 484, reaffirmed 2021). The psychiatric risks of exogenous testosterone administration are well documented in the medical literature, with higher doses of testosterone associated with hypomanic, manic, or psychotic symptoms (Moravek 2018 pg 694).

79. It has been shown in observational data that there is an increased mortality risk in transgender people using hormone treatment, regardless of type, over the course of five decades (de Blok et al. 2021). The study authors admit that "effects of safety of hormone treatments are scarce, leading to insufficient evidence to determine long-term safety, especially regarding cancer and hormone-sensitive cancers specifically, as well as cardiovascular disease" (De Blok 2021 pg 664).

80. The fertility risks with exogenous supraphysiologic doses of testosterone are not fully known, and there is an acute lack of data disambiguating patients by ages and stages of pubertal development when this drug is administered, noting whether GnRHa were administered prior to treatment, or stating the duration of either or both medications. As one literature reviewer recently wrote: "Unfortunately, in regards to best practices surrounding fertility treatment and/or fertility preservation in transgender men, there seem to be more questions than answers from the available literature… [T]here is a paucity of data directly translatable to the high levels of and prolonged postpubertal exposure to T that is characteristic of gender-affirming hormone therapy. As such, the current status quo is to recommend fertility preservation before initiation of T therapy and, for patients presenting subsequent to T therapy, cessation of T before ovarian stimulation… More clinical outcome data are also desperately needed, however, to ensure we are providing appropriate care to this patient population. The long-term goal should be to equip medical

providers with the information necessary to provide high-quality data-driven counseling regarding fertility options for transgender men" (Moravek et al. 2020 pg 13). This is a remarkable statement because it was written in 2020, years after GAC was widely adopted in the United States without any long-term data—not even animal studies—to help guide best practices. It highlights the medical experimentation being conducted on very vulnerable patients.

81. Further risks to females who undergo GAC with exogenous testosterone include gynecologic malignancies such as endometrial cancer and ovarian tumors, as well as breast cancer. Because prolonged exposure to a hyperandrogenic hormonal environment has been, until the advent of GAC, extremely rare, published information is limited.[6] Most reports are thus case reports. More concerning is the possibility that females who receive GAC are not getting proper healthcare while being put at iatrogenic risk of developing malignancies.

82. There are concerns that the testosterone used in GAC can increase risk of endometrial cancer. Testosterone is known to suppress the hypothalamic-pituitary-ovarian axis, which ultimately prevents estrogen and progesterone synthesis. However, testosterone is also aromatized ("converted") to estrogen. Estrogen, if not balanced with progesterone, will increase the risk of endometrial cancer. A case report of a precancerous lesion of the endometrial lining of the uterus was diagnosed in a young female transgender man at the time of hysterectomy; this is extremely rare in a young patient without any medical comorbidities that contribute to unopposed

[6] ACOG claims "most studies demonstrate that endometrium is atrophic secondary to testosterone use" (ACOG Committee Opinion 823 pg e85) but does not provide any studies demonstrating this to be true. ACOG Clinical Consensus on Menstrual Suppression on pg 536 cites the CO 823 when it again claims: "Although there has been concern for endometrial hyperplasia or malignancy due to aromatization of exogenous testosterone to estrogen with anovulation and therefore chronic unopposed estrogen, this risk is not supported by data. Most studies demonstrate endometrial atrophy with the use of exogenous testosterone as part of a gender-affirming protocol" (pg 536). But this claim does not reference any sources, either.

estrogen. The patient had been administered supraphysiologic testosterone to achieve the range of the male sex (O'Connor et al. 2022).

83. Testosterone administered exogenously induces changes to the ovarian histology similar to PCOS, with an increase in androgen receptors possibly leading to the increased risk of ovarian cancer. Ooophorectomy performed prior to natural menopause also is associated with increased risks of all-cause mortality, dementia, cardiovascular death (Carbonnel et al. 2021, pg 933). Testosterone used for gender affirming care in this population of females makes it difficult to disambiguate these risks, as these data are all for females who have not been exposed to long-term, supraphysiologic doses of exogenous testosterone. Females who identify as transgender often do not access routine gynecologic care, further risking their health (AOCG Committee On Health Care for Underserved Women 2021, Opinion 823).

84. Testosterone administered as part of the regimen in GAC suppresses estrogen production, even though it also gets "converted" to estrogen, which makes it extremely challenging to differentiate the risks to females on this regimen. The decrease in estrogen causes vaginal epithelial cell growth to slow, and the vaginal epithelium becomes thinner and more fragile. This can cause irritation, dryness, and atrophy of the vaginal tissue, which can cause significant discomfort and even bleeding. Critically, estrogen is imperative for the vaginal microenvironment and subsequent health. Estrogen promotes the production of glycogen by vaginal epithelial cells which is a preferred substrate of *Lactobacillus* species of bacteria. Lactobacilli use glycogen to produce lactic acid, which inhibits growth of pathogens such as sexually transmitted infections (*Neisseria gonorrhoeae, Chlamydia trachomatis)* and also bacterial vaginosis. If lactobacilli colonization is impeded, epithelial maturation of the vagina is impaired, which in turn causes

increased susceptibility to other infections such as HIV and HPV. HPV infection is common and is a known risk factor for cervical cancer (Krakowsky et al. 2022).

85. There is also concern for increased risk of breast cancer due to the unopposed estrogen (after aromatization/conversion from supraphysiologic doses of testosterone). One study reported breast cancer in four females who identify as female to male transsexual, two of whom were undergoing masculinizing exogenous supraphysiologic testosterone administration. Two patients developed breast cancer in residual breast tissue 10 years ***after*** breasts had been removed (Trum et al. 2015).

86. In another study, a female adolescent who identified as transgender was prescribed testosterone for under one year and developed a large, borderline malignant ovarian neoplasm, which is very rare in the adolescent population (Millington et al. 2021).

87. To summarize, a growing body of evidence shows females who are administered supraphysiologic doses of exogenous testosterone under the gender affirming care regimen develop an iatrogenic disease state of severe hyperandrogenism, the risks of which are still poorly understood given the duel effects that testosterone has on the female reproductive system (both suppression of estrogen and also conversion to estrogen). This has significant deleterious effects on nearly every female organ system including the associations of risk of certain gynecologic malignancies that are otherwise extremely rare in young, healthy females.

VII. Fertility Preservation Techniques in Gender-Diverse Children Who Undergo GAC at Tanner Stage 2 Are Experimental

88. In both female and male children, fertility-sparing procedures prior to full pubertal development are nascent and considered to be experimental. Currently these procedures are predominantly limited to children who suffer from cancer or other physical disease states that are life threatening and require treatment with chemotherapy, much of which is cytotoxic to gametes.

Because children with cancer do not have the option of waiting to administer chemotherapy (because waiting would introduce unacceptable risk), most often fertility preservation procedures are done in an expedited fashion, very shortly after the child's cancer diagnosis is confirmed. The invasive fertility preservation procedures and techniques are the only intervention available to have a chance of preserving the child's right to an open future in terms of possibly safeguarding their fertility (Klipstein 2020).

89. Pre- or very early pubertal children and adolescents at Tanner stage 2 generally do not have the same options for fertility preservation as those who have fully completed natal pubertal development. The reason for this is that the gametes have not reached maturity if the female has not undergone menstruation or the male has not undergone spermarche (both occur typically at Tanner stage 4 of development). As I will outline below, there are significant limitations with the technological ability to preserve fertility in pre- or early pubertal male and female children for any indication.

A. Fertility Preservation Options for Females

90. For females at Tanner stage 2 of puberty, ovarian tissue cryopreservation exists in theory as an option to preserve fertility, but not in practice for most people (American Society for Reproductive Medicine 2019). With only 2 recorded cases of live births in the world literature in females who underwent ovarian tissue cryopreservation (OTC) prior to the onset of mature gametes (menstruation), this option is extremely limiting in a young female who would otherwise mature to adulthood and perhaps not require any need for fertility preservation at all.

91. The American Society for Reproductive Medicine (ASRM) recently removed the experimental label for ovarian tissue cryopreservation (OTC) in 2019 in their committee opinion regarding fertility preservation in patients undergoing gonadotoxic therapy or gonadectomy

(American Society for Reproductive Medicine 2019). This document subtly broadened the indications for fertility preservation outside of those who have medical conditions that are life threatening, such as malignancy or blood disorders such as thalassemia or sickle cell disease, and for whom treatments are gonadotoxic. The recommendations were made based on the data that OTC has demonstrated success in women achieving 130 live births worldwide with this method as of 2017 (Donnez & Dolmans 3017). The authors acknowledge that the denominator of how many women have undergone OTC is not known, but they report 29%-33% pregnancy rates and live birth rates of 23%-25% from individual centers.

92. Proponents of safeguarding the pediatric population have appealed that this technology should be offered only within the context of institutional review board (IRB) approved research, in order to address the many scientific and clinical questions that are currently unknown in the pediatric patient population (Rowell et al. 2020; Nahata et al. 2020).

93. Currently, most indications for ovarian tissue cryopreservation in females under age 18 are malignant neurological disease, leukemia, sarcomas, and benign hematological disorders (Gjeterud et al. 2021). Most often, ovarian tissue is autotransplanted back into the female patient (Ainsworth et al. 2020) once treatment for the offending condition has been completed and the female has decided she would like to pursue childbearing (provided that the transplanted ovarian tissue is not going to further risk re-introduction of malignancy) (ASRM 2019). It is noted that benign disorders in females under 18 years of age which require treatment with gonadectomy or gonadotoxic agents comprise a growing indication for ovarian tissue cryopreservation in this age group (Gjeterud et al. 2020). However, as the ASRM notes: "efficacy, safety, and reproductive outcomes after ovarian tissue cryopreservation are still limited," and OTC should be offered only

by centers with the necessary laboratory and surgical expertise in carefully selected patients (ASRM 2019, p. 1025).

94. ***Successful live births in adult females who underwent OTC during pre-menarche (childhood or early puberty) are extremely low—based on the reported cases in the literature, fewer than three individual patients in the whole world***. There have been two pre-menarche female children who had ovarian tissue cryopreserved and subsequently auto-transplanted as adults who were able to have spontaneous pregnancies and live births. The first was reported in 2015 of a pre-menarche child who underwent OTC at age 13 years in order to prepare for treatment of sickle cell anemia (Demeestere et al. 2015); the other was reported in 2018 of a 9 year old child who underwent OTC prior to treatment for B-thalassemia (Matthews et al. 2018). A third adolescent who had OTC performed at age 14 later had a live birth, and another ongoing pregnancy, but it was not reported if she had already had menstruation at the time of OTC (Rodriguez-Wallberg et al. 2021).

95. A systematic review found 16 studies with data specific to pediatric patients who had undergone fertility preservation for gonadotoxic cancer treatments (Corkum et al. 2019). The reviewers found that of 298 patients who underwent OTC under the age of 13 (which generally indicates pre-pubertal/pre-menarchal status), just 3 underwent surgery later on in adulthood to autotransplant their ovarian tissue (Corkum et al. 2019). The total number of females aged 0-20 who underwent ovarian tissue cryopreservation numbered 1019 individuals. Eighteen of these patients had ovarian tissue auto-transplanted back into the peritoneal cavity or within the remaining ovary. The median age of the patients who underwent OTC between 0-20 years who then subsequently had surgery to undergo autotransplantation was 19 years. The age at which the ovarian tissue was autotransplanted back into the patient was 24 years. The ovarian tissue grafts

were found to be functional up to 7 years after autotransplantation of graft placement. One patient who underwent OTC prior to menarche was able to achieve a live birth; the other live births were in females who had OTC performed after menarche but under 20 years of age. Thus, in all, of the 1019 patients who underwent OTC between 0-20 years of age, just 18 of the patients underwent surgery to autotransplant the ovarian tissue back into the peritoneal cavity; and of these 18, just 3 were pre-pubertal at the time of OTC. Among these patients who had OTC under age 13, and who then subsequently underwent autotransplantation of cryopreserved ovarian tissue in adulthood, ***just one achieved a live birth***.[7] The technique for OTC in this age group is not standardized and there is significant heterogeneity of both the cryopreservation and transplantation processes (Corkum et al. 2019). The authors caution: "The success of autotransplantation in women who were children at the time of OTC may take decades to be fully understood. In addition, while a few institutions did mention unsuccessful transplantations in girls 20 years of age and younger at the time of OTC, there is a risk of reporting bias toward publication of only cases in which fertility and hormone restoration was achieved" (Ibid, pg 2207). That is, the true denominator of how often OTC is performed in pre-pubertal female children may be unknown, and thus success rates of achieving a live birth over-estimated, because only successful outcomes get reported rather than all who attempt OTC as an attempt to preserve fertility. This kind of reporting bias confounds the reported success of this procedure. The review cautions that the efficacy of fertility restoration in patients who are prepubertal at the time of OTC cannot be determined at this time (Ibid).

96. The technology of oocyte in vitro maturation (IVM) has also been used as a fertility preservation technique in women. Recorded live births from IVM technology are extremely low,

[7] This is the patient reported in Matthews et al 2018 who was 9 years old at the time of OTC.

and there are significant challenges for utilizing the technique in pre-pubertal or early pubertal female children who have not yet undergone menarche.

97. IVM techniques have been used for decades and used in breeding programs for animal husbandry. The ability of the technology to be used in humans was not developed, as oocyte maturation with controlled ovarian stimulation protocols (COS) were being generated simultaneously. As such, with greater utilization and investment in medical and laboratory infrastructure to develop COS technologies, the successful live birth rates kept improving with this method; COS is now the overwhelming technological modality used to overcome barriers to achieving fertility for individuals who have completed pubertal transition, but cannot be used in pre-pubertal or early pubertal children/adolescents.

98. Because IVM can be theoretically accomplished without female pubertal maturation, there has been some investigation using ovarian tissue from pre or very early pubertal females for fertility preservation in children who have cancer, as this avoids the transfer of the preserved ovarian tissue back into the female when she grows into adulthood (Gilchrist & Smitz 2023). The reason for this approach is to avoid the risk of possible malignancy being reintroduced into the patient if ovarian tissue cryopreservation was performed for an oncological (cancer) diagnosis. Instead of re-transplanting the cryopreserved ovarian tissue back into the patient and allowing the physiologic maturation of the oocytes in the body (as described earlier in this report), the process of IVM takes the cryopreserved ovarian tissue and matures the oocytes outside of the female body ("ex-vivo"). The rationale for this is to completely eliminate the risk of potentially re-introducing malignancy when the OTC is used to preserve the fertility in females with a cancer diagnosis. With IVM, when the female is an adult and decides she would like to pursue pregnancy, the oocytes obtained from the OTC process are fertilized by a technique called intracytoplasmic

sperm injection (ICSI). If a blastocyst develops from this method, it is then transplanted into the patient's uterus.

99. The IVM technology has resulted in a wide range of maturation rates of cumulus oophorus complexes, with overall maturation rates of 39% +/- 23% (Segers et al 2020). Recall that the follicular cells surrounding the primary oocyte are essential to the maturation of the primary oocyte into the dominant follicle capable of being ovulated, and this process of follicular maturation only occurs at the pubertal transition in response to LH/FSH. In the IVM process, this step does not occur because the ovarian tissue cryopreserved during childhood is not re-transplanted back into the female patient from whence it came. Instead, the primary oocytes within the ovarian tissue are matured outside of the female body using a variety of protocols to accomplish this process, with varying degrees of success (as described above).

100. To date, the youngest child from whom mature oocytes have been obtained after IVM was aged 5 years (Segers et al 2015 pg 1228), with a maturation rate in 6 pre-pubertal girls of 18% (Segers et al. 2015 pg 1223, 1228) to 22% (Segers et al 2020, pg 2028). It is very important to realize that maturation rates do not guarantee a live birth will result from this process. As of 2021, there have been only 5 live births from embryos generated from fertilization of oocytes matured "in vitro"; 5 live births from over 500 patients in total who had in vitro maturation from oocytes retrieved from ovarian tissue; all were adults at the time of ovarian tissue retrieved and then matured "in vitro" (De Roo 2021, Tables 1 and 2). Crucially, compared to adult ovarian tissue, the ovarian tissue from premenarchal children appears to contain a relatively larger population of abnormal follicles, and follicle development and oocyte growth in culture has been shown to be compromised; because of this, it is hypothesized that the prepubertal ovary needs a "maturation phase" in childhood to gain optimal follicle function as an adult (Segers 2015 pg 1228).

Concerningly, it is possible that the oocytes harvested from ovarian tissue of pre-menarche children might lack the capacity to resume meiosis (Ibid). ***There have been no live births from the IVM from ovarian tissue obtained in premenarchal female children, and no live births from transgender men (natal females) who had been on testosterone prior to gender affirming bilateral oophorectomy*** (De Roo 2021 Table 1). Because of the low maturation rates and concomitant viable pregnancies, even in adults, the fertility potential of IVM is still under evaluation (Choi 2022, pg 6), as fertilization and embryological developmental capacities seem to be impaired (De Roo 2021, pg 6).[8]

101. ***In summary, the live birth rate for female adults who underwent OTC and IVM technologies as a means to preserve fertility during pre pubertal/early pubertal (premenarchal) development are extremely low: 3 live births for the use of OTC, and 0 for the use of IVM (Demeestere et al. 2015, Segers et al. 2015, 2020; Matthews et al. 2018; Rodriguez-Wallberg 2021). There are also 0 live births in adult transgender men (natal females) who have utilized these technologies whilst receiving testosterone for gender affirming care (De Roo 2021, Stolk 2023).***

102. Such data are in stark contrast to the cumulative live birth rate for controlled ovarian stimulation (COS) followed by in vitro fertilization (IVF). Recall that COS is performed in settings also where there are no contraindications to these procedures as no intrinsic pathological process occurs within the body, much like gender dysphoria. The key is that the technology can be utilized

[8] IVM is, however, one of the only ways to avoid reintroduction of malignancy in females who suffer from cancer and undergo fertility preservation, since it removes the requirement of auto-transplantation. For females who identify as transgender, it also offers a way to avoid ovarian tissue autologous transplantation, or endogenous gonadotropin stimulation and oocyte retrieval with subsequent oocyte cryopreservation, but again, this process is experimental (Stolk & Asseler 2023) and the use of IVM in female transgender men has not been successful in generating a live birth (Ibid pg 33).

only once puberty has advanced to the level of endogenous gamete maturation (Tanner 4 or 5). One study noted the live birth rate above 24 weeks gestation in over 14,000 patients can be up to 70% with >25 oocytes retrieved after controlled ovarian stimulation (Polyzos et al. 2018). Critically, these data also note the increased risks to females with this approach, such as ovarian hyperstimulation syndrome.

103. There are limitations in interpreting success of assisted reproductive technologies since protocols, patient selection criteria, and methods used rates vary widely between centers. It is important to keep in mind that the use of assisted reproductive technology in females carries risks compared to those who do not require these technologies to conceive (ACOG Committee Opinion No. 671, reaffirmed 2020).

B. Fertility Preservation Options for Males

104. In males, fertility preservation options are only experimental before the gametes are mature. Currently there is no way to "mature" an immature germ cell/spermatogonia. These immature germ cells/spermatogonia are cells in the male testes present at Tanner stage 2 of very early pubertal development. Recall from earlier in this report that males are born with immature gametes which have not yet entered the cellular division stage of meiosis. Physiologic puberty in males where the gametes undergo the process of maturation is called spermarche and occurs at Tanner stage 4. The process can only occur if LH and FSH are able to act at the level of the Leydig and Sertoli cells at puberty, to sustain the developing sperm cells from their immature diploid form to the haploid mature spermatozoa.

105. If this action of LH and FSH is "blocked" before the natural pulsatile release of GnRH in natal puberty ever occurs, followed in succession by exogenous estrogen administered in supraphysiologic doses (without a "break" in this process), it is unknown if spermatogenesis

could ever develop; there are no data of this ever occurring because there are no fertility outcome studies for male children who ever underwent this regimen at Tanner stage 2. There is a report of spermatocytes retrieved from an adult male matured in vitro, but these spermatocytes had already started the process of meiosis when they were further matured in vitro, resulting in one live birth (Tesarik et al. 1999). This is very different from a pre-pubertal or early pubertal male who does not have any spermatocytes, only germ cells.

106. Consequently, ***for pre- or early pubertal male patients, testicular cryopreservation in this age group as a way to preserve fertility remains investigational and is done only in clinical trials*** (Rowell et al. 2020; Nahata et al. 2020, Klipstein 2020). The technology relies on the ability to generate mature spermatozoa from pre-meiotic diploid spermatogonia, which is experimental. Current knowledge of this technique is limited to animal studies (Delessard et al. 2020, Ibtisham et al. 2017, Wang et al. 2020, Ibtisham et al. 2020). Progress within this field is slow, with an immense amount of work to be done regarding fertility preservation for boys and adolescents (Ntemou et al 2019, pg 2); there is no report of any of the proposed experimental approaches (both in vitro and in vivo) resulting in spermatozoa generation from human immature testicular tissue cryopreservation (Ibid, pg 8)

107. Testicular tissue cryopreservation in male children is conceptually very similar to ovarian tissue cryopreservation in female children. For example, in the case of pediatric cancer, a testicular biopsy is obtained and cryopreserved, and the immature cryopreserved spermatogonia can be placed back into the testes once treatment has completed. This process, however, has the risk of reintroducing malignant cells. It also has not been successful in generating mature spermatozoa or live births once adulthood is reached. There are ongoing trials investigating this process (Clinicaltrials.gov).

108. Testicular cryopreservation may not be possible in males who undergo GAC because of the changes to the testes caused by prolonged GnRHa, testosterone blockers, and estrogen administration (de Nie 2022).

109. There are some data that show the possibility of autotransplantation to an ectopically located site away from the testes, as well as methods to mature the immature spermatogonia "in vitro" by trying to "match" the internal conditions of puberty during the time when this would normally occur. All such methods are experimental (Wang et al. 2022; Ibtisham & Honoramooz 2020; Stolk & Asselar 2023).[9]

110. ***There have been no live births from testicular cryopreservation performed during pre- or early pubertal male development, since there is not currently the ability to mature spermatogonia from these specimens in humans.*** There has been a live birth after an oocyte was fertilized with mature sperm retrieved from an adult male who underwent in vitro spermatogenesis, but this occurred after meiosis had already started, up to the level of the pachystene stage of meiosis 1; the male had already completed puberty (Tesarik et al. 1999).

111. In sum, testicular cryopreservation as a method to preserve fertility in pre-pubertal or early pubertal children is still experimental. Maturation of immature spermatogonia/germ cells has not been demonstrated in humans.

[9] There is a method to mature spermatogonia in the testes of a different species called xenotransplantation. This technique injects the spermatogonia germ cells of one species into the testes of another species where they mature in the seminiferous tubules of that species (Wang et al., 2022). To date the only ability to generate mature spermatozoa from human immature spermatogonia in vitro has been shown in one ethically fraught study from China where male fetal germ cells were matured from the fetal testes of an aborted male fetus (Yuan et al. 2020, pg. 244-45).

C. Fertility Preservation is Unrealistic at Tanner Stage 2

112. Although risk of infertility is nearly certain for children who initiate GAC at Tanner stage 2 and there are no known ways to reliably preserve fertility at this stage, there are more data for fertility preservation *after* gametes mature in the later stages of puberty/adulthood.

113. Assisted reproductive options, including fertility preservation, *after* pubertal transition for both males and females, are well-documented, and consist of (1) spermatozoa cryopreservation for adult male patients, (2) use of conventional "IVF" technologies (generation of cumulus oophorus complexes using "in vivo" maturation of the oocyte in the female post-pubertal adult), and (3) OTC/IVM in adult female patients. The first two modalities are more accessible within the existing clinical infrastructure and have documented success rates for live births depending on the methods used (up to 70% one multicenter analysis) (Polyzos et al. 2018). As discussed, OTC/IVM are still relatively new; however live births have been achieved in adult females utilizing these technologies if they do not have any other options to help them achieve their reproductive goals.[10] Even so, it is crucial to acknowledge there are still risks to assisted reproductive technologies and centers have varying degrees of success. There are also higher

[10] The ASRM reports live births reported around the world after OTC was used for post-pubertal adults, with 130 live births for this method reported thus far. The live births for IVM, as discussed, have occurred in adult patients only, with a total of 5 live births reported thus far worldwide using this technique. As discussed extensively, these are very different populations compared to premenarchal female children. For patients without any other options to preserve fertility, such as those who have a childhood diagnosis of cancer and cannot wait for gonadotoxic treatment initiation due to undue risks this poses to their lives, OTC in female children and testicular tissue cryopreservation in male children are techniques which can and should be utilized ethically. However, for early pubertal children who do not have a physical locus of malignancy threatening their survival, it is not medically necessary to utilize these nascent technologies for which live birth outcomes are either non-existent or extremely rare. Once natal pubertal transition has occurred, these young people can make further fertility preservation decisions which have a much higher success rate and are more accessible later in adolescence or adulthood, if need be.

perinatal risks to females who undergo assisted reproductive technologies which need to be taken into consideration as well.

114. Encouraged to delay GAC until after puberty, young people also may decide they are more comfortable in their natal sex, do not want any medicalization, and still identify as transgender.

115. Data show that one of the primary reasons young people do not utilize fertility preserving measures is because they do not want to delay the hormonal GAC regimen (Harris 2019 pg 2454; Stolk & Asseler 2023 pg 30; Robinson 2023 pg 10). Increasing the age where one can receive hormonal GAC regimen would thus provide more time for young people to complete puberty and increase their access to well tested, more successful, and accessible fertility preservation technology should they need to do so.

116. In summary, fertility preservation technology at Tanner stage 2, when gametes are not mature, is nascent, inaccessible, and experimental. In contrast, assisted reproductive technologies for those who have completed puberty are more widely accessible with much higher success rates in achieving a live birth. The evidence base for medicalizing a child's gender identity at Tanner stage 2 is insufficient and low quality, with purported benefits not shown to outweigh the harms of the loss of functional physiologic bodily capacity (Abbruzzese 2022; Levine 2023; D'Angelo 2019; Block 2023; Biggs Sept. 2022). There is no indication, therefore, for gender identity to be medicalized through transitioning treatments when Tanner stage 2 of puberty is reached. Requiring young people to wait until adulthood to pursue transitioning treatments will allow young people who identify as transgender to realize their fertility goals without risks of iatrogenic infertility caused by gender affirming care administered too soon, and may mean they never need to access assisted reproductive technologies.

D. Fertility Preservation Counseling for Youth Receiving GAC is Inadequate

117. Unfortunately, despite the risks, studies have shown that discussions about fertility preservation with children and young adolescents with gender dysphoria are limited (Choi & Kim 2022). The hazards to reproductive function and fertility related outcomes of medicalized GAC limits the ability to effectively counsel patients, and there are no guidelines regarding fertility preservation for transgender individuals (Ibid.). Despite data showing that interest in future parenting is high among adult individuals who identify as transgender (Ainsworth et al. 2020), and that quality of life is noted to be significantly higher for transgender-identifying adults who have children (Choi & Kim 2022), data for pre or early pubertal children remain understudied, with up to one third indicating their feelings about parenthood may change in the future (Schwartz & Moravek 2021).

118. For adolescents who identify as transgender, data are quite mixed regarding fertility preservation counseling and fertility preservation techniques utilized. While one review of the literature found that up to 88-100% of adolescents in the included studies received fertility preservation counseling, the exact counseling rendered was not described, nor were validated tools identified for such counseling. Indeed, the authors note: "[T]he main limitation of this systematic review is the low quality body of evidence presented… [S]tudies … were cross sectional questionnaires, case series, or small sample size cohort studies with limited follow up time and lack of control groups; however, it is the best available data at this time" (Stolk and Asseler 2023 pg 35). Another study revealed a very low rate of just 13.5% of adolescents reporting they had received fertility preservation counseling (Stolk et al. 2023 Table 3), with another reporting up to 100% of fertility preservation counseling (Ibid). As for actual use of fertility preservation options, the rate ranged from 0% to 62%. This top value is an outlier and only applied to males who had

already reached spermarche; the majority of studies reported fertility utilization of <10%, with more males utilizing these technologies than females. And it is important to note that the mean age of these adolescents in all studies were all after the ages at which spermarche and menarche typically occur (Stolk and Asseler 2023 table 3). Most data consistently show that less than 5% of adolescents underwent fertility preservation procedures with gamete cryopreservation (Pang et al 2020, Choi & Kim 2022, Stolk and Asseler 2023). The ASRM, Endocrine Society, and WPATH all recommend fertility preservation counseling prior to initiation of GAC, but studies have raised concern that this standard is not being met despite growing evidence that gender affirming regimen has a detrimental impact on the potential for future fertility (Ibid.).

119. It is unknown how many pre- or early-pubertal children with gender dysphoria undergo counseling for fertility preservation prior to administration of GnRHa followed by cross sex hormones. There remain significant gaps and low utilization in the counseling and education surrounding fertility preservation for children and young adolescents at Tanner stage 2 of pubertal development in whom medicalized GAC has and is currently being offered for several years. In the United States, the first gender clinic was opened in 2007, yet we still do not have any data to help elucidate these phenomena aside from the limited reports I have just described.

120. In summary, inadequate fertility-preservation counseling calls into question the completeness of the informed consent process for the GAC regimen in Tanner stage 2 children and young adolescents. The only "fertility preservation" techniques for which long term data exist are those for individuals who have already matured through the pubertal transition and who have mature gametes. Thus, accurate representation of the evidence regarding fertility preservation in individuals who identify as transgender compels delay in endocrine interventions until after pubertal maturation of the gametes has occurred—that is, until much later in adolescence/early

adulthood. As mentioned earlier in the report, those seeking reversals of permanent sterilization even when they had undergone these procedures between the ages of 18-24 years of age is over 40% even in adults. And it is well established that even adults under age 30 have increased rates of sterilization regret compared to those older than age 30, even when they have had their own children. It is in the best interest of the child to reduce this risk of sterilization regret by delaying any hormonal manipulation of healthy physiologic function until at least 19 years of age. The delay in such hormonal manipulation will allow preservation of a child's open future in which adult reproductive goals are preserved.

VIII. Response to Plaintiffs' Experts

121. I have reviewed the opening expert reports of Dr. Armand Antommaria, Dr. Daniel Shumer, Dr. Meredithe McNamara, Dr. Aron Janssen, and Dr. Morissa Ladinsky.

122. Dr. Shumer claims on page 6 of his report that "sex is comprised of several components, including, among others…gender identity." He then states on page 7 that "everyone has a gender identity." But gender is a social concept; it has no locus on the physical body (Schwartz 2021, Biggs 2022) and therefore has nothing to do with the objective locus of sex. The physiologic function of sex is to reproduce the species; in mammals, this occurs by the internal fertilization of an ovum by a spermatozoan. The function of sex is binary.

123. Dr. Shumer also states that gender identity "is an internal and largely biological phenomenon" but it is also "understood" and "may evolve." It is unclear what he means by "largely biological phenomenon." Biological phenomena are tangible, immutable (Dorland's 29th ed). For example, it is a biological phenomenon that only female-sexed individuals can gestate. There is no objective measure of gender identity.

124. Dr. Shumer claims that attempts to "force" someone with gender identity to "align" with their "birth sex" is harmful. He does not describe what this means, but seems to assert that the actual physical, biological processes of healthy human physiological development, including sexual maturation and puberty, are somehow unhealthy and must be externally "forced." What *is* forced is trying to provide the facsimile of an opposite sex by administration of supraphysiologic doses of either testosterone in females, or estrogen in males, in an attempt to appropriate the appearance of the opposite sex. Only the medical establishment can force this kind of bodily modification; it is not physiologic.

125. On page 15 of his report, Dr. Shumer states that "GnRHa have no long-term implications on fertility." As demonstrated above, this statement is decidedly not true when GnRHa are begun at Tanner stage 2 of puberty and followed without pause by cross-sex hormones, as WPATH and the Endocrine Society recommend. Dr. Shumer may be referring to the use of GnRHa in children with central precocious puberty (CPP), but those patients undergo natural puberty at the natural time—unlike patients receiving puberty blockers as part of gender affirming care.

126. Dr. Shumer cites the PREFER study to support his claim that GnRHa have been "proven" to "not have long-term implications on fertility." The study actually showed there were insufficient data at the primary endpoint of the study to make firm conclusions regarding the proportion of women desiring a pregnancy but who did not achieve pregnancy 6 and 12 months after stopping all contraceptive methods (Martinerie et al. 2020, pg 536). In other words, these are women who desired pregnancy but did not yet achieve it—the key question the study was meant to address. It is reassuring that pregnancy *can* be achieved after GnRHa administration for CPP in females, but even the study authors state that the results need to be consolidated with a subsequent

study to assess fertility and infertility rates when women will have reached their mid-thirties (Ibid pg 536). In males, limited data exist on reproductive function after treatment for CPP with GnRHa; data on paternity rates and fertility are not available (Bangalore-Krishna 2019, pg 364). Therefore, Dr. Shumer's statement that "GnRHa have no long-term implications on fertility" is too strong even when confined to GnRHa used to treat central precocious puberty.

127. Dr. Shumer asserts that GnRHa are used at the onset of puberty (Tanner 2) until mid-adolescence and that "the decision to continue treatment will be continually evaluated." "Should pubertal suppression no longer be desired," he states, "GnRHA would be discontinued, and puberty would re-commence." This statement has not been proven because the only data we have are for children who were placed on this medication for CPP, not normally timed puberty. An international consortium continues to lament the lack of long-term outcome studies, especially to address concerns regarding impacts on bone mineral density and infertility when used in patients who identify as transgender (Bangalore Krishna 2019).

128. Dr. Shumer states on page 20: "Adolescents diagnosed with gender dysphoria who have entered puberty (Tanner Stage 2) may be prescribed puberty-delaying medications." This is misleading. Tanner Stage 2 occurs on average at age 10 in female children and 11 in male children, but the normal range is 2 standard deviations from those ages. Thus, in females Tanner stage 2 of puberty can occur at age 8 in normally timed puberty, and for males, at age 9. The normal distribution of ages in Tanner stage 2 of puberty are 8-13 for female children and 9-14 in male children. By use of the term "adolescence" the reader unaccustomed to what "Tanner stage 2" means may be led to believe that GnRHa are only given to adolescents, but that is not true. They are also given to children, which the AAP defines as up to 12 years of age (AAP Policy Statement, Age Limit of Pediatrics 2017).

129. Another key detail omitted by Dr. Shumer is that once GnHRa are given for a time, especially at Tanner stage 2 when gamete maturation has not yet occurred, GnRHa will prevent the maturation of primary oocytes and spermatogonia and may preclude gamete maturation (Bangalore Krishna et al. 2019, pg 365). If gametes cannot mature, administration of supraphysiologic doses of hormones to match those of the opposite sex has the risk of damaging immature gametes, and there is a high likelihood for permanent sterility, especially in males (Stolk & Asseler 2023; de Nie 2022). Dr. Shumer admits this fact later, on page 22 of his expert report: "While GnRHa themselves do not have long-term implications on fertility, ***it is necessary for a person to complete puberty to produce viable eggs or sperm.***" (Emphasis added). Yet he does not connect the dots. Since GnRHa drugs are used precisely ***to*** block natal pubertal transition, and viable gametes can only occur ***with*** pubertal transition, if pubertal transition is blocked by the GAC regimen, with puberty blockers at Tanner 2 followed by cross sex hormones, the gametes cannot mature, and therefore the risk of sterility is very high. Even WPATH SOC 8 acknowledges this concern and recommends fertility preservation before initiation of GnRHa therapy (WPATH 2022 section 12.10, 16.3). Dr. Shumer says it again on pages 24-25 of his report: "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 reproductive technologies ***could*** be employed if needed." (Emphasis mine). He then cites a 2013 source that does not address early pubertal adolescents at all and refers to "transexual persons" who are adults—i.e., who by definition passed through puberty and whose gametes are already mature (T'Sjoen 2013). An adult patient who has not been administered puberty blockers followed by cross sex hormones beginning

at Tanner stage 2 of early puberty is not the same patient as a young person who has been subjected to this regimen.

130. I have discussed fertility preservation in detail earlier in this report. Fertility options in male children at Tanner 2 puberty blockade can be performed only if testicular cryopreservation is undertaken prior to starting the hormonal GAC regimen. The techniques for trying to mature spermatogonia from the testes of early pubertal male adolescents are still experimental and are not well studied in humans (except as proof of concept in animal studies), but there is no way to know if sperm matured this way (i.e., in vitro spermatogenesis) will be able to fertilize an ovum or if a live birth would result in humans. There has never been a live birth using sperm from a male who was administered GAC at Tanner stage 2, and there are no current data by which these young patients and their families can be assured their fertility and reproductive goals will ***ever*** be possible. The technology to mature spermatogonia in vitro and clinical infrastructure for this to occur in Tanner stage 2 males simply does not exist on a clinically relevant scale.

131. For female early pubertal children and young adolescents at Tanner stage 2, the "option" for fertility preservation is ovarian tissue cryopreservation as discussed earlier. There have been two patients who had live births after ovarian tissue was cryopreserved prior to menarche, and autotransplanted. A third patient had a live birth from ovarian tissue cryopreserved but the report did not describe whether or not menses had already started at the time of ovarian tissue cryopreservation. There are no data that a female young person who was administered GnRHa at Tanner stage 2 followed directly in succession by testosterone (the regimen of "gender affirming care") has ever had a live birth in adulthood. "There are no long term follow up studies studying the effect of puberty suppression and testosterone on gonadal function and gametes" (Stolk et al 2023, pg 3). The only reproductive outcomes data exist for post-pubertal females who

have taken testosterone alone, or GnRHa alone, each for a limited time period, *not* in direct succession. As discussed in this report, these are very different patient populations.

132. At Tanner stage 2, male gametes are immature spermatogonia. If gametes are "blocked" prior to the meiotic division of spermatogonia, not only will maturation halt, but also because GnRHa has blocked LH, the Leydig cells of the testes will not be capable of testosterone production. Since testosterone is inhibited, conversion to dihydrotestosterone (DHT) will not occur, preventing the physical maturation of the penis and scrotum. There are ***no*** data to show that males can regain this growth after pubertal blockade followed by exogenous supraphysiologic doses of estrogen. Estrogen in males will lead to hypospermatogenesis and eventually azoospermia, which will become irreversible after some time, as noted by the reference that Dr. Shumer used in his expert report. (T'Sjoen et al. 2013, pg 577). The peno-scrotal hypoplasia that develops from the GAC regimen initiated at Tanner stage 2 has significant ramifications if the male chooses, in adulthood, to undergo penectomy with penile inversion vaginoplasty. Peno-scrotal hypoplasia (an arrest in the growth of the male external genitalia from the time GnRHa were administered) is reported in the surgical literature to contribute to significant complications for these young patients and also increase the surgical risks, including bowel surgeries adding to the overall complications and surgical morbidity (Robinson et al 2023).

133. Dr. Shumer fails to discuss the key distinction between early pubertal children and young adolescents still at Tanner stage 2, on the one hand, and adults who have already gone through natal puberty, on the other. As mentioned earlier in this report, there are case reports of *adult* females who had been on testosterone for a period of time, stopped it, and then became pregnant (Light et al. 2014; Besse 2020). This is *not* the same patient population as an early pubertal child or young adolescent who received GnRHa before their gametes were even mature.

Ample data exist regarding fertility preservation options for adults as I have mentioned earlier in this report. Children who have puberty blocked and who are thus excluded from gamete maturation do not have these same fertility preserving options and warrant special consideration.

134. Dr. Shumer states that a young person exposed to GAC at Tanner 2 could, as an adult, "withdraw from hormones and allow pubertal progression." There are no data that this has ever occurred for a young person exposed to GAC beginning at Tanner stage 2. In fact, emerging data show that stopping gender affirming hormone treatment prior to orchiectomy did not affect possibilities for fertility preservation, since it is unknown if spermatogenesis can recover if gender affirming hormone treatment is stopped and how much time is needed for this purpose (de Nie 2021 pg 305). This may be why WPATH, ASRM, and the Endocrine Society recommend that fertility preservation options be discussed before transition (Coleman et al 2022, ASRM 2019, de Nie 2022, Ainsworth 2020). Dr. Shumer's lack of precision about the nature and timing of "hormones" obfuscates the fine details and differences in the risks of irreversible sterilization based on when natal puberty is blocked, which I have discussed at length.

135. Plaintiffs' expert Dr. McNamara further obscures the experimental nature of fertility preservation in pre-pubertal or very early pubertal males before any maturation of the spermatogonia. On pg. 15 of her report she states: "In a cohort of patients treated with puberty blockers starting at the onset of pubertal development (Tanner stages 2 and 3) and adding estrogen treatment starting at 16 years of age, histological examination of testicles showed normal appearing, immature sperm producing cells in the testes, ***suggesting*** those individuals had retained fertility potential" (emphasis added). Dr. McNamara's source for this statement shows that indeed, ***0%*** of males who had puberty blocked at Tanner stage 2-3, followed by estrogen at supraphysiologic doses, had any functioning mature spermatozoa in the testes at the time of

orchiectomy. All the spermatozoa were immature. Immature spermatogonia, which, as I explained at length in this report, and which is also reported in this very study (de Nie 2021 pg 299), *cannot* yet mature to spermatozoa "in vitro" or via germ cell transplantation (Klipstein et al. 2020 pg 5); functionally and practically, this renders the ability to actually preserve male children's fertility who undergo GAC at Tanner 2 impossible at this time, both pre- and post- GAC.

136. It is misleading for Dr. McNamara, or any physician counseling young male patients and their families about fertility preservation at Tanner stage 2, to declare that these data show it is "possible to preserve fertility." In doing so, she and other physicians obfuscate the reality of the limits of technological capacity of spermatogenesis (in vitro or via germ cell transplantation) and its purely experimental nature in humans. Discussion of "fertility preservation" when we do not have the actual capacity to deliver on any kind of male fertility preservation for those patients who undergo GAC at Tanner stage 2 of pubertal development is to discuss an experiment, one which at present is neither regulated nor closely or universally monitored. It is an experiment that has never been proven successful in humans and may never be. The only data that can be conveyed are the data that show banking of *mature* sperm. But mature sperm can be generated only if a male child is allowed to undergo endogenous puberty, which GAC prevents. This is why, in order to preserve an open future for a gender non-conforming young person to actualize their reproductive goals in the future, it is imperative to limit any gender affirming endocrine intervention until much later in adolescence, ideally over age 18, given the high rates of regret for sterilization procedures in young adults who have already had children. It is likely to be much higher for those who were sterilized as minors, before any fertility goals could ever be realized.

137. Children who have not even started puberty, or who are at the very earliest stages of puberty, do not have the emotional or intellectual capacity to be able to assent to a medicalized regimen that will cause them to lose functional bodily capacity to reproduce.

138. Hormonal interventions under the euphemism of gender affirming care are especially ethically compromised when one considers that the children to whom the regimen is recommended do not have any physical disease; the intervention itself *creates* the physiologic disease state for which the child will be dependent on the medical profession for the rest of their lives. This is the creation of iatrogenic disease in healthy children and adolescents which carries significant medical risks to numerous physiologic organ system functioning which are life-long.

139. Dr. Ladinsky states on page 23: "Providing transition-based medical care *can be* lifesaving treatment" (emphasis added). But if the patient has a diagnosis which requires *lifesaving treatment,* then why isn't this treatment recommended to all patients with such a diagnosis? There is no other clinical scenario where care considered to be "lifesaving" is ***not*** uniformly recommended to anyone who has a diagnosis which requires such intervention. To be sure, there are clinical scenarios where the diagnosis is uncertain or an intervention is experimental/emerging and shared decision-making is required. (Such interventions are given weak recommendations or are not typically recommended *because* the evidence quality is so low. An example in the field of gynecology is routine hysterectomy for the treatment of patients with the diagnosis of endometriosis). But it is completely at variance to have patients treated on an individualized basis for a diagnosis that requires "lifesaving" interventions; the recommendation should *always* be for that intervention if the diagnosis requires it, and a patient is free to agree to it or not. It is highly curious—and casts doubts on the enterprise—that in gender medicine, "lifesaving" care is only recommended *some* of the time; if it truly is "lifesaving," one would expect it to be recommended

all the time. Only if it *isn't* truly "lifesaving" could it follow that individual approaches to management are accepted. It cannot be both.[11]

140. My primary concerns as an obstetrician gynecologist are the unknown and known fertility effects that early pubertal suppression and cross-sex hormone administration has on female and male minors, both children and adolescents, during early pubertal development. Ample evidence exists for the inability of children to assent to these interventions on their healthy bodies where no physical locus of gender resides. (Abbruzzese & Levine 2023; Levine et al. 2022; Harris 2020). The process of physical alteration creates unethical risks that these children and young people are subjected to for the rest of their lives, which are life limiting. Moreover, our current ability to "preserve fertility" in children and young adolescents in whom puberty is blocked in Tanner stage 2 are nascent, largely unavailable, and experimental, making any discussion about "fertility preservation" for these children an exercise in disingenuousness.

141. It is my opinion that physicians who provide medicalized gender affirming care to minors believe they are helping children because they are following the guidelines set forth by leading professional medical societies in the United States. However, what is occurring now in the United States, in spite of much of the world (where these interventions were originally studied)

[11] As an example in obstetrics, a pregnant patient who experiences the diagnosis of eclamptic seizure requires immediate administration of medications such as magnesium sulfate to provide neuroprotection and reduce significant risk to her life; the intervention with medications to stop the seizure is *lifesaving*. Because it is a *lifesaving* intervention for all pregnant women who have the diagnosis of eclampsia, there is no shared decisionmaking to treat the woman with this diagnosis; the recommendation 100% of the time is to perform the intervention to stop the seizure. Another example is for pregnant women who have the diagnosis of complete placenta previa. It is 100% of the time recommended for all patients with this diagnosis to undergo cesarean to deliver their infant, and it is 100% *not* recommended (contraindicated) to undergo a vaginal birth for delivery. This is because the intervention of cesarean birth is *lifesaving*: it significantly reduces the risk of catastrophic maternal hemorrhage that a vaginal birth would uniformly cause for all women with the diagnosis of complete placenta previa.

curtailing endocrine interventions for minors based on systematic evidence reviews failing to show benefit over harms, can only be described as abnormal treatment behavior (Singh 1981). In my opinion, this is due in large part to established medical authorities in the United States, both organizationally and within the prevailing medical literature, reversing the tenets of beneficence and non-malfeasance to suit the profession and not necessarily the patient; such misrepresentation of the evidence can be considered coercive. The reversal of the ethical tenets of beneficence and non-malfeasance by major medical organizations has manipulated their members and created an unconscious fear in clinicians that gender dysphoria, or any manifestation of gender incongruence, carries such a poor prognosis it cannot be treated in any way other than the "gender affirming care" regimen, despite the poor evidence for doing so.

IX. Conclusion

142. For these reasons, I conclude that the Alabama Vulnerable Child Compassion and Protection Act is based on medical facts and serves to protect minors from unethical experimentation. The medical profession has not only failed to regulate itself, but is actively promoting such experimentation despite the known harms to vulnerable minors.

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American Board of Obstetrics and Gynecology
Obstetrics and Gynecology 2012 - Present
American College of Obstetricians and Gynecologists
Fellow, Obstetrics and Gynecology 2012 - Present

Licensure

North Dakota (Medicine and Surgery) 01/2008 - Present
Wisconsin (Medicine and Surgery) 01/2010 - Present
Minnesota (Medicine and Surgery) 11/2013 – Present
Texas (Medicine and Surgery) 02/2021 - Present
Florida (Medicine and Surgery) 12/2020 – Present
Arkansas (Medicine and Surgery) 02/2021 – present
People's Republic of China 03/2012 – 04/2014

Committees

Minnesota Department of Corrections Task Force on Justice Involved Women and Girls
Appointed 8/2022, reappointed 1/2023
Minnesota Mortality Review Committee. Appointed 2019 - 2021

Education

University of Minnesota Medical School, Minneapolis, Minnesota – Medical Fellow, Department of Obstetrics, Gynecology, and Women's Health 06/2004 - 06/2008

University of Utah School of Medicine, Salt Lake City, Utah - MD 09/2000-
05/2004

Yale University School of Medicine, New Haven,
Connecticut - MPH, Master of Public Health and Epidemiology 09/1998 - 05/2000

University of Wisconsin - Madison, Madison, Wisconsin - BS 09/1992 - 05/1996

Honors and Awards

CREOG National Teaching Award –American College of Obstetrics and Gynecology, Council for Resident Education in Obstetrics and Gynecology. Awarded to faculty by the residents in Obstetrics and Gynecology at Mayo Clinic - 06/2019

Teacher of the Year Award – Mayo Clinic Alix School of Medicine - 06/2019

Raymond J. Albrecht Award - University of Minnesota Department of
Obstetrics, Gynecology, and Women's Health
Awarded to the graduating resident exemplifying the highest values of the practice
06/2008

Arnold P. Gold Foundation Humanism and Excellence in Teaching Award
- Arnold P. Gold Foundation – 2006

Best PGY-2 Teaching Resident - University of Minnesota Medical
School, Minneapolis, Minnesota - 2006

Additional Education

Royal College of Obstetricians and Gynecologists
World Congress Annual Meeting
London, United Kingdom

06/2019

ACOG District II Annual Meeting
ACOG District II, New York, New York
10/2014, 10/2015, 10/2016, 10/2018, 10/2019

American College of Obstetrics and Gynecology (ACOG)
Department of Patient Safety and Quality Improvement, Washington DC, United States of America
04/2017 - 04/2017

National Rural Health Association Conference
Obstetric Care and Hospital Closures in Rural Areas, San Diego, California
05/2017 - 05/2017

High Risk and Critical Care Obstetrics
Symposia Medicus
05/2016

Society of Obstetrics and Gynecology Canada
ALARM course, Winnipeg, Manitoba
10/2016 - 10/2016

Management of the Labour Ward
Royal College of Obstetricians and Gynecologists, London, United Kingdom
06/2015 - 06/2015

Administrative Responsibilities, Committee Memberships

Mayo Clinic Rochester, MN USA
OB/GYN Quality Committee
Active Member 2016 - 2021
Department of Obstetrics & Gynecology
FBC Inpatient Practice Group
Active Member 2014 - 2021
FBC Labor & Delivery / Triage Practice Group
Active Member 2014 - 2021
Perinatal Practice Group
Active Member 2014 – 2021

Academic Career Development
Mayo Clinic Quality Fellow, Silver Certification 2021

American Congress of Obstetricians and Gynecologists (ACOG) Quality and Safety for leaders in Women's Health Care
Washington, District of Columbia
04/2017
Professionalism 1
Office of Leadership and Organizational Development
Rochester, Minnesota
05/2014
Healthy Dialogue
Office of Leadership and Organizational Development

Rochester, Minnesota
05/2014
Leading with Emotional Intelligence
Office of Leadership and Organizational Development
Rochester, Minnesota
08/2015

Professionalism 2
Office of Leadership and Organizational Development
Rochester, Minnesota
08/2015
Communication in Healthcare
Office of Leadership and Organizational Development
Rochester, Minnesota
08/2015

Professionalism 3
Office of Leadership and Organizational Development
Rochester, Minnesota
06/2016

Professional Memberships and Societies

Professional Memberships and Services

American College of Obstetricians and Gynecologists (ACOG)
Member 2012 - Present

Royal College of Obstetricians and Gynaecologists
(RCOG) Associate Member 2019- Present

Education Interests and Accomplishments

Teaching

OB Clinical Skills workshop
Instructor
Mayo Medical School
Rochester, Minnesota
07/2014, 07/2015, 07/2017, 07/2020

Mayo Clinic Department of Obstetrics and Gynecology
Clinical Reviews
OB emergency Simulation: Maternal Code
Rochester, MN
11/2016, 11/2017

MMSI Surgical Skills lab instructor
Mayo Medical School
Rochester, Minnesota
03/2015

Intrapartum Fetal Monitoring Review
Mayo Clinic Department of Ob/Gyn

Rochester, Minnesota
01/2015

Chief Case Review
Mayo Clinic OB/Gyn Residency Program
Rochester, Minnesota
12/2014

Presentations Extramural

National or International

Invited

National Rural Health Association Conference
Obstetric Care and Hospital Closures in Rural Areas
San Diego, California
05/10/2017

Oral

Differences Between Hospitals in Cesarean Rates for Term Primigravadis With Cephalic Presentation
Society for Gynecologic Investigation 2005 Annual Meeting
Houston, Texas

Poster

Acute Drug Abuse, Epidemiology and Local Trends
American Public Health Association Annual Meeting
Chicago, Illinois
1999

Regional

Oral

Macrophage Chemoattraction Protein-1Levels in Ovarian Cancer 'Matched' Tumor Specimens: Coorelation Between Macrophage Infiltration and Angiogenesis
University of Minnesota Resident Research Day
Minneapolis, Minnesota
05/2008

Clinical Practice, Interests, and Accomplishments

Maternal and child health quality; safety practices in both developed and low-resource settings. Volunteer activities: Medical service to Seguin and Jacmel, Haiti.

Research Interests and Accomplishments

7/2006-5/2008: University of Minnesota Dept of Gynecologic Oncology Research assistant; Investigated the role of MCP-1 production at the time of a secondary cytoreductive procedure amongst patients with ovarian cancer and how it correlates with increased markers for angiogenesis and with poor clinical outcome.
6/2003-5/2004: University of Utah Department of Obstetrics/Gynecology / Utah State Dept. of Health, Clinical research assistant; Contributed to clinical research in cesarean delivery rates and differences between hospitals in Salt Lake City.
5/2001-7/2001: University of Utah School of Medicine, Dept of Physiology, Experimental research assistant; Helped conduct research studying surfactant production in neonatal respiratory distress syndrome.
1/2000-5/2000: Yale University Dept of Molecular, Cellular, and Developmental Biology; Teaching Assistant to undergraduate Developmental Biology course.
5/1999-8/1999: United States Public Health Service, Eastern Arizona Office of Environmental Health and Engineering; Assisted in the development and implementation of injury prevention programs within four Native American Nations in the southwestern United States.

12/1996-4/1997: National Institute of Hygiene and Epidemiology, Hanoi, Vietnam: Research assistant
Contributed to ongoing research investigating enteric disease in children under five years of age.

Peer-reviewed Articles

1. Kim S., King A., Parikh P., Sangtani A., Shazly S., Brodrick E., **Thompson A**. Optimizing Post-Cesarean Opioid Prescription Practices at Mayo Clinic: A Quality Improvement Initiative. Am J Perinatology 2022; 39(04): 337-341; doi:10.1055/s-0041-1739491

2. Shazly S, Ahmed I, Radwan A, Abd-Elkariem A, Ell-Dien N, Ragab E, Abouzeid M, Shams A, Ali A, Hemdan H, Hemdan M, Nassr A, AbdelHafez A, Eltaweel N, Ghoniem K, Saman A, Ali M, **Thompson A.** Middle East Obstetrics and Gynecology Graduate Education (MOGGE) Foundation Practice Group. MOGGE Foundation Practice Guidelines: Prelabor rupture of membranes; Practice Guideline No. 01-0-19. *Journal of Global Health*. (2020); doi:10.7189/jogh.10.010325

3. Warner LL, Hunter Guevara LR, Barrett BJ, Arendt KW, Peterson AA, Sviggum HP, Duncan CM, **Thompson AC**, Hanson AC, Schulte PJ, Martin DP, Sharpe EE. Creating a model to predict time intervals from induction of labor to induction of anesthesia and delivery to coordinate workload. *International Journal of Obstetric Anesthesia* (2020); doi: https://doi.org/10.1016/j.ijoa.2020.12.004

4. **Fischer A**, LaCoursier Y. Differences Between Hospitals in Cesarean Rates for Term Primigravidas With Cephalic Presentation. *Obstetrics and Gynecology.* 2005; 105:816-21. ***(****former last name of 'Fischer')*

EXHIBIT 11

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

BRIANNA BOE, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
UNITED STATES OF AMERICA,	)	
	)	
Intervenor Plaintiff,	)	
	)	
v.	)	Civil Action No. 2:22-cv-184-LCB
	)	
HON. STEVE MARSHALL, in his Official capacity as Attorney General, of the State of Alabama, *et al.*,	)	
	)	
Defendants.	)	

CORRECTED EXPERT REPORT OF
GEETA NANGIA, M.D.

TABLE OF CONTENTS

I, Geeta Nangia, MD, have been retained by counsel for the Defendants in connection with the above captioned litigation.

1. I have been asked by counsel for the Defendants to provide my expert opinion on the diagnosis and treatment of gender dysphoria in minors as it relates to Alabama SB184.

2. I am over the age of 18. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion. I am being compensated at an hourly rate of $350.00 per hour for documentation and $550.00 per hour of testimony that I devote to this case. My compensation does not depend on the outcome of this litigation, the opinions that I express, or the testimony that I provide.

BACKGROUND AND QUALIFICATIONS

3. I am a Board-Certified Child and Adolescent Psychiatrist, and Board-Certified Adult Psychiatrist. I obtained my B.A. in Biochemistry and Molecular Biology from Boston University and my M.D. from Boston University School of Medicine. I graduated with the Ruth Hunter Johnson Prize in Psychiatry. My residency and fellowship training, in Psychiatry and Child and Adolescent Psychiatry, respectively, were at The Medical University of South Carolina (MUSC). I completed my fellowship in 2007.

4. I have been active in teaching medical students and residents throughout my

career and received the Circle of Excellence in Teaching at MUSC. In recent years, my clinical lectures have focused on child and adolescent development.

5. I have worked in the field of Child and Adolescent Psychiatry as a community psychiatrist in a wide range of settings, providing comprehensive psychiatric services for children and families. I chose to work as a community psychiatrist because I desired to evaluate and treat a wide range of mental health disorders and wanted to see young people in the context of their families and community "systems" (e.g., schools, extracurriculars, local supports). Throughout my career I have worked in rural, urban, and suburban areas, and in outpatient, inpatient, partial, as well as residential care settings. I have been very active in school consultations and advocating on a community level for mental health accommodations for youths in school. I have worked toward providing access to mental health care for youths who are underfunded and lack services due to barriers of access and cost. I have provided psychiatric evaluations, psychotherapy, and medication management for children and adolescents, as well as family therapy. I have been a part of multiple interdisciplinary teams.

6. Much of my career has been spent educating, equipping, and supporting families of children who struggle with depression, anxiety, and other mental health issues by stressing the importance of attachment between parents and

children. I believe that an attachment-centered approach to therapy helps children to find their homes as a safe place to connect, where they feel nurtured, supported, and loved. It is connection and secure attachment to safe caregivers that form the foundation for healthy childhood development, allowing a child to successfully progress through the developmental trajectory toward identity consolidation.

7. I continue to provide community mental health care through my private practice and am providing this opinion as a child psychiatrist working in private practice.

8. Over the course of my career, seeing a broad range of psychiatric disorders, I have treated many patients with active gender dysphoria or a history of gender dysphoria. Per my best reflection, I'd estimate that 550 of these have been minors. As discussed below, the modalities of care that I have utilized with minor patients who have gender dysphoria include supportive and exploratory (psychodynamic) therapy, family therapy, and psychopharmacology. The latter has only been used if children and adolescents are also struggling with mental health disorders such as depression or anxiety. I have collaborated with others in the community to garner a network of support for my patients, when deemed appropriate.

9. Given the nature of being a community child psychiatrist, I have the benefit

of being involved with children's health care not only in my office, but also with their families, schools, and outside support systems. This provides me with the ability to have a more complete perspective on their development, and the interventions that produce the best outcomes for their overall wellbeing.

10. My medical opinion below is based upon my training and clinical experience as a Child and Adolescent Psychiatrist, my knowledge of child development, and review of the literature (including standards) on this subject. I may wish to supplement my opinions or the bases for them as new research is published or in response to statements made in my area of expertise.

11. My previous expert witness testimony has been regarding abuse and trauma, and interventions for children struggling with mental health disorders. I also submitted a written report in *Dekker v. Marstiller*, No. 4:22-cv-325-RH-MAF (N.D. Fla.).

12. For medicolegal purposes, I have also, throughout my career in mental health, served as a designated examiner for persons during inpatient hospitalizations, and as part of this process, I have performed numerous capacity assessments and presented them to courts.

GENDER DYSPHORIA

I. Diagnostic Criteria

13. Gender dysphoria in adolescents is defined by the DSM-5-TR as: A marked incongruence between one's experienced/expressed gender and assigned gender, of at least six months duration, as manifested by at least two or more of the following:

- A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
- A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
- A strong desire for the primary and/or secondary sex characteristics of the other gender
- A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
- A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)

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

The condition is associated with clinically significant distress or impairment in social, occupational, and other important areas of functioning. (DSM-5, TR)

14. According to the American Psychiatric Association, gender dysphoria often begins in childhood, but some individuals may not experience it until puberty or much later. (DSM-5-TR)

15. The DSM-5-TR defines gender dysphoria in children as a marked incongruence between one's experienced/expressed gender and assigned gender, lasting at least six months, as manifested by at least six of the following (one of which must be the first criterion):

- A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender)
- In boys (assigned gender), a strong preference for cross dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.

- A strong preference for cross gender roles in make-believe play or fantasy play
- A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender
- A strong preference for playmates of the other gender
- In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities, and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities
- A strong dislike of one's sexual anatomy
- A strong desire for the physical sex characteristics that match one's experienced gender

As with adolescents and adults, the condition must also be associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning. (DSM-5-TR)

II. Prevalence

16. According to a 2022 study done by The UCLA School of Law Williams Institute, entitled "How Many Adults and Youth Identify as Transgender in the United States?" over 1.6 million adults and youth (13-17) identify as transgender in the U.S. Among youth ages 13-17, 1.4 percent identify as

transgender. The data used was from the CDC's BRFSS and YBRS (Behavioral Risk Factor Surveillance System and the Youth Risk Behavior Survey). The BRFSS questionnaire asks, "Do you consider yourself to be transgender?" (Herman 2022)

17. Research shows that transgender individuals are younger on average than the U.S. population, and youth ages 13-17 are significantly more likely to identify as transgender than adults ages 65 and older. (Herman 2022)

18. At the state level, estimates from this same study show that 3.0% of youth ages 13-17 are identifying as transgender in New York as compared to 0.6% in Wyoming. (Herman 2022)

19. Per a 2022 report from Herman et al. and The Williams Institute, when comparing the current report with estimates made by The Williams Institute in 2016-2017, researchers found that the percentage and number of adults who identify as transgender has remained steady over time. The YRBS data shows that youth comprise a larger share of the transgender identified population than what was previously estimated, currently comprising 18.3% of the transgender identified population in the United States, up from 10 percent previously. (Herman 2022)

20. There are several contributing factors to the rise of gender dysphoria that I observe in my own patient population: 1) an increase in "pathologizing" of

what I view — and what much of the reliable scientific literature has long viewed — as a normal part of childhood development, 2) shifts in cultural norms having to do with gender exploration in adolescence, 3) the advent of social media, 4) heightened vulnerability in youth, and 5) what some call "social contagion." These are explained below.

21. Increase in pathologization of a normal part of childhood development: When gathering a developmental history, it has been my experience that many parents and children describe a period of time, greater than six months, during which the child was a "tomboy" or "tomgirl" (per their own terminology). When discussing this further, most of these parents and children openly talk about how the child felt strongly that he/she wanted to be the opposite gender, preferred to play with stereotypical opposite gender toys and in opposite gender activities, preferred cross-gender roles in make believe play, wanted to wear opposite gender clothing, preferred opposite gender playmates, rejected same gender toys/activities, and had significant associated distress. These are the first six out of eight criteria in the gender dysphoria diagnosis, and only six criteria and significant distress are necessary for the diagnosis. However, these children weren't ever diagnosed formally, their parents didn't label or pathologize their behavior, and the symptoms eventually passed and the children became comfortable with their natal sex.

22. In colloquial English, in decades past, society referred to children who had such symptoms as "tomboys" and "tomgirls." Gender-medicine experts today distinguish between tomboys or tomgirls and children with gender dysphoria. They state that the former display an outward expression of the opposite gender to the world, but feel an internal comfort with their birth gender. The latter, they say, have an internal psychological sense that they are of another gender. (DSM-5-TR)

23. The American Academy of Child and Adolescent Psychiatry uses the terms gender nonconformity versus gender discordance to make this same distinction. However, they acknowledge in their Practice Parameters that "there may be clinical difficulty distinguishing between gender nonconformity and gender discordance." (Adelson 2012)

24. In my clinical experience, I have had difficulty appreciating this distinction. First, this is because both parents and children, who describe such a period in the child's life of having been a "tomboy" or "tomgirl," most often retrospectively endorse the criteria that are necessary for the gender dysphoria diagnosis. Second, this assertion — that children with gender dysphoria have an "internal psychological sense" of their gender incongruence — implies that children are able to have consolidated identity. This is not congruent with what we know about identity formation and consolidation, a stage which

doesn't occur until adolescence. While gender identity is in the process of forming in very early childhood, this formation continues to be influenced by multiple factors over many years, as the normal course of childhood development unfolds. It isn't until adolescence that several key psychosexual and psychosocial development models show identity forming and becoming more fixed. In other words, children's sense of who they are, or their "identity," can and often does shift over time as part of normal development. It is not until they reach the end of adolescence, at the cusp of adulthood, when identity is said to consolidate. (Erikson 1998)

25. Still, this notion that children have an internal sense of gender and should be offered specialized care if they endorse the above criteria has led to the unnecessary pathologization of what otherwise has been considered a normal phase of development. This mistaken notion has contributed to an increase in gender dysphoria diagnoses. Many parents, who in the past simply would have not worried about their children who had the above "symptoms," are now compelled to consider a diagnosis of gender dysphoria and treat the child because of the fear that their child may suffer if they don't. Physicians, likewise, are acting quickly to usher these children into gender-affirming care, out of the same fear. This is in spite of the data showing that "cross-gender wishes usually fade over time and do not persist into adulthood." (Adelson

2012)

26. Shifts in cultural norms in adolescence and the advent of social media: Culturally, society has created a new "norm" of gender questioning and exploration in adolescence. This cultural norm of gender exploration also has been reinforced by the medical community. According to a recent *New York Times* article, "It's developmentally appropriate for teenagers to explore all facets of their identity — that is what teenagers do," stated Dr. Angela Goepferd, medical director of the Gender Health Program at Children's Minnesota Hospital. "And, generationally, gender has become a part of someone's identity that is more socially acceptable to explore." (Ghorayshi 2022)

27. Hence, not only have cultural norms shifted due to information availability and social media, but they have also shifted due to physicians informing parents and children that gender exploration is healthy and appropriate. One can infer that if a child has never questioned their own gender previously, this new norm tells them that it is healthy to do so and encourages it as part of normal development.

28. Further, the advent and expansion of social media has created waves in what youth consider to be popular, acceptable, and normative. Youths are consuming more social media than ever before. Social media enables the

spread of information pertaining to many issues, including those related to sexual development, sexual orientation, sexual activity and practices, and gender. There has been a dramatic increase in the global public discourse surrounding LGBTQA issues amongst youths. There has been widespread content circulating throughout society on gender exploration, incongruence, and dysphoria. This is generally accompanied by passionate advocacy that is highly regarded by youths of all ages. Celebrities have highlighted LGBTQA issues and have used various forms of social media, like TikTok, to promote and celebrate gender incongruence. On a local level, information sharing has led to the popularity of LGBTQA clubs at schools, community groups dedicated to raising awareness and acceptance, and enthusiastic support networks for those who identify as LGBTQA. Many of these can easily be found online. With the spread of online information and cultural advocacy, the natural heightened propensity of youth to explore gender and see it as fluid has increased.

29. In a 2018 study on parent surveys of children with gender dysphoria, Littman writes: "Parents identified the sources they thought were most influential for their child becoming gender dysphoric. The most frequently answered influences were: YouTube transition videos (63.6%); Tumblr (61.7%); a group of friends they know in person (44.5%); a community/group of people

that they met online (42.9%); a person they know in-person (not online) 41.7%." (Littman 2018)

30. Youths are more vulnerable to novel information streams. According to another article in *The New York Times*,

> Helana Darwin, a sociologist at the State University of New York at Stony Brook who began researching nonbinary identities in 2014, found that the social-media community played an unparalleled role in people's lives, especially those who were geographically isolated from other nonbinary people. . . . Her research found that social media is a gathering place for discussing the logistics of gender — providing advice, reassurance and emotional support, as well as soliciting feedback about everything from voice modulation to hairstyles. . . . Psychologists often posit that as children, we operate almost like scientists, experimenting and gathering information to make sense of our surroundings. Children use their available resources — generally limited to their immediate environment — to gather cues, including information about gender roles, to create a sense of self.

(Wortham 2018)

31. In this same *New York Times* article, author Jenna Wortham asked Alison Gopnik, a renowned philosopher and child psychologist, "if it's possible that social media can function as a foreign country, where millions of new ideas and identities and habitats are on display — and whether that exposure can pry our calcified minds open in unexpected ways." Gopnik replied, "Absolutely. . . . Having a wider range of possibilities to look at gives people a sense of a wider range of possibilities, and those different experiences might

lead to having different identities." Wortham continued:

> When we dive into Instagram or Facebook, we are on exploratory missions, processing large volumes of information that help us shape our understanding of ourselves and one another. And this is a country that a majority of young adults are visiting on a regular basis. A Pew study from this year found that some 88 percent of 18-to-29-year-olds report using some form of social media, and 71 percent of Americans between ages 18 and 24 use Instagram. Social media is perhaps the most influential form of media they now have. They turn to it for the profound and the mundane — to shape their views and their aesthetics. Social media is a testing ground for expression, the locus of experimentation and exploration.

(Wortham 2018)

32. So, it would seem most plausible that the normalization and even encouragement of gender exploration in adolescence combined with the emphasis on building awareness of gender dysphoria, particularly through social media, would lead to a heightened prevalence of the gender dysphoria diagnosis. More adolescents naturally are exploring gender, more have awareness of gender fluidity and gender dysphoria, and more are seeking out help or guidance.

33. For example, an adolescent natal female who has been bullied by female peers for years now has shifted to having mainly male friends, preferring male athletic clothing, and wanting a short haircut to fit in with them. She believes her emotions to be more in line with theirs and feels distress over this. Later, through exposure to transgender friends and information she finds online, she

comes to believe that she has gender dysphoria and needs gender-affirming care, so she seeks help. Previously she may have viewed her feelings of distress and her behaviors to be a mere reflection of her vulnerability around females based on her negative experiences. In years past, such an adolescent natal female may not have interpreted that her feelings and negative experiences or the reactions of others had anything to do with a condition like gender dysphoria. But now, surrounded by widespread societal, cultural, and peer encouragement, she may contextualize those feelings and discomfort in ways that prompt her to inquire, first, into gender dysphoria as a concept, and then into riskier or more invasive and biologically systemic responses to her internal discomfort. Situations like this are common, in my experience, and I believe they have led to an increase in the diagnosis of gender dysphoria.

34. Heightened vulnerability: Youth today are also experiencing more vulnerability and a feeling of being disconnected, or not belonging. A new U.S. Department of Health and Human Services (HHS) study published in the American Medical Association's journal, *JAMA Pediatrics*, reports significant increases in the number of children diagnosed with mental health conditions. The study, conducted by the Health Resources and Services Administration (HRSA), finds that between 2016 and 2020, the number of children ages 3-17 years diagnosed with anxiety grew by 28.9% and those

with depression by 26.7%. (Lebrun-Harris 2022)

35. Certainly, there has been a large increase in mental health disorders in the United States over the last several years, with COVID increasing the numbers of vulnerable children. Families have been struggling, and there has been an increased rate of family disruption. Stress and trauma have exponentially increased, and all these stressors impact youth vulnerability, and youth seeking out places where they fit and belong. In my experience with adolescents, many are drawn to LGBTQ clubs and online groups, and find them to be a kind respite where they are cared for, affirmed, and feel a sense of comradery with other peers who've faced social vulnerability and had a feeling of not belonging. Feeling embraced and accepted by friends whom they can relate to may lead them to consider that they, too, may be transgender. In my adolescent patients, this type of feeling is echoed often and lends to them endorsing gender-dysphoria criteria.

36. Social Contagion: Lastly, heightened prevalence of gender dysphoria may be attributed to a "bandwagon effect" or, as others call it, "contagion." In my experience, adolescents presenting with gender dysphoria have often described being influenced by peers and social media to consider that they may be the opposite gender. Similar types of influence have been reported in the past with other mental health conditions in psychiatry. For example, a

study showed self-harming behaviors were socially contagious in adolescents, and studies on eating disorders have shown similar patterns. (Riggio 2022; Dishion 2011)

III. Treatments

37. According to the American Academy of Child and Adolescent Psychiatry, principles that are important in the treatment of youth with gender discordance are as follows:

1) A comprehensive diagnostic evaluation should include an age-appropriate assessment of psychosexual development for all youths

2) The need for confidentiality in the clinical alliance is a special consideration in the assessment of sexual and gender minority youth.

3) Family dynamics pertinent to sexual orientation, gender nonconformity, and gender identity should be explored in the context of the cultural values of the youth, family, and community.

4) Clinicians should inquire about circumstances commonly encountered by youth with sexual and gender minority status that confer increased psychiatric risk.

5) Clinicians should aim to foster healthy psychosexual development in sexual and gender minority youth and to protect the individual's full capacity for integrated identity formation and adaptive functioning.

6) Clinicians should be aware of current evidence on the natural course of gender discordance and associated psychopathology in children and adolescents in choosing the treatment goals and modality.

7) Clinicians should be prepared to consult and act as a liaison with schools, community agencies, and other health care providers, advocating for the unique needs of sexual and gender minority youth and their families.

8) Mental health professionals should be aware of community and professional resources relevant to sexual and gender minority youth.

(Adelson 2012) The parameters also note, with regard to medical or surgical transition: "In general, it is desirable to help adolescents who may be experiencing gender distress and dysphoria to defer sex reassignment until adulthood, or at least until the wish to change sex is unequivocal, consistent, and made with appropriate consent." They go on to describe

different treatment approaches when waiting until adulthood is not "feasible." One approach described is puberty suppression at age 12 followed by cross-sex hormones at age 16, and then gender reassignment surgeries at age 18. Another approach is waiting until Tanner Stage 2 to initiate pubertal suppression, and then proceeding with options for cross-sex hormones and gender reassignment surgeries. A therapeutic group approach with families to help them offer support is described. While the authors report negative outcomes with conversion therapies, they repeatedly comment on the lack of controlled trials looking at other therapeutic (including psychodynamic therapy) approaches in children with gender discordance. (Adelson 2012)

IV. Medical Interventions and Associated Risks

38. Medical gender transition involves puberty blockers and subsequently cross-sex hormones. These interventions are frequently followed by surgeries that can include but not limited to breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery.

39. Puberty blockers (gonadotropic releasing hormone agonists or GnRHa) are a form of medication that block the physiological production of sex hormones and are given during the Tanner Stage 2 of development when puberty has just started. (Delemarre-van de Waal 2006)

40. Testosterone (in males) and estrogen (in females) are responsible for changes that occur in puberty. Puberty blockers stop the production of follicle-stimulating hormone (FSH) and luteinizing hormone (LH) from the pituitary, and this then prevents the production of sex hormones.

41. None of the puberty blockers are currently FDA-approved for use in gender dysphoria.

42. In gender dysphoria, puberty blockers are given "off-label" to postpone the changes that occur with puberty. The clinical reasoning behind this is that proponents say that it gives youth time to decide whether to "fully" transition, through a trajectory of cross-sex hormones and then surgeries, while preventing changes that may cause distress. (Delemarre-van de Waal 2006)

43. There is marked debate on the safety of puberty blockers, cross-sex hormones, and surgeries utilized in gender transition.

44. Some of the risks that are debated in the literature are the long-term effects of these medications on the endocrine system, reproductive system, bone growth, brain maturation, psychological functioning, and metabolic functioning.

45. I am generally familiar with the literature surrounding these debates. I have reviewed the report of Dr. James Cantor submitted in this case and agree with his conclusion that the existing studies of puberty-blockers and cross-sex

hormones in minors provide no reliable evidence of effectiveness for improving mental health relative to mental health treatments that lack medical risk. I also agree with his conclusion that all existing systematic reviews of safety and effectiveness of these treatments have concluded that the evidence on medicalized transition in minors is of poor quality.

V. Clinical Experience with Gender Dysphoria

46. As part of an initial evaluation, I ask individuals how they identify in terms of sexual orientation and gender. When taking a developmental history during an in-person assessment, I ask about an individual's social development, as well as questions pertaining to self-concept (how one views oneself). As part of this, I may delve into questions that deal with gender, in an age-appropriate manner, with the child, adolescent, and/or parent. Questions that I ask pertaining to gender identity include, but are not limited to:

- 1) How did you feel about your gender early on in your life?
- 2) Did you feel comfortable with your gender?
- 3) If not, did you identify with another gender?
- 4) How did this affect you, and the way that you saw yourself?
- 5) What types of play did you enjoy the most?
- 6) Were most of your friends of the same gender or opposite gender?
- 7) Do you remember feeling discomfort with your body in any fashion?

- 8) Did you prefer to ever dress as another gender?
- 9) If you previously felt more comfortable as another gender, or unsure of identifying with your birth sex, how long did this persist?
- 10) If you now feel comfortable with your natal sex, but previously did not, what led to you feeling comfortable?

47. The reason such questions are important in addressing self-concept — and gender as a part of self-concept — is that, developmentally, an individual's early experiences and view of oneself in the context of a greater environment are important to understanding the individual's presenting clinical issues.

48. Since becoming a physician in 2002, I estimate that I've evaluated and treated 550 children and adolescents (and hundreds of adults) who have met criteria at some point in their lives for a "gender dysphoria" diagnosis. Of 550 adolescent patients, I approximate that 350 of these patients had a history of gender dysphoria, as discovered on evaluation or over the course of patient care. This was ascertained via parent or child retrospective report wherein they had met criteria for the diagnosis. For these children, the gender dysphoria resolved with age maturation alone prior to seeing me. Many of these children were referred to by their parents as having been a "tomboy" or "tomgirl," and their parents were not concerned. I discuss these terms above. I did not label or pathologize these children during the course of their mental

health treatment as having had "gender dysphoria," despite the diagnostic criteria seeming to have been met. But for the purpose of this declaration, I am including them in the discussion of patients I have treated who have had gender dysphoria.

49. I estimate that I've seen close to 100 additional child patients who meet criteria for gender dysphoria on clinical interview during or over the course of treatment with me (as opposed to retrospective report). I have often observed that children's feelings regarding their own gender are a reflection of their perception of gender roles within their family unit and sphere of influence. I have had many female child patients who enjoy climbing trees and playing "boy sports," playing with "boy toys," who have a strong desire to be boys like their brothers, play with only boys on the playground, reject "girly" toys and activities, and want to use the restroom standing up like boys do. These children often are emotional and experience some real distress for significant periods about having been born as girls and wanting to be boys in every imaginable way. I've had male child patients who do the opposite. With all these children, I have told their parents not to become anxious, and not to pathologize or characterize their child based on their observations.

50. In every case that I have observed, children grow out of such "gender dysphoria" and become comfortable with their natal sex. In fact, these

children are naturally some of the most confident children I've seen over time. I have always attributed this to their parents being comfortable allowing them to explore and engage in free play without feeling any anxious desire to push them toward the toys and activities that are stereotypical of only one gender. They have not pathologized or seen their child's preferences for play and fun as something to be concerned about. Hence, their children learn confidence to explore the world around them, feel validated and affirmed by their parents, without any assumptions that their exploration is anything more than a normal part of growing up.

51. My experience has been that periods of gender incongruence and associated distress are normative and transient, with resolution as the child matures. I have provided these parents and children with guidance; support; and, when needed, exploratory therapy.

52. I also estimate that I have seen just over 100 adolescents who have presented with gender dysphoria that has been more abrupt in onset. The majority of these are biological females, and these cases have grown increasingly frequent over recent years.

53. In these cases, adolescents and/or their parents reported at least one of the following issues as also being primary within their life "systems" (e.g., school, family, peer group, community): 1) a feeling of not fitting in with peers, or

feeling "different" and not belonging, 2) an experience of gender roles within their own families, or within their peer groups, that has had a marked influence on their own perception of gender and gender identity, 3) a history of trauma, 4) a history of disruption of primary attachment, 5) a history of feeling vulnerable and emotionally unsafe, 6) a history of depression, anxiety, or social anxiety, 7) a history of an autism spectrum disorder, 8) an exposure to information on gender via social media, TV, or the internet, with a subsequent curiosity about gender exploration, 9) a feeling of vulnerability, followed by a search for belonging, or 10) a feeling of a good "fit" among peers who have also felt vulnerable in an LGBTQA group online or in school.

54. Almost all of the adolescent patients had taken steps to access additional information about their gender dysphoria from readily available online sources and social media, and many found friendship within LGBTQA clubs at school or online friends in the LGBTQA community. They described feeling accepted, supported, and affirmed within these social groups. Some did not identify as the opposite gender, but rather stated they were "gender queer" or "non-binary."

55. For all of these youth, I provided exploratory therapy, supportive therapy, and family therapy, or I worked with a therapist who collaborated with me in treatment, to address these factors within the adolescent's life systems. I also

provided medication management where needed for other mental health issues. Their treatment plans included crafting an individualized approach from the above therapies, harnessing community support, and providing guidance to parents in two key areas: 1) How to best be "present" and establish an emotionally safe environment at home, and 2) how to grow in connection and relationship with their child by loving them for who they are. Among these adolescents, the vast majority realigned with their natal sex over the period of treatment. Some stated, over time, that they were questioning their sexual orientation, and not their gender. All responded to these interventions positively such that, over time, regardless of whether they'd realigned with their natal sex or had a future plan to transition, they no longer experienced gender dysphoria and their mental health improved. Those who had continued gender incongruence felt that they wanted to see how they felt over time rather than pursuing options to medically transition as minors. They were appreciative of the support and therapy and found it helpful.

56. I've treated approximately 25 children/adolescents during their social and/or medical transition. I supported them where they were at on their journey, through psychotherapy and medication management, and I respected their decision based on what treatment options had been afforded to them by other doctors. To clarify, I have never personally referred a minor for medical

transition, as I don't believe the option should be given to minors based on reasons I explain below.

VI. The Role of Exploratory Therapy for Gender Dysphoria in My Practice

57. Minor patients with gender dysphoria benefit tremendously from therapy that explores their feelings and experiences within their "life systems," past and present. I have found that adolescents with gender dysphoria are generally very open to this. They voice that they feel supported and that they gain clarity in the process. Through therapy, just like most youth with presentations other than gender dysphoria, these patients improve in self-concept and mindfulness, becoming aware of how their experiences have affected them, and what defenses they employ when feeling challenged or stressed. They learn to identify their own values and what matters to them, which makes their choices and decisions clearer.

58. The primary modality of therapy that I have utilized in treating gender dysphoria is psychodynamic therapy, I have also utilized cognitive behavioral therapy, interpersonal therapy, and family therapy. I *do not* endorse conversion therapy and I believe it is detrimental. I have treated one adolescent who underwent conversion therapy as part of a religious school prior to seeing me, and she suffered significant trauma as a result. This patient required specific therapy to help her process that trauma.

59. Psychodynamic therapy engages individuals in "free association." Free association is the idea that whatever is on a patient's mind guides the clinical session. The free association, or whatever the patient brings up, is deemed of importance and is used to spur exploration of the patient's past and how that past may be affecting the patient's present circumstances and feelings.

60. In this context, then, the therapist can help the patient identify how repressed feelings from the past may be influencing the patient's current decision making, relationships, and behaviors. Over time, this leads to natural "uncovering" of coping and defense mechanisms, fears, desires, and values that are rooted in a person's past experiences.

INFORMED CONSENT

61. To provide children the best-quality care, physicians should abide by the ethical standards that are universal to the practice of medicine. One of these standards is informed consent. Implicit to the informed consent process are related standards of medical ethics that are central to the practice of medicine, taught in medical school, and widely accepted.

I. Medical Ethical Standards

62. These universal ethical standards include beneficence, non-maleficence, autonomy, truth-telling, confidentiality, and justice.

63. Beneficence is the obligation of the physician to act for the benefit of the

patient. In principle, the physician should support moral rules to protect and defend the rights of others, prevent harm, remove conditions which cause harm, help persons with disabilities, and rescue persons in danger. This means not simply avoiding harm, but actively seeking to promote the welfare of the patient. Beneficence is applied most often during clinical assessment, but also throughout treatment (Varkey 2020).

64. Non-maleficence is the obligation of the physician to not harm the patient. This is supported by moral rules (e.g., do not cause pain or suffering, do not kill, do not cause offense, or deprive others of the goods of life). Hence, the doctor must weigh the benefits of interventions with risks or burdens they may place on the patient. Nonmaleficence and beneficence are both part of the quality-of-life discussion between a doctor and patient. (Varkey 2020)

65. Autonomy is the supposition that all persons have intrinsic and unconditional value or worth, and therefore, should have the power to make moral choices and rational decisions, and to do so for self-determination. (Guyer 2003)

66. Autonomy does not extend to persons who lack capacity to act autonomously. Thus, children, adolescents, or individuals who have disorders that prevent capacity or competency lack autonomy. (Grisso 1998) Autonomy is at its most important as the doctor considers patient rights and preferences.

67. Truth-telling is the principle that doctors must not withhold information, nor

misrepresent it, but rather provide information plainly and honestly to the patient, so that the patient or parent can, in turn, demonstrate full understanding in order to provide voluntary consent. Informed consent is at its most important in discussing treatment options, and truth-telling is critical throughout patient care.

68. Confidentiality is maintaining the patient's privacy. This must apply to all domains of treatment.

69. Justice is the fair, equitable, and appropriate treatment of persons. Distributive justice is the equitable distribution of health care resources determined by justified norms. This standard is at its most important in the discussion of external forces and context for a patient, including their cultural, spiritual, religious, and economic beliefs and circumstances. (Fleischacker 2005; Varkey 2020)

70. In providing care for gender dysphoria, or for any other medical or mental health condition, these ethical standards must be adhered to.

II. Informed Consent as an Ethical Standard in Minors

71. The principle of informed consent rests upon the moral and legal premise of patient autonomy. In all populations, informed consent must balance the respect for patient autonomy with the protection of patient vulnerability. (Appelbaum 2007) This is particularly relevant as it applies to minors.

72. The informed consent process requires that certain criteria be met, and these are dependent on development (neurologic, cognitive, psychosocial) and experience. Informed consent involves the following principles: a) decision-making capacity, b) full disclosure of medical options, c) comprehension, and d) voluntary consent. (Grisso 1998) Voluntary consent is one's agreement to the intervention, without coercion or distress. Explanation of the other principles, and the neurodevelopmental requirements for each, follows.

A. Decision-Making Capacity

73. To provide informed consent, one must have the ability to make the decision at hand. In a model of assessing decision-making capacity in children, Miller et al. identified cognitive development and experience as being pivotal. (Miller 2004)

74. In an article published in BMC Pediatrics, researchers expanded on this by undertaking a multidisciplinary approach to describing capacity in their research. Taking from neuroscience research concerning the developing brain, and other fields such as psychology and decision-making science and ethics, they highlighted the development necessary to meet the four standards for capacity. (Appelbaum 2001) They then identified certain neurodevelopmental skills and abilities that needed to be developed for each standard to be met. (Grootens-Wiegers 2017) These skills include:

A. **The ability to communicate a choice:** This is the least rigorous standard for decision-making capacity. To consent to treatment, a person needs to be able to communicate that there is a choice to be made and a preference of treatment, via written or spoken language. This neurologic skill is "communication", either spoken or nonverbal. Nonverbal communication is an indication of dissent or implicit consent, but not legal consent. Hence, this standard depends on language development, which is initiated in early childhood. Children have a reasonable understanding of language by age five, with refinement continuing until age nine. Further development of vocabulary and expression occurs throughout adolescence. (Shaffer 2007)

B. **The ability to understand:** In order to understand information presented about diagnosis and treatment options, and comprehend what choices for treatment are, and that a choice needs to be made, a person must be able to orient and direct attention to information. They must have sufficient intelligence, language proficiency to process the information, and memory and recall to integrate information beyond the short term. The foundation for this is laid down during infancy. Maturity in orientation and attention develops from ages seven to ten. (Rueda 2004) Memory increases between ages six and twelve, and then increases slightly during adolescence. (Thaler 2013)

C. **The ability to reason:** One must understand information, and then be able to reason regarding risks, benefits, and possible consequences of treatment. (Appelbaum 2007; Grisso 1997) To do this, one must have the "ability to engage in consequential and comparative reasoning and to manipulate information rationally." (Palmer 2016) Children, between the ages of six and eight years old, can engage in logical reasoning, and this ability grows from ages eight through eleven, as they use and access their own knowledge. (Markovits 1998) Complex reasoning, about alternative causal relations, develops into adulthood. Risk identification develops strongly between ages six through ten. (Hillier 1998) Although risk identification is mature in late adolescence, adolescents are paradoxically more inclined toward risky behaviors due to the impulse control centers of their brains not having yet matured. (Casey 2015) This is further discussed below.

D. **The ability to appreciate:** This is the strictest standard of decision-making capacity. It requires that one understand the various options for treatment, and the relevance of those options to one's personal circumstances, values, and beliefs. Therein, one needs to have the ability to think abstractly and to understand the intangible consequences of a decision. This includes being aware that others have a mind of their own.

(Appelbaum 2001) Many different areas of the brain are involved in this skill. Children start to recognize their own beliefs and desires, which contribute to their personal values and norms, between the ages of three and four. (Shaffer 2007) They begin to understand how these beliefs influence their actions. As an individual ages, due to the efficiency of working memory, one can think about more abstract and hypothetical things. (Markovits 2013; Pike 2010)

75. Capacity judgments should also take into consideration the factors, or circumstances and stressors, that affect minors in decision-making competency (competency being a legal decision). These are: personality (the child's predisposition to view information a particular way), emotional state (which can be seen as a motivator for information and preferences), and disease severity (which can affect understanding, retention of information, and reasons to consent).

76. Additionally, the minor's decision-making capacity for medical treatment should be assessed in the context of parental and clinician attitude and influence. (Miller 2004; Alderson 1992; Mann 1989)

77. Finally, the minor's capacity should also take into consideration the type and complexity of the decision, the setting, and the timing of the decision and time constraints.

78. Decision-making capacity can be considered in terms of neurodevelopment, psychosocial development, and cognitive development. Each is considered below.

79. **Neurodevelopment.** The MacArthur Competence Assessment Tool is often used to assess medical decision-making capacity. It was shown to be valid and reliable in children. (Palmer 2016; Appelbaum 2001) In a group of children six to eighteen years of age, it demonstrated that age limits for children to be deemed competent were estimated as early as 11.2 years old. (Hein 2014; Hein 2015) However, the authors point out that the cut off age of 11.2 years does not imply competence for any decision, in any situation. Rather, it is an age when, given favorable environmental factors, competency may be considered. (Hein 2014) Furthermore, with adolescence approaching, a child this age will continue to experience specific events in brain development that influence competency. (Appelbaum 2001) As noted by Hein et al. in a 2015 study, "[C] hildren may differ from adults by not having developed yet stable long term goals and values in life, meaning that children may procedurally be classified as competent although their decisions are based on values that might change. This could imply that later on they might regret decisions based on those early-life values." (Hein 2015)

80. These specific events in adolescent brain development (Appelbaum 2001)

contribute to a non-linear increase in decision-making competency from ages twelve to eighteen. During this adolescent stage of development the most significant changes in the brain have to do with processing rewards and risks, and self-regulation. Because of this, adolescence is often marked by risky behaviors, sensation seeking, and high prioritization of peer influences when making decisions. This also is the explanation for the higher rates of health issues and mortality in adolescents. (Steinberg 2004)

81. The increase in adolescent decision-making competency is non-linear due, in part, to "cross talk" between various brain structures during development. The three areas of the brain that are developing during adolescence and that pertain to decision making are the pre-frontal cortex (the brain's control system), the ventral striatum (the reward system), and the amygdala (the emotional center). The "cross talk" between these structures is not fully developed until early adulthood. (Steinberg 2013)

82. The prefrontal cortex is involved in impulse control and self-regulation. The ability to self-regulate develops significantly by age eighteen, and then further into early adulthood. The prefrontal cortex also is involved in functions that require control, like paying attention, planning, organizing tasks, weighing risks and benefits, and processing more complicated decisions. (Gogtay 2004)

83. The ventral striatum is pivotal in the brain's reward system. It produces dopamine in response to rewards. During adolescence, the reward system is hyperresponsive. (Van Leijenhorst 2010) This means that the dopamine response to reward is much higher and is associated with increased reward seeking and sensation-seeking. This heightened responsiveness applies even to "small" rewards, making the positive effect of small rewards greater than in adults. Hence, "in a dilemma in which there is a small chance of reward, this reward may be attributed such a high value that the situation is no longer perceived a dilemma by the adolescent and there is only one path to choose." (Steinberg 2004)

84. The amygdala is involved in emotional processing and input to the reward system. The maturation of the amygdala stabilizes in late adolescence.

85. There is a mismatch in timing and pacing between the development of the amygdala, the ventral striatum, and the prefrontal cortex. The control system in the prefrontal cortex develops slowly and is last to complete maturation in early adulthood, whereas the reward system and emotional input system (ventral striatum and amygdala) begin change in early adolescence and complete maturation at a quicker pace. This accounts for the fact that even though adolescents can estimate risk or make responsible decisions, they often end up in precarious and risky situations and their behavior is not always

consistent with their capacities. This also accounts for their often "too quick" decision making. Adolescents are prone to picking pathways with more immediate reward, regardless of consequences or consideration of other pathways. (Mills 2014; Steinberg 2013)

86. Consider, as a simple example, the "kid in a toy store" scenario. Children and adolescents are more likely to choose a flashy toy or item that they encounter first and feel instantly drawn toward rather than waiting to explore the rest of the store where they may find toys and items they like even more and that are more valuable. They seek out immediate gratification and pursue impulse-driven choices when confronted with reward stimuli rather than contemplating other options that carry the same or better reward but entail delayed gratification.

87. Steinberg puts it another way by discussing "hot" and "cold" contexts. An emotionally laden context is hot, whereas a minimally emotional context is cold. When emotions play a role in a situation, this can influence the decision-making process and the outcome. In adolescence, risk taking in a cold situation may be similar to that in children and adults. However, in hot situations, risk taking is increased, and this affects decision-making severely. This explains "the often-risky decisions adolescents make, seemingly only thinking about short term rewards, even though afterwards they can

reasonably assess their 'leap in judgment.'" (Steinberg 2013; Metcalfe 1999)

88. These neurobiological models of adolescence are summarized in Appendix A. (Ernst 2006; McClure 2004; Metcalfe 1999; Casey 2008)

89. Johnson et al. also report similar conclusions in their work. The brain continues to mature into an individual's mid-20s. Functional MRI studies show that the prefrontal cortex is still maturing; this is the part of the brain involved with executive functioning and impulse control. Johnson et al. state that "[a]mong the many behavior changes that have been noted for teens, the three that are most robustly seen across cultures are: (1) increased novelty seeking, (2) increased risk taking, and (3) a social affiliation toward peer-based interactions." (Johnson 2009)

90. B.J. Casey confirmed this in her research on adolescent decision making. Her research concludes that the adolescent brain is more vulnerable when tasked with decision making in emotionally laden situations and in situations with peer involvement. (Casey 2008a; Casey 2008b; Casey 2010; Casey 2013; Chein 2011)

91. Casey's team studied adolescent response time when pairing stimuli with rewards and incentives. (Hare 2008, Appendix B and C). Naturally, without conscious awareness, people have quicker responses when they associate certain stimuli with positive outcomes or incentives. Individuals have slower

responses to stimuli when there are fewer expected positive outcomes or rewards. (McClure 2004) Representation of rewards and incentives is found in the ventral striatum. Across development, studies show that adolescents activate this deeper region of the brain more than young children and adults. When greater activity is seen in the ventral striatum, it is correlated with a higher degree of risk-taking behaviors or impulsivity. (Casey 2015)

92. Per Casey's research, the presence of peers also influences response time and accuracy for the adolescent. According to studies, when peers are present, adolescents make more errors in social cue interpretation and response time. They react more quickly to incentives and are more drawn to danger and risk taking or impulsive behaviors. Their brains are activated in the areas of the ventral striatum and the amygdala shows heightened activity relative to younger children and adults. (Casey 2015; Chein 2011)

93. Essentially, then, peers serve as reinforcers to influence behavior. (Chein 2011). Jones et al. (2014) developed a social reinforcement learning model to evaluate the degree to which peers reinforce behaviors from childhood to adulthood. The investigators manipulated the probability of the participant receiving positive social feedback from three virtual peers, who provided 33 percent, 66 percent, or 100 percent positive feedback. The results showed that different amounts of positive feedback enhanced learning in childhood

through adulthood. However, based upon response latency measurement, it was concluded that all positive social reinforcement from peers equally motivated adolescents. Furthermore, adolescents, unlike children and adults, had an increase in premotor circuitry when receiving positive social feedback regardless of the expected outcome. (The premotor cortex communicates with other parts of the brain to cause motion.) Hence, peer interactions appear to motivate adolescents toward action. (Jones 2014)

94. Casey concludes that adolescents show impairment in overriding impulses in emotionally charged situations. The imbalance appears to reflect earlier developing emotional centers in the brain and those involved in self-control. Lastly, she states that diminished self-control is transient and continues to develop in adulthood as these brain systems mature with experience. (Casey 2008; Casey 2015).

95. **Psychosocial development.** Children are developing human beings. Children go through several stages of psychosocial development according to Erik Erikson, a developmental psychologist whose theories are utilized across the fields of mental health and development. He stated that children enter the stage of "Industry vs. Inferiority" between ages five and twelve, wherein their major milestone is attaining the virtue of competence. (Erikson 1998)

96. During this stage, a child's peer group becomes more important. The child

views his or her peers as being highly significant. The child's self-concept begins to form more closely around peer approval or disapproval. Children's reactions of feeling confident or proud, rejected and incapable, often form around their accomplishments and the responses of their peers. If their efforts are reinforced by praise and reward, they feel industrious (or "competent"). They exude a readiness to move past this stage and further along the developmental trajectory. If, however, they feel rejected or disapproved of, they feel inferior ("incompetent"), causing a halt in development and an inability to move forward along the developmental trajectory. (Erikson 1998)

97. Adolescence, which is the next stage, is a time when youth develop the capacity to navigate social situations, and process social cues in more abstract ways. The ability to understand others' perspectives is expanding. Additionally, self-awareness is increasing into late adolescence and early adulthood, and modulating decision making as identity is consolidated.

98. According to Erikson, adolescents ages twelve to eighteen, who successfully moved forward from the former phase of development, enter the stage of "Identity vs. Role Confusion." During this stage, they are searching for a sense of self and identity. They experience intense exploration of personal values, beliefs, and goals. Adolescents begin to analyze and think more deeply about their own morality and ethics, and to determine their individual

identities based upon their life experiences.

99. Body image is critical in this stage of development, and Erikson suggests that two identities are forming: "sexual" and "occupational." Erikson says that adolescents may feel discomfort with their bodies for some period until they can adapt and grow into the changes. Success in this stage leads to the virtue of "fidelity," which he defines as the ability to commit oneself to others on the basis of accepting them even where there are differences.

100. Adolescents have a desire to belong to society and to be productive. During this period, those adolescents who fail to form a sense of identity experience role confusion, feeling unsure where they fit into society in the long term.

101. Also, during this stage, youth are particularly impacted by peers, and are seeking to approve of themselves while being approved of by their peer group. Their exploration of their identities is ongoing throughout this stage and not solidified until they reach adulthood. (Erikson 1998)

102. **Cognitive development:** A model of cognitive development in children and adolescents was developed by Jean Piaget, another developmental psychologist.

103. Piaget described children between the ages of 2 to 7 as being in the "preoperational stage" of development. During this stage, children struggle with logic and have difficulty with the idea of constancy. They use their

imagination and engage in pretend play but are concrete in the way they view their immediate surroundings. They also think symbolically and enjoy role play. Their cognitive skills (working memory, attention) are being developed.

104. He stated that between ages 7 through 11 (middle childhood through pre-adolescence), children entered the stage of "concrete operations." During this stage, children use logic in problem solving, and can engage in inductive (inferential) reasoning. However, they struggle with deductive reasoning, which involves the ability to use a general principle to predict an outcome. They are able to see another person's perspective. They lack the ability to solve problems that deal with more abstract concepts, while they can solve concrete problems (actual objects or events). They have difficulty with understanding and utilizing common sense, and difficulty applying what they know to more hypothetical situations. (Santrock 2008)

105. Children in this stage also begin to think through social matters differently. Piaget's theory suggests that during the stage of concrete operations and on into the stage of formal operations, adolescents experience a feeling of uniqueness and invincibility. He refers to this as "imaginary audience" and "personal fable." Imaginary audience is evidenced by the adolescent always thinking others are watching, and personal fable is the adolescent's belief that he or she is exceptional in some way.

106. From age 11 through adulthood, adolescents go through "formal operations," the final stage in Piaget's theory. An adolescent during this stage is starting to engage more in deductive reasoning (Berger 2016), and is able to consider the hypothetical and "what if?" type of situations. The adolescent's metacognition is also developing, which is the awareness and understanding of their own thought processes.

107. Piaget's theories were rooted in observation and testing and are still utilized in our field. Neuroscientific developments through functional imaging have helped refine our understanding of his cognitive development theory.

108. To summarize, neurological, psychosocial, and cognitive development in the child and adolescent all play a role in the determination of decision-making capacity.

B. Full Disclosure

109. To provide informed consent to treatment, a patient must be given full disclosure. (Varkey 2020) This must include: a) an explanation of the diagnosis and how it was arrived upon, b) information about the diagnosis and what is known regarding outcomes, c) the options that the patient has for treatment (including no treatment), d) the risks and benefits surrounding each treatment option, including those risks and benefits that are unknown, and e) the likelihood of the risks and benefits (occurring over the short and long term)

for each treatment option.

110. Additionally, the physician must present details of the treatment options, including but not limited to, the preparation for the treatment that is necessary, and the follow up that should occur afterward for the best outcomes.

111. The physician should have knowledge of the subject area, and be objective in approach, placing the decision in the hands of the patient. The physician's role is to provide information and education to the patient based on expertise and to allow the patient to voluntarily consent.

C. Comprehension

112. Comprehension in the informed-consent process requires that the patient understand the diagnosis, the treatment options, and risks and benefits. To demonstrate comprehension, patients are asked to explain these things back to the physician in their own words, indicating that they intellectually have grasped the content. Adolescents are developing the ability to engage in deductive reasoning as they grow toward adulthood. They can consider the hypothetical, which makes their ability to think about abstract consequences of treatments possible as they mature. However, it is important to note that the adolescent brain's ability to "appreciate" is evolving throughout adolescence and into adulthood. Hence, being able to fully appreciate outcomes of treatment, particularly those that are more abstract, is difficult

through this period. Additionally, adolescents are still prone to impulse-driven decisions that end in more immediate gratification or reward, regardless of risk.

III. Parental Consent with Child Assent When Minor Informed Consent Is Unattainable

113. An adolescent's capacity and competency are not assumed in most cases, and parents are generally seen as medical decision makers for them. The rationale underlying this presumption is that "parents have what children lack in maturity, experience, and capacity for judgment when making difficult life decisions." (Diaz 2015).

114. There are exceptions to parents' ability to provide consent for the minor. In certain circumstances, a state may substitute its judgment that a medical procedure is in a child's best interests, even if parents do not consent. Likewise, a state may determine that a medical procedure is *not* in a child's best interest, even if parents attempt to give consent — an example being parents seeking to permit sterilization of their children.

GENDER DYSPHORIA AND INFORMED CONSENT IN MINORS

115. As explained above, informed consent requires that a patient have decision-making capacity, which includes the ability to understand, reason, appreciate, and comprehend the information presented in a full disclosure of a diagnosis, its prevalence, available treatments, and the treatments' risks and benefits.

There are at least two problems with this within the minor population when it comes to gender dysphoria.

116. First, patients must understand, reason through, and appreciate that the prevalence of gender dysphoria has been on the rise in adolescents, and there has been little research as to contributing factors. Additionally, there are a host of other co-occurring issues that need to be weighed in navigating treatment direction. Patients must understand that when these factors and co-occurring issues are brought to conscious awareness in therapy, gender dysphoria is often transient and remits. This is, at minimum, a difficult task for minors to understand.

117. Second, when considering treatment options for gender dysphoria, patients must be able to appreciate and weigh their options. The option of exploratory therapy inherently has far less risk than undergoing medical gender transition, but it takes time and considerable emotional investment as it explores the various systems in an adolescent's life. Albeit very fruitful and with minimal risks, it can still be emotionally taxing. Research confirms that adolescents devalue delayed outcomes relative to adults. (Huang 2017) Adolescents are less inclined to plan ahead or anticipate the future consequences of their actions before acting. (Steinberg 2009).

118. Gender affirming care and medical transition may appear to be "quicker"

answers to dysphoria and internal discomfort, as they aim to directly and immediately validate the adolescent's feelings about becoming the opposite gender, and they summarily dispense with any need to understand or explore causation. Considering both options, the impulse-prone adolescent is likely to find the latter far more rewarding.

119. In order for the minor to provide informed consent, the adolescent would need to be developmentally capable of appreciating the long-term consequences and risks of each option, and to be able to supersede impulse and desire for reward (to become the opposite gender), and attribute both options equal consideration. This requires complex deductive reasoning, planning, and thinking through future hypothetical life events like the desire to have children and potentially breastfeed. They would have to be able to fully comprehend and appreciate the debate over medical gender transition side effects, risks, benefits, and outcomes, and the issue of data quality. The complexity of the debate over the safety and outcome data is remarkable, and essential for the patient to understand as the potential risks involved can affect a minor patient's entire life. This particular task, in my opinion, is insurmountable for a minor patient.

120. These two barriers and necessary prerequisites to minor informed consent — (1) the requirement to understand, reason through, and appreciate that the

prevalence of gender dysphoria has been on the rise in adolescents, that there has been little research as to both contributing factors, and the long-term effects of suggested medical interventions; and (2) that there can be a host of other co-occurring issues that need to be weighed in navigating treatment direction — are discussed further below. These details must be adequately and sensitively considered by all persons involved in the informed consent process to accurately ascertain and preserve the range of informed choices and effective options available to the patient. This more detailed discussion of these prerequisites and barriers will be followed by a discussion of why parental consent with minor assent should not be sufficient in the case of medical or gender transition.

I. Minor Gender Dysphoria Prevalence and Informed Consent

121. When the prevalence of a particular presentation increases, regardless of what presentation is, physicians must first ask themselves what factors are leading to the increased prevalence and what co-occurring issues are also presenting.

122. For example, if there were an increase in the prevalence of hypertension (high blood pressure) in teenagers, physicians would naturally craft a two-pronged response. One would be tailored to the potential factors that have led to the heightened prevalence, and the second would be tailored to any co-occurring conditions they see accompanying the hypertension in the event that those are

linked or causative. They would not simply advise all teens with hypertension to take medications that could carry associated risks. They would first take measures to address factors that may affect prevalence, like an increase in sugar consumption among youths, or an increase in cultural acceptance of childhood obesity. Second, they would also take measures to address co-occurring factors like obesity, stress, and sedentary lifestyles. Patients would be informed of these factors and co-occurring issues, and physicians would help each patient to appreciate them and to address them with education about the effects of obesity and too much sugar and about the need for improved diet, exercise, and stress-relieving measures. While these interventions may take time in comparison to medicines that relieve hypertension quickly, they would carry far less risk to the adolescent.

123. Second, when looking at increased prevalence of a presentation, physicians should ask themselves if the presentation is transient or continual over a meaningful span of time. Patients, in the informed-consent process, would need to know if their diagnosis is one that can resolve over time, if it is permanent, whether or not it requires immediate treatment, how soon it might require an intervention that entails proportionally significant risk, the relative likelihood or probabilities of all of the above, and how all of this information relates to the reliability of existing research and the current frontiers and limits

of scientific inquiry.

124. For example, if teens were showing signs of mood lability through a particular stage of puberty, physicians would look at whether the lability was transient, and whether it would resolve completely on its own. If a known external cause was identified, they would seek to address it. If it were determined to be transient and a normal part of youth maturation, then physicians would likely provide support through that stage and see if the lability declined naturally. If not, they'd address it later.

125. Taking a second example, in mental health, if a five-year-old patient presented with difficulty with affect regulation, as well as trouble focusing and being still in the classroom, most physicians would not diagnose ADHD on initial assessment. The diagnosis and labeling of ADHD carelessly or prematurely can have negative implications for the child. Rather, they would investigate what other issues are happening in the child's life, and consider the child's development, family history, abilities according to a psychoeducational assessment, teacher input, the way the child learns, his classroom structure, social skills, and his stressors. Additionally, they would consider that children who are five years of age are in the developmental stage of initiative vs. guilt, and the milestone of this stage is "purpose." The child is learning to navigate social rules and gain self-regulation. From a neurodevelopmental perspective,

the child's brain is presently at the stage in which impulse control centers, motor centers, and expressive language centers are not yet fully matured, and hence, his behavior may be merely a result of him needing to grow more. Any treatment interventions beyond parental guidance, teacher guidance, and therapeutic support may be unnecessary or even detrimental as risk would likely outweigh benefit. Further time and observation would allow physicians to gain a better understanding as to whether the child will outgrow these behaviors, or whether they will be sustained once he grows and other factors resolve. The child and his parents, as part of informed consent, would need to know that these behaviors sometimes pass on their own with maturation. They would also need to understand the evidence (or lack thereof), risks, and benefits of all treatment options that are available if these behaviors did not resolve with maturation.

126. With regard to gender dysphoria, the heightened prevalence in recent years should cause physicians to identify possible contributing factors and co-occurring issues, and then craft a two-pronged response that addresses these, all prior to recommending medical transition which entails risk. Patients need to be able to understand, reason through, and appreciate these factors and co-occurring issues and have the opportunity to explore them prior to considering transition. The factors I've observed to contribute to the heightened

prevalence of gender dysphoria are an increase in "pathologizing" of a normal part of childhood development, shifts in cultural norms having to do with gender exploration in adolescence, the influence of social media, heightened vulnerability in youth, and what some call "social contagion." Some co-occurring issues that I have observed are trauma, depression, anxiety, autism spectrum disorders, influential gender-role experiences, vulnerability and a lack of feeling socially accepted, and the influence of social media. These are identified and addressed as the patient goes through the therapeutic process and supports for the patient are also harnessed. As part of informed consent, patients should understand and appreciate that when these issues are addressed, frequently gender dysphoria is transient and remits. As stated above, this understanding and appreciation is an extremely difficult task for adolescents.

II. Minor Treatment Recommendations and Informed Consent

127. Major medical associations, including WPATH, have endorsed puberty suppression and cross-sex hormones as treatments for youth with gender dysphoria. Patients, in the informed-consent process, need to be able to understand, reason through, and appreciate the limits of medical knowledge and the issues that are of ongoing debate regarding gender transition, including the debate over long-term outcomes, safety, and potential risks.

128. The WPATH SOC-8, in its adolescent chapter, states: "We recommend health care professionals working with gender diverse adolescents undertake a comprehensive biopsychosocial assessment of adolescents who present with gender identity-related concerns and seek medical/surgical transition-related care, and that this be accomplished in a collaborative and supportive manner." (Coleman 2022, Recommendation 6.3) It goes on to state:

> ***The following recommendations are made regarding the requirements for gender-affirming medical and surgical treatment (All of them must be met):***
>
> **6.12- We recommend health care professionals assessing transgender and gender diverse adolescents only recommend gender-affirming medical or surgical treatments requested by the patient when:**
>
> **6.12.a- the adolescent meets the diagnostic criteria of gender incongruence as per the ICd-11 in situations where a diagnosis is necessary to access health care . . . .**
>
> **6.12.b- the experience of gender diversity/incongruence is marked and sustained over time.**
>
> **6.12.c- the adolescent demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment.**
>
> **6.12.d- the adolescent's mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed.**
>
> **6.12.e- the adolescent has been informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility, and these have been**

> **discussed in the context of the adolescent's stage of pubertal development.**
>
> **6.12.f- the adolescent has reached [T]anner [S]tage 2 of puberty for pubertal suppression to be initiated.**
>
> **6.12.g- the adolescent had at least 12 months of gender-affirming hormone therapy or longer, if required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.**

(Coleman 2022, Recommendation 6.12)

129. On page S5 of the WPATH SOC-8 guidelines, the Introduction presents the guidelines as reliable, comfort-oriented, safety-oriented, and evidence based. "The overall goal of the . . . (SOC-8) is to provide clinical guidance to health care professionals to assist transgender and gender diverse (TGD) people in accessing safe and effective pathways to achieving lasting personal comfort with their gendered selves with the aim of optimizing their overall physical health, psychological well-being, and self-fulfillment." The introduction continues: "WPATH envisions a world wherein people of all gender identities and gender expressions have access to evidence-based health care, social services, justice, and equality." In the next paragraph, WPATH assures readers that "[o]ne of the main functions of WPATH is to promote the highest standards of health care for individuals through the Standards of Care (SOC)

for the health of TGD people," and that "[t]he SOC-8 is based on the best available science and expert professional consensus." The Abstract itself, in the Methods paragraph, expressly offers the following assurance:

> The SOC-8 is based on the best available science and expert professional consensus in transgender health. International professionals and stakeholders were selected to serve on the SOC-8 committee. Recommendation statements were developed based on data derived from independent systematic literature reviews, where available, background reviews and expert opinions. Grading of recommendations was based on the available evidence supporting interventions, a discussion of risks and harms, as well as the feasibility and acceptability within different contexts and country settings.

(Coleman 2022)

130. Reading these statements, the natural assumption of patients, parents, caregivers, and many physicians is that the factors contributing to gender dysphoria have been well established and that based on those factors, "seek medical/surgical transition-related care." (Coleman 2022, Recommendation 6.3) It is further assumed that when the recommendations above are followed with minors who have gender dysphoria — directing the patient to gender-affirming care, then on toward medical suppression of puberty, cross sex hormones, and gender reassignment surgeries. — these interventions will automatically be the best course of treatment. Furthermore, the WPATH recommendations leave ample room for physicians, patients, and parents to erroneously assume that recommendations for medical and surgical gender

transition are evidence-based, that is, founded in rigorous scientific inquiry through randomized controlled trials and long-term follow-up studies that affirmatively show positive medical and psychological outcomes and established safety records. Lastly, the physician and the patient (and parent) might naturally assume that the quality of the studies must be high, given that altering the natural course of development in youth is a significant measure; that it is relatively new; that it is not something that the medical community has engaged in historically; and that common sense would indicate that such major interventions generally would only be justified on the basis of thorough deliberation, ample and solid research, and strong evidence.

131. However, there is remarkable controversy and debate over these recommendations and the data that supports them.

132. While physicians can understand and appreciate the controversies that follow below, in my view adolescents are not developmentally able to do so. Their neurodevelopment and proneness to impulse-driven decisions make it highly possible that they will disregard or undervalue the critical issues of controversy and debate and move forward with assent/consent to medical or surgical transition, all to achieve the perceived reward of achieving secondary sex characteristics of the opposite gender.

133. I believe that several issues must be fully considered and appreciated by

patients in order for them to be able to provide appropriate informed consent. However, many of the most vital issues cannot be sufficiently appreciated in adolescence. These issues are listed below:

- The Dutch Studies have been foundational in the formation of the WPATH recommendations but are suspect in terms of their quality and their applicability to the patient population currently presenting in America. "Several recent international systematic reviews of evidence have concluded that the practice of pediatric gender transition rests on low to very low quality evidence—meaning that the benefits reported by the existing studies are unlikely to be true due to profound problems in the study designs." (Abbruzzese 2023)
- Gender dysphoria is the only diagnosis that I am aware of for which an alteration of bodily integrity is being clinically advised for the purpose of affirming identity.
- There is debate over the quality of data used in studies assessing links between suicide rates and gender dysphoria, including the change in suicide rates post-transition.
- The WPATH recommendations state that only one comprehensive psychological assessment should be required for minors in order to proceed to transition. (Coleman 2022) Patients should understand that

such co-occurring health concerns and issues accompanying gender dysphoria take time to identify, and one comprehensive assessment is not sufficient to do so for any practically condition in mental health.

- The WPATH recommendations state that decision-making capacity has to be determined in each adolescent wanting to undergo gender transition based on each adolescent's development. (Coleman 2022) But WPATH elides the crucial issue: both patients and parents/guardians should understand that it is not well established that adolescents can *ever* meet such requirements for decision-making capacity when they are offered non-emergent treatments that substantially affect bodily integrity and that have potentially life-long irreversible consequences on reproduction and multiple other bodily systems.
- There is significant debate about whether the majority of children and adolescents with gender dysphoria realign with their birth sex with time and maturation.
- There is debate as to the lack of studies that evaluate the factors that are leading to the heightened prevalence of gender dysphoria.
- Patients and their parents must understand that while gender medicine experts claim minimal risk with puberty blockers, this is highly controversial. They should also understand that almost one hundred

percent of those taking puberty blockers go on to receive cross-sex hormones. Hence, even if puberty blockers themselves were of low risk, the trajectory of medical gender transition includes cross-sex hormones, which render a patient infertile.

- There is additional debate over the long-term side effects and consequences of the medical transition trajectory, including but not limited to potential problems with bone growth, brain maturation, metabolic function, endocrine function, sexual health, psychological function, and reproductive capacity.
- There is debate as to whether minors can appreciate the potential impact that infertility can have on an individual's psyche should they one day desire to have children.
- There is insufficient data on detransitioners, and there is literature that states that those who detransition may not access adequate follow up or support.
- The interplay between gender dysphoria and common co-occurring conditions, and how treating those conditions may affect an individual's gender dysphoria, have not been adequately studied.
- Alternative approaches to treating gender dysphoria have not been adequately studied.

134. In my experience, the task of understanding, reasoning through, appreciating, and comprehending the above matters is insurmountable for adolescents.

135. Furthermore, I don't believe that parents should be able to provide medical consent with minor assent for medical gender transition. This is because the debate that exists has to do with the safety of treatments that affect the bodily integrity of the minor, and there is debate as to the long-term outcomes of such treatments. Many of these debated outcomes would stand to permanently affect the quality of life of the minor, in multiple arenas such as romantic relationships, marriage, sexual intimacy, childbirth, child rearing, self-concept, social and workplace relationships, potential adversity due to discrimination, and long-term psychological and medical health. In my opinion, for a parent to provide consent to non-emergent treatments that stand to affect the rest of a minor's life in every arena, and to do so without the minor's full ability to appreciate the above debate and potential long-term ramifications, violates the minor's future right to autonomy.

TRAUMA AND GENDER DYSPHORIA

136. Children and adolescents with gender dysphoria who have been through trauma may have an even greater difficulty with appreciating and weighing the various treatment options for gender dysphoria. Trauma affects how children and adolescents process the world around them, how they interact

and engage in relationships, how they perceive various events and situations, and how they react and behave. Trauma influences the way individuals perceive their own bodies. Their sense of bodily safety and how they feel about their outward appearance is often significantly affected. The risk in offering medical or surgical transition to adolescents who have gender dysphoria and a history of trauma is that they may find gender transition to be appealing and a "quick fix" to their complex internal emotions and feelings about their bodies. This may stand in contrast to a child or adolescent's perception of trauma-focused therapy modalities that are directed at helping an individual work through, process, and recover from trauma, as these treatments take an extensive amount of time (months to years) and are emotionally very difficult. While trauma-focused therapies are data-driven and effective and allow an individual to experience healing and then to make more consequential life decisions, the child or adolescent may not give them consideration when perceiving that medical or surgical transition would help them to feel better faster by changing how they feel about their body. It may prove tempting to try and resolve internal woundedness by changing external appearance, but an adolescent is likely to experience regret after transition if the internal woundedness is not first addressed through the therapeutic process.

137. Trauma can be due to a number of different experiences. Trauma arises when there is a "failure of the natural physiologic activation and hormonal secretions to organize an effective response to threat." In early childhood development, the orbitofrontal and limbic structures in the brain mature in response to the caregiver. Dysfunctional associations in this relationship between caregiver and child result in permanent physicochemical and anatomical changes which impact the child's developing personality and behaviors. Children who have been exposed to ongoing stress lose the ability to use their own emotions to guide effective actions. They often cannot recognize their own feelings, and so they are not able to respond appropriately to stressors. The inability to identify emotional states also often affects the child's ability to recognize others' emotions. Due to difficulty in regulating their own internal state, they become very reactive to their environment. They respond with emotion and impulsivity, behaviors that are often an externalization of the chaos and stress they feel inside. (Trauma Recovery Institute)

138. Trauma can occur outside the parent-child relationship. Exposure to domestic violence, abuse, neglect, animal abuse, poverty, substance abuse, bullying, disasters, loss of a loved one, or parental illness can cause similar psychological and physiological responses in children. Some forms of

trauma, particularly interpersonal trauma and abuse, place children and other survivors at increased risk of future trauma because past experiences of victimization are associated with an increased risk of subsequent victimization. (Jaffe 2019)

139. Trauma can cause:

- Loss of self worth
- Heightened Reactivity (e.g., explosivity and anger outbursts)
- Hyperarousal
- Withdrawal from others or avoidance
- Difficulty with trusting others
- Shame
- Loss of danger cues
- Loss of a sense of self
- Poor self-esteem
- Hypervigilance
- Confusion or feelings of being lost
- Depression and anxiety
- Impulsivity
- Negative body image and desire to hide body or change appearance
- Oversexualized behavior or sexual avoidance

- Dissociation
- Hallucinations or Re-experiencing
- Flooding
- Frequent somatic symptoms
- Enuresis (bedwetting)/encopresis (soiling)
- Body inflammation or repeated infections, autoimmune problems

140. Trauma impacts every system in the body: gastrointestinal, genitourinary, endocrine, cardiovascular, neurologic, and immune systems. (Heim 2008) With regard to neurodevelopment, functional neuroimaging of children and adolescents exposed to maltreatment has shown executive, attentional, and affective emotional dysregulation. (Mueller 2010).

141. Children do not generally disclose trauma on initial assessment. Disclosure can take months and sometimes years. Children must experience safety within the therapeutic relationship, which takes time and patience to establish. As therapy continues, children will disclose trauma when they feel safe enough to do so and trust the examiner's response.

142. Trauma treatment (psychodynamic therapy and trauma focused cognitive behavioral therapy) focuses on a) education surrounding trauma; b) identification of feelings and emotions; c) understanding safety and practicing mindfulness, relaxation, and the ability to calm the sympathetic nervous

system; d) exploration and processing of the trauma and its effects through a trauma narrative in a safe therapeutic setting; e) harnessing family/loved one support and validation; f) clarification where appropriate; g) building a healthy self-concept; h) a reorientation to the environment through awareness that trauma can impact all arenas of life; and i) continued support. The goal in recovery is for the individual to heal emotionally, to have internal and external ability to self-regulate and respond to stress appropriately, and to be able to engage in relationships in a healthy fashion. This type of treatment takes time, as there must be patient-therapist rapport and adequate trust laid down as a foundation.

143. Due to the effects of trauma on all bodily systems, and its effects on self-concept and body image and appearance, it is critical to realize that it can contribute to gender dysphoria. Explorative (psychodynamic) therapy and Trauma Focused Cognitive Behavioral Therapy is important to help the patient identify, process, and work through trauma in order to ensure that the patient is not experiencing gender incongruence due to the trauma itself. This information is valuable to patients as they navigate and chart their own courses through their unique, individual processes of healing and growth.

144. Research suggests relatively higher levels of reported trauma among children with gender dysphoria and among transgender and gender-nonconforming

adults. In one study that considered relational trauma up to age 14 within primary relationships:

> Results showed that 10% of GD participants had not experienced any early adversity, 13% had experienced one form of trauma, 8% had experienced two forms, 13% had experienced three forms and 56% had experienced four or more forms. In the control group, 30% of participants had not experienced any form of trauma, 37% had experienced one form of trauma, 16% had experienced two forms, 9% had experienced three forms and 7% had experienced four or more forms.

(Giovanardi 2018) Another study reported similar findings. (Schnarrs 2019)

145. Timely and compassionate assessment, diagnosis, and trauma-informed treatment is likely to meaningfully improve long-term outcomes for children with gender dysphoria, whether they come to identify with their natal sex or whether they persist in their transgender identity.

146. It has been my clinical experience that when youths with gender dysphoria are treated with psychodynamic therapy, and a history of trauma is identified and subsequently treated, gender dysphoria often remits or resolves. In other cases, youths have gained clarity about how trauma has affected them and can move forward as adults with the ability to make mindful decisions surrounding gender dysphoria treatments. Each of these children deserves the option to achieve this clarity, treatment, education, and support, regardless of which options they ultimately choose.

147. Because actual patient cases cannot be discussed in this report, I have

provided four hypothetical situations based on my experiences to illustrate how trauma affects gender incongruence and gender dysphoria, and when treated, can result in its resolution or provide clarity for future treatment decisions.

a. A female teen describes gender dysphoria. She wants to be called "she/her" and not change pronouns yet because she is worried that her grandmother may find out about her gender dysphoria and be angry. On initial assessment, it becomes clear that she experienced maternal abandonment at a young age.

   Over the course of therapy, she says has a vivid recollection of her mother leaving her at her grandmother's home and not returning. Her grandmother is emotionally and physically abusive toward her often and a child protective report has to be filed. She has remarkable difficulty in trusting others and isolates herself socially due to fear of not being accepted. She has been bullied by female peers. She says that she is unsure of others' responses and fears rejection. Inside, she feels persistently anxious, struggles to enjoy normal activities for girls her age, and describes feeling uneasy. She expresses that she identifies as male. When her perception of gender roles is explored further, she talks about women being angry, uncaring, and harsh. She describes

wishing she'd had a father who had protected her and kept her safe. She says she always thinks about how she could have kept herself safe and struggles with guilt and shame associated with the abuse because she believes she allowed it to happen.

As trauma-focused treatment is provided, she learns about the effects of trauma and what emotions survivors struggle with. After working through her trauma narrative, she realizes that her identification with male gender is due to an unconscious desire to protect herself from abuse, and to be strong enough to "fight it," and to not feel anything in common with the females in her life who have been neglectful, abusive, and wounding. This conscious awareness allows her to begin recovering. She learns new ways to feel in control and safe and learns to identify her feelings and process them and use logic alongside emotion in decision making and in relationships. Over the course of many months, and ongoing support and psychodynamic therapy, she realigns with her natal sex. She says she feels safe and in control of her own body now.

b. A male teen is nonbinary and prefers to be called "they/them." On initial assessment, they report having been bullied at school and not fitting in since a very young age. They have suffered from ADHD

related impulsivity and reactivity and often got in trouble in elementary school. Peers were unkind and often refused to eat with them at lunch or play with them at recess. Due to ADHD medication side effects, they reported being very thin and feeling awkward. As other kids developed and boys became more athletic, and girls developed breasts, they described feeling uncomfortable in their body because they remained thin, lanky, and of short stature through middle school. Last year, while being online playing video games, they met a couple of transgender peers online. They began to get to know one another and establish friendships. This was the first time they felt connected and safe. Engagement with them during daily gaming became routine, and they got to know one another and built friendships. They began to learn more about gender incongruence online and began to feel that they were nonbinary and that maybe this was why they never fit it and felt so anxious socially. They discussed this with their friends online, and friends supported gender exploration and made statements that they "knew the feeling" and "were there for them."

In exploratory therapy, they discuss several incidences of bullying that were traumatic and caused marked emotional harm. Trauma focused-therapy is initiated, and they are able to bring to conscious awareness

past feelings of being trapped, of being unwanted, being unworthy, and being unloved by others. They also identify fear of bodily harm due to bullying and wanting to go unnoticed by peers at school to preserve a sense of safety. As they learn ways to identify and work through the intense emotion that accompanies memories of past trauma, they begin to realize that being gender nonbinary has allowed them to feel safer. It has been a way to describe a deep feeling of discomfort with their own body and a feeling of being different. Having made strong friendships with transgender peers who also had gone through similar feelings, they realize that identifying as nonbinary allowed them to also feel closer to their friends. Over time, they begin to feel more positively about their own self-concept and friendship making ability, and to use coping skills to work through memories of past trauma. They begin to want to be referred to as "he" and describe realigning with natal sex. He is able to process and understand trauma and its impact on feelings about bodily appearance, bodily safety, and a need for secure relationships.

c. A female teen has gender dysphoria. She describes wanting to be called "he/him." He talks about wanting to medically transition and denies any past history of psychiatric issues. He describes having a good

relationship with his mom, and not knowing where his father is, who left their home when he was ten years old. He describes having a history of urinary tract infections, enuresis (bedwetting), and constipation. Medical records are consistent with his description. Throughout early therapy, he talks about his relationship with his mother and how she is dating someone new. He says he doesn't mind, but becomes more uncomfortable when mom's partner moves in. He begins to have difficulty with sleep, and his mother reports that he is very reactive and at times hostile toward her partner. He begins to have enuresis again and also stomachaches.

Over the course of therapy, he eventually discloses that his father had touched his (female) privates several times and shown him naked pictures of girls. Trauma-focused therapy is initiated. He learns about trauma, its impacts, and normal feelings that children experience when victimized. He learns how to calm himself and self-regulate intense emotion through progressive muscle relaxation and deep breathing. He engages in developing a trauma narrative and is able to detail what happened to him over the upcoming many weeks. He talks about past fear of his father that turned into rage and fantasies of fighting his father and making sure that he could never harm anyone again. This brings

to his conscious awareness that identifying as male allowed him to feel power over his abuser and to feel a sense of control. When thinking of being in a male body, he felt safer, and he didn't have to feel the fear and feeling of being trapped that he used to in a female body. Over the course of a couple of years, as he begins to recover from the sexual trauma he'd suffered, through ongoing therapy and support, he begins to come in wearing female clothes. He wants to be called "she/her" and says that she feels more comfortable being female now. She feels safe and in control in her own body.

d. A male teen is struggling with gender dysphoria and prefers to be called by "she/her." She talks about being raised by her single adoptive mother since age four. Her dad was not active in her life. She struggled with ADHD and anxiety throughout elementary and middle school. She struggled with academics and didn't feel like she fit in. She began experiencing gender dysphoria at the age of eleven when she began to develop body hair and sweat and feel "gross." She talks about male features (like her broad shoulders) having made her feel angry when she looked in the mirror.

   Through explorative therapy, she began to talk about how she often wondered about her birth family and why she was given up. She

wondered if she looked like her birth father, and she said this thought made her physically ill. She said she'd have panic attacks when looking at her shoulders widening and at hair in her armpits and private areas. As therapy progressed, she talked about having been told her birth father had been in jail and was a drug addict. She wondered if she'd be like him, and this caused her to have tremendous anxiety. She is able to bring to conscious awareness that she felt more comfortable as a female because she didn't want to grow to up be like her birth father, because he abandoned her and was a "criminal."

Through additional work with a therapist specializing in adoptions, she is able to understand that she suffered trauma as a child due to separation from her birth mother, regardless of being moved to a safer adopted home. She is able to learn about the feelings that children who've experienced adoption often go through and understand that her feelings are reasonable and normal. She is able to bring to conscious awareness that her feelings about not wanting to be like her birth father are a normal part of processing her past and considering who she wants to be in the future. She learns from her therapist about neurodevelopment and how the adolescent brain is still developing. With good support from her family in place, she continues in her social

transition, but also continues therapy for support and ongoing processing of her stressors. She decides to medically transition as an adult, and says she feels her decision making is clearer as she has been able to understand her gender identity, come to terms with how trauma has affected her, and be confident in her ability to provide informed consent as an adult with a lesser risk of regret.

CONCLUSIONS

148. In my clinical experience, informed consent is remarkably difficult with minors. Even when prescribing a psychiatric medication, adolescents are most often unable to appreciate the long-term risks, nor are they able to comprehend the details of full disclosure. I find this is secondary to their psychosocial and neurodevelopmental stage of development. They can communicate a choice. They can understand the diagnosis and treatment options to an extent. However, they are less able to comprehend and appreciate the implications of the diagnosis and treatment options long term. Generally, they are focused on "feeling better" and choosing the treatment pathway that leads to feeling better quickly regardless of treatment side effects or risks. Once they have identified the path they want to take, they most often lose sight of other treatment options that may take longer, though they are just as effective at helping them feel well, and with lesser risk. In the setting with

outside influences, this push to choose the path with the immediate reward while devoting less attention to other options, is even more evident.

149. For this reason, with very rare exceptions, I employ parental consent with minor assent in the process of prescribing treatments to minors, and only after weighing the risk/benefit ratio of treatment interventions and providing full disclosure.

150. If there are insufficient evidence-based benefits to treatment, and if benefits do not substantially outweigh risks of treatment, I do not prescribe medication.

151. In the event, that parental consent and minor assent is provided for a medication, but there is an issue of the growing child or adolescent's future autonomy being affected, I do not prescribe, unless there is medical necessity to treat due to an imminent risk to the child's safety or to others if the child is not treated.

152. Individuals with gender dysphoria deserve compassionate care that is not only equitable, but also well thought out, well researched, and well executed. In the matter of medical and surgical gender transition in minors, the overarching questions I ask myself regarding my own patients and the informed consent process, when reviewing all the literature and processing my own clinical experience, are:

- Can youths understand, reason through, appreciate, and comprehend all of the issues with the present data, the ethical dilemmas that are present, and the debate in the medical community?
- Can youths appreciate the future risks that medical gender transition entails, particularly regarding circumstances that only present later in life (like the desire to bear children and breastfeed)?
- Can they understand, appreciate, and comprehend the unknown risks of treatment on brain maturation?
- Can they appreciate and comprehend that there is debate as to whether suicidality improves or worsens post-transition?
- Can they understand the significance of the paucity of data on de-transitioners?
- Can parents provide consent (with minor assent) for treatments that affect bodily integrity, that are appropriately considered experimental due to lack of quality data, that carry marked long-term medical and psychological risk, for which long-term safety and efficacy is unproven, and that have the potential to create irreversible consequences such as infertility? All for the purpose of affirming an identity that has not yet solidified, based on what we know about the developing adolescent?

My answer to all these is, "Absolutely not."

153. With this context, I draw three primary conclusions:

I. Informed Consent Is Not Attainable for Medical or Surgical Transition in Minors

154. Minors lack decision-making capacity for medical and surgical transition. In my opinion, due to a lack of full neurologic, psychosocial, and cognitive developmental maturation, adolescents are unable to understand, reason through, appreciate, and comprehend the impact of the shortcomings of the present data, the lack of FDA indication for puberty blockers, the long-term risks and consequences of transition, and the low-grade rating of studies that have been used to support medical and surgical transition. Hence, they lack decision-making capacity.

155. As discussed in the section above regarding neurodevelopment and psychosocial development, when there is perceived reward with one pathway, despite long-term risks associated with that pathway, adolescents will generally select it rather than consider that there are alternative pathways with fewer long-term risks. With medical gender transition, adolescents are likely to perceive reward (in this case, reduced dysphoria) with the pathway of puberty blockers and cross-sex hormones and hence, they are likely to choose this path rather than considering other paths (such as engaging in exploratory or supportive therapy, socially transitioning, and waiting until adulthood for medical transition). Additionally, as peer and cultural influences are more

significant in adolescence, adolescents may make more impulsive decisions to pursue medical transition without considering risks. This also factors into a capacity judgment.

156. The risks associated with puberty blockers and cross-sex hormones are difficult for adolescents to comprehend and appreciate. First, the near certainty of infertility on the transition pathway is likely to not be appreciated until the age during which most individuals consider having children. The debate over impacts on hormonal shifts, bone density, cardiovascular risk, and brain maturation are simply too difficult for minors to grasp. Furthermore, effects of transition on more abstract situations that the adolescent may face decades later, such as effects on intimate relationships, sexual gratification, reproduction, breastfeeding, child rearing, family relationships, and self-concept are even more difficult to fully realize. Adolescents have not fully developed the ability to appreciate the treatment options in this context of "later life", which is part of decision-making capacity. Their deductive reasoning is developing, but not yet complete.

157. Furthermore, while parental consent and adolescent assent is possible for other medical interventions, it is insufficient in the matter of gender transition in minors. First, the risks to the growing adolescent are remarkable, including infertility, irreversible changes to secondary sex characteristics, potential

issues with bone density, cardiovascular risks, metabolic function, endocrine function, reproductive capacity, psychological and medical health, and brain maturation. Second, a parent is unable to determine whether their child will realign with his or her natal sex. This presents inherent risk. Third, the present data supporting the benefit of transition in adolescence is rated "very low quality." There is no reliable long-term data on safety or efficacy of these treatments.

158. For this reason, I believe that parental consent with adolescent assent for medical gender transition is problematic and can result in long-term detriment to the adolescent that later cannot be reversed. Parental consent may be deemed in the short term to be preserving the adolescent's autonomy by prioritizing the adolescent's desire to self-actualize and reduce dysphoria. However, in the long term, there is remarkable intrusion on the growing adolescent's autonomy as an adult. When the adolescent matures to adulthood and can't reverse consequences (e.g., fertility) of interventions that the parent consented to without the adolescent having had full capacity to appreciate, psychological repercussions are likely to be profound.

159. Regarding other medical diagnoses, where bodily integrity is challenged as a result of treatment, such as with cosmetic surgery in minors, informed consent has been a central issue.

160. In 2005, in the *AMA Journal of Ethics*, pertaining to teens who desire cosmetic surgery, authors cited The American Society of Plastic Surgeons statement against breast augmentation for patients under 18. In the absence of longitudinal research, they said,

> [I]t is impossible for physicians to warn patients, or their parents, about the risks of performing cosmetic surgery on bodies that have not reached maturation, the operative complications and long term physical effects of these surgeries and the psychological implications of surgery on developing body image, or the extent to which distorted body image common among adolescence may result in the pursuit of plastic surgery.

(Zuckerman 2005)

161. During the FDA hearings on breast augmentation, several physicians noted that obtaining meaningful informed consent from teenagers and their parents can often be difficult. According to one speaker, this difficulty is largely related to the fact that the kind of information being given to potential breast implant surgery patients is largely "probabilistic information" and "probabilistic thinking is the most abstract kind of thinking and the last one to develop in the range of skills and capacity that we have." Several physicians in attendance agreed. Dr. Charles Bailey noted that, "with respect to interacting with the patients, it's not uncommon to be sitting in front of a very young patient where you feel like nothing that you're saying is being heard." This is the exact sentiment echoed by physicians who are opposed to medical

and surgical gender transition in minors, an area in which data is even more controversial and the long-term risks of far greater magnitude. (Cohen Cooper 2014)

162. Furthermore, within my own clinical experience, I cannot envision a circumstance with my own patients wherein parental consent and minor assent would be sufficient for medical or surgical gender transition based on the above explanation. The justification of imminent risk to the child's safety or others around the child is not present. Additionally, not only could proceeding to medical or surgical gender transition profoundly affect the child, but also the parent-child relationship, which is of remarkable concern to me as a child psychiatrist.

II. A Better and More Compassionate Approach is Provision of Therapy Until Adulthood When Consent Can be Provided

163. Gender dysphoria can be a normal part of childhood development, as discussed in the section on my clinical experience above. It should not be labeled or pathologized, as it is most often transient, making a "watch and wait" approach sensible.

164. A compassionate approach to gender dysphoria in adolescents entails: a comprehensive assessment, individual and family therapy, and harnessing a support network for the patient. I have used this approach for years and have found it to be beneficial and far less risky. The child patients I've treated that

meet criteria for gender dysphoria realign with their birth sex with maturation (children) and a "watch and wait" approach. Adolescents most often realign with their natal sex with maturation, therapy, and support. Further, my patients who have decided to transition as adults have been grateful that they waited and that therapy helped them to be sure of their choice. They have felt positively about their decision-making capacity as adults.

165. This approach takes into consideration that medical and psychological risks are far too great to risk providing unproven treatment to a substantial number of minors who would otherwise realign with their natal sex.

166. Additionally, this compassionate approach adheres to ethical standards in the field of medicine, while medical and surgical transition for minors, individually and in combination, substantially risks violating those standards.

167. As an example, beneficence requires that the physician actively promote the welfare of the patient and protect the patient from harm. Regardless of positive intentions to provide relief for the minor with gender dysphoria, when a physician is seeking to use controversial treatments for a diagnosis 1) that has an increasing prevalence 2) for which contributing factors have not yet been adequately identified 3) for which alternative treatment pathways with less risk may not have not been well studied 4) that may resolve in children without any intervention or respond to very low risk supportive interventions

in adolescence and 5) could be intertwined with co-occurring conditions that could be treated with low risk interventions first, there should be concern over whether the physician violates the standards of beneficence and nonmaleficence. That is especially true when the risky treatments 1) have marked effects on a minor's bodily integrity, 2) carry significant long-term risks, 3) are unsupported by reliable long-term data about safety and efficacy, and 4) are recommended based on evidence deemed to be of very low quality by systematic reviews.

168. The physician seeking to recommend medical transition to a minor also risks violating the principle of informed consent, considering the minor patient lacks decision-making capacity.

169. If all of the above issues of debate and controversy have not been fully disclosed to the minor patient, and comprehended, the standard of truth telling is also not met.

170. And, lastly, the standard of distributive justice may be violated if the minor patient has not been meaningfully offered available resources such as exploratory therapy, family therapy, and supportive mental health care that may be offered to others in this same situation, given these are low in risk and likely high in benefit.

III. SB184 Appropriately Protects Minors

171. Individuals with gender dysphoria deserve compassionate care that is not only equitable, but also well thought out, well researched, and well executed.

172. They deserve to not be subjected to experimental treatments that, to date, lack high-quality studies, long-term outcome measures, and proven psychological benefit. Instead, they should all be afforded well-researched options that entail less risk and are more likely to be effective. They should also receive the time and patience and ongoing support necessary in order to pursue those options.

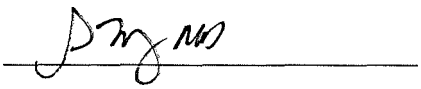
173. They deserve to have methodologically and scientifically sound research conducted on all possible pathways of treatment, so that they can make well informed decisions as adults about which pathway of treatment they'd like to choose.

174. They deserve to be supported, cared for, and shown that they are valued, as all individuals should.

175. Minor patients with gender dysphoria deserve to be treated with respect for their vulnerability and their stage of development, which makes them unable to provide informed consent. They deserve for their future autonomy to be protected.

176. While their immediate desire for relief needs to be addressed, they also need their desire for long-term happiness honored, as growing members of society.

They deserve to have the capacity to make their own decisions about treatments that would systemically alter their bodies and thereby affect their future relationships, their ability to have children, their ability to breastfeed, their ability to experience and feel positively about sexual intimacy, and their ability to feel well about themselves. This capacity cannot be reached until adulthood.



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May 22, 2023

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APPENDIX A. TRIADIC MODEL OF NEUROBIOLOGY

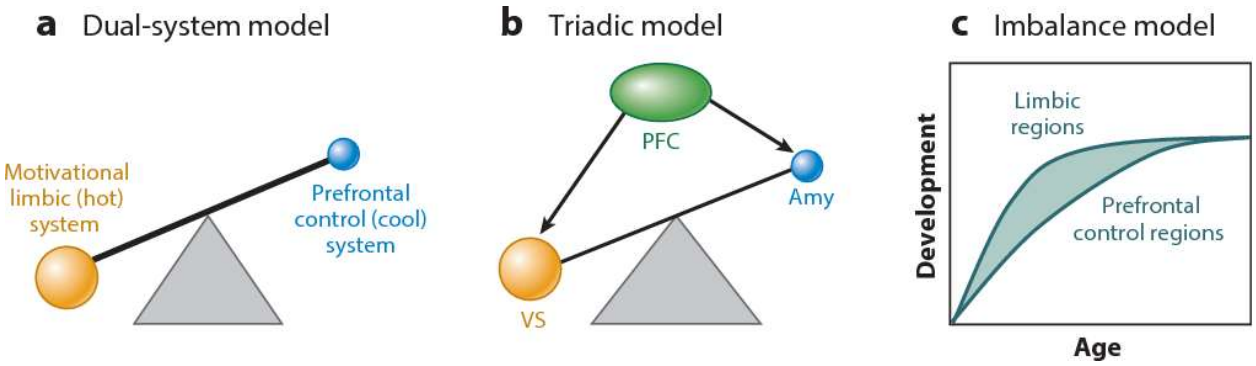

Figure 2

Published in Annual Review of Psychology 2015

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

B. Casey

APPENDIX B. ADOLESCENT FMRI STUDIES WHEN PRESENTED WITH REWARD

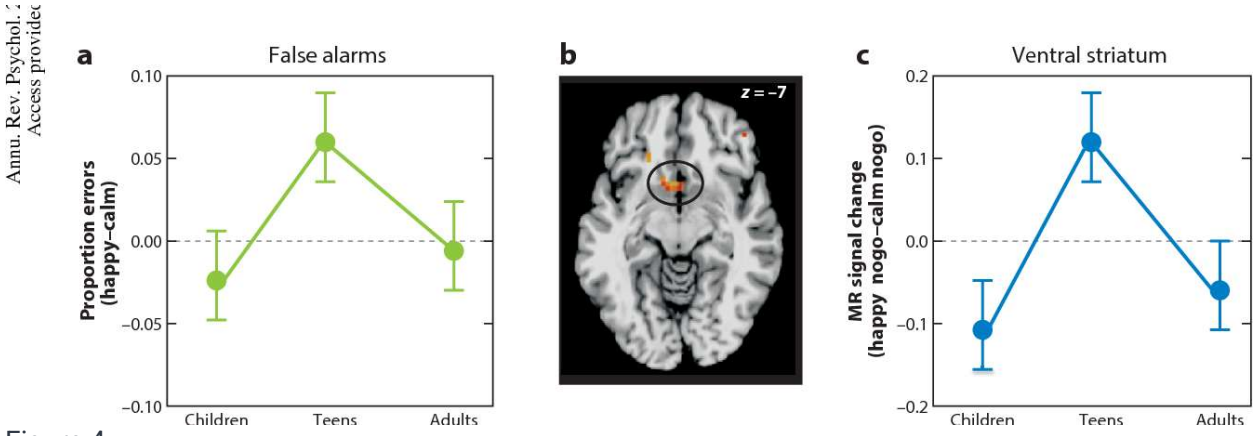

Figure 4
Published in Annual Review of Psychology 2015

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

B. Casey

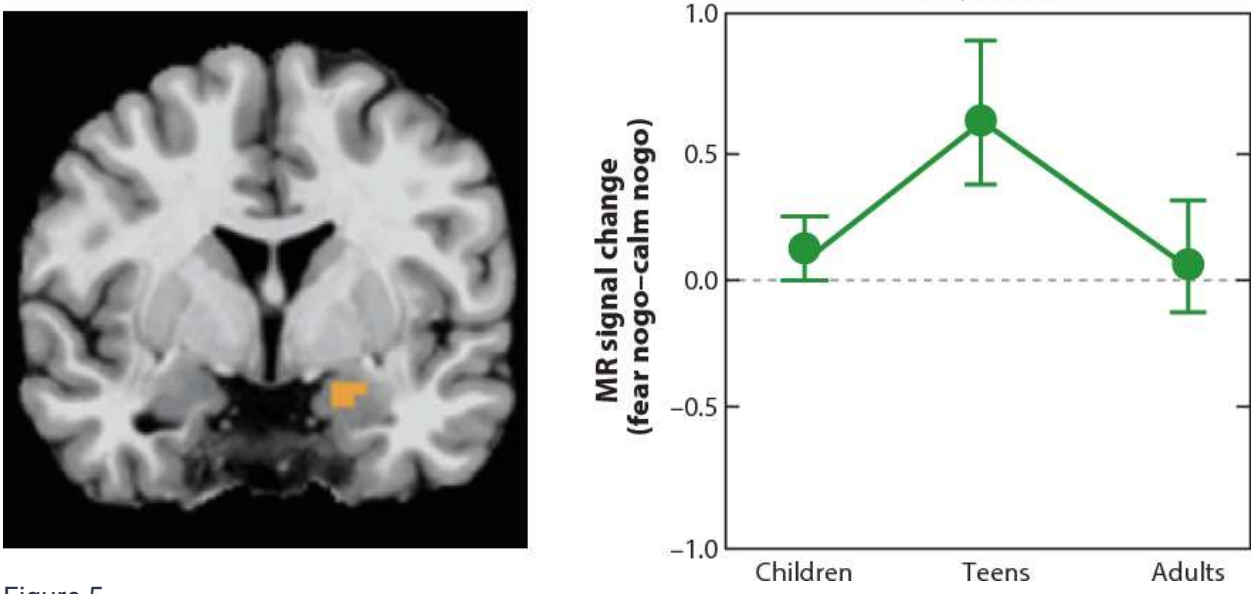

Figure 5
Published in Annual Review of Psychology 2015

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

APPENDIX C. CROSS TALK BETWEEN THE PFC AND VENTRAL STRIATUM

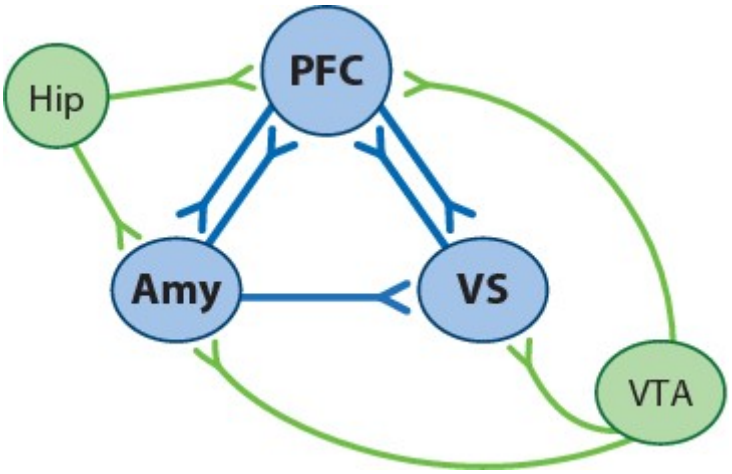

FIGURE 3

Published in Annual Review of Psychology 2015

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

B. Casey

APPENDIX D. ERIKSON'S PSYCHOSOCIAL DEVELOPMENT MODEL

EXHIBIT 12

SUBMITTED UNDER SEAL

EXHIBIT 13

SUBMITTED UNDER SEAL

EXHIBIT 14

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

BRIANNA BOE, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
UNITED STATES OF AMERICA,	)	
	)	
Intervenor Plaintiff,	)	
	)	
v.	)	Civil Action No. 2:22-cv-184-LCB
	)	
HON. STEVE MARSHALL, in his Official capacity as Attorney General, of the State of Alabama, *et al.*,	)	
	)	
Defendants.	)	

SUPPLEMENTAL EXPERT REPORT OF
DR. FARR CURLIN, M.D.

Table of Contents

I. CREDENTIALS

1. I am the Josiah C. Trent Professor of Medical Humanities in the Trent Center for Bioethics, Humanities, and History of Medicine, and Professor in the Department of Medicine, at Duke University. I am also Co-Director of the Theology, Medicine, and Culture Initiative at Duke Divinity School and Senior Fellow in Duke University's Kenan Institute for Ethics. Prior to joining the Duke University faculty in January 2014, I served on the faculty of the University of Chicago.

2. I am licensed to practice medicine and maintain medical licensure in the State of North Carolina. I am an internist with board certification in Internal Medicine, as well as subspecialty board certification in Hospice and Palliative Medicine. From 2001 to 2013, I practiced general internal medicine, maintaining an outpatient primary care clinic from 2001 to 2008, and attending on the inpatient wards at the University of Chicago Hospitals from 2003 until I moved to Duke University at the end of 2013. Since January 2014, I have served as a palliative medicine consultant and hospice physician at Duke University.

3. I completed a fellowship in clinical medical ethics at the University of Chicago, and I have served on the medical ethics faculties of the University of Chicago and Duke University for 19 years, providing clinical ethics consultations (at the University of Chicago), attending regular ethics case conferences, teaching medical ethics, and completing research studies and other scholarly work regarding medical ethics. In addition, I was named to the Greenwall Foundation Faculty Scholars Program in Bioethics, through which, over the subsequent decade, I met numerous times with a community of leading scholars in bioethics.

4. My work on medical ethics has included peer-reviewed publications, invitations to lecture at universities nationwide and internationally, and being asked to speak as an expert before national advisory bodies. I have received awards in bioethics. My training, research, and experience give me familiarity with professional ethical norms regarding clinical medicine—their content, history, and application to clinical contexts, including the context of "gender affirmation." As reflected in my CV, I have published an academic book that addresses, and have given invited talks at a major medical school concerning, ethical issues surrounding transgender medicine.

5. In addition, I completed a two-year postdoctoral fellowship in health services research at the University of Chicago, and I have spent a substantial portion of my time since then conducting and publishing empirical research, including research on physicians' attitudes and practices regarding controversial practices. This training and experience give me added expertise in interpreting and applying scientific data to clinical contexts. My credentials and experience are

documented in further detail in my curriculum vitae, which I attach as Appendix B to this Report.

6. This report presents my independent, expert opinions based on my study, training, and experience as a physician, biomedical ethicist, and health services researcher; my review of relevant scholarly literature; and my discussions over the years with colleagues in medicine and bioethics. I do not speak herein for Duke University, nor is the affidavit intended to represent the opinions or policies of Duke University. I am being compensated for my time spent on this matter at a rate of $500 per hour, and $250 per hour for time spent on travel required to give testimony.

7. My most recent curriculum vitae, which lists my publications and my testimony provided within the last four years, is provided as Appendix B to this Report.

II. MATERIALS REVIEWED

8. As part of my preparation of this report, I have reviewed the materials listed in Appendix A to this Report.

III. QUESTIONS ADDRESSED

9. Dr. McNamara has asserted that "no institutional review board would approve a research protocol on a randomized control trial in essential medical treatment for gender dysphoria because of the established science which demonstrates the efficacy of treatment with transitioning medications." (McNamara Report 20-21.) Similarly, Dr. Antommaria states that "For randomized trials to be ethical, clinical equipoise must exist; that is, there must be uncertainty about whether the efficacy of the intervention or the control is greater." He asserts that a randomized trial in which the control group does not receive puberty blockers or cross-sex hormones would be unethical. (Antommaria Report 15-16.)

10. More recently, the Intervenor United States, through its agency the FDA, has issued a letter stating that it would be "reasonable" to include males down to age 13 in a clinical trial of cross-sex administration of estradiol as a medicalized gender transition ("MGT") treatment,[1] while suggesting that such a trial need not include a placebo control.[2] Meanwhile, the American Academy of Pediatrics (AAP), which has submitted an amicus brief in this case and which issued the 2018 "Policy Statement" which Plaintiffs and their experts have cited to this Court, recently

[1] In this report I use the term "medicalized gender affirmation" to refer to the use of puberty blockers and cross-sex hormones in patients experiencing gender dysphoria.
[2] https://www.statnews.com/2023/11/28/fda-gender-affirming-care-estrogen-approval/.

submitted a brief in another litigation addressing restrictions on MGT for minors in which the AAP asserted:

> '[I]n transgender clinical research individual randomized controlled trials (RCTs) may not always be feasible or ethically acceptable.' Sari L. Reisner et al., Advancing Methods for U.S. Transgender Health Research, 23(2) Curr. Opin. Endocrinal Diabetes Obes. 198, 199 (2016). With preexisting guidelines that recommend gender-affirming care for those with gender dysphoria, randomized controlled trials would violate the principle of equipoise, which safeguards the rights of individual trial participants. Richard J. Lilford & Jennifer Jackson, Equipoise and the Ethics of Randomization, 88 J. R. Soc. Med. 552, 552 (1995).[3]

11. Plaintiffs will likely claim that this letter from the FDA and this statement from the AAP support their experts' contention that it is unethical to withhold medical transition from minors.

12. I have been asked to give my expert opinion regarding whether withholding medicalized "gender affirmation" or "gender transition" treatments (MGT) from minors, whether to provide a control arm in a clinical experiment, or out of concern for potential harm to the patients, is consistent with the principle of equipoise in clinical research and other well-established principles of medical ethics.

IV. SUMMARY OF OPINIONS

13. While I set out my opinions throughout this report, I summarize here key aspects of those opinions.

14. I take as a premise, based on the science reviewed and the opinions offered by Drs. Cantor and Laidlaw, that the mental health benefits that are claimed to justify the administration of medicalized gender affirmation treatments to minors are currently unproven and disputed among informed observers. Position statements from professional associations cannot substitute for scientific evidence.

15. I also take it as a premise, based on the science reviewed and the opinions offered by Drs. Cantor and Laidlaw, that the known or reasonably anticipated harms to children and adolescents from MGT treatments are substantial and serious, threatening sterilization, failure to develop healthy sexual

[3] Brief of Amicus Curiae American Academy of Pediatrics submitted to the Supreme Court in *Williams et al. v. Skrmetti* (No. 23-466) on Petition for a Writ of Certiorari, dated December 4, 2023, at 22 n. 72.

response, impaired neurological (brain) development, and multiple other harms to bodily health.

16. There is not a consensus among medical professionals that MGT is beneficial or suitable for minors. This is amply supported by the published literature and the evaluations and position statements of a number of national health authorities of respected jurisdictions. Further, I know from my own experience and that of professional peers that both what is said and what is published in this field is severely distorted by what is sometimes referred to as a "cancel culture," with professionals fearing for their reputations and even their employment and livelihoods if they criticize or raise concerns about administration of MGT to minors, whether in scientific publications or in public discussion.

17. It is not possible to conclude that it is known beyond "equipoise" that MGT is on the whole beneficial for minors who suffer from gender dysphoria. Therefore, the ethical principle of equipoise does not prohibit including control groups that receive only psychological counseling but not MGT in studies to evaluate the benefits and harms of MGT. Nor is there a basis to assert that it is unethical to withhold MGT from minors in a clinical setting *outside* the context of formal clinical experimentation.

18. On the contrary, for multiple reasons there is a serious question whether it is allowable, under accepted principles of medical ethics, to administer MGT to minors. Based on the descriptions of the available science provided by Dr. Cantor, Dr. Laidlaw, and position statements from national health authorities, it appears that animal studies that could give meaningful information about potential harms of MGT (including sterilization, brain development, bone development, and cardiovascular health) have not yet been done; that well-designed studies to evaluate both harms and efficacy have not been conducted; and that plans for careful long-term monitoring and management of reasonably anticipated risks of such disruptions of natural hormone levels and bodily maturation and function have not been identified and followed.

19. Further, it is not at all clear that meaningful informed consent for administration of MGT to minors can be obtained. There are strong reasons to doubt that minors can adequately appreciate and appropriately weigh the lifetime implications of sterilization, loss of sexual response, impaired neural development, and the other potential health and relational impacts identified in the literature, nor is it apparent that doctors possess (much less consistently disclose) adequate scientific information about these risks to enable anyone to make meaningfully informed decisions. Nor do ethical principles give parents unfettered power to provide effective consent on behalf of their children for medical interventions that pose such severe risks of irreversible harm to the bodily health of the child (including sterilization) in the absence of a countervailing and imminent threat of

bodily harm from a medical condition to be treated. No such imminent threat exists in the case of minors who experience gender dysphoria.

V. THE SCIENTIFIC CONTEXT RELEVANT TO ETHICAL ANALYSIS.

A. The hoped-for benefits from MGT are unproven.

20. I have read the descriptions of the state of knowledge provided in the expert reports submitted by Drs. Cantor and Laidlaw. I have been asked to and do assume that the descriptions of the articles and studies that they provide are accurate for purposes of forming my opinions provided in this case. On that basis, it is evident that multiple respected health authorities and sources have recently opined that the safety and efficacy of hormonal interventions to treat gender dysphoria in minors remain uncertain and unproven. While I rely on Dr. Cantor's and Dr. Laidlaw's descriptions of the scientific literature, I have myself also reviewed the illustrative examples that I summarize below.

21. An extensive review commissioned by England's National Health Service and chaired by eminent pediatrician Dr. Hilary Cass concluded that there has been "very limited research on the sexual, cognitive, or broader developmental outcomes" from the use of puberty blockers for gender dysphoria (Cass 2022 at 19), that it is an unanswered question "whether the evidence for the use and safety of [puberty blockers] is strong enough as judged by reasonable clinical standards" (Cass 2022 at 37), and that "the available evidence was not strong enough to form the basis of a policy position" with regard to use of both puberty blockers and cross-sex hormones in minors (Cass 2022 at 35).

22. Systematic reviews of the safety and efficacy of puberty blockers and cross-sex hormones as treatment for gender dysphoria in minors have been conducted by the England National Institute for Health & Care Excellence (NICE). These reviews concluded that available clinical evidence of efficacy and safety in the relevant population is uniformly of "very low quality." (Cantor ¶¶ 79-84.) "Very low quality" within the GRADE system of evaluation of medical information means: "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." (GRADE Handbook at 13 (Section 5).)

23. In 2022, the Swedish National Board of Health commissioned its own systematic review and concluded that "the evidence on treatment efficacy and safety is still insufficient and inconclusive for all reported outcomes," and that "[f]or adolescents with gender incongruence, the . . . risks of puberty suppressing treatment with GnRH-analogues and gender-affirming hormonal treatment currently outweigh the possible benefits." (Cantor ¶¶ 28, 86; Swedish Socialstyrelsen Support 2022 at 10-12.)

24. In 2022, Norway's Healthcare Investigation Board (Ukom) concluded that "The knowledge base, especially research-based knowledge for gender-affirming treatment (hormonal and surgical), is insufficient and the long-term effects are little known" and that "This applies particularly to the teenage population." (Cantor ¶ 30-31; Ukom 2023, Summary and Section 7.)

25. In 2020, the Finnish Council for Choices in Health Care in Finland concluded that medical transition of minors "is an experimental practice." (Cantor ¶ 169, quoting COHERE Recommendation (2020) translation.) Dr. Riittakerttu Kaltiala, Chief Psychiatrist in the Department of Adolescent Psychiatry at Finland's Tampere University Hospital, has recently stated that young people who received MGT were "deteriorating" rather than "thriving," that her clinic has observed gender dysphoria spreading like a "social contagion" among teenage girls, and that increasing numbers of patients have begun returning to their clinic saying that they now regret their transition. (Kaltiala 2023b [Free Press Interview].)

26. Even the WPATH organization, which strongly advocates for medical transition of minors, repeatedly acknowledges the absence of vital science in its recently released and self-designated "Standard of Care" version 8 (SOC 8). The SOC 8 notes that a 2014 Dutch study "is the only study that followed youth from early adolescence... through young adulthood" (SOC 8 at S46) and "It is not clear if deviations from [the age and mental and social health screening requirements of the Dutch study approach] would lead to the same or different outcomes" (at S65). It also acknowledges that, "Despite the slowly growing body of evidence supporting the effectiveness of early medical intervention, the number of studies is still low, and there are few outcome studies that follow youth into adulthood." It adds, "A key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments." (at S45-46.)

27. Studies summarized by Drs. Cantor and Laidlaw likewise document serious uncertainty about the efficacy and safety of MGT as a treatment for gender dysphoria. (Cantor ¶¶ 148-154, 178-201; Laidlaw ¶¶ 90-175.)

28. For example, a study from the Tavistock and Portman clinic in the UK found, "Relative to the time point before beginning puberty suppression, there were no significant changes in any psychological measure, from either the patients' or their parents' perspective." (Cantor ¶ 186.)

29. Multiple other studies have found persistently high suicide rates after MGT. (Cantor ¶ 149.) A cohort study of minors by Kuper et al. found that suicidal ideation, suicidal attempts, and non-suicidal self-injury all went up after starting MGT (Cantor ¶ 1521), and, "No studies have documented any reduction in suicide rates in minors (or any population) as a result of medical transition" (Cantor ¶ 148), a fact acknowledged by WPATH (Cantor ¶ 150).

30. I also reviewed two large and very recent studies discussed in Dr. Cantor's supplemental report dated February 2, 2024. The first (Glintborg 2023) examined the medical records of all individuals in Denmark diagnosed with gender dysphoria or gender incongruence from 2000 through 2021 (3812 patients, among whom 2089 underwent MGT). That study found that prescriptions of psychoactive medications increased rather than decreased after the start of MGT and remained elevated across multiple years. (Glintborg 2023 at. 341.) It also found that measures of negative mental health, compared against controls, "were stable after initiation of gender-affirming hormone treatment, without sign of decrease after date for first prescription of gender-affirming hormone." (at 342:2.) That is, the mental health of the patients who received MGT did not improve on average.

31. The second study (Kaltiala 2023) examined the medical records of persons who had contacted the national gender identity service of Finland between 1996 and 2019 (3665 persons) and compared them to age and sex-matched controls. That study found that the need for psychiatric treatment did not go down after MGT interventions. (Kaltiala 2023 at 2:1.) The authors referenced similar findings from an earlier study and noted, "Their findings and ours do not suggest that medical GR interventions resolve psychiatric morbidity among people experiencing gender distress." (at 6:1.)

32. Finally, I have reviewed the expert reports of Drs. McNamara, Antommaria, and Ladinsky and note that none of those reports cite any study that has found that medical transition reduced suicides in any population.

33. All of this contradicts the plaintiffs' claim that MGT is medically necessary, since an intervention cannot be said to be medically necessary if the benefits of the intervention are unproven, or indeed are cast into serious doubt by the most recent large-scale studies.

B. The risks of harm from MGT are substantial and serious.

34. While the benefits of MGT for minors are at best unproven, the evidence summarized by Drs. Cantor and Laidlaw also indicates that MGT in minors poses risk of objective, often irreversible, harms to health, while also requiring life-long dependence on medical interventions.[4]

[4] McNamara writes, "The overwhelming majority of adolescents who receive transitioning medications continue to do so as adults." (McNamara at 23.)

35. Risks of harm recognized in the literature include:

a. Sterilization (Cantor ¶¶ 206-207; Laidlaw ¶¶ 90-98, 157-159);

b. Lifetime lack of orgasm and sexual function (Cantor ¶ 208)—an adverse effect acknowledged by Marci Bowers, current president of WPATH (Cantor ¶ 209; Laidlaw ¶¶ 99-100);

c. Potential adverse effects on neurological and cognitive development (Cass Review Letter 2022 at 6; Cantor ¶¶ 210-214);

d. Reduced bone development, especially in male to female transition (Cantor ¶¶ 217 – 220; Laidlaw ¶¶ 101-112), the long-term effects of which have not been studied;

e. Harm to psychosocial development (Laidlaw ¶¶ 114-117); and

f. "Increased cardiovascular risk, osteoporosis, and hormone dependent cancers." (Cass 2022 at 36; Cantor ¶ 224; Laidlaw ¶¶ 126-129.)

36. The leading Swedish pediatric gender clinic, following a systematic review of the available scientific evidence commissioned by Sweden's National Board of Health, concluded that hormonal interventions in minors are "fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis," and that "In light of the above, and based on the precautionary principle, which should always be applied, it has been decided that hormonal treatments (i.e., puberty blocking and cross-sex hormones) will not be initiated in gender dysphoric patients under the age of 16." (Karolinska 2021, cited in Cantor ¶ 27.)

C. The fact that a particular intervention is medically indicated for one condition in one population does not imply that it is medically or ethically defensible for a different condition in a different population.

37. The plaintiffs' experts have suggested that because the drugs used in MGT have been used to treat conditions such as precocious puberty and complete androgen insensitivity syndrome, it is unjust to prevent their use in minors with GD. But the plaintiffs' experts are comparing apples and oranges.

38. While treatments for precocious puberty and complete androgen insensitivity syndrome aim to preserve and restore healthy development of secondary sex characteristics, MGT intentionally blocks healthy development of those characteristics. As Dr. Cantor notes, the former aim "to bring the patient within healthy norms", while the latter "is applied precisely to take the patient outside of healthy norms." (Cantor ¶ 276.) Similarly, while the Court noted that

"Doctors have also long used hormone therapies for patients whose natural hormone levels are below normal" (Opinion and Order dated 05/13/22, at 18), MGT contradicts this medical pattern; rather than correcting hormone levels that are abnormal, it induces hormone levels that are abnormal.

39. Dr. McNamara asserts that MGT in minors is safe, because puberty blockers have long been prescribed "in adolescents with cancer who need menstrual suppression as they undergo marrow-ablative chemotherapy." (McNamara at 13.) But as Dr. McNamara concedes, "puberty blockers are used in these patients to protect their gonads from toxicity induced by chemotherapy as a means of fertility preservation", whereas, by contrast, MGT directly hinders and suppresses healthy gonadal development and function, harming fertility. In one case, the drugs have medicinal effects; in the case of MGT, the drugs have toxic effects. As a result, the ethical analysis is entirely different and opposite.

D. The fact that GD is listed as a disorder in the Diagnostic and Statistical Manual of Mental Disorders (DSM 5) does not imply that GD marks a disorder of the body that warrants MGT in minors.

40. McNamara notes that the DSM 5 identifies GD as a disorder. (McNamara at 15.) But the DSM is a manual specifically of what it terms "*mental* disorders" created by the American Psychiatric Association; it does not identify or provide diagnostic criteria for medical illnesses. The Plaintiffs have not identified any other "mental disorder" for which the indicated treatment is to block or damage the development of healthy organs and functions. On the contrary, MGT in minors contradicts ordinary medical standards with respect to disorders of perception. The person suffering GD perceives their objectively healthy secondary sex characteristics as not compatible with their mental self-perception and therefore needing to be suppressed. MGT problematically takes the minor's mental perception as sufficient reason to treat healthy anatomy and physiology as if it were diseased, thereby contradicting medicine's ordinary regard for the healthy body as its standard. To my knowledge, in no other case do we treat a disordered perception by treating normal physiology and anatomy as diseased. We do not, for example, prescribe hand soap to children who, because of obsessive compulsive disorder, misperceive their hands as needing to be washed repeatedly. We do not lock children indoors who, because of agoraphobia, fear going outside. We do not encourage fasting in patients with anorexia nervosa.

41. Indeed, there is one historical precedent where doctors have removed or damaged healthy tissue attempting to treat mental disorders—that is, performing lobotomies on patients who suffered from mental illnesses, including schizophrenia, depression, melancholy, and obsessive-compulsive disorder. As with MGT, "The treatment was introduced … despite the fact that little research had been carried out on its effects." (Torkildsen 2022.) As with MGT, in the absence of adequate scientific data, many people "were convinced that lobotomy reduced

suffering." As with MGT, "those who promoted the method, were driven by idealism and a strongly held belief that their treatment alleviated suffering," and they "gave overwhelmingly positive reviews of the efficacy of the treatment, while grossly under-communicating its adverse effects." Lobotomy has come to be seen "as one of the greatest mistakes in modern medicine" (Torkildsen 2022)—a prominent example of a collective scientific and ethical misstep by the medical profession that harmed many patients. In my opinion, MGT is likely to be judged the same, not least because it treats a disorder of perception as if it were a disorder of the body, harming the healthy body in efforts to reduce mental suffering.

E. Statements by U.S. medical and advocacy organizations do not establish that MGT is medically necessary.

42. As already summarized above, ample objective evidence demonstrates dissensus regarding MGT across the community of experts and clinicians. Indeed, the health authorities and independent bodies that have systematically reviewed the scientific evidence regarding MGT in minors have concluded that evidence is insufficient to justify the conclusion that MGT improves even mental health outcomes. Indeed, the recent large studies from Denmark and Finland have found that mental and behavioral disorders do not decrease after MGT. (Glintborg 2023 at 341, Kaltiala 2023 at 1.)

43. In contrast to these reviews of evidence, "The Endocrine Society guidelines do not rely on any systematic review of evidence of efficacy of any form of treatment for gender dysphoria." (Cantor ¶ 256.) The AAP's 2018 policy statement, "unique among the major medical associations in being the only one to endorse an affirmation-on-demand policy" (Cantor ¶ 257), was authored by one physician and likewise was not based on a systematic review of available evidence. The policy statement cited no new evidence to justify offering MGT rather than therapy and watchful waiting, and the statement is contradicted by the very reports it cited. (Cantor ¶ 257.) Meanwhile, "the systematic review on which WPATH based its standards for minors included exactly one study on puberty blockers and three studies on cross-sex hormones. All other references represent cherry-picked citations of studies rejected by its own systematic process. Moreover, even among the four studies in WPATH's review, three were rejected by the Swedish review, due to the low quality of the science they contained." (Cantor ¶ 250.) WPATH likewise cited no reference or rationale to justify removing minimum age restrictions for MGT.

F. If WPATH allowed the SOC 8 development process to be influenced by financial and other non-medical considerations, then WPATH's Standards of Care report is unreliable not only because it is contradicted by the evidentiary base, but also because it is the product of ethical misconduct.

44. My own review of SOC 8 indicates WPATH has problematically minimized the doctor's responsibility to exercise independent judgment and fiduciary responsibility to guide patient care for minors. In addition, Cantor and Laidlaw conclude that the WPATH committee members who participated in creating SOC 8 were subject to direct financial conflicts of interest as the guidelines would likely impact their own income (more procedures permitted, and increased insurance coverage, and their liability risk. (Laidlaw ¶ 187; Cantor Supp. ¶ 102-115, 119.) Insofar as these descriptions are accurate, then WPATH ignored significant conflicts of interest and violated accepted principles of medical ethics.

45. Beauchamp and Childress note:

> A conflict of interest exists when an impartial observer would determine that a professional's judgments, decisions, or actions are at risk of being unduly influenced by his or her personal interests, such as financial interests … The risk is that the professional's personal interests will create temptations, biases, and the like that will lead to a breach of role responsibilities through judgments, decisions, and actions other than those reasonably expected in the role. The reasonable expectation is that clinicians will seek the patient's welfare and respect his or her rights, that researchers will pursue objective and valid results, and so forth. A conflict of interest poses a risk that the professional in question will compromise these expectations and thereby damage patients' interests and rights, distort research, or teach trainees in a biased way. (Beauchamp and Childress at 328.)

46. As this explanation makes plain, it is beyond dispute that clinicians who practice (and are paid for) MGT have a conflict of interest in assessing whether MGT is supported by the evidence. It is problematic that this conflict of interest was neither mentioned in the SOC 8 report nor managed by including outside experts and perspectives in the standard-writing process. Insofar as changes in the recommendations were motivated not by dispassionate assessment of the data but by concern to protect clinicians' financial interests or professional reputations, or to further political or litigation agendas, that clearly "damage[s] patients' interests and rights, distort[s] research" and promulgates standards "in a biased way." All of this contradicts professional ethical norms and undermines trust in the medical profession. As Beauchamp and Childress also write, "Health care professions specify and enforce obligations for their members, thereby seeking to ensure that persons

who enter into relationships with these professionals will find them competent and trustworthy." (Beauchamp and Childress at 7.) If WPATH permitted its standard-development process to be dominated by individuals with a direct financial interest in providing the services covered by that document, without disclosing those conflicts of interest, then WPATH is neither competent nor trustworthy regarding its evaluations or advocacy of MGT.

G. The problematic influence of fear and intimidation on the scientific discourse relating to responses to gender dysphoria.

47. When confronted with claims of "medical consensus," the Court needs to be aware that social pressure and fear of censure within the United States medical and academic communities is affecting both what is published about MGT and the willingness of doctors to voice concerns about MGT.

48. Reuters recently published an investigative report documenting both growing concerns among physicians about MGT as well as intense backlash that clinicians, experts, and patients themselves have received when they voice such concerns. (Respaut 2022.)

49. I know from personal conversations with many medical ethicists and practitioners that doctors are afraid to speak up for fear of both social and employment repercussions, a problem also described by colleagues in Europe (Cass 28, Kaltiala 2023b).[5] I recently participated in a meeting of the Greenwall Faculty Scholars Program in Bioethics, which brings together a community of leading bioethicists nationwide. The meeting included a closed-door session titled, "Hot Topic: Bioethics Dilemmas in the Care of Transgender Minors." In that session, several colleagues voiced concerns, including a number of the ethical concerns I have raised in this report. Colleagues also expressed reservations about raising these concerns in public, for fear of being treated as a bigot or someone who is insensitive to the needs of people experiencing GD. This pattern reflects what the Cass report also reported in the UK, that clinicians there "are afraid of the consequences of ['taking a mental health approach to formulating a differential diagnosis'] in relation to gender distress because of the pressure to take a purely affirmative approach." (Cass 48.)

50. In December 2023 I participated in a meeting of the faculty of Duke University's Trent Center for Bioethics, Humanities & History of Medicine focused on this topic. In that meeting several faculty members voiced similar concerns about MGT and similar fears about speaking up. In November 2023 I gave an invited

[5] Kaltiala writes: "… health providers were failing to speak up. I understood this silence. Anyone, including physicians, researchers, academics, and writers, who raised concerns about the growing power of gender activists, and about the effects of medically transitioning young people, were subjected to organized campaigns of vilification and threats to their careers." (Kaltiala 2023b.)

lecture on this topic at the University of Chicago's MacLean Center for Clinical Medical Ethics, and there more than one colleague told me that they feared speaking up about their concerns regarding MGT, and that they had observed that other colleagues at the University, when they learned of the topic, had sought to have me disinvited prior to the lecture. After the lecture an undergraduate student waited until everyone who wanted to talk to me had left, and then came up and quietly thanked me for speaking up about the ethical problems with MGT for minors. She said that she had been on the pathway to MGT a few years before, but as she had gone through puberty she slowly had come to grips with being a woman and now calls herself a desister.

51. Both medical students and faculty at Duke University, where I am employed, have told me that they fear voicing concerns about MGT, and I probably would not have felt able to voice my own concerns were I not tenured. Having voiced my concerns, I was cancelled from giving a talk on an unrelated topic at Michigan State University spring of 2022, because students alleged that they would not feel safe listening to me lecture on that topic due to the concerns I had expressed elsewhere about MGT. I have found resistance to hosting public dialogue and debate about the topic even among colleagues that agree that MGT is ethically problematic. All of this makes evident that fear is muzzling open expression of widespread and growing dissent within the medical community regarding MGT.

VI. APPLICATION OF PRINCIPLES OF MEDICAL ETHICS TO THE STATE OF SCIENTIFIC KNOWLEDGE CONCERNING THE BENEFITS, HARMS, AND RISKS OF MGT.

A. The state of evidence does not support the conclusion that the ethical principle of equipoise forbids withholding MGT from minors, including in studies in which a control group does not receive MGT.

52. Benjamin Freedman, the bioethicist who first promoted the concept of equipoise in clinical research, has written, "The ethics of clinical research requires equipoise — a state of genuine uncertainty on the part of the clinical investigator regarding the comparative therapeutic merits of each arm in a trial." (Freedman 1987.) In their respected textbook, *Principles of Biomedical Ethics*, Beauchamp and Childress note that "[t]he community of reasonable physicians is … in a state of 'clinical equipoise'" when "No one knows, prior to conducting the research, whether it is more advantageous to be in the control group or in the experimental group … No patient, then, will receive something known to be less effective or to have a higher risk than an available alternative." (Beauchamp and Childress 2012 at 335.) Notably, clinical equipoise depends on both foreseen benefits and foreseen harms.

53. To conclude that the principle of equipoise forbids an "untreated" "active control" arm in a clinical study of MGT, one would have to conclude that it is known as a matter of medical science that MGT brings about benefits that outweigh known or foreseeable but unstudied harms, and that those benefits cannot be

achieved by some other "established effective intervention" which could be included in the "active control." (Beauchamp and Childress at 336.) In the case of GD, such an active control (also called the "active comparator" (Cantor ¶ 265)) could include any customary psychotherapeutic interventions. Since large studies find that MGT does not lead to improved mental health outcomes, it is incorrect to assert that *not* offering MGT is contradicted by the principle of equipoise.

54. Importantly—and contrary to what Dr. Antommaria suggests (Antommaria at 10)—whether clinical equipoise exists is not determined by what any one clinician or group of clinicians or investigators believes. Nor, contrary to the American Academy of Pediatrics, can the physician's ethical obligation to determine the existence (or absence) of clinical equipoise based on the available science be obviated by "preexisting guidelines that recommend gender-affirming care." (AAP amicus brief, *Williams v. Skrmetti*, supra n. 3.) Rather, clinical equipoise exists when, "[o]n the basis of the available evidence" (Beauchamp and Childress at 335), "there is genuine uncertainty within the expert medical community—not necessarily on the part of the individual investigator—about the preferred treatment" (Freedman 1987). As the above summaries make clear, the community of reasonable clinicians, as well as the international community of relevant experts, is at best genuinely uncertain about whether MGT is to be preferred to standard psychotherapeutic treatment without MGT. This is confirmed by the fact that multiple international bodies of experts have described MGT as "experimental." (Cantor ¶ 168-172.)[6]

55. Plaintiffs' assertions that it would be unethical to do clinical research with an arm that does not receive MGT are thus unsupported. I see assertions but no science cited by Plaintiffs' experts that should cause an Institutional Review Board (IRB) to reject a clinical trial in which the active control does not include MGT. IRBs do not defer to clinicians' judgment about equipoise, much less to those who are most enthusiastic about some intervention. When IRBs are fulfilling their role, they require clinicians and researchers to show sufficient evidence to justify their beliefs.

56. Moreover, that such studies can be ethical is evidenced by the fact that multiple countries, including the United Kingdom, have now announced policy changes to provide MGT only as part of formal research protocols. (Cantor ¶¶ 168, 170, 266.) Even pioneers of MGT have called for such research, with Dr. de Vries writing recently that "rigorous longitudinal outcomes studies that provide evidence about whether this approach [MGT in minors] is effective and safe are needed" and

[6] See also a 2023 article published in one of the world's most prestigious medical journals, the *British Journal of Medicine*, that was entitled, "Gender dysphoria in young people is rising and so is professional disagreement." (Block 2023.)

that "Future studies that *compare outcomes with different care models are needed*." (de Vries 2023 at 276; cited Cantor ¶ 283 (italics added).)

57. Thus, even if a trial cannot be randomized or blinded as a practical matter, the principles of medical ethics do not preclude a carefully constructed trial that includes an arm comprised of patients with GD who undergo psychotherapeutic care but do not undergo hormonal intervention.

B. An Institutional Review Board that approved the expanded clinical trial apparently advocated by the FDA would likely be violating its ethical obligations.

58. As I have summarized above, multiple international reviews of the available evidence have concluded that MGT has not been shown to improve mental health outcomes. Without reliable evidence of better mental health outcomes than achieved by psychotherapy alone, the known or reasonably foreseeable harms of MGT cannot be reasonably accepted. That is to say, the condition of equipoise not only does not forbid *withholding* MGT, it likely forbids *offering* MGT until and unless appropriately conducted research generates evidence that MGT is likely to generate health benefits that are at least proportionate to its known harms. Based on the reviews of the published evidence provided by Drs. Cantor and Laidlaw, such reliable evidence is lacking at present.

59. A clinical trial of MGT on minors would likely violate other accepted principles of medical ethics as well.

60. The Nuremberg Code, adopted after World War II in response to the human experimentation performed by medical doctors under the Nazi regime, is one of the foundational and internationally accepted statements of key principles of medical ethics pertaining to experimentation on humans. Paragraph 3 of the Nuremberg Code states:

> "The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment."

61. One point of this principle is that if a proposed treatment poses potential risks that could be explored through experiments on animals, then those animal experiments should be done before the treatment is tested on humans.

62. Animal experiments would be possible with respect to many widely recognized risks of puberty blockers and cross-sex hormones. For example, Chen (2020) validates the ability to do useful animal studies of effects of hormones on brain development, writing, "studies in rodents show ovarian hormones, acting during puberty, program cognitive flexibility by exerting long-lasting effects on

excitatory-inhibitory balance in the pre-frontal cortex . . . [and] testosterone, acting during puberty, programs the ability to adapt behavior as a function of social experience." (Chen 2020 at 253:2a.) Animal studies might also help to clarify whether and under what conditions MGT-induced sterilization is reversible; whether suppressed bone development leads to later fractures or other complications; and how MGT impacts cardiovascular health over time. To my knowledge, such studies have not been undertaken. A responsible IRB recalling the Nuremberg Code would want to know what animal studies were feasible, which had been done, and (if true) why feasible studies had not been done, before approving clinical trials of MGT on humans.

63. Another universally respected statement of principles of medical ethics is the Declaration of Helsinki, first adopted by the World Medical Association in 1964, and periodically updated since then. Paragraphs 17 and 18 of the Helsinki Declaration state that it is unethical to undertake any human experiments without first conducting a "careful assessment of predictable risks" and reaching a well-grounded conclusion that all of those risks "can be satisfactorily managed." (Helsinki Declaration ¶¶ 17, 18.)

64. A trial that subjects adolescents to MGT does not meet these standards insofar as the available science does not enable a conclusion that "predictable risks" of MGT in adolescents—including sterilization, negative impact on neurodevelopment, and negative impact on bone and cardiovascular strength—can be "satisfactorily managed."

65. A third respected statement of principles of medical ethics is the Belmont Report, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, authorized by the National Research Act of 1974. The Belmont Report states that prior to administration of experimental treatments to humans:

> "there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. … It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies."
>
> "When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject . . . .)" (Belmont Report § C.2.)

66. There can be no doubt that the known or potential harms of MGT discussed in the literature by knowledgeable observers—including sterilization, impairment of brain development, permanent deprivation of sexual response, and impaired bone development—constitute "risk of serious impairment." Further, the known facts and available studies as reviewed by Drs. Cantor and Laidlaw indicate that assertions that the benefits of MGT outweigh the potential harms are not empirically justified given the existing scientific record.

67. In my opinion, the plaintiffs have not met the bar of justifying the risk associated with MGT insofar as: the evidence to date does not support the claim that MGT brings mental health benefits; animal studies relevant to safety that can be done have not been done; there has not been "careful assessment of predictable risks," and no plan for how all the known risks "can be satisfactorily managed" has been identified.

C. Large and well-resourced medical systems have violated ethical principles by engaging in large-scale prescription of unproven therapies without undertaking well-designed research to evaluate safety and efficacy.

68. As the Helsinki Declaration states, a physician, in certain circumstances, may reasonably use an unproven intervention in the treatment of an individual patient, but "This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available." (Helsinki Declaration ¶ 37.) The Belmont Report likewise states, "in order to determine whether ['radically new procedures'] are safe and effective it is the responsibility of medical practices committees . . . to insist that a major innovation be incorporated into a formal research project at an early stage." (Belmont Report Part A.)

69. It follows that well-resourced academic medical centers with affiliated clinics where unproven MGT interventions are being clinically deployed bear a responsibility under these respected codes of medical ethics to sponsor research capable of investigating the harms and benefits of those interventions. Of course, such research must itself satisfy ethical principles. For example, thorough animal experimentation might be the only ethically justified experimentation given the present state of knowledge. (See above.) At the very least, academic medical centers are obligated to undertake long-term follow-up—into adulthood—of minors undergoing these unproven and "radically new" interventions. This they have not done (or at least, have not yet published), as evidenced by numerous systematic reviews concluding that there is very little evidence regarding the long-term effects of these interventions, and the evidence that exists is of very low quality.

VII. THE POSSIBILITY OF MEANINGFUL INFORMED CONSENT TO MGT FOR MINORS IS DOUBTFUL.

70. The Belmont Report further states that respect for persons requires that research can only be conducted ethically if the subjects have given *informed consent*. In 1982, soon after the Belmont Report was published, the principle of informed consent was applied to clinical medicine in another landmark government report, *Making Health Care Decisions*. Since then, the principle and practice of informed consent has been uniformly established across the domains both of clinical research and clinical medicine. Beauchamp and Childress write, "Virtually all prominent medical and research codes and institutional rules of ethics now hold that physicians and investigators must obtain the informed consent of patients and subjects prior to a substantial intervention." (Health Care Decisions at 121.) The Belmont Report notes "widespread agreement" that informed consent requires the presence of sufficient "information, comprehension and voluntariness." (Belmont Report § C:1.) In my opinion, minors cannot give duly informed consent to MGT, because it is doubtful that any of these three conditions of informed consent can be met.

A. Doctors do not possess and are not providing information sufficient to enable children or parents to make "informed" decisions.

71. The absence of well-designed and controlled studies makes it impossible to give minors and their parents information sufficient to consider their consent duly informed, and the plaintiffs' experts by their own admission are misinforming patients regarding that fact. "*Caveat emptor*" does not meet the bar required for consent to be duly informed within clinical medicine and clinical research. It is not enough to say "we don't know" without doing the careful, incremental research to generate information needed for a consent to be duly informed. Moreover, by their own admission the plaintiffs' experts do not disclose to minor patients and their parents that the evidence base does not support their claims of benefit from MGT. As such, by their own admission, they are misinforming minors and their parents who are considering MGT, and therefore contradicting the first condition on which informed consent depends.

B. It has not been shown that minors are able to comprehend and reasonably evaluate the risks and lifelong implications of MGT.

72. It is doubtful that minors have the intellectual maturity to sufficiently *comprehend* the decision to undergo MGT and the potentially life-long consequences that decision will bring.

73. It is well recognized that the ability to evaluate and balance risk and reward, to consider long-term as well as short-term implications, and to make prudent and well-considered decisions is not well developed in children and

adolescents. WPATH's recently published SOC 8 acknowledges problems with minors' immature capacity for judgment, noting, "adolescence is . . . often associated with increased risk-taking behaviors" (SOC 8 at S44), and "Adolescents often experience a sense of urgency that stems from hypersensitivity to reward, and their sense of timing has been shown to be different from that of older individuals" (SOC 8 at S44). Beauchamp and Childress likewise note that immaturity hinders adequate understanding. (Beauchamp and Childress 2012 at 131.) For this reason among others, with few exceptions minors are *not* considered capable of granting informed consent to medical interventions. (Katz 2016 at e1, e9.)

74. Minors seem particularly incapable of comprehending the long-term implications of MGT, insofar as those implications involve relationships and experiences that come only with adulthood. As I have noted above, MGT brings lifetime physical and social implications including risks of impaired brain development, sterilization, and loss of sexual response. These risks cannot be adequately comprehended by children insofar as these risks relate specifically to aspects of human life that go with being an adult and are outside the life experience of children.

75. Moreover, one form of MGT—puberty blockers—*by design* blocks the mental, physical, and emotional maturation of puberty which may be essential for a child to come in time to comprehend decisions of this magnitude. (Cantor ¶ 214.) Dr. Cantor notes that "Blocking puberty blocks the awareness of sexuality and sexual orientation that can play an important role in the individual's understanding of gender identity" (Cantor ¶ 234), and "for all children, blocking puberty necessarily blocks the onset of adult sexual interest, sexual arousal, and sexual response which are part of 'the usual process of sexual orientation and gender identity development'" (Cantor ¶ 235, quoting Cass 2022 at 38).

76. In connection with the comprehensive review commissioned by the English National Health Service, Dr. Cass wrote, "We do not fully understand the role of adolescent sex hormones in driving the development of both sexuality and gender identity through the early teen years, so by extension we cannot be sure about the impact of stopping these hormone surges on psychosexual and gender maturation. We therefore have no way of knowing whether, rather than buying time to make a decision, puberty blockers may disrupt that decision-making process." (Cass Review Letter 2022 at 5.)

77. It is ethically problematic when the treatment in question—puberty blockers—not only cannot be comprehended adequately by minors, but also prevents the otherwise healthy development of their capacity to comprehend such decisions. This is all the more true for younger children, "[g]iven the highly reliable, repeatedly replicated finding that childhood-onset gender dysphoria resolves with puberty for the large majority of children," and that "the evidence indicates that

blocking a child's puberty blocks the child's natural maturation that itself would resolve the dysphoria." (Cantor ¶ 159.)

78. With respect to adolescents, WPATH's SOC 8 states that "decision-making regarding gender affirming medical treatments that have life-long consequences requires thoughtful, future-oriented thinking by the adolescent." (SOC 8 at S63.) However, neither WPATH nor any other source referenced by plaintiffs' experts establishes that minors, whether pre-pubertal or adolescent, are *able* to meaningfully comprehend and reasonably evaluate the risks and lifelong implications of MGT.

C. There is evidence that many minors who are subjected to MGT cannot meet the informed consent requirement of "voluntariness."

79. The opening statement of the Nuremberg Code declares,

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision.

80. As the Nuremberg Code indicates, voluntariness depends on adequate information and comprehension ("*sufficient knowledge and comprehension of the elements of the subject matter involved*"), both of which, as already noted, are doubtful in the case of minors considering MGT. But voluntariness also depends on freedom from controlling influences, both external and internal.

81. With respect to external influences, minors obviously are commonly under the controlling influence of parents, which I will address below. In addition, a number of international experts have indicated concern that the rapid increase in prevalence of GD, especially among adolescent females, reflects undue influence of social pressure. WPATH's recently published SOC 8 itself acknowledges, "For a select subgroup of young people, susceptibility to social influence impacting gender may be an important differential to consider." (SOC 8 at S45.)

82. Beauchamp and Childress note that in addition to external controlling influences, "no less important to autonomy are internal influences on the person, such as those caused by mental illness. All of these conditions can limit voluntariness." (Beauchamp and Childress 2012 at 105; see also id. at 138.) Dr. Cantor documents ample evidence that a high proportion of minors experiencing GD suffer from mental illnesses. (Cantor ¶ 160-162.) These mental illnesses constitute

an internal controlling influence that can prevent genuine voluntariness. As WPATH itself recognizes, "A young person's mental health challenges may impact their conceptualization of their gender development history and gender identity-related needs, the adolescent's capacity to consent, and the ability of the young person to engage in or receive medical treatment," and "The adolescent's mental health concerns . . . may interfere with diagnostic clarity [and] capacity to consent . . .". (SOC 8 at S62.) WPATH also recently admitted that "autistic/neurodivergent transgender youth represent a substantial minority subpopulation" of those seeking medical transition. (SOC 8 at S50.)

83. Despite the serious obstacle posed by mental health conditions to genuine voluntariness in decision-making by a minor, WPATH's SOC 8 is problematically unclear as to how these conditions will be addressed prerequisite to any MGT. Instead, it refers to an undefined "biopsychosocial assessment" (SOC 8 at S50), and only calls for known mental health concerns to be "addressed" rather than resolved before accepting consent (or assent) as voluntary (SOC 8 at S62). SOC 8 provides no guidance grounded on empirical evidence as to how or when consent/assent given by a minor who suffers from a mental health condition could be determined to be voluntary.

D. The fact that MGT is *wanted* by minors and their parents is not sufficient to justify MGT, medically or ethically.

84. WPATH's revisions of guidelines to eliminate or minimize the doctor's responsibility regarding decision-making with respect to MGT violate accepted principles of medical ethics. In its Standards of Care, version 8, WPATH suggests that gaps in evidence demonstrating the safety and efficacy of MGT should not prevent the use of MGT in adolescents "given the ethics of self-determination in care." (SOC 8 at S45.) The new guidelines also emphasize a "right to bodily and mental integrity, autonomy, and self-determination,"[7] and a putative need for healthcare practitioners to "[m]atch the treatment approach to the specific needs of patients, particularly their goals for gender identity and expression." (SOC 8 at S21.) This language ignores the potential conflict with MGT between "bodily integrity" and "self-determination," as well the conflict between the "needs of patients" and "their goals."

85. Much has been made of the importance of autonomy, but the ethical standard for medical decision-making with respect to minors is decidedly not "self-determination." Rather, as noted in the AAP Committee on Bioethics Report, "Informed Consent in Decision- Making in Pediatric Practice" (Katz 2016), the

[7] Among the "General Principles" asserted by WPATH are: "Respect universal human rights including the right to bodily and mental integrity, autonomy and self-determination; freedom from discrimination, and the right to the highest attainable standard of health." (SOC 8 at S21.)

physician acts in a fiduciary relationship with the child, governed by "the duties to protect and promote health-related interests of the child and adolescent … [, and] these duties may conflict with the parent's or patient's wishes." (Katz 2016 at e2.) Parents likewise have "an ethically parallel fiduciary obligation" (e2) to promote the child's best interests, whether or not that corresponds with what the child wants. "Historically and legally," the AAP report continues, "medical decision-making in children has centered on the best-interest standard, which directs the surrogate to maximize benefits and minimize harms to the minor." (e6) "A reliance on individual liberties and autonomy in the pediatric patient", the AAP report notes, "is not realistic or legally accepted." (e2)

86. By appealing to self-determination to justify MGT for minors, WPATH is putting the onus on children to make clinical decisions that they haven't information, comprehension, or authority to make, and thereby retreating from physicians' ethical obligations to protect children—a class of vulnerable subjects—from interventions that subject children to risks and harms without clear evidence of proportionate medical benefit.

87. For all of these reasons, it is doubtful that minors experiencing GD have sufficient information, comprehension, or voluntariness to make possible informed consent to MGT. If any minors do possess the level of comprehension and voluntariness required by ethical principles for a choice as momentous as undergoing MGT, I am aware of no evidence-based criteria for identifying those specific minors, and plaintiffs' experts cite none.

E. Parental consent cannot satisfy the doctor's ethical obligation to obtain informed, comprehending, voluntary consent.

88. In many medical contexts, medical ethicists speak of obtaining "assent" from minors, while obtaining "consent" from the child's parents. (Katz 2016, e8) This combination of adolescent assent and parental consent, however, cannot cure the problems with informed consent to MGT.

89. Children have long been considered a category of vulnerable subjects and therefore as deserving more protections. (Beauchamp and Childress at 63.)[8] For example, the Declaration of Helsinki requires that where a clinical trial or experiment involves "vulnerable groups and individuals", those patients must "receive specifically considered protection." (Helsinki Declaration ¶ 19.)

90. In the clinical domain, the vulnerability of children is addressed in part by requiring both parents and physicians to act in ways that are reasonably consistent with the child's medical best interest. (Katz 2016 at e2, e12.) That is to

[8] See also HHS policy statement, "Vulnerable and Other Populations Requiring Additional Protections," available at https://grants.nih.gov/policy/humansubjects/policies-and-regulations/vulnerable-populations.htm.

say that whereas adults are given greater latitude to refuse even medically indicated and life-saving treatments, children and their parents generally are not.[9] In parallel, parents have much more latitude to accept experimental interventions and even interventions that contradict bodily health (e.g. cosmetic procedures, physician-assisted suicide) for themselves than they have latitude to accept such interventions for their children. (Katz 2016 at e5.)

91. Because of the vulnerability of children, it is widely accepted that both physicians and the state are obligated to act as fiduciaries of children's best interests with respect to health, and if necessary to act *en loco parentis*. Just as parents are ethically obligated to prioritize the child's good over their own wishes, medical professionals are obligated to prioritize the child's best interest (where that involves the child's health) over the wishes of the parents. Beauchamp and Childress (at 221) describe such "paternalistic" actions as justified by the ethical principle of beneficence—the obligation to do good and promote the health of individuals, while protecting them from harm. The AAP report on informed consent comments:

> This parental responsibility for medical decision-making in caring for their child or young adult is not an absolute right, however, because the state also has a societal interest in protecting the child or young adult from harm and can challenge parental authority in situations in which the child or young adult is put at risk (the doctrine of *parens patriae*). Pediatric health care providers have legal and ethical duties to provide a standard of care that meets the pediatric patient's needs and not necessarily what the parents desire or request. (Katz 2016 at e5.)

92. By definition, minors experiencing GD are vulnerable subjects, and all the more so in light of the already noted high prevalence of mental illness and other comorbidities among this population. As such, minors experiencing GD are owed protection from interventions that contradict their medical best interest—their health. Because MGT disrupts and contradicts bodily health in several ways, it is doubtful that physicians have ethical warrant to offer, or that parents have ethical authority to consent to, MGT in minors.

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[9] Beauchamp and Childress note, "Courts have often allowed adult Jehovah's Witnesses, for example, to reject blood transfusions for themselves, while disallowing parental rejections of medically necessary blood transfusions for their children. Parents are also sometimes appropriately charged with child neglect when they fail to seek or permit potentially beneficial medical treatment recommended by physicians." (at 325)

93. In addition, for the same reasons I have reviewed above, it is not possible to say that parents are receiving information about the implications of MGT sufficient to make any consent they might provide "informed."

94. If persons suffering GD faced imminent bodily harm from their condition, and if there were no other way to respond but to deploy MGT, and if evidence from animal studies and carefully controlled human trials gave reason to anticipate benefits from MGT proportionate to known harms, then an adult could potentially give valid consent to MGT in knowledge of the absence of otherwise necessary information. But none of these conditions in fact have been met, and that makes it doubtful that the principle of informed consent within clinical medicine and clinical research can be met at all with respect to MGT, much less with MGT for minors.

95. The fact that MGT creates a material risk (or even expectation) of sterilization and failure to develop healthy sexual response raises special ethical problems with accepting parental "consent" on behalf of the child. With respect to loss of healthy sexual response, I note that our society strongly disapproves of clitoral mutilation of girls (denying them sexual response in their future adult lives) despite parental consent. Indeed, such "medical" procedures have been prohibited by law as a felony subject to imprisonment.[10]

96. Sterilization has likewise long been recognized to raise special ethical issues. One systematic review found that a significant percentage of women who consent to sterilization at relatively young ages (under 30, in that study) later deeply regret that decision. (Curtis 2006; see also Burgart 2017; Hillis 1999.) Given the possibility of regret and deprivation of what is considered a basic human right in other contexts, it is generally accepted that sterilizing procedures should only be performed on a minor when necessary to save his or her life. And even then, "The validity of parental consent to a sterilizing procedure can be challenged when the procedure could be safely postponed until the child can consent [i.e., when the child reaches adulthood], or where less-invasive alternatives are available." (Burgart 2017; Tamar-Mattis 2009.)

[10] https://travel.state.gov/content/travel/en/us-visas/visa-information-resources/fact-sheet-on-female-genital-mutilation-or-cutting.html#:~:text=Violation%20of%20the%20law%20is,are%20prohibited%20under%20U.S.%20law.

97. While medical procedures that impose substantial risk of serious harm are ethical in some settings, plaintiffs' experts do not remotely establish that the necessary conditions justifying such procedures exist in the case of GD and MGT, especially for minors.

98. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

This declaration was executed on February 2, 2024.

Farr A. Curlin, MD

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World Medical Association (1964). Declaration of Helsinki: Ethical principles for medical research involving human subjects. (“Helsinki Declaration”)

Other Materials Considered

1. Vulnerable Child Compassion and Protection Act (the "Act").

2. Opinion and order granting preliminary injunction dated May 13, 2022 ("Order granting PI")

3. Second Amended Complaint dated September 19, 2022.

4. Expert Report of Meredithe McNamara, dated Feb 8, 2023

5. Expert Report of Armand Antommaria, dated Feb 13, 2023

6. Expert report of James Cantor, dated May 19, 2023

7. Supplementary Expert Report of James Cantor, dated February 1, 2024 (Nonconfidential portions)

8. Expert Report of Michael Laidlaw, dated May 19, 2023

9. Supplementary Expert report of Michael Laidlaw, dated May 19, 2023

10. Eleventh Circuit Court Opinion dated August 21, 2023

11. Production documents HHS-0169973 to -0619991

Appendix B: Curriculum Vitae of Dr. Farr Curlin, MD

January 2024

CURRICULUM VITAE

Farr A. Curlin, MD

EDUCATION AND TRAINING

College: University of North Carolina at Chapel Hill, BA with distinction, Biology, 1992
Medical School: University of North Carolina School of Medicine, MD, 1998
Residency: University of Chicago Hospitals in Internal Medicine, 1998 – 2001
Fellowship: Robert Wood Johnson Clinical Scholar, The University of Chicago, 2001-2003
Fellowship: MacLean Center for Clinical Medical Ethics, University of Chicago 2003-2004
Summer Institute for Survey Research Methods, University of Michigan – 2006
Program in Palliative Care Education and Practice, Harvard University – 2008

BOARD CERTIFICATION

Diplomate American Board of Internal Medicine 204781, 2001, 2011, 2022
Hospice and Palliative Medicine Certification (ABIM), 2010, 2022

MEDICAL LICENSURE

North Carolina License No: 2013-01944

MEMBERSHIPS

American Medical Association
American Society for Bioethics and Humanities

ACADEMIC APPOINTMENTS:

Duke University

2014 -	Josiah C. Trent Professor of Medical Humanities, Trent Center for Bioethics, Humanities & History of Medicine
2014 -	Professor of Medicine, Center for Palliative Care, Section of General Internal Medicine, Department of Medicine
2014 -	Professor and Co-Director, Theology, Medicine, and Culture Initiative, Duke Divinity School (tmc.divinity.duke.edu)
2017 -	Senior Fellow, Kenan Institute for Ethics

The University of Chicago:

2003 – 2005	Instructor of Medicine, Section of General Internal Medicine
2003 – 2006	Associate Faculty, Robert Wood Johnson Foundation Clinical Scholars Program
2004 – 2013	Faculty, the MacLean Center for Clinical Medical Ethics
2005 – 2010	Assistant Professor of Medicine, Section of General Internal Medicine
2009 – 2013	Co-Director, Program on Medicine and Religion (pmr.uchicago.edu)
2010 – 2013	Associate Professor of Medicine, Section of General Internal Medicine

HONORS, AWARDS, SCHOLARSHIPS (selected)

1989	Valedictorian, Jackson Central Merry High School, Jackson, TN
1989	William Richardson Davie Scholar, University of North Carolina
1992	Phi Beta Kappa, University of North Carolina – Chapel Hill
1995	Herbert H. Fritz special merit award for scholastic excellence, UNC School of Medicine
1995	North Carolina Albert Schweitzer Fellowship Award
1995	Foreign Fellowship Award, UNC School of Medicine

1997 Alpha Omega Alpha Honor Medical Society, UNC School of Medicine
1998 Heusner Pupil Award, for showing "a great capacity to grasp the principles of science, to heal the sick, to comfort the troubled, to be humble before God." UNC School of Medicine
1998 Cecil G. Sheps Award in Social Medicine – chosen by the Department of Social Medicine as the graduating student who most embodies the department's ideals, UNC School of Medicine
1998 Terri Brenneman Award - for "the graduating student who has most demonstrated a commitment to the underserved." UNC School of Medicine
1998 Merck Award – chosen by the UNC faculty as one of four graduating students to be honored for their contributions to the medical school community, UNC School of Medicine
2000 Norris L. Brookens Award – chosen by the state chapter of the American College of Physicians as the Most Outstanding Internal Medicine Resident in Illinois
2003 John A. Oremus Memorial Scholar – MacLean Center for Clinical Medical Ethics, The University of Chicago
2006 Greenwall Foundation Faculty Scholar in Bioethics (2006-2009)
2007 Outstanding Physician Scientist Award. Central Society of Clinical Research and the Midwestern Section of the American Federation for Medical Research
2008 Early Career Development Award. Central Society for Clinical Research
2011 Arnold P. Gold Foundation Humanism in Medicine Award Nominee. Pritzker School of Medicine student body
2012 David B. Larson Fellowship in Health and Spirituality, The Library of Congress
2012 White Coat Ceremony Keynote Speaker, Pritzker School of Medicine, August 5
2014 Gold Humanism Honor Society Induction Ceremony Keynote Speaker, Pritzker School of Medicine, Chicago, IL. March 13
2017 Inaugural Robert D. Orr, MD, Lecture in Medical Ethics, University of Vermont, October 27
2018 The Steve Thorney Career Award for Spiritual Care, MD Anderson Cancer Center
2018 Paul Ramsey Award for Excellence in Bioethics, Paul Ramsey Institute
2019 Pellegrino Medal for Healthcare Ethics, Samford University
2021 Inaugural Lisio Family Lecture (medical ethics). Columbia University
2022 Educator of the Year, Christian Medical and Dental Associations
2023 Englehardt Award (bioethics), The Ohio State University Center for Bioethics and Medical Humanities

REVIEW AND EDITORIAL EXPERIENCE

Ad hoc journal and book review

Academic Medicine, American Journal of Bioethics, AJOB – Empirical Bioethics, American Journal of Hospice and Palliative Medicine, American Journal of Law and Medicine, American Journal of Psychiatry, Annals of Family Medicine, Annals of Internal Medicine, Archives of Internal Medicine, British Medical Journal, BMC Medical Education, Cancer, CHEST, CMAJ, Elsevier, Explore, Georgetown University Press, Harvard University Press, Health Affairs, International Journal of Psychiatry in Medicine, Johns Hopkins University Press, Journal of Christian Bioethics, Journal of Clinical Oncology, Journal of General Internal Medicine, Journal of Medical Ethics, Journal of Medicine and Philosophy, Journal of Oncology Practice, Journal of Pain and Symptom Management, Journal of Religion and Health, Journal of the Scientific Study of Religion, Lancet, Medical Care, Mayo Clinic Proceedings, Medical Journal of Australia, New England Journal of Medicine, Oxford University Press, Pediatrics, Perspectives in Biology and Medicine, Plos One, Social Science & Medicine, Southern Medical Journal, Stanford University Press, Theoretical Medicine and Bioethics, Zygon

Editorial experience

2008	Guest editor of special issue of *Theoretical Medicine and Bioethics*, focused on conscience and clinical practice, published 2008
2014 -	Editorial Board, *Perspectives in Biology and Medicine*
2016	Guest editor of special issue of *Christian Bioethics*, focused on setting the medicine in the context of a good and faithful life
2019	Guest editor of special issue of *Theoretical Medicine and Bioethics*, focused on defining and measuring death
2019	Guest editor of special issue of *Perspectives in Biology and Medicine*, focused on disputes about conscience in medicine
2023	Guest editor of special issue of *Christian Bioethics*, focused on moral and theological questions raised by medicalizing risk

CLINICAL PRACTICE

2001 – 2003	Primary Care Internist, Lawndale Christian Health Center
2003 – 2008	Primary Care Physician, University of Chicago Primary Care Group
2003 – 2013	General Internal Medicine attending physician. University of Chicago Hospitals.
2004 – 2013	Ethics consult service, University of Chicago
2008 – 2013	Associate Medical Director – Horizon Hospice Care, Chicago, IL
2008 – 2013	Palliative Medicine Consult Service. University of Chicago Hospital
2014 –	Attending physician. Duke Hospice and Palliative Care

ADMINISTRATIVE LEADERSHIP / COMMITTEE WORK (selected)

2000 – 2003	Best Practices Project Steering Committee. The US Bureau of Primary Health Care and the Christian Community Health Fellowship
2003	Working group on the ethics of spirituality in medicine. George Washington Institute for Spirituality and Health and the Association of American Medical Colleges
2006 – 2008	Ethics Research Group. Division of Standards and Survey Methods. Joint Commission on Accreditation of Healthcare Organization
2008 – 2013	Founding Co-Director (with Daniel Sulmasy, MD, PhD), Program on Medicine and Religion, The University of Chicago. https://pmr.uchicago.edu
2010 – 2015	The Witherspoon Council on Ethics and the Integrity of Science. Member.
2012 – 2015	Bioethics and Christian Theology Affinity Group, Founding Co-Director (with Jeffrey Bishop). American Society for Bioethics and Humanities
2014 –	Co-Director (with Warren Kinghorn, MD, ThD), Theology, Medicine, and Culture Initiative (TMC), Duke Divinity School. https://tmc.divinity.duke.edu
2017 – 2020	Founding Director, Arete Initiative, Kenan Institute for Ethics, Duke University
2018 – 2021	Provost's Advisory Committee for Online Education, Duke University
2021 – 2023	President's Advisory Committee on Institutional History, Duke University

INVITED EXTRAMURAL PRESENTATIONS (selected)

1. Wabash College. February 23, 2004. Crawfordsville, IN
2. Loyola University School of Law. March 21, 2004. Chicago, IL
3. Christian Community Health Fellowship Conference (keynote). Atlanta, GA, May 21, 2004.
4. Spirituality and Healthcare Dialogue. The University of Texas Medical Branch. March 30, 2005. Galveston, TX.
5. God in the clinic: Religion, medicine, and the dilemmas of "patient-centered care." Lee University, Cleveland, TN, October 4, 2005.

6. Getting below the surface: The ethics of religious/spiritual interaction in the clinical encounter. Duke University, Durham, NC. October 6, 2005.
7. Program in Genetic Counseling. Northwestern University, February 6, 2006.
8. Duke University Center for Theology and Medicine, Durham, NC, June 22, 2006.
9. Annual Faith in Medicine Conference, (keynote) The Faith and Medicine Institute, Boston, MA, September 2, 2006.
10. Spirituality/Medicine Interface Conference (keynote). Southern Medical Association. Atlanta, GA, September 14-16, 2006.
11. Sr. Alice Potts Endowed Lectureship for Spirituality and Medicine, MD Anderson Cancer Center, Houston, TX, October 30, 2006.
12. 4th Annual Vincent C. DeStefano Memorial Conference. Memorial Hospital. South Bend, Indiana. June 13, 2007.
13. University of Michigan Ethics Conference, Ann Arbor, March 11, 2008.
14. Louise Kingston Endowed Lectureship in Spirituality and Medicine. Princeton University Medical Center, Princeton, NJ. April 1, 2008.
15. American Medical Association, Division of Medical Ethics. Chicago. May 30, 2008.
16. Christian Medical and Dental Associations National Conference (keynote). Bloomingdale, IL. June 19, 2008.
17. Patient Rights vs. Doctor Conscience. DeVos Medical Ethics Colloquy. (keynote, along with R. Alta Charo). Grand Rapids, MI. September 8, 2008.
18. Conscience and clinical practice. President's Council on Bioethics. September 11, 2008. https://bioethicsarchive.georgetown.edu/pcbe/transcripts/sept08/session3.html
19. The Role of Conscience in Medicine. (keynote) Center for Law, Health & Society, Georgia State University. Atlanta, GA. October 9, 2008
20. Religion, Science, and the Moral Life of Medicine. (keynote) Sentara 2008 Ethics Conference. Williamsburg, VA. November 7, 2008.
21. Controversial Bodies: How to View and Think about Plastinated Corpses. (keynote) University of Kansas Medical School and Center for Practical Bioethics. Kansas City, MO. December 5, 2008.
22. Medicine Grand Rounds, University of Saskatchewan College of Medicine, Saskatoon, CA. January 9, 2009.
23. David Larson, MD, Memorial Lecture, Society for Spirituality, Theology and Medicine Annual Conference. Durham, NC. June 5, 2009.
24. Veritas Forum. Mayo Clinic, Rochester, MN. September 23, 2009.
25. 8th Annual Contemporary Catholic Healthcare Ethics Conference. Stritch School of Medicine at Loyola University. October 9, 2009. Chicago, IL
26. Florida Hospital Annual Conference on Spirituality and Medicine. March 25, 2010. Orlando, FL
27. Spirituality and Medicine Conference. Brody School of Medicine. April 1, 2010. Greenville, NC
28. The Lupina Centre for Spirituality, Healthcare and Ethics at Regis College, University of Toronto. October 15/16, 2010
29. Children's of Minnesota Westgate Pediatric Ethics Forum, Minneapolis, MN. November 12, 2010
30. Grand Rounds. Methodist Hospital, and Lecture in the Religion and Public Life Program. James Baker Institute for Public Policy. Houston, TX. December 3, 2010.
31. International Institute of Restorative Reproductive Medicine (IIRRM). Dublin, Ireland. March 26, 2011.
32. Terminal Sedation and Active Euthanasia: What are the Boundaries? 3rd Annual Bioethics Symposium. (keynote) University of Wisconsin. Madison, WI. April 7, 2011

33. Where Religion, Policy, and Bioethics Meet: An Interdisciplinary Conference on Islamic Bioethics and End-of-Life Care. (keynote) University of Michigan. Ann Arbor, April 10, 2011
34. Religion, Spirituality, and Mental Health (keynote). Loyola University Chicago. April 12, 2012
35. Kluge Center, United States Library of Congress, Washington, DC. June 28, 2012
36. 26th Annual A. Kurt Weiss Lecture in Biomedical Ethics, University of Oklahoma Health Sciences Center. September 27, 2012
37. Turner Conference on Faith and Medicine (keynote), Muncie, IN. October 10, 2012
38. Allen M. Boyden, M.D, Memorial Lecture. Providence St. Vincent Medical Center. Portland, OR. November 8, 2012
39. Speaking About the End of Life, Spiritual, Religious and Community Conversations (keynote). Mount Sinai Medical Center & Greater Miami Jewish Federation. December 4, 2012
40. Ethics Grand Rounds. Loyola University Medical Center. January 8, 2013
41. Workshop on Comparative Studies of Religion and Values among Healthcare Professionals. Freiburg Institute of Advanced Studies. Germany. February 20-22, 2013
42. 28th Annual Notre Dame Medical Ethics Conference. Notre Dame, IN. March 8-10, 2013
43. Trent Center Lecture on Medical Humanities, Duke University. Durham, NC, April 17, 2013
44. Reverend Edward J. Drummond, S.J. Lecture, Medicine Grand Rounds, Saint Louis University. May 10, 2013
45. Association of Professional Chaplains national webinar journal club. May 14, 2013
46. Institute of Medicine. Committee on Approaching Death: Addressing Key End of Life Issues. Houston. July 22, 2013
47. Spirituality and Ethics in Health Care (keynote speaker). Catholic Health Partners. Cincinnati, OH. October 3, 2013
48. Institute for Ethics and Culture Annual Conference. Notre Dame University. November 9, 2013
49. Loyola University Annual Medical Ethics Conference. March 13, 2014
50. Notre Dame Annual Medical Ethics Conference. March 21-23, 2014
51. Physician Well-Being Conference. Adventist Health Care. Jacksonville, FL. April 11, 2014
52. 4th European Conference on Religion, Spirituality and Health (Keynote). Malta. May 23, 2014
53. Harvard Lecture Series on Spirituality and Medicine, Harvard University. November 17-18, 2014
54. Medicine Grand Rounds. Medical College of Virginia. Richmond, VA, February 19, 2015
55. Institute for Faith and Learning. Baylor University. Waco, TX. September 11, 2015
56. Annual Conference. MacLean Center for Clinical Medical Ethics. November 14, 2015
57. 2016 Conference on Medicine and Religion. Houston, TX. March 4, 2016.
58. Reimagining Medicine Conference. Denver Institute for Faith and Work. April 6, 2016
59. Hagop S. Mekhjian Lecture. The Ohio State University. Columbus, OH. September 15, 2016
60. Ohio State University Center for Bioethics Annual Conference. September 16-17, 2016
61. The Basil Society. UT Southwestern. Dallas, TX. September 24, 2016
62. What is the place of sedation in care at the end of life? (symposium). The University of Chicago. October 14, 2016
63. 2016 MedConference. Florham Park, NJ. October 15, 2016
64. Medical Ethics Grand Rounds. UNC School of Medicine. Chapel Hill, NC. November 3, 2016
65. Schiltz Lecturer in the Medical Humanities, University of Kansas School of Medicine. Wichita, KS. January 12-13, 2017
66. Weston Lecture. Augustine College. Ottowa, ON. March 16, 2017
67. 35th Annual MacLean Center Interdisciplinary Seminar Series on Reproductive Ethics. The University of Chicago. April 26, 2017
68. Z. Stanley Stys Memorial Lecture. Princeton University Medical Center. May 23, 2017
69. Robert D. Orr, MD, Lectureship. University of Vermont. October 27, 2017

70. Gender Transition Services: Progress or Medical Hubris? The 29th Annual Dorothy J. MacLean Fellows Conference on Clinical Medical Ethics, University of Chicago. November 10, 2017
71. Grand Rounds, Department of Pediatrics. University of Illinois. Chicago, January 5, 2018
72. Grand Rounds, Department of Medicine, Medical College of Georgia. January 9, 2018
73. The Steve Thorney Life Career Award and Lecture in Spiritual Care, MD Anderson Cancer Center, Houston, TX, February 9, 2018
74. Provonsha Lecture. Loma Linda University. March 2, 2018
75. Thomistic Institute. Harvard University. April 23, 2018
76. Grand Rounds, Department of Obstetrics and Gynecology, Vanderbilt University. May 5, 2018
77. Holy Friendship Summit, Bristol, TN. May 18-19, 2018
78. Commencement Address. Trinity Academy of Raleigh. Raleigh, NC. May 26, 2018
79. Grand Rounds, Department of Medicine, Texas Tech University. November 8, 2018
80. Physician Assisted Suicide and Euthanasia: Theological and Ethical Responses (symposium): Georgetown University. November 9, 2018
81. Affirming Ethical Options for the Terminally Ill. Heritage Foundation. Washington, DC. March 11, 2019
82. Bioethics Grand Rounds. National Institutes of Health. April 3, 2019
83. Grand Rounds. Biomedical Ethics Research Program. Mayo Clinic. April 30, 2019
84. Center for Ethics and Culture, Notre Dame University. May 13, 2019
85. HEAL Institute, Samford University Center for Faith and Culture, September 6, 2019
86. King Institute for Faith and Culture, King University, Bristol, TN, September 16-17, 2019
87. 88th Annual Educational Conference. Catholic Medical Association. Nashville, TN. September 26, 2019
88. Thomistic Institute. Queen's University School of Medicine. Kingston, Ontario. October 9, 2019
89. Lehman Lecture in Medical Ethics. Allegheny College, Meadville, PA. February 18, 2020
90. Carol Carfang Nursing & Healthcare Ethics Conference. Tampa, FL. February 28, 2020
91. School of Civic and Economic Thought and Leadership. Arizona State University. June 15, 2020
92. McDonald Centre for Theology, Ethics & Public Life. Oxford University, UK. September 4, 2020
93. Hoover Lecture, York Hospital. York, PA. September 17, 2020
94. Program in Medical Ethics, Humanities, and Law. Western Michigan University Homer Stryker M.D. School of Medicine. October 7, 2020
95. 2021 Scholar in Residence. Union University. March 8-12.
96. Character and the Professions Conference (panelist). Wake Forest University. March 13, 2021
97. Inaugural Lisio Family Endowed Lectureship. Columbia University School of Medicine. September 20, 2021
98. Thomistic Institute, Yale University. November 3, 2021
99. MacLean Conference on Clinical Medical Ethics, University of Chicago, November 13, 2021
100. Thomistic Institute, Johns Hopkins Medical Institute, November 15, 2021
101. Maurice B. Siegel, M.D., Lecturer in Humanism and Medicine. Cedar's Sinai. January 19, 2022
102. John Collins Harvey Lecture, Pellegrino Center for Clinical Ethics, Georgetown University, February 25, 2022
103. Foglio Lecturer, Michigan State University School of Medicine. March 22-23, 2022 (rescheduled—now pending new date)
104. Veritas Forum at Harvard Medical School, May 23, 2022
105. Celebrating and Defending the Freedom to Care, Christian Medical and Dental Associations, Washington, D.C. January 2023

106. Conditions for corrosion: how are just healthcare practitioners made and lost? University of Oxford McDonald Centre for Theology, Ethics and Public Life, Oxford, UK. June 27-29, 2023
107. Detransitioners, civil discourse, and the silence of clinical ethics. Annual Interdisciplinary Lecture Series, MacLean Center for Clinical Medical Ethics, University of Chicago. November 14, 2023

PEER-REVIEWED PRESENTATIONS AT SCHOLARLY MEETINGS

1. Holism or Evangelism? A consideration of religion in medicine. [Special session]. Robert Wood Johnson Clinical Scholars Program National Conference. Ft Lauderdale, FL, November 22, 2003.
2. Religion and Health: Theological Limits and Concerns. [Panel presentation] American Society for Bioethics and Humanities. National Conference. Denver, CO. October 27, 2006.
3. Religion, Conscience, and Controversial Clinical Practices. Central Society for Clinical Research/Midwestern Section American Federation for Medical Research. [Chosen as the top observational science abstract.] April 13, 2007. Chicago, IL.
4. Does Conscience Have a Place in the Healthcare Encounter? [Panel presentation] American Society for Bioethics and Humanities. National Conference. Washington, DC. October 19. 2007
5. Social and Ethical Implications of Supporting or Limiting a Right of Conscientious Refusal for Health Care Providers. [Panel presentation] American Society for Bioethics and Humanities. National Conference. October 15, 2009. Washington, DC.
6. Whose outcomes? Which notion of health? Ethical issues in the measurement of religious experience and its relation to health. [Panel presentation] American Society for Bioethics and Humanities. National Conference. Washington, DC. October 18, 2009.
7. Empirical research in bioethics: A toolkit for beginners. Pre-conference workshop. American Society for Bioethics and Humanities. National Conference. San Diego, CA. October 21, 2010
8. Serving two masters? [Panel presentation] American Association for Hospice and Palliative Medicine Annual Assembly. February 11,2011
9. Representing death, anticipating the corpse [Panel presentation]. American Society for Bioethics and Humanities. National Conference. Washington, DC. October 19, 2012
10. Towards a new art of dying [Panel session]. 2013 Conference on Medicine and Religion. Chicago, IL. May 29, 2013
11. Is traditional inpatient bioethics suited to outpatient settings? [panel] American Society for Bioethics and Humanities. National Conference. Atlanta, GA. October 26, 2013.
12. Among all physicians, is there a physician? Irony and the practice of medicine. American Society for Bioethics and Humanities. National Conference. Atlanta, GA. October 26, 2013.
13. "Do not be anxious ... about your body." Assessing contemporary primary care in light of the Sermon on the Mount. 2014 Conference on Medicine and Religion. Chicago, IL. March 8, 2014
14. Pharmacist on the execution team [panel]. American Society for Bioethics and Humanities. National Conference. San Diego. October 18, 2014.
15. Project on the Good Physician: Relevance of the Rationalist-Intuitionist Debate for Ethics and Professionalism in Medical Education. American Society for Bioethics and Humanities. National Conference. San Diego. October 18, 2014.
16. Can Religion Find Its Voice at a Secular Deathbed? [panel] 2016 Conference on Medicine and Religion. Houston, TX. March 4-6.
17. Doctor's Beliefs and Medical Practices: Transatlantic Comparisons. [panel] 2016 Conference on Medicine and Religion. Houston, TX. March 4-6.
18. The Religion and Medicine of the Future: An Orthodox Critique of Scientific Theology and Ecumenism. [panel] 2016 Conference on Medicine and Religion. Houston, TX. March 4-6.
19. Reimagining Medicine: Theological Formation for Those with Vocations to Health Care. [panel] 2017 Conference on Medicine and Religion. Houston, TX. March 25.
20. Solidarity with the suffering: Why physicians, *as physicians*, must oppose assisted suicide. International Congress on Law and Mental Health. Prague, Czech Republic. July 11, 2017

21. Searching for a Foundation for Medicine that Christians Share with those who are not Christians [panel]. 2018 Conference on Medicine and Religion. St. Louis, MO. April 14.
22. Remembrance, Resilience, and Religious Formation in Medical Education: Two Case Studies [panel]. American Society for Bioethics and Humanities. National Conference. Pittsburgh. October 27, 2019
23. Improving Palliative and End-of-Life Care for African Americans: Remembering Dr. Richard Payne. [panel]. American Society for Bioethics and Humanities. National Conference. Pittsburgh. October 25, 2019
24. Is there a future for Hippocratic medicine? (panel) 2021 Conference on Medicine and Religion. March 23
25. Healing and Economy: The Question of Charity in a Secular Age (panel). 2021 Conference on Medicine and Religion. March 22
26. "Sufficient for the day is its own trouble": Medicalizing risk and the way of Jesus. 2022 Conference on Medicine and Religion. March 22
27. Secular medicine in the saeculum: An honored but humble servant. 2023 Conference on Medicine and Religion. March 13
28. Still Searching for Moral Certainty? The Physician-Patient Accommodation after 40 Years. 2023 Conference on Medicine and Religion. March 15

CONFERENCES DIRECTED

2008 Conscience and Clinical Practice: Medical Ethics in the Face of Moral Controversy. Hosted at the University of Chicago, March 18

2011 Practice and Profession: Setting Medicine in the Context of a Good and Faithful Life. University of Chicago, November 10.

2012 Responding to the Call of the Sick: Inaugural Conference on Medicine and Religion. May 23-25. Chicago. (with Daniel Sulmasy, MD, PhD)

2012 Judaism, Medicine, and the Formation of Clinicians. September 10, 2012. The University of Chicago (with Daniel Sulmasy, MD, PhD)

2013 What Does it Mean to *Care*? 2013 Conference on Medicine and Religion. Chicago. May 28-30. (with Daniel Sulmasy, MD, PhD)

2014 Responding to the limits and possibilities of the body. 2014 Conference on Medicine and Religion. Chicago. March 7-9. (with Daniel Sulmasy, MD, PhD)

2015 Spiritual Dimensions of Illness and Healing. 2015 Conference on Medicine and Religion. Cambridge, MA, March 6-8. (with Daniel Sulmasy, MD, PhD, and Michael Balboni, PhD)

2016 Approaching the Sacred: Science, Health, and Practices of Care. 2016 Conference on Medicine and Religion. Houston, TX. March 4-6. (with Michael Balboni, PhD)

2016 - Practice and Presence: A Gathering for Christians in Health Care. Duke Divinity School. Durham, NC. (annual three day conference, with Warren Kinghorn, MD, PhD)

2017 Re-Enchanting Medicine. 2017 Conference on Medicine and Religion. Houston, TX. March 24-26. (with Michael Balboni, PhD)

2019 Theological Approaches to Persons in Pain. J.B. Duke Hotel & Conference Center. Durham, NC. March 28.

2019 "My pain is always with me"; Medicine & Faithful Responses to Suffering. 2019 Conference on Medicine and Religion. JB Duke Hotel & Conference Center. Durham, NC. March 29-31.

2021 2021 Conference on Medicine and Religion (Virtual). March 22-24.

2022 2022 Conference on Medicine and Religion, The Nines Hotel, Portland, OR. March 13-15.

2022 Questioning Preventive Medicine: Is a Pound of Prevention Worth an Ounce of Cure? Duke University. May 17.

TEACHING EXPERIENCE AND CURRICULUM DEVELOPMENT (selected)

Undergraduates

2006 Things, bodies, persons: Human goods in the technological era. Big Problems Course, The University of Chicago. (faculty, with J Lantos and D Brudney)

2022 - Medicine and Human Flourishing. Course for sophomores in "Transformative Ideas" series. Worked with primary instructor, Jose Gonzalez, to design course.

Medical Students

2002, 2003 Medicine and Spirituality Course. University of Chicago. (guest lecture)

2002, 2003 National *Wit* Education Initiative. Discussion group facilitator.

2003 – 2013 Cultural competence in medicine. Preceptor

2004 – 2006 Committee for Medical Student Retreats, Co-created and co-directed sessions on humanism and medicine (90 students/session).

2004 Essentials of Physicianship. MS1 course. Small Group facilitator/instructor

2004, 2005 Spirituality and Healing in Medicine. medical student elective (course co-director).

2004, 2006 Clinical Skills 1C course. (lecture: Religion and the doctor-patient relationship).

2005 – 2013 Summer Research Program. (faculty mentor to 10 medical students)

2005 – 2013 Death, dissection, and doctor formation. (Annual lecture before MS1 cadaver lab)

2005 – 2013 Doctor-Patient Relationship course. (Core faculty and lecturer)

2010 – 2013 Physician Development and Formation. (Co-director of required small group discussion component of MS1 Gross Anatomy course)

2015 – 2019 MS2 Practice Course. Teach session(s) on the ethics of clinical decision-making, and on religion, spirituality, and medicine

2019 – Clinical Medical Ethics: What Would a Good Physician Do? (annual 8-week elective, now co-taught with Dr. Josh Briscoe)

Residents

2004 – 2013 Internal Medicine Residency Morning Report. (Faculty discussant for 55 total sessions over 9 years, focused on cases with clinical ethical complexity)

Fellows

2004-5, 2007 Research Proposal Design Workshop. Co-directed summer workshop for fellows in health services research and ethics.

2004 – 2013 MacLean Center for Clinical Medical Ethics Fellowship. Taught three sessions/year

2006 – 2013 Religious Traditions and Clinical Ethical Decisions. (director of annual, quarter-long seminar for fellows in clinical medical ethics and interested medical students)

2010 – 2013 Summer Program in Outcomes Research Training. Teach 90-minute session for clinical research fellows on Practical Survey Development and Design.

Divinity Students

2014 Healing Arts: Suffering, Illness, and the Witness of the Church. Duke Divinity School. (course co-director, with Kinghorn and Barfield)

2016 – Health Care in Theological Context II (formerly *Theological Bioethics*). Semester-length course. Duke Divinity School

GRANT FUNDING

Current:

Farr A. Curlin, MD

1. Forming Distinguished Scholars for Christ across Academic Medicine
PI: Kinghorn (Curlin Co-Investigator) Agency: McDonald Agape Fund
Period: 1/1/23 – 12/31/26
This project gathers, mentors, and resources a network of outstanding colleagues from other major academic medical centers seeking to renew medicine through attention to its theological dimensions.

Past:

1. The integration of religion and spirituality in patient care among US physicians
PI: Curlin and Chin Agency: The Greenwall Foundation
Period: 07/01/02 – 06/30/04
Project conducted the first comprehensive national study of physician's religious characteristics and how those characteristics are associated with physicians' clinical practices.

2. Religious commitments and clinical engagements
PI: Curlin Agency: NCCAM
Type: K23 AT002749-01A1 Period: 10/01/05 – 09/30/10
Project developed a mixed-methods framework for assessing the religion-associated variations in physicians' self-reported and self-predicted practices in different clinical domains.

3. Variance on the margins of religion and medicine
PI: Curlin Agency: The Greenwall Foundation
Period: 07/01/06 – 06/30/09
[Greenwall Foundation Faculty Scholar in Bioethics] Project refined a methodology for assessing religion-associated variance in physicians' self-reported and self-predicted practices, and applied that methodology to assess variations in physicians' approaches to sexual and reproductive health care.

4. Conscience and Clinical Practice: Medical Ethics in the Face of Moral Controversy
PI: Curlin Agency: The Greenwall Foundation
Period: 01/01/08 – 06/30/09
Grant supported a conference on the place of the clinician's conscience in ethical practice, held at the University of Chicago on March 18, 2008.

5. The Chicago Program on Spirituality, Theology and Clinical Decision-Making
PI: Curlin Agency: The John Templeton Foundation
Period: 10/01/08 – 09/30/12
This project established the Program on Medicine and Religion at the University of Chicago and supported four national physician surveys to assess religion-associated variations in physicians' practices related to 1) sexual and reproductive health care, 2) primary care mental and behavioral health care, 3) decision-making in advanced illness and end of life care, and 4) the doctor patient relationship and meaning in medicine.

6. Project on the Good Physician: A New Science of Virtues
PI: Curlin Agency: Arete Initiative, The University of Chicago
Period: 3/1/10 – 2/28/12

This grant supported a national longitudinal study of the moral and professional formation of American physicians over the course of medical training

7. Physician Heal Thyself: The University of Chicago Medicine and Religion Faculty Scholars Program
PI: Sulmasy (Curlin Co-PI) Agency: The John Templeton Foundation
Period: 7/1/12-6/30/15
Project established a Faculty Scholars Program in Medicine and Religion, funding eight junior faculty nationwide at 50% effort for two year tenures.

8. Toward Policies that Accommodate the Concerns of African Americans in Resolving Disputes about the Use of Life-Sustaining Technology
PI: Johnson (Curlin Co-I) Agency: Greenwall Foundation
Period: 3/1/2015 – 2/29/2017
This project examined the attitudes of African Americans toward futile treatments and futility policies.

9. Training Research-Literate Chaplains as Ambassadors for Spirituality and Health
PI: Fitchett and Cadge (Curlin Co-I) Agency: John Templeton Foundation
Period: 7/1/2015 - 6/30/19
This project advanced research literacy among the nation's health care chaplains.

10. Toward Effective Cooperation between Clinical and Other Community Stakeholders Committed to Stemming the Opioid Epidemic
PI: Curlin (McCarty Co-PI) Agency: The Greenwall Foundation
Period: 7/1/2019 – 6/30/2022
This project aims to 1) describe the barriers to institutional collaboration among those responding to the opioid epidemic; and 2) create policy recommendations for effective collaboration in efforts to stem the opioid epidemic.

11. The Arete Initiative at Duke University's Kenan Institute for Ethics
PI: Curlin Agency: Foundation for Excellence in Higher Education
Period: 7/1/17 – 6/30/21
The Arete Initiative sponsors scholarship and learning opportunities focused on recovering and sustaining the virtues in contemporary life, especially in the workplace, the university, and the public square.

12. Fellowship in Theology, Medicine, and Culture
PI: Kinghorn (Curlin Co-Investigator) Agency: The Issachar Fund
Period: 7/1/15 – 12/31/22
Project invites students and practitioners in health professions, as well as others with full-time vocations to health-related contexts, to participate in a program of theological formation that will equip them for faithful, disciplined, and creative engagement with contemporary practices of health care.

13. Out of Our Meds? Building a Theological and Moral Framework for the Use of Medications
PI: Kinghorn (Curlin Co-Investigator) Agency: McDonald Agape Fund
Period: 2016 – 2022
This project conducts a series of five annual symposia on theological, ethical, and clinical questions raised by pharmaceutical prescribing.

PUBLICATIONS
Original peer-reviewed scholarship

Farr A. Curlin, MD

Books

Curlin FA, Tollefsen C. *The Way of Medicine: Ethics and the Healing Profession*. Notre Dame University Press; 2021.

Papers

1. Iwashyna TJ, Curlin FA, Christakis NA. Racial, ethnic and affluence differences in elderly patients' use of teaching hospitals. *J Gen Int Med*. 2002;17(9):696-703.
2. Hall DE, Curlin F, Koenig HG. When clinical medicine collides with religion. *Lancet*. 2003;362:S28-S29
3. Hall DE, Curlin FA. Can physicians' care be neutral regarding religion? *Academic Medicine*. 2004;79:677-679.
4. Curlin FA and Moschovis PP. Is religious devotion relevant to the doctor-patient relationship? *Journal of Family Practice*. 2004;53(8):632-640.
5. Curlin FA, Roach CJ, Gorawara-Bhat R, Lantos JD, Chin MH. When patients choose faith over medicine: Physician perspectives on religiously related conflict in the medical encounter. *Archives of Internal Medicine*. 2005;165(1):88-91
6. Curlin FA, Hall DE. Strangers or friends? A proposal for a new spirituality-in-medicine ethic. *J Gen Intern Med*. 2005;20(4):370-374.

   Editorial: Scheurich N. Spirituality, Medicine, and the Possibility of Wisdom. *J Gen Intern Med*. 2005;20(4):379-380.
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8. Curlin FA, Roach CJ, Gorawara-Bhat R, Lantos JD, Chin MH. How are religion and spirituality related to health? A study of physicians' perspectives. *South Med J*. 2005; 98(8):761-6.

   Editorial: Daly CC. Religion and the attending physician's point-of-view. *South Med J*. 2005; 98(8):759
9. Gee L, Smucker D, Chin M, Curlin FA. Partnering together? A study of current relationships between faith-based community health centers and local religious congregations. *South Med J*. 2005; 98(12):1245-50

   Editorial: Flannelly KJ, Weaver AJ, Tannenbaum HP. What do we know about the effectiveness of faith-based health programs? *South Med J*. 2005; 98(12):1243-4.
10. Curlin FA, Hall DE. Regarding Plan B: Science and politics cannot be separated. *Obstet Gynecol.* 2005;105(5):1148-50
11. Curlin FA, Chin MH, Sellergren SA, Roach CJ, Lantos JD. The association of physicians' religious characteristics with their attitudes and self-reported behaviors regarding religion and spirituality in the clinical encounter. *Med Care*. 2006;44:446-53
12. Curlin FA. Spirituality and lifestyle: what clinicians need to know. *South Med J*. 2006;99:1170-1.
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Curlin FA, Lawrence RE, Lantos JD. Letters and author reply. Religion, conscience, and controversial clinical practices. *N Engl J Med*. 2007;356(18):1889-92

15. Curlin FA, Sellergren SA, Lantos JD, Chin MH. Physicians' observations and interpretations of the influence of religion and spirituality on health. *Arch Intern Med*. 2007;167(7):649-54

16. Curlin FA, Dugdale LS, Lantos JD, Chin MH. Do religious physicians disproportionately care for the underserved? *Annals of Family Medicine.* 2007;5(4):353-60.

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    Editorial: Eichelman B. Religion, spirituality, and medicine. Am J Psychiatry 2007;164: 1774-1775

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32. Fitchett G, Rasinski K, Cadge W, Curlin FA. Physicians' experience and satisfaction with chaplains: a national survey. Arch Intern Med. 2009;169(19):1808-10.

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49. Lawrence RE, Rasinski KA, Yoon JD, Curlin FA. Obstetrician-gynecologists' beliefs about safe-sex and abstinence counseling. *Int J Gynaecol Obstet.* 2011;114(3):281-5.

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7. *Sistersong v. State of Georgia,* No. 2022-CV-367796 (Superior Ct., Fulton County, GA)

Farr A. Curlin, MD

8. *Planned Parenthood v. Medical Licensing Board,* No. 53C06-2208-PL-001756 (Monroe County Circuit Ct, IN)

EXHIBIT 15

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

BRIANNA BOE, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
UNITED STATES OF AMERICA,	)	
	)	
Intervenor Plaintiff,	)	
	)	
v.	)	Civil Action No. 2:22-cv-184-LCB
	)	
HON. STEVE MARSHALL, in his Official capacity as Attorney General, of the State of Alabama, *et al.*,	)	
	)	
Defendants.	)	

EXPERT REPORT OF
KRISTOPHER KALIEBE, M.D.

TABLE OF CONTENTS

1. I am a medical doctor. I am trained in general psychiatry, child and adolescent psychiatry, and forensic psychiatry. My professional background, experience, and publications are detailed in my curriculum vitae, which is attached to this report.

2. I have been retained by counsel for Defendants in the above-captioned lawsuit to provide an expert opinion concerning care of patients with gender dysphoria and the need for open, scientific dialogue regarding how best to treat gender dysphoric youth. My opinion will be based primarily on my own experience as a physician, psychiatrist, and associate professor, as well as the relevant literature in this area. I have reviewed the expert reports of Dr. Armand Antommaria, Dr. Daniel Shumer, Dr. Meredithe McNamara, Dr. Aron Janssen, and Dr. Morissa Ladinsky. I have also reviewed the initial production of the Plaintiffs' medical records in this case. I may wish to supplement my opinions or the bases for them as new evidence comes to light or new research is published.

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

a. Civil Testimony, 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

ii. August Dekker et al. v. Simone Marstiller et al., Case No. 4:22-cv-00325-RH-MAF, U.S. District Court, Tallahassee FL, May 18, 2023

b. Civil Testimony:

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. Civil Testimony, court appointed:

   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. Criminal Testimony, retained by the defense:

   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. Civil Depositions, retained by the defense:

   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

   iii. August Dekker et al. v. Simone Marstiller et al., Case No. 4:22-cv-00325-RH-MAF, U.S. District Court, Tallahassee FL, March 20, 2023

f. Civil Depositions, retained by the plaintiff:

i. 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, 2022

4. I am over the age of 19, am qualified to give this declaration, and have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion. I am being compensated at a rate of $400 per hour. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony that I provide.

BACKGROUND AND QUALIFICATIONS

6. I am an associate professor at the University of South Florida in Tampa Florida. I was recently promoted to full professor, active July 1, 2023. 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 mainly include working with juvenile corrections and supporting primary care physicians through the Florida Medicaid Psychiatric Medication hotline. I also cover on call at Tampa General Hospital and practice forensic psychiatry, working on both child and adult cases in both criminal and civil court.

9. In addition, I work in two university-based training clinics. For my entire stay at University of South Florida I have supervised a child and adolescent psychiatry clinic, and I recently added an adult psychiatry resident clinic to my schedule.

10. 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 also evaluate new patients directly and then see patients as needed. I oversee the residents' work product and function as the physician of record. In this clinic I evaluate and treat pediatric patients with gender dysphoria. In addition to these direct clinical experiences, my duties at the Silver Child Development Center include training residents regarding the treatment of patients, including those with gender dysphoria.

11. Similarly, at the University of South Florida's Outpatient Psychiatry Center, my duties include supervising and instructing psychiatry residents. At this clinic as well, general psychiatry residents serve as the primary patient evaluators and clinicians, and I evaluate new patients directly and see them afterward as needed. I oversee the residents' work product and function as

the physician of record. As part of my role in this clinic, I evaluate and treat patients with gender dysphoria.

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

13. In addition to direct clinical care, I am routinely consulted by colleagues. For instance, I have provided an opinion on whether a pediatric patient was competent to assent to the administration of puberty blockers to enter on a path toward sex hormone treatment and potential surgeries. I have also been consulted regarding psychotherapeutic approaches to young adult patients who detransitioned. And I have collaborated in the care of patients with gender dysphoria as part of my work with the Florida Medicaid Psychiatric Hotline.

14. I have extensive teaching experience, including teaching 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.

15. I practice and support conventional medicine, and I have also strongly advocated for the expansion of Federally Qualified Health Centers, along with improved collaboration of mental health with primary care (Kaliebe 2016, Kaliebe 2017).

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

17. Another clinically relevant academic interest of mine is the tradeoffs and influence of technology and mass media, especially on young people. (Kaliebe 2002, Gerwin 2018). I have

long focused on 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. With Paul Weigle, I co-edited the Child and Adolescent Psychiatric Clinics of North America *Youth Internet Habits and Mental Health* edition in 2018. This compilation of clinical review articles included 16 chapters by invited experts on digital and mental health related issues. (Kaliebe 2018). I presented on distraction and misinformation at the 2022 conference of the American Academy of Child and Adolescent Psychiatry.

18. I am a member of the American Academy of Child and Adolescent Psychiatry, the American Academy of Psychiatry, and the Law and the American Psychiatric Association. I have been most active in 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 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, and was an author on the AACAP's clinical practice guidelines for telepsychiatry. I served as the Liaison from AACAP to the American Academy of Pediatrics from 2016-2022. I have also served AACAP in the state affiliates, acting as the Louisiana Council for Child Psychiatry as secretary/treasurer for 4 years and as president for 2 years.

19. I have extensive experience in psychotherapy, and have received 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 at USF regarding psychotherapy. 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.

SUMMARY OF MAIN POINTS

20. While historical reports of gender dysphoria exist, they were rare until approximately the last decade. Since then, the number of youth suffering from gender dysphoria has skyrocketed across countries in the economically advanced Western world.

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

22. Small numbers of advocate physicians within medical organizations have been able to leverage moralized claims and low-quality evidence to promote medical interventions for gender dysphoria in minors.

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

24. The language and assumptions supporting affirmative care for gender dysphoria are often conjecture, opinion, or misinformation presented as established fact.

25. Due to the highly politicized and ideological nature of the issue of gender dysphoria, and efforts by proponents to silence debate, there is limited rigorous scholarly dialogue within American professional medical organizations and medical journals.

THE RECENT RISE IN TRANSGENDER AND NON-BINARY IDENTIFICATION AMONG YOUNG PEOPLE

26. The discussion regarding transgender care is in the context of an unexplained and remarkable rise in minor patients reporting gender dysphoria. During my medical school experience and three residencies, I never encountered a patient reporting symptoms of gender dysphoria. For eleven years, from 2005 to 2016, I had a busy psychiatry clinic composed of roughly 80% minors and 20% adult patients. Not a single patient presented with gender dysphoria.

27. 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.

28. By contrast, on a single day in the last year, I treated three adolescent patients who had been diagnosed with gender dysphoria.

29. My experience is consistent with statistics indicating an abrupt rise in gender dysphoria and presentations to medical clinics for related services. 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 100,000 (American Psychiatric Association p. 454). 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).[1]

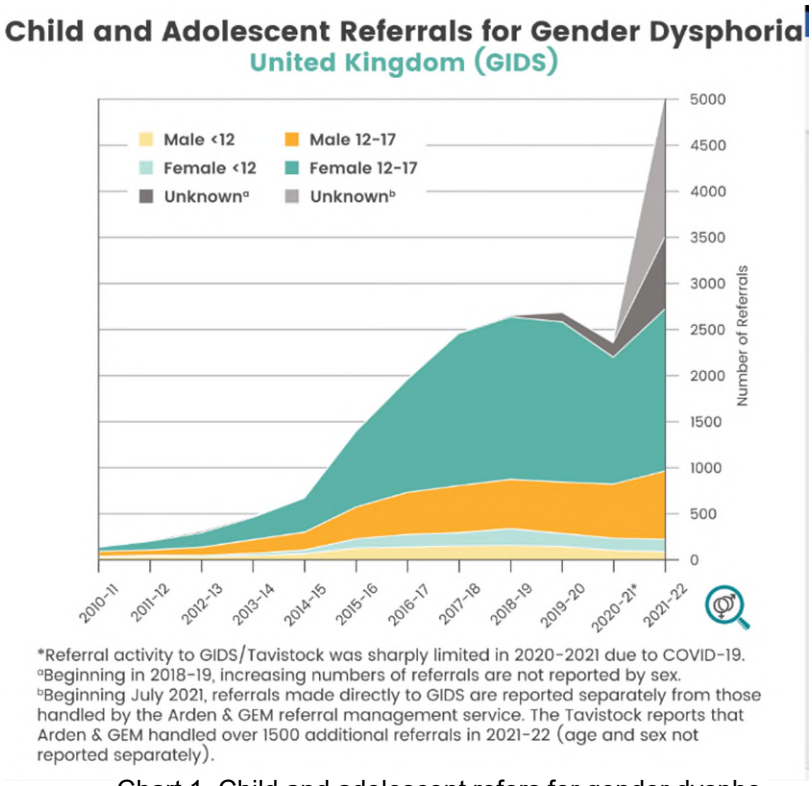

Chart 1. Child and adolescent refers for gender dysphoria in the United Kingdom

[1] Chart 1 was created by the Society for Evidence Based Gender Medicine drawn from data by the Tavistock clinic in the United Kingdom. Chart 2is from Marianowicz-Szcygiel's 2022 paper "Rise of gender identity disorders among children and adolescents – data from 10 countries. Possible explanations, conclusions for parents."

30. Similar increases have been reported across much of the Western world, many showing over 1000% rise in gender dysphoria over the last decades (Marianowicz-Szczygiel 2022).

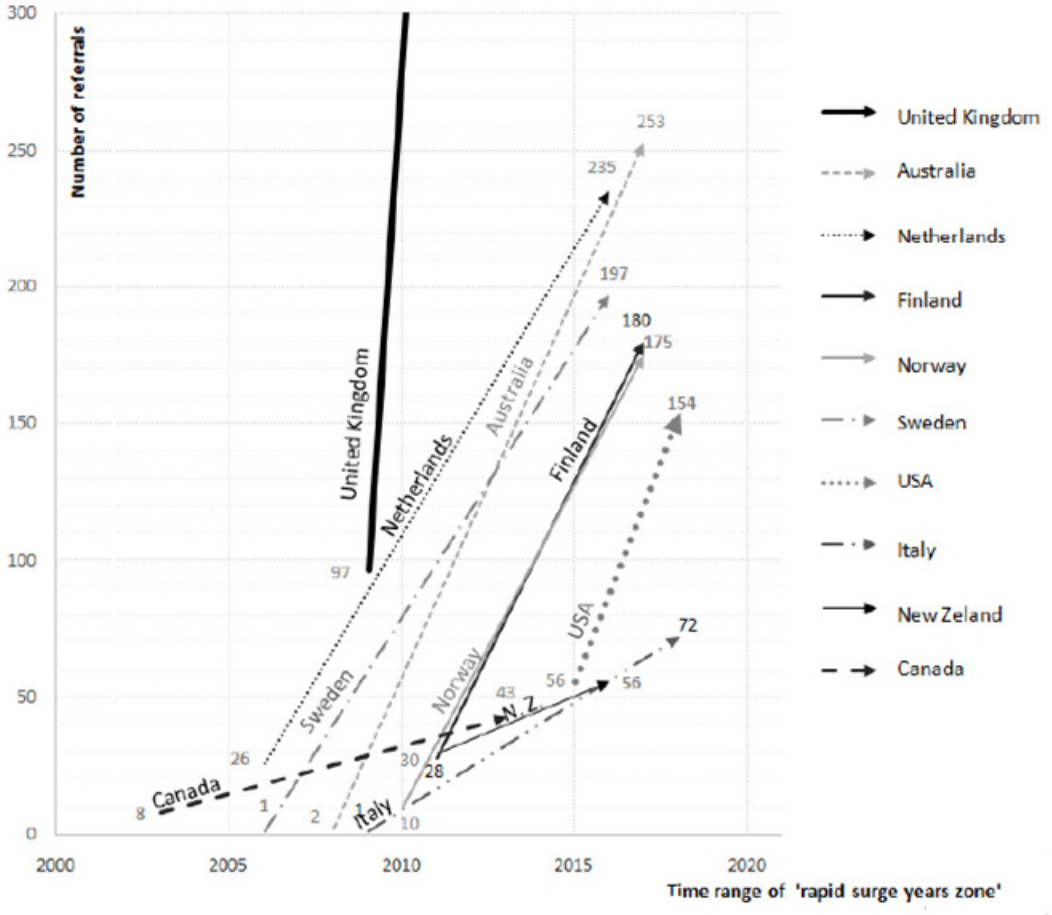

Chart 2. Increase of the number of referrals in clinics in 10 countries in 'rapid surge years zone'.

31. 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. As the independent review of the gender identity services for children and young people in the UK noted, the sudden "increase in referrals has been accompanied by a change in the case-mix from predominately birth-registered males presenting with gender incongruence from an early age, to predominately birth-registered females presenting with later onset of reported gender incongruence in early teen years." (Cass 2022).

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

33. I have observed bodily discomfort more often in females, 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.

34. When a new patient population emerges, as it has with minors suffering from gender dysphoria, it creates challenges for physicians to respond. 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 major contributors to the remarkable rise in gender dysphoria in adolescents.

35. The influence of culture, medical theories, and ideology on symptom production is long-standing and well known. Numerous examples of how culture has intersected with psychiatric illness from the Victorian to modern era have been detailed in the literature (Shorter 1993). The

mere act of codifying a psychiatric disorder can cause a new clinical presentation among those with pre-existing mental health challenges (Gauld 2022; Horesh 2022).

36. Humans evolved as a sexually dimorphic, ultra-social, and cultural species. Culture has comingled with our evolution because 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).

37. Humans thus cannot explain the original rationale for many of our routines, habits, and customs because they have been shaped over time. 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, much of which is caused by media and online experiences.

38. In ancient evolutionary environments, copying others aided survival via the transmission of acquired knowledge about what areas were safe, how to make shelters or weapons, what berries or mushrooms were safe to eat, and what type of social behavior was acceptable within a group. Human brains are particularly adapted with exceptional abilities to notice and copy the behavior of others, and transmission of culture occurs in part via humans naturally mimicking what we observe in others.

39. Unfortunately, these same instincts that develop helpful behavioral norms also enable social contagions that comingle 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 to enable the spread of mental health problems (Haltigan 2023). For instance, in recent years technology has aided the spread of suicide contagion (Yıldız, 2019), non-suicidal self-injury (Jarvi, 2013), and contagion related to eating disorders such as anorexia (Allison 2014).

40. Since the Covid 19 pandemic, there has been an explosive increase of young people displaying features of Dissociative Identity Disorder (Gauld 2022) and movements similar to those seen in Tic Disorders such as Tourette's (Pringsheim 2021). 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.

41. 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 social media enabled self-diagnosis (Rettew 2022, Weigle 2023).

42. Similarly, significant evidence suggests that the dramatic rise in minors presenting with gender dysphoria may be attributable to technologically induced contagion effects. In 2018, researcher Lisa Littman conducted a survey of parents of gender dysphoric youth whose gender dysphoria began during or after puberty (Littman 2018). "Most (86.7%) of the parents reported that, along with the sudden or rapid onset of gender dysphoria, their child either had an increase in their social media/internet use, belonged to a friend group in which one or multiple friends became transgender-identified during a similar time-frame, or both." (Littman 2018 p.2) Littman thus hypothesized that, as with other social contagions such as disordered eating, aggression, bullying, and drug use, "it is plausible that the following can be initiated, magnified, spread, and maintained

via the mechanisms of social and peer contagion: (1) the *belief* that non-specific symptoms (including the symptoms associated with trauma, symptoms of psychiatric problems, and symptoms that are part of normal puberty) should be perceived as gender dysphoria and their presence as proof of being transgender; (2) the *belief* that the only path to happiness is transition; and (3) the *belief* that anyone who disagrees with the self-assessment of being transgender or the plan for transition is transphobic, abusive, and should be cut out of one's life." (Littman 2018 p. 33)

43. As explain below, Littman's paper and her hypothesis of a "rapid-onset gender dysphoria" received remarkable blowback from advocates of "gender affirming care." The journal that published the paper retracted the initial paper, issued a "correction," and re-published the paper (with the initial data unchanged). Since then, the hypothesis of a social contagion element to adolescent gender dysphoria has only grown stronger.

44. Clinicians working at the Tavistock clinic in London (before its closure, the world's largest adolescent gender clinic) expressed support for Dr. Littman's concept of Rapid Onset Gender Dysphoria: "While some of us have informally tended toward describing the phenomenon we witness as 'adolescent-onset' gender dysphoria, that is, without any notable symptom history prior to or during the early stages of puberty (certainly nothing of clinical significance), Littman's description resonates with our clinical experiences from within the consulting room" (Hutchinson 2019). They added: "[I]t is commonplace for clinicians to engage in conversations regarding this phenomenon. Furthermore, from speaking with international colleagues, it seems to us that this phenomenon is also being observed in North America, Australia, and the rest of Europe."

45. Littman's research and her conclusions should not have surprised those following the literature on gender dysphoria. Three years earlier, a leading Finnish clinician (Kaltiala-Heino,

2015) showed that a new cohort, mostly females with significant emotional disturbance, was presenting to gender clinics: "It is important to be aware of the different groups, or developmental pathways, in gender dysphoric adolescents in order to be able to find appropriate treatment options. In the presence of severe psychopathology and developmental difficulties, medical [sex reassignment] treatments may not be currently advisable. Treatment guidelines need to be reviewed extended to appreciate the complex situations." In other words, three years *prior* to Littman's work, researchers had already identified the new cohort of patients Littman later wrote about: "In our data, most of the adolescents first presented with gender dysphoria and cross-gender identification well after the onset of puberty, and the vast majority suffered significant psychopathology and broader identity confusion than gender identity issues alone. It is important to be able to openly discuss these alternative presentations of gender dysphoria in order to find appropriate treatment options." The UK Cass Review recently came to a similar conclusion: "At present we have the least information for the largest group of patients—birth-registered females first presenting in early teen years." (Cass 2022 p.58).

46. A recent paper (Diaz 2023) analyzed survey results of parents of children who believe their children to have Rapid Onset Gender Dysphoria. This survey found a large portion of natal males with prior onset of video game addiction (17%), and substantial numbers of these youth were reported to have internet addiction (14% for natal males and 16% for natal females) prior to gender dysphoria. The paper concluded: "Youths with a history of mental health issues were especially likely to have taken steps to socially and medically transition…. parents believed gender clinicians and clinics pressured the families toward transition. The finding is particularly concerning given that parents tended to rate their children as worse off after transition."

47. Dr. Jack Turban, a psychiatrist and transgender activist, recently attempted to argue against social influences on gender dysphoria and transgender status, warning that "the notion of ROGD has been used in recent legislative debates to argue for and subsequently enact policies that prohibit gender-affirming medical care for [transgender and gender diverse] adolescents." As is often the case when activism is prioritized over scholarship, Dr. Turban's article is replete with misinformation. The article begins by asserting, for instance, that the ROGD "hypothesis was formed solely through the analysis of online parental survey data." (Turban 2022). But as shown above, clinicians had already reported the change in patient profile three years *before* Littman's article, in 2015.

48. Even more significantly, a letter to the editor published in *Pediatrics* noted that Turban's article contained "critical theoretical and methodological concerns specific to its conceptualization of social contagion and its data analysis." (Lett 2022). Much more substantial critiques were rejected by the editors at *Pediatrics*; while not searchable or indexed as scholarly work, some of the critiques are available as comments on the article's web page. One group of authors, led by Leonora Regenstreif at McMaster University (home of evidence-based medicine), documented concerns about "the non-random sampling," "the information not solicited in the survey, the wording and possible interpretations of the questions, as well as the accuracy and completeness of the data generated… [and] the imprecise wording of several questions regarding self-identity and sexuality." (Regenstrief 2022.) This group noted how Turban "assume[d] away" the key question of how trans-identified teens will answer "What is your sex?", even though the CDC had "urg[ed] caution in interpreting the 'sex' variable" because it is known that some trans-identified teens will give their *gender* rather than their biological sex when asked for their sex. Yet Turban's entire study was based on this assumption. (Regenstreif 2022). Another researcher ran the data and found

out that, indeed, transgender respondents who identified as male were on average 2.5 cm shorter than non-transgender male respondents, indicating "that some of the transgender respondents who identified themselves as male were natal females." (Biggs 2022A) As that researcher concluded: "Given the ambiguity of the [survey's] question on sex—evidently confusing to respondents and to scientists alike—no conclusion about the sex ratio of transgender youth can be drawn from this survey. The article does, however, provide considerable insight into the editorial standards maintained by *Pediatrics*." (Biggs 2022A)

49. Regarding social contagion and Rapid Onset Gender Dysphoria, Turban also reported in that same article that he is attempting to influence political and legislative actions and theorizes that scholarly discussion of the data supporting social influence as a causes of the rapid increases in gender dysphoria is somehow harmful. He lamented: "The deleterious effect of unfounded hypotheses stigmatizing [transgender and gender diverse] youth, particularly the ROGD hypothesis, cannot be overstated, especially in current and longstanding public policy debates." (Turban 2022). This statement alone reveals that Turban prioritizes advocacy over science and the search for the truth.

50. Whereas "gender affirming" organizations like WPATH have been critical of the "rapid-onset gender dysphoria" hypothesis and the possibility of a social element to the rise in cases of adolescent gender dysphoria, healthcare authorities other countries have paid more attention. As already noted, the independent Cass Review in the UK has recognized the rapid change in patient profile and warned that little data exists "on the more recent case-mix of predominately birth-registered females presenting in early teens" because "[m]uch of the existing literature about natural history and treatment outcomes for gender dysphoria in childhood is based on a case-mix of predominately birth-registered males presenting in early childhood." (Cass 2022 p.19).

51. Likewise, last February the French National Academy of Medicine noted: "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 recommended "[t]he 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."

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

53. My personal conversations align with recent polling. As part of the Social Media Institute at the October 2022 American Academy of Child and Adolescent Psychiatry annual conference, program chair Paul Weigle anonymously polled the audience was 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%) of the child psychiatrists in attendance indicated social media was an influence "somewhat often" or "very often." This data was recently published in *Psychiatric Times* (Weigle 2023), and to my knowledge, is the first data suggesting that the vast majority of a group of child and adolescent psychiatrists acknowledge that social contagion may be a major contributor to the rise in gender dysphoria.

54. A similar poll was conducted by Dr. Weigle at the January 18, 2023, meeting of the Child & Adolescent Psychiatry Society of Greater Washington, where all attendees were physician members. When asked, "How often do you see teens who seem to be influenced by social media in regards to their sexual and/or gender identity?", there were 34 respondents. 47% indicated *Occasionally* and 35% indicated *Often*. So again, 82% of these child and adolescent psychiatrists reported that they see teens' gender identity being influenced by social media. These polls suggest that practicing child and adolescent psychiatrists have direct clinical experience leading them to believe social media is influencing gender identity in their patients. More research is needed into Rapid Onset Gender Dysphoria and other possible causes of the recent change in patient profile in gender dysphoric youth.

55. In my opinion ideological and social factors underlie much of the recent increase in gender dysphoria in adolescents. While this does not rule out other factors, the ongoing research demonstrating an association between social factors and gender dysphoria in adolescents raises serious doubts about the wisdom of using transitioning treatments like puberty blockers and cross-sex hormones to treat the new population of gender dysphoric youth.

THE DANGERS OF PROCLAIMING A FALSE SCIENTIFIC CONSENSUS FOR HOW BEST TO TREAT GENDER DYSPHORIC YOUNG PEOPLE

A. Best Practices for Scientific Dialogue

56. 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. In my opinion, medical organizations and journals have recently prioritized advocacy over science when it comes to considering treatments for gender dysphoric young people.

57. Evidence based medicine requires "the development and promotion of a universal set of scientific rules that ensure accurate inferences on the basis of experience" (Djulbegovic,

2009). 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.

58. This framework would depersonalize the search for truth and esteem empirical dialogue.

59. For this reason, clinical practice guidelines and documents providing generalized medical recommendations must objectively reflect the evidence base. 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."

B. How Breakdowns in Scientific Dialogue Occur

60. Ideological homogeneity and group identity are risk factors for developing irrational beliefs and spreading misinformation. (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, such as Littman, are treated as heretics.

61. The dynamics of this polarization and lack of intellectual humility are understandable. Within psychiatry and medicine, practitioners face patients suffering from enormous suffering. Gender non-conforming patients 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 adolescent gender clinics hoped to relieve suffering. Yet in medicine excessive optimism regarding low quality treatments can cause rather than reduce suffering.

62. All humans, including physicians, tend to find arguments in favor of conclusions we want to believe, and this bias is 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 their relatively weak evidence base (Brignardello-Peterson 2022).

63. Once a group, such as a gender committee, endorses a statement of belief, such as "gender affirmative care is life-saving," 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.

64. Especially if the "experts" assert a strong moral claim regarding a clinical approach, other physicians would assume it is based on strong evidence. This creates a group process where 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 (Noelle-Neumann 1974). These dynamics, especially leadership's endorsement, make opinions appear like facts within the group. Members of this group never hear counterarguments or disconfirming data and become ever more confident.

65. 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 arisen before in medicine, and it is my assessment this has occurred again with regards to medical interventions to treat gender dysphoria in minors.

66. 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 serious problems. In cognitive therapy, it is known as "emotional reasoning." Emotional reasoning helps explain opinion cascades, partisanship, and group-think, as those who identify strongly with a group tend to feel positively toward those in the group and negatively toward the out-group.

67. The moralized framing of affirmative treatments for gender dysphoria encourages a cognitive shortcut known as attribution substitution (Sunstein 2009, p 216). Attribution substitution is the process whereby a simple, related moral judgement is substituted for various concep-

tually 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" sounds compassionate and supportive, and these minor semantics can have a surprising influence.

68. Physicians can be especially susceptible to manipulation. Psychiatrist Anna Lembke, in her 2016 book *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop*, explained that "[d]octors are by and large pleasers" because "[t]hey 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 are susceptible to acquiesce to patient narratives and overtreat.

69. 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, as has been noted in the Cass Interim Review: "We have heard that some young people learn through peers and social media what they should and should not say to therapy staff in order to access hormone treatment." (Cass Review 2022) 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.

C. Historical Examples of Harmful Scientific "Consensus" and Overtreatment

70. The medical system has a long history of spurts of overdiagnosis and overtreatment. Oncologist Otis Brawley laments that "our medical system fails to provide care when it is needed and fails to stop expensive, often unnecessary, and frequently harmful interventions even in situations when science proves these interventions are wrongheaded" (Bawley 2011, p. 22). Many of

our harmful interventions such as frontal lobotomies were celebrated at the time. Eventually society sees the harm, pushes back, and the medical profession eventually reforms.

71. Hydrotherapy, sterilization, lobotomy, and clitoridectomy (removal of clitoris to treat "hysteria") were each a part of the medical establishment in the first half of the twentieth century (Braslow 1997). Prior to the age of antibiotics, neurosyphilis was a common cause of psychiatric admission, diagnosed at that time as general paralysis of the insane. The causative theory was the premature using up of cerebral vitality through excessive enjoyment of wine, women, and life. A common treatment of the time was malarial induced fever. It was thought this "treatment" saved patients from general paralysis of the insane, which had a fatal course (Shaw 1927).

72. For decades, sterilization was legitimized by the medical establishment. Not long ago, "[t]he most important elite advocating eugenic sterilization was the medical establishment," which advocated "with near unanimity" for the procedure. "[E]very article on the subject of eugenic sterilization published in a medical journal between 1899 and 1912 endorsed the practice." (Cohen 2016).

73. Similarly, pioneers of frontal lobotomies spun their procedure with enthusiastic endorsement of the therapeutic nature of the procedure, ignoring evidence to the contrary. Their overstatements propelled lobotomies to gain acceptance among physicians desperate for new tools to address clinically challenging patients (Afkhami 2022). When the developer of the lobotomy, António Moniz, won the Nobel Prize in 1949, it further legitimized the operation. Even in 1954, the American surgeon and proponent of the surgery Walter Freeman claimed that transorbital lobotomies had mortality and morbidity rates that were "gratifyingly and consistently low" (Afkhami 2022) . Yet by this time, medical journals were already documenting harms done (Afkhami 2022).

Afkhami et al's linguistic analysis displays how lobotomy proponents projected a sense of heroism. They showed confirmation bias, i.e., these advocates ignored evidence disconfirming their theories. They tracked onto social norms in order to aggrandize their treatments and create a moral imperative to use lobotomies; as Freeman argued in 1954, "it seems not only possible, but obligatory, to extend the program of psychosurgery into the state mental hospitals in an effort to relieve human misery" (Afkhami 2022).

74. Medical educators teach residents and students when reviewing research to look for bias. Who initiated this research? Did they have a certain goal or outcome in mind, or are they neutral? This is because when advocates or industry fund research, multiple mechanisms cause the research to typically obtain the result desired by the funders. (Sismondo 2008). Within my career, I witnessed the pharmaceutical industries' manipulations to promote antidepressants. These manipulations were aided by our professional organizations, such as the American Psychiatric Association and American Academy of Child and Adolescent Psychiatry, who at the time were receiving significant funding from industry. "It's possible for good people, in perversely designed systems, to casually perpetuate acts of great harm on strangers, sometimes without ever realizing it" (Goldachre 2014, p. xi). In the 2000s, an audit found that over 90% of the psychiatrists who created the clinical practice treatment guidelines were also paid by the pharmaceutical industry (Cosgrove 2009). Not surprisingly, the treatment guidelines at the time were overly focused on medications and downplayed other approaches. At psychiatric meetings and in our medical journals, those of us whose approach went beyond medications were marginalized.

75. It was only after being sued that pharmaceutical companies were forced to release all their data, revealing that overall antidepressants often do not beat placebo, especially when

treating children and adolescents. After this embarrassment, in the late 2000s, the American Psychiatric Association and American Academy of Child and Adolescent Psychiatry put in reforms to limit undue influence of pharmaceutical companies. In part, overtreatment occurred at scale because providers were fooled by their clinical experience, as antidepressants have such a strong placebo response. In fact, it now appears that four out of five positive responses are arguably a placebo response (McCormack 2018, Hopcroft 2018).

76. For years, when antidepressant medications research obtained unfavorable or neutral results, these results were often never submitted for publication or buried in an obscure journal. (Turner 2008). Unfavorable results of antidepressant trials were also significantly delayed, known as time lag bias (Reyes 2011). Positive antidepressant trials were typically published quickly and in prestigious journals; thus, psychiatrists following the published literature were falsely led to believe, for many years, that medications like paroxetine (Paxil) effectively treat depression in children. We now know, after the complete set of research has been released, that for children, many medications, including paroxetine, do not beat placebo. This is all the more concerning as psychiatrists and other providers exposed thousands of youth to paroxetine's side effects, which include increased suicidality. It was quite humbling to realize how medical journals and distorted medical dialogue can lead to mass adoption of ineffective and potentially damaging treatment. It wasn't just financial incentives that led to harm, but also doctors' egos, observations of placebo effects, and desires to relieve suffering.

77. Within psychiatry and mental health, we have seen waves of theories. Psychoanalysis no longer dominates psychiatry but serves as an example of how a non-empirical theoretical approach can gather support, become dominant, and enforce ideological hegemony within psychiatry. When I was a trainee, many psychiatric leaders were trained as psychoanalysts, and it was

clear that it was not socially acceptable for trainees to challenge the psychoanalytic orthodoxies. An anthropologist even documented our psychiatric sub-cultures and how we are "of two minds" (Luhrmann 2001). For decades psychoanalysis dominated American psychiatry. "By 1960, virtually every major psychiatry position in the U.S. was occupied by a psychoanalyst. More than half of all psychiatrists were training to become analysts or were analytically-inclined in their orientation. All of the major psychiatry departments appointed psychoanalysts as chairmen." (Rufalo 2019) Furthermore, psychiatrists "seemed more interested in becoming respected members of the establishment than in challenging it. Insular, highly competitive, and prestigious, psychoanalysis became a 'status symbol.'" Psychoanalysis rose to and maintained dominance for decades not because it was effective at treating mental illness but because it served as a marker of intellectual sophistication and membership in the leadership class. It is my opinion that these same dynamics have led to the over-enthusiastic support for affirmative treatments for gender dysphoria among psychiatrists.

78. The repressed and false memories movement of the 1980s and 1990s is another example of wide adoption of a theory without adequate evidence. While human memory is indeed flawed, and reports of distant memories being retrieved cannot be uniformly ruled as false, we know, and should have also known at the time, that human memory is susceptible to manipulations and is frequently inaccurate. A large contingent of mental health practitioners displayed a lack of skepticism, which led to harms both to patients and those who were at times falsely accused. (Otgaar 2022)

79. The recent opioid epidemic is medicine's most recent and deadly episode of overtreatment. Harmful and unnecessary interventions are especially likely to occur when patient de-

sires are combined with financial incentives and the best of intentions. The American opioid epidemic was ushered in by "expert" physicians who proposed physicians needed more compassion because "pain is the 5th vital sign" (Mandell 2016, Adams 2016). Advocates for this approach were able to convince administrators and hospitals to push "improvements" in clinical care which prioritize documenting and reducing pain, with the result that opioid prescriptions skyrocketed. While a small number of patients may have achieved better pain control as a result, it came at the cost of creating legions of addicts. The Veterans Health Administration launched the "Pain as the 5th Vital Sign" initiative in 1999, requiring a pain intensity rating (0 to 10) at all clinical encounters. In 2001, the Joint Commission on Accreditation of Health Care Organizations warned that it would be looking at organizations' pain assessments in their accreditation judgments, thus using government fiat to force health providers en masse into harmful medical practice.

80. Similar to medicalization of transgender care, this government-backed proclamation regarding pain treatment came without sufficient proceeding scholarly dialogue or even evidence that the suggested approach would actually solve the problem it claimed to be addressing (Mularski 2006). Nor did those "expert" physicians promoting increased use of opioids show any consideration for the potential long-term harms. Many patients suffer from physical and emotional pain, but when patient-driven medicine is allowed, too much compassion can cause harm.

THE POLITICIZATION OF GENDER CARE AND SUPPRESSION OF DISSENTING OR QUESTIONING VOICES

81. With rapidly growing cohorts of patients expressing novel symptom clusters in a new area of medicine where a limited evidence base exists, differences 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).

82. 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 2022A, Biggs 2022B).

83. Much of the push for "affirmative treatment" for gender dysphoria treatment has come from professional organizations such as the World Professional Association for Transgender Health, Endocrine Society, American Academy of Pediatrics, American Psychiatric Association, and American Academy of Child and Adolescent Psychiatry.

84. Just as with other groups, professional medical organizations are susceptible to tribal influences and politicization. Medical professional organizations are large bureaucracies that serve many functions. They are important components of our medical system, but their influence and credibility can be misused. I have directly observed over the last decade, but particularly the last 5 years, that 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.

85. I have directly observed that within these organizations, the members most enthusiastic about a certain type of medicine self-select 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.

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

87. As gender clinics spread across America in recent years, enthusiasts of "gender affirming care" self-selected into these clinics and also into gender-relevant committees. In my experience, most physicians are wary of the very concept that it can be beneficial to block puberty or give cross-sex hormones to 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 psychotherapy committee members, gender committee members have strong personal and professional investments in the success of their favored type of treatment. This creates a well-intentioned but homogenous group of supporters of "gender affirming care."

88. Without the knowledge of most members of a professional organization, as few as the dozen members in a committee can steer these organizations' 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.

A. American Academy of Pediatrics

89. The highly influential 2018 Policy Statement from the American Academy of Pediatrics (AAP) (Rafferty 2018) contains a preamble confirming that the author[2] wanted his Policy Statement to be an advocacy document; the document begins with "As a traditionally underserved

[2] Dr. Rafferty alone "conceptualized the statement, drafted the initial manuscript, reviewed and revised the manuscript, [and] approved the final manuscript as submitted." (Rafferty 2018)

population that faces numerous health disparities" and ends with "while eliminating discrimination and stigma." These themes are continued in the introduction and throughout the document. This Policy Statement contained many citation errors, overstatements, and mischaracterizations of the evidence base (Cantor 2020). The policy statement unfortunately denigrated and mischaracterized the longstanding and well-regarded clinical approach of watchful waiting, which the statement called "outdated" and claimed that "Watchful waiting is based on binary notions of gender in which gender diversity and fluidity is pathologized." In fact, watchful waiting respects fluidity and identity development to a greater degree than "gender affirming care" because it leaves room for the patient to continue to grow in his or her identity. This policy statement has been particularly detrimental to the scholarly exchange of ideas related to gender dysphoria treatments, as it used the prestige 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.

90. Rather than encourage scholarly debate, the American Academy of Pediatrics has gone to great length to suppress its own members concerns about gender affirming treatments (Mason 2022). When an AAP fellow explained in the *Wall Street Journal* how the AAP had quashed member resolutions to conduct a systematic evidence review and reconsider its positional stance on "gender affirming care" (Mason 2022), the AAP's President responded publicly with multiple mischaracterizations of the debate, distortions of the AAP's own advice to clinicians, and divisive rhetoric characterizing those who urge caution as "anti-trans" (Szilagyi 2022)

91. 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 28, 2022 American Academy of Pediatrics (AAP) press

release regarding the State of Oklahoma condemns 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.

92. 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. Those concerns of "gender affirming care" include large-scale, potentially irreversible damage to minors and a dysfunctional informed consent process that overstates the evidence of benefits and does not offer alternative treatments—all in a context in which many providers of gender affirming treatments do not even acknowledge that the recent surge in patients expressing gender dysphoria represents a never before-studied cohort without long term outcomes (Levine 2022). 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 and examine the logic and data behind these moral frameworks and treatments. It is ethical to seek to find more cautious ways to care for and support youth with gender dysphoria or to seek a higher level of evidence before allowing minors to make permanent decisions regarding altering their bodies.

93. 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, and would rather frame them as biased, which is an indication of how politicized the AAP organization has become.

94. The AAP has also demonstrated its politicization by publishing statements and joining amicus briefs across a range of political issues, including immigration (American Academy of Pediatrics 2017), affirmative action (Brief for Amici Curiae Association of American Medical Colleges et al. 2022), firearms (Letter to Chairman Patrick Leahy 2022), critical race theory (Trent et al. 2019, AAP Board of Directors 2020, AAP 2022), and climate change (Council on Environmental Health et al. 2015).

95. As the Liaison from the American Academy of Child and Adolescent Psychiatry to the American Academy of Pediatrics, I sat on the AAP's Council on Communication and Media and witnessed the organization's increased politicalization firsthand.

B. American Academy of Child and Adolescent Psychiatry

96. Like other medical organizations, the American Academy of Child and Adolescent Psychiatry (AACAP) has come out strongly for affirmative care, supporting the opinion that minors have the emotional and cognitive development to consent to treatments that may have adverse lifelong consequences such as sterility. Yet when the question was mandatory life in prison in *Miller v. Alabama*, the AACAP (and the American Medical Association) Amicus Curiae (2012 p. 2-3) claimed:

> 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.

97. Unless this organization is willing to backpedal on its well-substantiated and well-documented arguments in *Miller v. Alabama*, 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?

98. In 2018, Lisa Littman presented her research data at American Academy of Child and Adolescent Psychiatry conference and received personal enmity which caused a colleague to remark he had 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.

99. Members of AACAP (and other organizations) who observe scholars being condemned in this manner will certainly think twice before voicing their concerns about gender affirming care. 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. 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.

100. The 2022 AACAP conference featured at least six presentations related to gender dysphoria or transgender patients, none presenting new research. Yet a research symposium was rejected which was to include prominent international gender dysphoria researcher and clinician, Riittakerttu Kaltiala, MD, PhD, Dr. Littman, and detransitioners. The AACAP program committee co-chair James McGough later indicated via a May 28, 2022 email that 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 a "concern" is when the results of the research raises questions about affirmative care. Furthermore, I am aware

of a number of presentations that 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 was presented.

101. Dr. McGough indicates he took these concerns seriously. He referred concerned parties to "Aron Janssen, co-chair [of] the AACAP committee charged with taking the lead on trans issues." Dr. McGough also noted that "Aron is also on the program committee." As a program committee member "taking the lead on trans issues," Dr. Janssen would have significant power to support or suppress presentations Those concerned with free exchange of scholarly ideas should notice the words Dr. Janssen chose in his 2021 "Perspectives" article (Janssen 2021), where 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".

102. Dr. Janssen characterizes those arguing for caution regarding gender affirmative treatments as making "an effort to oppress." In his report in this case, Dr. Janssen claims that "[m]edical treatment for gender dysphoria has immense psychological benefits for youth, bringing their mental health to a level similar to non-transgender peers" (P. 16). This uncited statement does not square with the research and displays his willingness to exaggerate in a manner detached from the evidence base.

103. For those not familiar with the proceedings of medical conferences, research symposiums are eagerly sought out by the medical societies. The program chair, Dr. McGough, 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 Drs. Kaltiala and Littman, a proposal for a Special Interest Group presentation, which was to feature data on detransitioning. This

proposal would have created a space for discussion of data that raised questions about affirmative care. The proposal was also silenced.

104. For the October 2023 Conference, I offered Dr. Janssen the opportunity to be the discussant for a Clinical Perspectives session entitled *International Perspectives on Care for Gender-Dysphoric Children & Adolescents*. This presentation was to include researchers and clinicians from England, Sweden, and Finland, as healthcare authorities in each of these nations have dramatically curbed the availability of gender affirming care for minors as a result of the systematic reviews of the evidence they conducted. Dr. Janssen not only refused to participate, but he also rejected the request to suggest another committee member to serve as discussant. As a replacement, we submitted the proposed session with the past President of the American Academy of Pediatrics serving as discussant. Again this presentation was denied.

105. Similarly, I also submitted for the AACAP 2023 conference a research symposium with researchers from England, Sweden, and Finland: *Epidemiology, Suicidality and co-morbidities of Gender Dysphoria, New International Findings*. This presentation was similarly rejected.

106. Even more revealing, the AACAP March 18, 2022 press release reveals the leadership's strident position by remarking on an education bill, outside psychiatrists' area of expertise. (AACAP 2022). 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 that the 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 that must include skepticism, not just affirmation. Indeed, the AACAP has taken policy positions on a wide range of political issues, including climate change (AACAP Mar. 2022), gun

control (AACAP June 2022), immigration (AACAP Oct. 2021, AACAP May 2018, AACAP Sept. 2017), affirmative action (Brief for Amici Curiae Association of American Medical Colleges et al. 2022), and critical race theory (AACAP, proposal deadline June 1, 2023; AACAP Jan. 2023).

C. American Psychological Association

107. The American Psychological Association has also taken seemingly contradictory positions on brain development in the context of two political issues: transgender care and the death penalty. The 2022 American Psychological Association Resolution on the Imposition of Death as a Penalty for Persons Aged 18 Through 20, Also Known As the Late Adolescent Class goes into significant detail regarding their position on brain immaturity through at least age 21:

> WHEREAS developmental neuroscience, including research on both the structure and function of brain development, establishes that significant maturation of the brain continues through at least age 20, especially in the key brain systems implicated in a person's capacity to evaluate behavioral options, make rational decisions about behavior, meaningfully consider the consequences of acting and not acting in a particular way, and to act deliberately in stressful or highly charged emotional environments, as well as continued development of personality traits (e.g., emotional stability and conscientiousness) and what is popularly known as 'character'.

I removed the many citations for clarity, but they can be found in the original document. The APA Resolution continues:

> WHEREAS it is clear the brains of 18- to 20-year-olds are continuing to develop in key brain systems related to higher-order executive functions and self-control, such as planning ahead, weighing consequences of behavior, and emotional regulation. Their brain development cannot be distinguished reliably from that of 17-year-olds with regard to these key brain systems.

128. It is clear the American Psychological Association understands that the entire cohort of minors submitting to irreversible hormones and surgeries have under-developed abilities to understand the risks and meaningfully consider the consequences. I agree with the American Psychological Association that these deficits maintain up until at least age 21, and the courts should take these impairments seriously in *all* contexts.

D. American Psychiatric Association

108. 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).

109. 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, there was a preamble. In a practice I had never before seen at a conference, representatives from the 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 base and logic supporting current affirmative psychotherapy and medicalized practice regarding the treatment of transgender youth.

110. 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 of "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.

111. The politicization of the American Psychiatric Association can also be seen in the many political positions taken by the organization, including climate change (Ursano et al., n.d.),

firearms (Letter to Chairman Patrick Leahy 2022, American Psychiatric Association Aug. 2019), affirmative action (Brief for Amici Curiae Association of American Medical Colleges et al. 2022), immigration (American Psychiatric Association Stress & Trauma Toolkit.

E. WPATH

112. The World Professional Association for Transgender Health (WPATH) is an international, multidisciplinary, professional association whose reported "mission is to promote evidence-based care, education, research, public policy, and respect in transgender health."[3] WPATH Standards of Care (SOC) documents share some features with what a medical organization would call clinical practice guidelines. The 2011 edition of WPATH's SOC documents are known as SOC-7, and the 2022 version is 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 [transgender and gender-diverse] 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."

113. Dahlen et al. reviewed WPATH SOC-7 as part of a systematic review and quality assessment of international clinical practice guidelines for gender minority/trans people. They noted that WPATH SOC-7 "contains no list of key recommendations nor auditable quality standards." (Dahlen et al., 2021). 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,

[3] World Professional Association for Transgender Health, *Mission and Vision*, https://www.wpath.org/about/mission-and-vision (last accessed May 10, 2023).

and clarity of presentation. The reviewers noted that WPATH and other international clinical practice guidelines tended to prioritize stakeholder involvement rather than methodological rigor.

114. Among the implications were that "[c]linicians should be made aware that gender minority/trans health [clinical practice guidelines] outside of HIV-related topics are linked to a weak evidence base" and that "[o]rganizations producing guidelines and aspiring to higher-level quality could use more robust methods, handling of competing interests and quality assessment."

115. Despite the well-known methodological weakness to SOC-7, WPATH created SOC-8 in a similar manner, only selectively using the conventions expected to create a trustworthy clinical practice guideline. WPATH SOC 8 did not clearly document what reviews were attempted, raising the possibility that reviews were stopped or buried upon unfavorable results. WPATH SOC-8 obscures the most important element required for a trustworthy clinical practice guideline: the assessment of the strength of the evidence used to make recommendations. Hiding the strength of evidence hides critical data from readers trying to evaluate the evidence base for an organization's recommendations. (Murad 2017).

116. My analysis is supported by the British Medical Journal Investigations Unit's review of the evidence for transgender treatments, including the WPATH SOC-8. (Block 2023). The British Medical Journal (BMJ) investigators interviewed Gordan Guyatt, M.D., an internationally recognized leader on systematic reviews and, in fact, the co-developer and first author of the original GRADE guidelines. BMJ also interviewed expert Mark Helfand, professor of medical informatics and clinical epidemiology at Oregon Health and Science University. Helfand noted that "WPATH's recommendations lack a grading system to indicate the quality of the evidence—one of several deficiencies."

117. This same BMJ article highlighted transparency issues with the guidelines: "Both Guyatt and Helfand noted that a trustworthy guideline would be transparent about all commissioned systematic reviews: how many were done and what the results were." But whereas SOC-8 claimed that the evidence was so limited regarding transitioning treatments for gender dysphoric youth that "a systematic review regarding outcomes of treatment in adolescents is not possible," as Guyatt pointed out, "systematic reviews are always possible, even if few or no studies meet the eligibility criteria." (BMJ 2023).

118. While SOC-8 is beyond the scope of this report to review completely, I must note four major concerns as a mental health professional:

a. SOC-8 makes no analysis for why it prioritizes affirmation of gender identity over affirmation and acceptance of the physical sexed body. For clinicians and psychotherapists, these trade-offs are complex matters in developing adolescents and fundamental to treatment, yet SOC-8 treats the question as though it had a clear answer supported by the evidence: affirmation always. That is not the case.

b. SOC-8 suggests consumer-driven medical and surgical interventions and deems these medically necessary without adequate supporting evidence. In no other field of medicine does a life-altering intervention become medically necessary based on the desire of the patient.

c. SOC-8 normalizes self-mutilation via inclusion of "Eunuchs" as just another non-binary category without any suggestion that these individuals require mental health assessment prior to any consideration of chemical or surgical procedures.

d. SOC-8 downplays concerns related to de-transitioning.

119. There have been a number of other episodes I have learned about that have caused me to conclude that I do not feel comfortable relying on WPATH or its U.S. affiliate, USPATH, to guide my care of gender dysphoric patients.

120. For instance, it appears there are calls for ideological hegemony at USPATH. Zander Keig, a longstanding WPATH member and former chair of the USPATH advocacy committee, related on a public podcast that he received a call from Dr. Joshua Safer, a WPATH board member, former president of USPATH, and author of the 2017 Endocrine Society Guideline. (Heterodorx 2023). According to Keig, Keig had agreed to be an advisor to the Gender Dysphoria Alliance, an organization composed of transgender people, detransitioners, and researchers that is "committed to thoughtful and respectful dialogue" and hearing from multiple perspectives regarding gender dysphoria. (Lisa Littman is also on the advisory board.) Presumably because the Gender Dysphoria Alliance is not unquestioningly "affirming" in all circumstances, Dr. Safer asked Keig to resign from USPATH or threatened to remove him as chair of the USPATH advocacy committee due to advising the Gender Dysphoria Alliance. Keig also stated that Dr. Safer suggested that he (Keig) lie about the reasons for resigning. This instance is illuminating on multiple grounds. First, silencing a member of USPATH and cleansing USPATH leadership of dissenters brings into question the ethics and scientific integrity of Dr. Safer. This is made more concerning because Dr. Safer was an author of the Endocrine Society Clinical Practice Guideline and other scientific research articles promoting transgender care. Second, as in this episode Dr. Safer appears to be representing the USPATH board, this demonstrates an institutional problem. WPATH and USPATH claim to be open to scientific exchange and diversity of thought, but their leaders risk termination if they are affiliated with a less politicized and ideological transgender group, such as the Gender Dysphoria Alliance.

121. Similarly, USPATH has clearly become an uncomfortable place for clinicians or researchers whose perspectives do not fall into a narrow ideological slice represented by USPATH (Ciszek 2021). In 2016, for instance, renowned psychologist Kenneth Zucker had his USPATH conference presentation drowned out by protestors because he had previously suggested that affirmation-only therapy could cause gender dysphoric children to "persist" when they would otherwise have their gender dysphoria "desist." After shutting down Dr. Zucker's panel, the activists made demands to the USPATH board, which subsequently removed Dr. Zucker from remaining panels and apologized to the activists for allowing Zucker to attend the conference. The board thus rewarded the activists who silenced scholarly debate.

122. Even prominent leaders at USPATH / WPATH like Laura Edwards-Leeper and Erica Anderson have acknowledged that, as they titled their Nov. 24, 2021 Washington Post article, "*The Mental Health Establishment is Failing Trans Kids.*" (Anderson 2021). USPATH and WPATH responded to the article by releasing an Oct. 12, 2022 joint statement condemning "the use of the lay press … as a forum for the scientific debate." (WPATH/USPATH 2022). The board of USPATH then privately censured Anderson, who later resigned as president. (Bazelon 2022).

123. Based on these and other public accounts, I conclude that USPATH and WPATH are not scientific organizations that prioritize the search for truth and the safeguarding of vulnerable children, but instead are organizations that seem to prioritize preserving their image and enforcing their advocacy positions.

F. Endocrine Society

124. Similar to AACAP and AAP, it appears that the Endocrine Society also takes a polarized position and misstates the strength of the evidence regarding "gender affirming care." In particular, the April 20, 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 the organization cites the Endocrine Society's own clinical practice guidelines. Endocrine Society's guidelines themselves graded the supporting evidence as low or very low quality for their clinical recommendations.

125. Another area of concern is the relationship between WPATH and Endocrine Society. It appears that nine out of ten authors of the Endocrine Society Clinical Practice Guideline are also WPATH leaders or authors. (Hembree 2017). This shows that a small number of physicians, empowered by these organizations, can create the false impression of broad consensus through campaigns of advocacy.

126. These professional organizations' portrayal of medical interventions for gender dysphoria as both effective and virtuous has had a chilling effect on scholarly dialogue regarding gender dysphoria in the medical community.

G. Medical Literature

127. 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 all been openly involved in political advocacy in support of gender-affirming care, their journals are no longer scientifically neutral. This politicization is re-

flected 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 promote open scholarly debate.

128. 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. Journal editors have wide discretion to filter topics that 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. It is curious that there has been minimal dialogue exploring the unanswered questions related to informed consent in medical journals associated with medical organizations. Instead, these matters are left to be discussed disputed in academic journals not affiliated with these organizations. (Latham 2022, Levine 2022).

129. The medical journal I follow most closely, *The Journal of the American Academy of Child and Adolescent Psychi*atry, has only published articles seeking conformity of thought with gender ideology and affirmative care and has not allowed actual scholarly dialogue to be voiced. This can be seen across commentaries (Dixon 2022), clinical perspectives (Turban 2017, Turban 2018), and book reviews (Suto 2021, Chilton 2021, Kim 2021).

130. The 2017 Turban article, for instance, provided the perspectives of transgender and gender nonconforming youth; reading that viewpoint can certainly be valuable for clinicians. Yet most striking were the youth's ideological assertions, misunderstanding of the evidence, and pleas for their physicians to believe suppositions such as that "[s]exuality and gender are two different things. TOTALLY separate" and "[p]uberty 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 the 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 authors contend depression, anxiety, and suicide attempts "likely" arise from minority stress and as a result of gender dysphoria (Turban 2017). Yet as detailed throughout this report and cited, it appears more likely that those with pre-existing psychological disturbance are more likely to later express gender dysphoria. (Bechard 2017, Diaz 2023, Littman 2018, Kaltiala 2015, Moradini 2022).

131. *The Journal of the American Academy of Child and Adolescent Psychiatry* even published a Commentary that 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.

132. For example, 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 discussing the problems with the article cited above; the journal editor refused to even send this letter out for review.

133. Not only are the articles one sided, but 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 overstate the strength of the evidence when articles support affirmative care or related concepts (Biggs 2020C), Deangelo 2021, Kalin 2020, Giovanelli R. 2022). A few years ago, for instance, the *Journal of the American Psychiatric Association* published a study with an erroneous positive conclusion regarding gender surgeries in Sweden. The article prompted a flurry of letters to the editor that pointed out serious problems with the methodology and resulted in significant revision, including to the study's central finding (Bränström 2020).

134. As discussed above, in 2018, Lisa Littman published an article that 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. (Littman 2019). This showed a disregard for the typical rules of scientific discourse because, importantly, this was not a correction; there was no finding of error, misconduct, or faulty methods with Littman's original paper. As confirmed by the PLOS ONE re-review, Dr. Littman's research methods were unremarkable and comparable to other mental health research.

135. In her report, Dr. McNamara mislabels Littman's study "discredited" and reiterates spurious criticisms, such as criticizing the use of parent reports. At the same time, Dr. McNamara does not disparage the work of Dr. Kristina Olson, but actively relies on it. But Dr. Olson used only parent reports in her 2016 research article published in *Pediatrics* (the flagship journal of the

American Academy of Pediatrics). In fact, Olson's article was widely lauded, and Dr. Olson has received a McArthur genius award for her work.

136. Further, given that Dr. McNamara claims that Littman used a questionable recruitment sample, note that Dr. Olson's Transyouth Project also used selective recruitment. This becomes extremely clear when you examine the income level of participants: 44% of families had a household income greater than $125,000, while 36% were between $75,000-125,000. When you consider that the 80th percentile of the US starts around $100 000, Olson's convenience sample clearly pulls from a highly privileged demographic (McKean 2016). Likewise, Dr. McNamara also cites Turban (2022), who utilized the 2015 USTS, which in its own methods reports, "Transgender adults ages 18 years or older were recruited in collaboration with over 400 community organizations." (James 2016).

137. Precisely because of the data supporting for Littman's theories of Rapid Onset Gender Dysphoria, many advocates of medicalized treatment of youth with gender dysphoria appear to have panicked in an attempt to suppress scientific exploration rather than reformulate their own deeply held beliefs. McNamara echoes various journals that published articles deriding Dr. Littman's work, which resulted in her being personally harassed by activists. Brown University also did not make any effort to defend Dr. Littman from attacks on her freedom to pursue science.

138. 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. The affidavit of whistleblower Jamie Reed (Reed 2022) shows how this worked on a direct level in a gender clinic: "Doctors at the Center would ignore and dismiss as social contagion the claims about the tics and multiple personalities; but then those doctors would uncritically accept the children's

statements about gender identity and place these children on puberty blockers and cross-sex hormones."

139. Similarly, clinicians at the Tavistock center, which before its closure was the world's biggest gender identity service, documented their own experience with similarly-named "adolescent onset" gender dysphoria. This involves gender dysphoric patients presenting without any noticeable symptom history prior to or during the early stages of puberty. (Hutchinson 2020). They further note how clinicians around the world are witnessing the phenomenon they call "adolescent onset gender dysphoria" and how unhelpful it is to suppress research or malign scholars who bring uncomfortable facts to light: "Unless we are free to discuss, explore, and research differential presentations of gender dysphoria, the range of interventions which might best serve each young person may not be available to them. We do not think that this is good enough for our patients."

140. Dr. Littman's other heresy was revealing how many parents perceive the gender-affirming approach to be dysfunctional. (Littman 2018). Now a similar controversy is brewing with another paper that provides data behind the ROGD concept, "Rapid Onset Gender Dysphoria: Parent Reports on 1655 Possible Cases" (Diaz 2023). This research documents parent reports from a convenience, non-neutral sample. Yet it explicitly discusses the disadvantages of such an approach and the rationale for publishing the data. Like Littman's work, this data undermines theories that gender identity is primarily biologically based, a theory advocated by Dr. Janssen in his report.

141. Research that runs counter to the prevailing orthodoxy causes panic among gender ideologues and activist scholars. Again, a mob has arrived to attempt to undermine credible research. This is an excerpt from the International Academy of Sex Research (IASR) list-serve in response to the publication of the Diaz / Bailey article:

> Dear IASR members,
> In the interest of transparency, we want to communicate to the Membership about recent concerns regarding a publication in our official journal, the Archives of Sexual Behavior. On March 29th, the journal published an article authored by Suzanna Diaz & J. Michael Bailey entitled, "Rapid Onset Gender Dysphoria: Parent Reports on 1655 Possible Cases." Since its publication, significant concerns about the ethical conduct and integrity of the editorial process have been raised about this study. . . . [signed by] The IASR Executive Committee.

(Bailey 2023).

142. This focus on the "editorial process" only seems to go one way on this issue, against exploration of the massive rise in gender dysphoria and against scholars like Dr. Bailey and esteemed editors like Kenneth Zucker.

143. There are many more examples of politicization squelching scholarly research. This includes the firing and restricting of research data from Laura Favaro by City, University of London as she attempts to research the perspective of academics with regard to gender issues. Ms. Favaro appears to have found a culture of fear and suppression regarding gender issue. As a result, this data is hidden and may never be revealed. (Sales 2023).

144. In February, UCLA researchers were forced by activists to pause or perhaps abandon their study because it aimed to expose transgender individuals to different views of themselves. The researchers "explained that 'by demonstrating that body-self incongruence was linked to brain structure and function, we aimed to help provide a biological basis and increase empathy for the life stories of transgender individuals." Yet the activists who helped shut down the research revealed their disdain for this basic research because in their minds: "It is suggestive of a search

for medical 'cure,' which can open the door for more gatekeeping and restrictive policies and practices in relation to access to gender-affirming care." (California LGBTQ HHS Network 2021).

145. Similar dynamics are in place even in newsletters. A colleague told me about 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 in his inpatient unit. This silencing of actual clinical situations undermines the exchange of ideas on how to best provide clinical care.

146. 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.

147. 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 received (Soh 2021).

148. My personal interactions with many thoughtful well-regarded psychiatrists display a full range of views. In my experience, 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.

149. 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 using the "gender affirming care" model to treat 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 little evidence of this sort of scholarly dialogue happening.

HOW ADVOCACY UNDERMINES SCIENTIFIC DISCUSSION AT MEDICAL ORGANIZATIONS

150. The major medical organizations involved with promoting "gender affirming care" have relinquished their former role of curators of neutral science with regards to gender dysphoria. They have adopted unproven theories, become advocacy organizations, and have used their prestige to support their approved opinions and ideology. They have made public statements dismissing or even demonizing scholars who raise concerns. It cannot be seen as a coincidence that whereas there is serious debate throughout society and throughout the globe, little to none is to be found at the Endocrine Society, the American Psychiatric Association, the American Academy of Child and Adolescent Psychiatry, the American Academy of Pediatrics, or WPATH. Even more concerning, their respective journal editors, as shown, have also chosen advocacy over science.

151. These advocates convinced the medical leadership to support affirming care in large part by framing medicalized treatments for gender dysphoria as "rights" and "discrimination" issues rather than an examination of evidence. This moralized and tribalized gender medicine and thereby stifled open exchange and silenced skepticism within medical journals. As these medical organizations put their prestige and influence behind this type of care, those overseeing conference programs, newsletters, and press statements and the editors of journals systematically distorted scholarly dialogue by promoting medical interventions. Moralizing and advocacy silenced concerned physicians, but most didn't even know their organizations had staked out such extreme

stances. Thus, the members of these professional medical organizations have never had an opportunity to observe, or participate in, open and honest dialogue regarding the evidence for transgender care. As such, the positions of these organizations reflect mostly a tribal mentality and the politicization of gender affirming care. It does not reflect the views of members who have had a sober review of the evidence base and decided celebratory support of gender affirming care is warranted.

152. I offer three examples of the kinds of discussions that should be occurring with frequency in the medical organizations with regard to how best to treat young people suffering from gender dysphoria, but sadly are not.

A. Psychotherapy

153. 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 received additional training in a number of psychotherapies (talk therapies) including Cognitive Therapy, Rational Emotion Behavior Therapy, and Trauma-Focused Cognitive Behavioral Therapy. I also have training and experience in meditation and mind-body techniques including mindfulness meditation, trauma focused yoga, and Accelerated Resolution Therapy. It should also be noted I trained under and worked for over a decade with former AACAP president Martin Drell, MD, who was intimately involved in training at LSU and ensured my training emphasized psychodynamic therapy and family therapy. Doctor Drell is well known as an eminent psychotherapist among child and adolescent

psychiatrists. Not only do I have experience with psychotherapies, I have been teaching them to medical students, psychiatry resident and supervising residents' psychotherapy for years. This background and experience distinguishes me from the majority of psychiatrists.

154. 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.

155. 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).

156. Is it, for example, sensible, compassionate, or good medical practice to, for instance, soon after a sexual assault, automatically agree with a teen's new self-assigned gender label? What about when a nine-year-old girl who spontaneously says, "I feel like I am a boy"—do we immediately ask what boy name to call the child?

157. In psychotherapy with a patient with gender dysphoria, the therapist should neither advise a patient to change a gender identity nor "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.

158. 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 conversion therapy which has ever been researched is the attempt to change, or convert, sexual orientation. Such conversion therapy is widely discredited, which is perhaps why lodging accusations of conversion therapy has been so effective at creating an all-or-nothing atmosphere concerning "gender affirming care."

159. In his report Dr. Janssen claims that "[g]ender identity has a biological basis and cannot be altered through medical or psychological interventions. The evidence demonstrating that gender identity cannot be altered, either for transgender or for non-transgender individuals, underscores the innate nature of gender identity." (p. 5-6). Yet Dr. Janssen fails to provide the reference to any studies backing up this claim of innate nature or biological basis. This broad claim might be more accurate for childhood onset gender dysphoria (i.e., children who experience gender dysphoria from a young age like 3 or 4). Yet, when this cohort reaches puberty, experiencing natural puberty typically leads gender identity to change, as most go on to be same-sex attracted and cisgender. Dr. Janssen's claim is even more spurious when examining the late childhood and adolescent onset of transgender identity. This is a much larger cohort, and gender identity already did change for them, as they were not transgender from early childhood. This cohort typically had

emotional and psychological problems but no signs of transgender orientation during childhood (Holt 2016, Kaltiala 2015, Bechard 2017, Hutchinson 2020, Daiz 2023, Littman 2018). Furthermore, this later onset female cohort identity is the largest group in treatment. Data from Tavistock clinic shows that as levels of psychopathology of new intakes increased the percentage of pre-pubertal onset natal females decreased. In 2012 this natal female pre-pubertal cohort was 7.3% and declined to only 4.8% of in 2015 (Morandini 2022). For natal females from 2012 to 2015 mood problems went from 39% to 60%, anxiety increased from 23% to 44%, and autism spectrum disorders increased from 10% to 15%. This was all in a context when the same cohort actually reported less bullying and abuse. This surge in patients with higher degrees of psychopathology and later-onset presentation has also been documented elsewhere (Holt 2016, Kaltiala 2015). All these factors make the most likely reality that in our current culture we are siphoning gender non-conforming youth with emotional problems into medicalized treatments for gender dysphoria.

160. Gender identity is often described as fluid, and as this implies, often changes over time, particularly in young people. Dr. Janssen does not explain how gender is both fluid and biologically determined, nor what studies he believe resolves this paradox. This gender fluidity is also why it is unwise 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.

161. 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 and depression and in reducing self-harm.

162. 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.

163. Advocates of affirmative treatment and their 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 lead to the resolution of these comorbid illnesses. I can provide three examples.

164. 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 co-occurring gender dysphoria showed frequent childhood sexual abuse (Soldati 2022). Thus, a child's gender expression can be a reaction to trauma rather than an intrinsic identity to be strictly "affirmed." This is what is termed diagnostic "overshadowing" in the Cass Interim Report of the United Kingdom's review of services for gender dysphoric youth: "Another significant issue raised with us is one of diagnostic overshadowing—many of the children and young people presenting have complex needs, but once they are identified as having gender-related distress, other important healthcare issues … can sometimes be overlooked" (Cass 2022, p. 17).

165. Thus, rather than allowing clinicians flexibility to proceed as longstanding clinical wisdom would dictate, advocates of affirmative treatment discourage discussion of the relationship between trauma and gender dysphoria. This affirmative model pressures clinicians to steer away from exploration whether a trauma reaction is the primary problem.

166. Relatedly, a core feature of Post-Traumatic Stress Disorder (PTSD) is avoidance, and in some patients, adoption of a transgender identity may be a method to avoid addressing the suffering caused by a trauma, such as a sexual assault. While this avoidance may temporarily block some negative feelings, in the long run continued avoidance can lead to terrible consequences, and a failure to resolve the trauma reaction. 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. All these struggles to get patients engaged in the best treatment is unfortunate as trauma focused therapies such as Trauma Focused Cognitive Behavioral Therapy have an excellent evidence base.

167. 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.

B. Autism

168. 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 four times as likely in patients with Autism Spectrum Disorders (Hisle-Gorman et al. 2019). Another review found that compared to typically developing controls, 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.

169. Autistic people experiencing gender dysphoria are a complex patient cohort. There is limited evidence of how best to help and support this specific population. 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. Adolescent 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.

C. Borderline Personality Disorder

170. Personality Disorders are enduring patterns of inner experience and behavior that deviate from expected and cause 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 with diagnosed personality disorders at 4%, versus matched community sample of 1%. The hospitalized sample was at 5% among transgender patients versus 2% in controls (Lam 2021). Little scholarly guidance exists regarding specific approaches related to the various personality disorders with comorbid gender dysphoria.

171. 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, self-harm, and substance use. This population is extremely difficult to treat.

172. 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 that 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.

173. 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

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.

174. Yet in his report, Dr. Janssen (p. 15-16) suggests "treating the underlying gender dysphoria is essential to alleviating the psychological distress associated with co-occurring conditions." Prioritizing the gender identity over other co-morbidities has no empirical basis and likely leads to other conditions being untreated—again, what Dr. Cass calls "diagnostic overshadowing." (Cass 2022, p. 17). Treating these other conditions entails minimal risk and does not require life-long alteration of one's body.

CONCLUSION

175. It is a 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. These mental health problems generally pre-date or co-occur with the development of gender dysphoria.

176. There is not a scientific or medical consensus that comorbid mental health disorders are due to "untreated" gender dysphoria, although this "minority stress" theory is frequently cited and goes along with the social justice ideology frequently exposed by advocates of gender affirming care. These same advocates of affirming care claim that medical transition, and only medical transition, will resolve these youth's mental health problems.

177. 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.

178. 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.

179. For many reasons, the "gender experts" are not neutral observers. 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. Physicians who doubt the merits of affirmative gender care should be able to speak freely, without being attacked as immoral, and their warnings about medical interventions for minors should be heeded.

180. Psychotherapy is a valid alternative mental health approach to medicalized treatments for gender dysphoria in youth. Existing psychotherapeutic approaches have already shown effectiveness at treating anxiety, depression, PTSD, Borderline Personality Disorder, which are frequent co-morbidities. These established approaches could be augmented with more recently developed techniques including mindfulness-based therapies, mind-body techniques, and specific exploratory therapies.

181. 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 shows that we are not meeting the needs of our youth. In the debate regarding treatments for gender dysphoria, the medical system should still apply rules of evidence and proceed with caution. Whistleblowers in the United States (Reed 2022) have made anyone paying attention realize we do need "Time to Think" (Barnes 2023) and to reconsider our medicalized approach to Gender Dysphoria in youth.

Executed this 19th day of May, 2023.

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PUBLICATIONS

Kristopher Kaliebe, M.D.

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.

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

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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.

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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.

CURRICULUM VITAE

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

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3515 E. Fletcher Avenue, MDC 14
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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 Psychiatry

- Acted 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.
- Supervise one morning clinic of outpatient general psychiatry at the USF OPC Clinic who performed assessment, consultation, and treatment.
  - February 2023 to present

Tampa General Hospital Psychiatrist on Duty September 2016 to present

Manage the night, weekend and holiday clinical responsibilities of Tampa General 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 South Florida.

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 July 2002 to July 2005
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 September 2003 to July 2005
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 September 2001 to June 2002
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 2017-2022. Offered for up to 12 students as a credited elective including study guide, organizing readings, and experiential class learning.
2017 to 2022

At Louisiana State University Health Science Center New Orleans:

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 - 2017 to present
MEL 8109 L69 M
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 Ill 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 Country", 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 1st / 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

"Assessing and Addressing Digital Distraction, Misinformation, and Disarray", part of the Social Media Institute, Annual Meeting of the American Academy of Psychiatry Annual Meeting, Toronto, CA October 19, 2022

Licensure:

Florida Medical License, expires January 31st, 2024

Federal DEA Controlled Substances License 12/31/2023

Certification: 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? STUDY002335

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

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)

Kass, 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.

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.

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.

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 2022

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 (LCCP)
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 Integrative Medicine Student Interest Group faculty advisor
January 2020 to present

University of South Florida Medical School Mindfulness and Meditation in Medicine Group faculty advisor
January 2022 to present

University of South Florida Interdisciplinary (university wide) Psychedelics Interest Group faculty advisor
March 2022 to March 2023

Editorial Posts and Activities:
Journal editorships, Reviewer

LSUHSC Institutional Review Board alternate reviewer 2008-2012

Safety Committee Member, Accelerated Resolution Therapy for Treatment of Complicated Grief in Senior Adults, University of South Florida
2017-19

Expert reviewer for *Adolescent Psychiatry* Thematic Special Issue: Coming of Age Online: Challenges of Treating the Internet Generation: (2), 4, 2014

Expert reviewer for *Academic Psychiatry* Media Column June 2018

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. Youth Internet Habits and Mental Health, 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: March 2023

EXHIBIT 16

SUBMITTED UNDER SEAL

EXHIBIT 17

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

BRIANNA BOE, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
UNITED STATES OF AMERICA,	)	
	)	
Intervenor Plaintiff,	)	
	)	
v.	)	Civil Action No. 2:22-cv-184-LCB
	)	
HON. STEVE MARSHALL, in his Official capacity as Attorney General, of the State of Alabama, *et al.*,	)	
	)	
Defendants.	)	

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

TABLE OF CONTENTS

BACKGROUND AND QUALIFICATIONS

1. 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 have been Board Certified in Surgery (American Board of Surgery, 1992-2002) and Plastic Surgery (American Board of Plastic Surgery, 1997-2018). My professional background, experience, and publications are detailed in my curriculum vitae, which is attached to this report.

2. I have been retained by counsel for Defendants in the above-captioned lawsuit to provide an expert opinion concerning the nature of gender surgeries. My opinion will be based primarily on my own experience as a physician and surgeon, as well as the relevant literature in this area. I have also reviewed the expert reports of Dr. Armand Antommaria, Dr. Daniel Shumer, Dr. Meredithe McNamara, Dr. Aron Janssen, and Dr. Morissa Ladinsky. I may wish to supplement my opinions or the bases for them as new research is published or in response to statements made in my area of expertise.

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

4. I have testified at trial or deposition in the following cases:

a. *Brandt v. Rutledge*, No. 4:21-CV-00450-JM (E.D. Ark. filed May 25, 2021).

b. *Kadel v. Folwell*, No. 1:19-CV-272 (M.D.N.C. filed Mar. 11, 2019).

c. *Dekker v. Weida*, No. 4:22-CV-00325-RH-MAF (N.D. Fla. filed Sept. 7, 2022).

d. *Siefert v. Hamilton Cnty. Bd. of Commissioners*, 354 F. Supp. 3d 815 (S.D. Ohio 2018).

5. I have also had experience in making judgements 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.

6. 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 as 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.

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

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

9. 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.

10. 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.

11. 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.

12. 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; the award was presented by Claude Organ, MD, a past President of the American College of Surgeons.

13. 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.

14. 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 re-certified in Plastic and Reconstructive Surgery in 2008.

15. I served as a staff plastic surgeon at Naval Hospital Portsmouth, Virginia from 1994 to 2002. I became Department Chairman in 1998 and served in that office until my retirement. We had five 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.

16. 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 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.

17. 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.

18. I moved my practice to northern Alabama in 2005. I have been a solo practitioner in Alabama for the last 18 years. I was brought here by a local hospital that wanted to offer comprehensive breast reconstruction to women affected by breast cancer. I co-authored a groundbreaking 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]

19. I also started a comprehensive wound care center in Alabama and have 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.

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

20. 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.

21. 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.

22. As can be gleaned from this summary, I have a meaningful breadth of experience in the advanced surgical care of trauma, cancer, head/neck disease, and 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 the same techniques employed by today's gender surgeons.

23. Since 2014, I have made a concerted effort to examine the medical literature pertaining 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 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, and administrators on the subject of transgender care and the medical-scientific evidence that informs that care.

24. In 30 years of active practice as a plastic and reconstructive surgeon, I have never performed any gender affirmation surgery. That is because, while I recognize gender dysphoria to be a serious psychiatric condition, in my opinion it is unethical to attempt to treat that psychiatric condition with surgery, just as it is unethical to attempt to treat body dysmorphic disorder with surgery. This will be fully explained in the course of this opinion. This fact should not exclude me from offering my expert opinion on the validity and ethics of gender affirmation surgery. All of the specific procedures, from mastectomy to breast enhancement to genital reconstruction to complex sensate microvascular flap surgeries, are within the scope of my experience. In fact, I instructed resident surgeons on these procedures. To claim that I have no expertise to offer an opinion about gender affirmation care would be akin to excluding a board-certified neurosurgeon from opining on the merits of frontal lobotomy, which are too harmful to ethically perform.

I. SURGERY IS PART OF PLAINTIFFS' "STANDARD OF CARE"

25. The plaintiffs in this case seek to enjoin enforcement of the VCAP law in the state of Alabama, claiming that it prevents minor persons from obtaining medical services that are necessary for health and quality of life. They claim that there is an irrefutable body of scientific evidence to support the position that the treatment

model called "gender affirmation" is so superior to other established models of care as to qualify gender affirmation as the standard of care.

26. The gender-affirmation model of care includes three distinct elements that overlap to varying degrees throughout the life of the patient. Those elements are social transitioning, medical transitioning, and surgical transitioning. All three elements are based in the same model of care which claims that the condition known as gender dysphoria is safely and effectively treated by drastically and irreversibly modifying the appearance of the minor person's body through the use of powerful hormonal medications and very aggressive surgical procedures.

A. Gender Affirmation is a Continuum of Care

27. Opinions and testimony concerning gender affirmation surgery are relevant even though plaintiffs have dropped their challenge to the VCAP law's prohibition of affirmation surgery in minors. Plaintiffs' decision appears to be an attempt to make their claim more reasonable by avoiding discussion of the gruesome realities of gender affirmation care. It must be remembered that the fundamental principle upon which gender affirmation rests—that the psychological condition of gender dysphoria is safely and effectively treated by modification of the appearance of the child's body, including the use of powerful hormonal drugs and aggressive surgery—is the same in all three elements of social, medical, and surgical transition. If the gender affirmation of minors is correct on the social level, it must be correct in

medical transitioning as well, given that the minor was prepared for hormonal manipulation by the prevenient step of social transitioning. Likewise, the minor is prepared for surgical transitioning by the prevenient step of medical transitioning. Both steps are supported by the continuing social affirmation of gender identity. All of it is based on the experimental principle that the medical and surgical modification of the body will cure a profound emotional condition.

28. If the complete and successful transitioning of the minor is the goal, and if the supporting documents which plaintiffs offer (such as the WPATH Standards of Care) consider the surgical transitioning of minors to be proven safe and effective treatment (which the WPATH Standards do), then we must examine the issue of affirmation surgery given the fact that so many minor patients undergo—or will in the future undergo—surgery.[2] While breast surgery has been the most common gender-transition surgery, genital surgery on self-identified transgender adolescents is reported in the literature.[3] The fact that genital surgery is routinely performed

[2] *E.g.*, *Chest reconstructive surgeries in transmasculine youth: Experience from one pediatric center*, Marinkovic M, Newfield R, Published 19 July 2017 Medicine International Journal of Transgenderism DOI:10.1080/15532739.2017.1349706 (describing mastectomies in adolescents ranging in age from 13 to 19); WPATH Standards of Care Version 8, Statement 6.12.g (recommending gender-affirmation surgery on adolescent minors).

[3] *E.g.*, *Age Is Just a Number: WPATH-Affiliated Surgeons' Experiences and Attitudes Toward Vaginoplasty in Transgender Females Under 18 Years of Age in the United States*, Milrod C and Karasic DH, J. Sex. Med. 2017; 14(4): 624-34. doi: 10.1016/j.jsxm.2017.02.007; *Transgender adolescents and genital-alignment surgery: Is age restriction justified?*, Horowicz E, Clinical Ethics 2019; 14(2): 94-103. doi: 10.1177/1477750919845087.

on minors is evidenced by the fact that the WPATH Standards of Care describe it as a part of the affirmation surgery guidance.[4]

29. This continuum of care is particularly evident when care is begun in early childhood. The rate at which patients continue from one phase to another is very high. Young children started on social affirmation and transition have a very high likelihood of continuing on to puberty blockade. Singh, Bradley, and Zucker state that socially transitioned boys are over 80% likely to persist in gender dysphoria and so continue on to medical transitioning.[5] And as the Interim Cass Review in the UK recently found, "almost all children and young people who are put on puberty blockers go on to sex hormone treatment."[6]

30. It is remarkable that plaintiffs' experts claim that puberty blockade and cross-sex hormones reduce the likelihood that patients will seek surgery later in life (Shumer p.22; McNamara p.13; Ladinsky p.23). The use of high-dose testosterone in natal females seeking to present as men has been clearly demonstrated to increase the likelihood of surgical removal of ovaries, uterus, and vagina because it produces

[4] WPATH Standards of Care Version 8, Statement 6.12.g.
[5] *A Follow-Up Study of Boys With Gender Identity Disorder*, Singh D, Bradley SJ and Zucker KJ (2021), Front. Psychiatry 12:632784. doi: 10.3389/fpsyt.2021.632784 ("Steensma et al. found two other predictors of persistence: boys who were assessed at an older age and boys who had made either a partial or complete gender 'social transition.' Of the 12 boys who had partially or completely transitioned prior to puberty, 10 (83.3%) were classified as persisters. In contrast, of the 67 boys who had not socially transitioned, only 13 (19.4%) were classified as persisters.").
[6] *The Cass Review: Independent review of gender identity services for children and young people: Interim report*, Hilary Cass (Feb. 2022), https://cass.independent-review.uk/publications/interim-report/.

the conditions of polycystic ovary syndrome, uterine atrophy, and vaginal atrophy. Likewise, such treatment produces fibrous involutional breast atrophy [7,8,9,10,11] In the case of young males hoping to present as adult females, the well-known additional effect is to exclude the possibility of one surgery (penile inversion vaginoplasty, which would normally be an available method in adult males), necessitating other risky surgeries, such as proximal thigh flap and large bowel interposition flap vaginoplasty.[12] This is because early hormonal treatment of natal males results in the underdevelopment of the genital and inadequate tissue to create the counterfeit vagina.

31. Plaintiffs' expert Dr. Shumer claims (Shumer p. 32) that "there is not an assumption that a patient prescribed GnRHa (puberty blockade) will desire hormonal therapy in adolescence (cross-sex hormones)." Dr. Shumer's assumptions notwithstanding, the medical literature consistently shows approximately 96.5% to

[7] Labrie F. Progress in Brain Research Vol. 182, pp. 97-148 (2010).
[8] *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons*, Radix A, Davis AM, JAMA.2017;318(15):1491–1492. doi:10.1001/jama.2017.13540.
[9] *Long-term health consequences of premature or early menopause and considerations for management*, Faubion SS, Kuhle CL, Shuster LT, Rocca WA, Climacteric. 2015;18(4):483–491. doi:10.3109/13697137.2015.1020484.
[10] *Cardiovascular Disease Risk Factors and Myocardial Infarction in the Transgender Population*, Alzahrani, Talal, et al. Circulation: Cardiovascular Quality and Outcomes, vol. 12, no. 4, 2019, doi:10.1161/circoutcomes.119.005597.
[11] *Breast cancer risk in transgender people receiving hormone treatment: nationwide cohort study in the Netherlands*, Christel J M de Blok, et al., BMJ 2019; 365. https://www.bmj.com/content/365/bmj.l1652.
[12] *Current Approach to the Clinical Care of Adolescents with Gender Dysphoria; Acta Biomed*, Kyriakou A, Nicolaides N, Skordis N., 202;91 (1): 165-175.

98% of children who are started on puberty blockers will continue on to cross-sex hormones.[13]

32. When puberty blockade results in underdevelopment of the child at every level, and since the desire for cross-sex presentation is often the primary outcome that patients and parents have been offered, the next step of cross-sex hormones is started. Similarly, when cross-sex hormones have manifested the fullness of their effects on the minor's appearance, yet the dysphoria remains because the adolescent's appearance isn't yet sufficient to "affirm" their subjectively perceived gender, then surgical transitioning often begins.

33. In the paper by Olson-Kennedy et al., which will be discussed in detail below, the authors note that cross-sex hormones (there, testosterone) resulted in an increase in "chest dysphoria," which in turn presented a *greater* motivation for surgery as the result of hormone treatment.[14] This is why affirmation care must be viewed as a continuum. Advocates of affirmation often dismiss all other forms of care outside the continuum as abusive and emphasize this idea with patients, parents, and the broader world. This continuum extends into the area of medical and surgical complications and the need for continuing medical and surgical interventions.

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[13] *The Cass Review: Independent review of gender identity services for children and young people: Interim report*, Hilary Cass (Feb. 2022), https://cass.independent-review.uk/publications/interim-report/.

[14] *Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts*, Johanna Olson-Kennedy J., Warus J, Okonta V, Belzer M, and Clark LF, 2018 May 1;172(5):431-436. doi: 10.1001/jamapediatrics.2017.5440.

B. Surgery in the Continuum of Care (Including Among Minors)

34. The body of literature cited in support of gender affirmation care, such as the WPATH Standards of Care, consistently supports surgical "affirmation" in minor persons. Those surgeries include surgery of the breast and genital surgery. While Version 7 of the WPATH Standards of Care recommended age 13 as the lower limit for mastectomy in self-identified transgender males (i.e., natal females), among the changes in Standards of Care 8 is that it no longer contains *any* reference to age limitation for gender affirmation surgery. Both versions support these surgeries with the same citations, which are Level-V case-series retrospective reports that include mastectomy in natal females as young as 13 and averaging less than 19 years old. Moreover, recent papers suggest that any lower limit on ages at which children might undergo these irreversible genital surgeries can be thought of as subject to individual clinical decisions.[15] This approach of essentially ignoring age limits as set out in the WPATH Standards of Care for the sake of particular patients makes meaningless the very definition of a "standard of care." The words "standard of care" are used to describe conduct of care that is not subject to clinical judgement and which, if ignored, has a high likelihood of harm to the patient.

[15] *Age Is Just a Number: WPATH-Affiliated Surgeons' Experiences and Attitudes Toward Vaginoplasty in Transgender Females Under 18 Years of Age in the United States*, Milrod C and Karasic DH, J. Sex. Med. 2017; 14(4): 624-34. doi: 10.1016/j.jsxm.2017.02.007; *Transgender adolescents and genital-alignment surgery: Is age restriction justified?*, Horowicz E, Clinical Ethics 2019; 14(2): 94-103. doi: 10.1177/1477750919845087.

II. CHARACTERISTICS OF GENDER AFFIRMATION SURGERIES

A. Problems in Gender Affirmation Surgeries

35. The predominant demographic of new patients in pediatric gender clinics is adolescent natal females, and the most common surgery performed on these females is called "chest masculinization." This surgery involves the complete removal of both breasts, the placement of free-nipple grafts, and chest wall liposuctioning. In addition to the broad and life-long scars, the minor patient loses the ability to breast feed. Additionally, erotic sensibility of the chest is lost due to the amputation of the fourth intercostal nerve branches. Cosmetic breast augmentation for anything other than congenital breast deformities (such as Poland Syndrome) in minors is not considered ethical professional conduct.[16] Yet this surgery is promoted as a standard of care by WPATH based upon the lowest level of scientific evidence. Such evidence is insufficient even to suggest ethical experimental design. It presents no long-term data to support efficacy in resolving suicide risk or any other long-term benefit since none of the cited studies follows the patients for more than 3 to 5 years.

36. Gender affirmation surgery of the genital is even more concerning. For natal males, all such surgeries involve castration—the removal of the testicles and mutilation of the penis in natal males. For females, such surgeries require removal

[16] *Considerations in Breast Augmentation in the Adolescent Patient,* Jordan SW and Corcoran J, Seminars in Plastic Surg. 2013; 27(1): 67-71. doi: 10.1055/s-0033-1343998.

of ovaries, fallopian tubes, uterus, and vagina. This results in reproductive sterility and life-long medical dependance on prescribed hormones with their associated risks described above.

37. Most genital surgeries involve the distal urinary tract, and there are frequent complications of urinary fistulas (leakage of urine through the skin), urinary obstruction caused by scarring, urinary tract infections, and need for re-operation to correct these complications. Similar processes in male to female genital surgery can result in fecal fistulas (or connections) due to communication between the neo-vaginal construct and the lower bowel. Loss of urinary continence, extrusion of implanted devices, re-operation to maintain patency of the neo-vaginal construct, and the need for daily self-dilation to maintain the dimensions of the structure are typical. Significant if not complete loss of erotic arousability is typical. If the patient has previously undergone puberty blockade at Tanner Stage 2 and cross-sex hormonal treatment, then loss of orgasmic capacity is a near certainty.[17]

38. Comparable issues in transgender versus reconstructive surgery can be seen by comparing identical operations. On several occasions I have performed the reconstructive surgery called "sensate radial-forearm microvascular free flap

[17] Abigail Shrier, *Why Marci Matters* (Oct. 6, 2021), https://abigailshrier.substack.com/p/why-marci-matters; Libby Emmons, *'Gender-affirming' Surgeon Admits Children Who Undergo Transition Before Puberty Never Attain Sexual Satisfaction* (May 1, 2022), https://thepostmillennial.com/gender-affirming-surgeon-admits-children-who-undergo-transition-before-puberty-never-attain-sexual-satisfaction.

hypopharyngeal reconstruction." I operated to reconstruct the tongue and throat of patients who had suffered a grievous wound of the mouth and throat that resulted from removal of an aggressive cancer. 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.

39. That throat reconstruction operation is in almost every way identical to the second most commonly performed female-to-male genital surgery, the "sensate radial forearm microvascular free flap phalloplasty." In that operation, the identical flap is raised and transferred. It also must be resistant to abrasion, water tight, pliant, sensate, and of correct volume. Through a process of incision, plication, and suturing, a tubular phallus is constructed within which is placed a skin lined tube which will serve as the urethra. The suture closures in both flaps are where most things go wrong because the skin edges that define the suture line can lose sufficient blood supply. When this happens in the phalloplasty the patient suffers from delayed healing, urine leakage, varying degrees tissue death, and scarring. All those problems can happen with either the throat flap or 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 untreated. 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.

40. Notably, 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 had not yet been adequately addressed with psychiatric care.

41. Both operations involve the use of 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 (castration, loss of pelvic organs of reproduction, degloving injury of the forearm, skin graft donor site injury), with their associated risks of complications. The surgery is performed in an attempt to remedy a subjective, patient-reported sense of their identity.

B. Problems of Surgical Consent

42. Whereas typical patients undergoing mastectomy have historically been middle-aged, and already a mother, in the case of the transgender patient, they are typically young, nulliparous females even as young as 14 years old.[18] The purported justification for the surgery is the severe emotional distress of the patient, often including suicidal ideation, or even a history of suicide attempt. In all other areas of surgery, a patient who reports major depression, anxiety, suicidal ideation, or suicide attempt would be considered incompetent to give informed consent for surgery. They would be referred for psychiatric care, which, if successful in resolving the depression, anxiety, and suicidal ideation, would remove the only claimed indication for the surgery in the first place.[19,20]

C. Erroneous Use of the Word "Reconstructive" to Describe Gender Affirmation Surgeries

43. Those in favor of "gender-affirming" surgeries often use the word "reconstructive" to characterize a group of surgical treatments that seek to alter the

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[18] *Behavioral Health Concerns and Eligibility Factors Among Adolescents and Young Adults Seeking Gender-Affirming Masculinizing Top Surgery,* Boskey ER, et al., LGBT Health 2020; 7(4). https://doi.org/10.1089/lgbt.2019.0213.

[19] *See Cosmetic Surgery and Body Dysmorphic Disorder – An Update,* Higgins S and Wysong A, Int'l J. Womens' Dermatol. 2017; 4(1): 43-48. doi: 10.1016/j.ijwd.2017.09.007; *Body Dysmorphic Disorder,* Bjornsson AS, et al., Dialogues Clin. Neurosci. 2010; 12(2): 221-32. doi:10.31887/DCNS.2010.12.2/abjornsson.

[20] *Body Dysmorphic Disorder and Cosmetic Surgery,* Crerand CE, et al., Plastic & Reconstructive Surgery. 2006; 118(7): p 167e-180e. doi: 10.1097/01.prs.0000242500.28431.24.

sexed appearance of the person.[21] It is important to understand that these procedures, because of the indications for surgery, the motivations for surgery, and the outcomes of surgery, are not reconstructive, but are properly understood to be cosmetic in nature.

44. Cosmetic and reconstructive surgery are distinct. Reconstructive surgery is surgery that aims at the structural and functional restoration of what has been lost due to trauma, infection, cancer care, or developmental condition. It always involves measurable structural and functional problems that surgery is designed to correct or restore. The physician can discover the condition through the physical examination of the patient and can quantify the deformity both by physical dimension and functional deficit.

45. By contrast, in aesthetic or cosmetic surgery, there is no objective physical criteria for the diagnosis. The patient presents with a subjective complaint ranging in severity from annoyance to profound sorrow concerning the appearance of certain features of their physical appearance. They seek to change the appearance of those features in the hope of obtaining happiness and relief from their emotional burden. The most essential criteria in selecting patients for cosmetic surgery is that

[21] *Gender Confirmation Surgery: Cosmetic or Reconstructive Procedure?*, Laungani A and Brassard P, Plastic & Reconstructive Surgery – Global Open: 2017 Jun; 5(6): p e1401. doi:10.1097/GOX.0000000000001401. Members of the American Society of Plastic Surgery are encouraged to "interpret" for lay persons and other medical specialists that, although normal anatomy and function is being manipulated for a cosmetic result, the procedures should be labeled "reconstructive."

it be offered only if the physical change is reasonable, does not involve harm or loss of function, and is likely to result in subjective improvement. It is axiomatic in plastic surgery that the more profound the sorrow the patient associates with their appearance, the less likely it is that the patient will obtain happiness (relief from dysphoria) from surgery. To expect resolution of profound emotional conflicts through the use of cosmetic surgery is unreasonable and contrary to foundational principles of plastic surgery.

46. This is the case for patients seeking "gender affirmation" surgery. The diagnosis which guides all three elements of affirmation treatment is "gender dysphoria." This diagnostic term is found in the Diagnostic and Statistical Manual of Mental Disorders. It describes the unhappy subjective life of the person who suffers distress caused by a felt incongruence between their sex and their gender identity. The entirety of the presenting complaint of the patient is in their psychological/emotional life.

47. When a patient has profound anxiety or sorrow concerning their physical appearance in the absence of any objective meaningful deformity, their condition is called "body dysmorphic disorder." It is foundational to cosmetic surgery that persons who present with body dysmorphic disorder should not be offered surgery but should instead be referred for psychological treatment. There is no reason why this principle should not apply to the hormonal manipulation of the minor as well,

since the patient is seeking modification of their appearance in the hopes of obtaining a life-changing effect in their emotional life. The fact that high-dose sex hormones are being used instead of surgery to achieve the cosmetic result does not mitigate the ethical problem; it only changes the likely complications given that high-dose sex steroids have a very high association with heart disease, peripheral vascular disease, pulmonary embolism, metabolic syndrome with diabetes, elevated cholesterol, obesity, and overall early mortality as cited above.

48. Plaintiffs' expert Dr. Ladinsky (Ladinsky p.23) asserts that "[m]edical treatment recommended for and provided to transgender adolescents with gender dysphoria can substantially reduce lifelong gender dysphoria and can eliminate the medical need for surgery later in life." (Dr. McNamara makes a similar claim at page 13 of her report.) This is an assertion with no quality evidence to support it. In fact, Dr. Ladinsky herself offers no citation to support this claim. Practitioners of gender affirmation care, however, routinely make this assertion while offering only low-quality, retrospective or case-series data without comparison cohorts, massive self-selection bias, high drop-out rates, and study periods of only a few years. To assert that such studies can draw conclusions about lifelong benefit is unsupportable. To offer no support for this crucial claim in her expert opinion is evidence of the poverty of scientific support that gender affirmation care has.

III. EVIDENCE DOES NOT SUPPORT "GENDER AFFIRMATION" SURGERIES AS A STANDARD OF CARE

A. Experimental Practices

49. The distinction between medical practices that are experimental versus those that can be considered proven options of care, or even standards of care, rests on the quality of the scientific data offered in its support. Historically there have been occasions of serious harms to patients because a particular medical practice lacked scientific foundation, even while esteemed experts considered the matter settled in their favor. For example, consider the use of Thalidomide to manage the nausea of pregnancy and the associated disaster of profound arm and hand deformities that resulted.[22] Or the performing of frontal lobotomy to manage emotional conditions.[23] The developer of the frontal lobotomy operation received the Nobel Prize. He was celebrated until the long-term results became better understood. Many patients suffered permanently debilitating neurological injuries as a result.

B. Evidence-Based Medicine

50. It is in response to such disasters that professional organizations of physicians and surgeons have developed instruments for determining the quality of scientific evidence, as well as methods of translating the findings of that examination

[22] *Thalidomide: the tragedy of birth defects and the effective treatment of disease*, Kim JH and Scialli AR, Toxicol Sci. 2011 Jul;122(1):1-6. doi: 10.1093/toxsci/kfr088.
[23] *Spinning lobotomy: A conventional content analysis of articles by the pioneers of the procedure in the United States*, Afkhami AA, Fatollahi JJ, Peace MA, & Yadgar RJ, SSM Mental Health, Vol. 2, 2022, 100123, ISSN 2666-5603, https://doi.org/10.1016/j.ssmmh.2022.100123.

into safe and effective decision making by practitioners. This process is given the name "evidence-based medicine." In recent years, professional medical societies have been making a concerted effort to strengthen the scientific basis upon which their particular specialties stand. Evidence-based medicine 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 were 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 Surgery.[24,25] 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:

[24] https://www.plasticsurgery.org/documents/medical-professionals/health-policy/evidence-practice/ASPS-Rating-Scale-March-2011.pdf

[25] *The Levels of Evidence and their role in Evidence-Based Medicine*. Burns PB, Rohrich RJ, and Chung KC, Plast. Reconstr. Surg. 2011 Jul; 128(1): 305–310.

a. Level I: High quality prospective cohort or comparative study with adequate power or systematic review of these studies.

b. Level II: Lesser-quality prospective cohort or comparative study, retrospective cohort or comparative study, untreated controls from an RCT (randomized control study), or systematic review of these studies.

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

d. Level IV: Case series with pre/post-test or only post-test.

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

51. 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 so grave, that professional 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.

52. To that end, the ASPS document provides a grading system for Practice Recommendations that helps in 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 experimental option if at all because the treatment outcome cannot yet be reasonably predicted or compared to established methods with known outcomes.

53. If a novel treatment for a known condition is proposed, ethical patient care demands that we examine the reliability of the evidence and compare results of treatment to the established treatment. In the case of gender dysphoria, there is high-quality outcomes data that demonstrate successful resolution of sexual identity issues in greater than 80% of minors (over 90% if followed to adulthood) when the treatment model used is what is called "watchful waiting."[26,27] This process includes

[26] One examination of the result of care that did not include affirmation care is a study from 2013, which is a long-term prospective study showing that over 80% of children desisted from their cross-sex self-identification. Essentially, studies like these establish the control group, which provides a more reliable baseline for comparison. The paper additionally examines multiple published studies and concludes: "To date, the prospective follow-up studies on children with GD, for whom the majority would meet the DSM-IV diagnostic criteria for Gender Identity Disorder (GID) collectively reported on the outcomes of 246 children. At the time of follow-up in adolescence or adulthood, these studies showed that, for the majority of children (84.2%; n= 207), the GD desisted." *Factors Associated With Desistence and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study*, Steensma TD, Mcguire JK, Kreukels BPC, Beekman AJ, & Cohen-Kettenis PT, Journal of the American Academy of Child & Adolescent Psychiatry, 52(6), 582-590. doi:10.1016/j.jaac.2013.03.016.

[27] Endocrine Society Guidelines also support this conclusion: "[T]he large majority (about 85%) of prepubertal children with a childhood diagnosis (of GD) did not remain gender dysphoric in

individual cognitive and behavioral psychological care, family therapy, and other methods all aimed at resolution of the internal psychological conflict concerning the minor person's sexed appearance. Furthermore, watchful waiting accomplishes this without irreversibly sterilizing the minor or iatrogenically harming them with the disfigurements of surgery as described above.

C. Watchful Waiting vs. Gender Affirmation

54. The watchful waiting treatment model is based in very long-term Level-III data. Such data are sufficient to drive clinical decision-making as outlined in the ASPS instrument described above. The gender affirmation model of care must be compared to the existing watchful waiting/psychotherapeutic model, and the existing model should be compared with all documents submitted by plaintiffs' experts, including the WPATH Standards of Care v.8, and all the publications cited by them. None of those documents present any evidence above Level-IV, and the bulk of them are Level-V. This means that, at present in the American medical community, the transgender treatment model of affirmation rests only on expert opinion (Level-V) woven into policy statements produced by historically flawed consensus methodology and is therefore insufficient to make clinical decisions such as abandoning watchful waiting in favor of affirmation medicine and surgery.

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adolescence." *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, Hembree WC, Cohen-Kettenis PT, Gooren L, et al., The Journal of Clinical Endocrinology & Metabolism 2017; 102(11): 3869-903.

55. An example of the poor-quality evidence that is driving clinical decision-making in the U.S. is one of the most frequently cited papers offered in support of chest masculinization in minor females seeking to present as males.[28]

56. 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, WPATH, and the Society for Adolescent Health and Medicine.

57. 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." The article 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 post-surgical patients by phone. 26% of the clinic's post-

[28] *Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts*, Johanna Olson-Kennedy J., Warus J, Okonta V, Belzer M, and Clark LF, 2018 May 1;172(5):431-436. doi: 10.1001/jamapediatrics.2017.5440.

surgical patients could not be reached for various reasons including no working phone or failure to respond to multiple messages.

58. 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. The loss to follow-up of post-surgical patients is a serious concern, particularly when the surgery is of such a serious nature and intended to radically improve the life of the patient. In my experience, such loss can result from outcomes that are so disappointing that the patient has lost confidence in the abilities of the surgeon and does not return for follow-up care. Additionally, if major issues such as risk of medical complication, surgical complication (as described above), or self-harm are involved, the patient may have come into the care of other physicians including emergency medical and psychiatric providers, and continuity of care has been broken.

59. 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 un-validated 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*. Subjective, psychological test instruments, such as Quality of Life surveys, are the product of a long and laborious process of developing questions that, when answered by the patient, will have some ability to distinguish very subtle psychological processes of response in the patient. To ask an adolescent child, who has no training in the development of psychological test instruments, and who is suffering from a DSM-V diagnosed psychological conflict, to write questions about that very same psychological conflict, is a scientifically unsupportable decision on the part of Olson-Kennedy et al.

60. 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 five 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 seven post-surgery.[29] The

[29] *Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden*, Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Långström N, Landén M, PLoS One 2011 Feb 22;6(2):e16885. doi: 10.1371/journal.pone.0016885.

Olson-Kennedy paper is a low-quality Level-V document that has no prognostic power since it was a poor sample of patients followed only briefly.

61. Having promised in the introduction to their paper that "chest dysphoria" is reduced by surgery, at the conclusion the authors confess 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. 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."

62. 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 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.

CONCLUSION

63. It is my professional opinion that the VCAP legislation is a prudent and necessary step in protecting Alabama minors from scientifically unproven treatments that have known harms. The social, medical, and surgical transitioning of self-identified transgender minors is a treatment model that has no basis in scientific evidence to support efficacy, and it results in well-known severe and life-long harms to the minor.

Executed: May 18, 2023

Patrick W. Lappert, M.D.

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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

Faculty Appointments:

— 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

— Commissioned an Ensign, MC, USNR 1979 and Commissioned as a Lieutenant, MC, USN 1983 .

— Designated Naval Flight Surgeon, Naval Aerospace Medical Institute, 1985

— Flight Surgeon, Marine Fighter/ Attack Squadron-451

— 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.

EXHIBIT 18

SUBMITTED UNDER SEAL

EXHIBIT 19

SUBMITTED UNDER SEAL

EXHIBIT 20

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EXHIBIT 31

SUBMITTED UNDER SEAL

EXHIBIT 32

SUBMITTED UNDER SEAL

EXHIBIT 33

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

CASE NO: 2:22-cv-00184-LCB-CWB

BRIANNA BOE, individually and on behalf of her minor son, MICHAEL BOE; et al.,
Plaintiffs,
and
UNITED STATES OF AMERICA,
Plaintiff-Intervenor,
v.
STEVE MARSHALL, in his official Capacity as Attorney General of the State of Alabama, et al.,
Defendants.

DEPOSITION
OF
MORISSA J. LADINSKY, M.D.
APRIL 12, 2023

Deposition of MORISSA LADINSKY, M.D., called as a witness by the Defendants, before Jennifer Madaris, Certified Court Reporter for the State of Alabama, with principal offices in Jefferson County, commencing at 9:00 a.m., on the 12th day of April, 2023, at 20th Street North, Birmingham, Alabama 35203.

A P P E A R A N C E S

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I N D E X

Page 9

I, Jennifer Madaris, CCR, RPR, a Court Reporter and Notary Public of the State of Alabama, acting as Commissioner, do certify that on this date, as provided by the Alabama Rules of Civil Procedure and the foregoing stipulation of counsel, there came before me at 20th Street North, Birmingham, Alabama 35203, on April 23 2023, beginning at 9:00 a.m., MORISSA LADINSKY, M.D., witness in the above cause for oral examination, whereupon the following proceedings were had:

MORISSA LADINSKY, M.D.
having been first duly sworn, was examined and testified as follows:

COURT REPORTER: Everyone on Zoom, please state your appearance.

MR. REINKE: Adam Reinke of King & Spalding on behalf of the private plaintiffs.

MR. SHORTNACY: Michael Shortnacy from King & Spalding also on behalf of the private plaintiffs.

MR. MINTER: Shannon Minter from NCLR also on behalf of the private plaintiffs.
MS. TOYAMA: My name is Kaitlin Toyama for the Department of Justice.
MR. BOWDRE: Bethany Lee and Bob Overing are from the Attorney General Office.

EXAMINATION BY MR. BROOKS:

Q. I am Roger Brooks with Alliance Defending Freedom representing Alabama, and I'll be asking a few questions today.
A. All right.
Q. Thank you for being here.
A. My pleasure.
MS. EAGAN: Before we get started we reserve the right to read and sign the deposition.
Q. (BY MR. BROOKS) And Dr. Ladinsky, let me ask first whether you have ever been through this deposition process before?
A. I've only been party to a deposition once, and that was in the context of a divorce, family law kind of thing ages ago.

Q. I'm not going to try to explain law to you, but you have seen the process?
A. Yes, sir, I have.
Q. I will ask questions. At any point feel free to ask for clarification if you think one of my questions is unclear. I'm going to show you a lot of documents today and ask you questions about documents. And I will hand you in advance to save trouble, there are four documents that I think we may refer to frequently enough that having them in one place as the pile builds up will be handy. And I'll tell you right now what those are. That includes a transcript of your testimony at the preliminary injunction hearing, your expert report submitted a couple of months ago in this matter, the Endocrine Society Guideline 2017 Edition, and a report -- a document that we, of course, will discuss that's titled the Cass Review.
A. Yes, sir.
Q. That's what's in this binder. Everything in it we will come to in due course, but I want you to have that in front of you.

A. Thank you.
MR. BROOKS: Let me ask the reporter to mark as Ladinsky Exhibit 1, a copy of the witness' curriculum vitae.

(Whereupon, Ladinsky Exhibit 1 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) And, Dr. Ladinsky, let me just ask: Does this appear to be a copy of your curriculum vitae?
A. It does.
Q. And am I correct that you consider yourself to be a pediatrician?
A. Correct.
Q. You have a license that is titled physician and surgeon, but am I correct that you are not a surgeon? That is simply the formal licensing title?
A. That is correct.
Q. All right. And you are not an endocrinologist; am I correct?

A. You are correct.
Q. And you're not a psychiatrist?
A. You are correct.
Q. And you have no degree in psychology?
A. I do not.
Q. Are you a neurologist?
A. I am not.
Q. And you consider yourself to be an expert in cognition and the study of development cognition?
A. On the level a primary care and board-certified pediatrician is and should be.
Q. That is, you have the expertise in cognition and developmental -- cognitive development that you consider to be standard for a pediatrician?
A. That's fair.
Q. But you don't consider yourself a specialist in cognition or cognitive development?
A. That's fair.
Q. Describe for me what training you have in adolescent developmental psychology.

A. Again along the lines of a primary care pediatrician. We do a lot of work throughout residency, life experience, and a fellowship in academic general pediatrics. That takes that up to a level of being able to impart concepts to trainees, pediatric trainees. I also have 31 years of frontline work with the entire range of the pediatric population, 0 through about 21 or 22.

Q. Am I correct that you came to the University of Alabama Medical Center in 2015?

A. That's correct.

Q. And you came for the purpose of starting a pediatric gender clinic?

A. I would not say I came here to do that, no, sir.

Q. Okay.

A. No, sir. I came here to accept a faculty attending spot. This developed after I -- well, in proximate to.

Q. All right. Tell me -- describe for me if you would when you and colleagues decided to start that pediatric gender clinic.

A. In 2014 in the lead-up to my relocation here or the early part of 2015. Because I relocated to Alabama in the summer of 2015 to take this position.

MS. EAGAN: I think he asked you when.

THE WITNESS: Okay.

Q. (BY MR. BROOKS) I asked you to describe when you and your colleagues formed the plan to start a pediatric gender clinic at the University of Alabama?

A. Sure. Absolutely. The early part of 2015.

Q. Okay. So essentially close in time to your move here?

A. That's fair.

Q. Okay. Is there any other gender clinic in the state of Alabama to your knowledge?

A. Not to my knowledge, no.

Q. And --

MS. EAGAN: Pediatric, correct?

MR. BROOKS: That is -- I will clarify the question.

Q. Is there any other pediatric gender clinic in the state of Alabama?

A. There is not to my knowledge. I presume that's what you had been asking. I'm sorry.

MR. BROOKS: Thank you for the clarification.

Q. What number of pediatricians or primary care physicians in Alabama outside your clinic do you consider to be expert in diagnosing gender dysphoria?

MS. EAGAN: From her personal knowledge?

MR. BROOKS: Correct.

A. From my personal knowledge, I mean, primary care pediatricians are well trained and taught to recognize what could be emerging gender dysphoria. They don't -- no pediatrician has the level of expertise that, for example, a Ph.D. psychologist does --

Q. Well --

A. -- in that domain.

Q. -- how many pediatric physicians,

primary care physicians in Alabama outside your clinic, in your view, have the expertise necessary to make an actual diagnosis of gender dysphoria in a child?

MS. EAGAN: Object to the form.

A. Tell me more about make a diagnosis. What do you mean in that way? Because do you mean it as it is asserted in guideline documents or as we may see that on the ground?

Q. (BY MR. BROOKS) Gender dysphoria is a mental health diagnosis defined in DSM-5; am I correct?

A. It is.

Q. And appropriately trained mental health professional may be tasked to make an evaluation as to whether a child does or does not fit the criteria for mental -- for gender dysphoria as set forth in DSM-5, correct?

A. Correct.

Q. That's what I mean by diagnosis. So my question is: How many primary care physicians in Alabama outside of your clinic, in your view, have the expertise necessary to actually make a

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diagnosis of gender dysphoria according to the DSM-5 guidelines?
A. I could not answer that question.
Q. Your clinic receives referrals from doctors around the state; am I correct?
A. That's correct.
Q. Do you rely on doctors outside your clinic to make an actual diagnosis of gender dysphoria?
A. It's fair to say that we rely on doctors outside of our clinic to recognize gender dysphoria and recognize when referral to our clinic is necessary and warranted.
Q. Do you ever rely on doctors outside your clinic in Alabama to make a diagnosis of gender dysphoria as a sufficient basis to proceed with medical treatment or do you always insist on making a diagnosis within your own clinic?
A. I don't -- I mean, specifically -- restate that because it was a two part.
MR. BROOKS: Let me ask you to read the question back.

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(Whereupon, a portion of the testimony was read by the court reporter.)

MS. EAGAN: Just for clarification, by medical treatment, you're referring to puberty blockers and hormones; is that correct?
MR. BROOKS: Hormones or surgery, yes.
A. Okay. What judge -- or transitioning treatments for the purpose of this? Okay.
Q. I think we're all on the same page.
A. That's good. So for Part 1, that would be a no. We rely on them to recognize. And by them, I mean MDs or primary providers of pediatric care around the state. The second, yeah. Go ahead.
Q. You finish your answer. I apologize.
A. You're fine. The Part 2 is: Do we always require them to come to us? Let's just say that is not something in our, you know, plans of

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care if you make that diagnosis you have to come to us. Does that help? In other words, if someone in the community is working closely with a well-trained psychologist who understands, knows, and works in the space of gender dysphoria, they still need to come to us but we will pick up from there.
Q. Does it ever happen that your clinic prescribes puberty blockers or cross-sex hormones for a minor for whom no mental health professional associated with your clinic has confirmed a diagnosis of gender dysphoria?
A. Can you restate that?
Q. She can read it back.
THE WITNESS: Can you read it back?

(Whereupon, a portion of the testimony was read by the court reporter.)

A. That is not part of our practice parameter. But as I've stated before, there is the occasional case where a youth will come to us

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having been under the care of a very well-trained experienced competent Ph.D. psychologist in the community and may arrive with that diagnosis. It will then be also -- there are many other factors that go into prescribing. So, like I said, we will pick up from there. Short answer, no.
Q. In your clinic do you attempt to follow the WPATH Standards of Care --
A. We do.
Q. -- for treatment of adolescents and children?
A. We do.
Q. And have you accordingly made any changes to your procedures since the issuance of WPATH Standards of Care Version 8?
A. No, not formally.
Q. Do you personally diagnose gender dysphoria? Do you personally make diagnoses of gender dysphoria in minors?
A. We do.
Q. My question is you personally?
A. Me personally, in the context of our team setting.

Q. What is your role in the process of diagnosing whether a young person who presents to your clinic does or does not suffer from gender dysphoria?

A. A very robust history with not just the youth but their parents, guardians, household members, those that love them that they bring with them to appointments. We review all records that come to us from the referring primary care doctor as well as mental health professionals that youth may be seeing in community.

Q. My question was: What is your personal role in the diagnostic process?

A. My personal role is to bring out and help my team understand through elevation of the various elements that that youth manifest that may indicate gender dysphoria.

Q. Who within your team or what job description of your team has the responsibility to make the final decision as to whether a child does or does not suffer from gender dysphoria as defined in DSM-5?

A. Our psychologist's view of all of it

weighs heavily, and that must resonate with everyone on the team.

Q. So ultimately with heavy reliance on the psychologist, it's a collective decision?

A. That's fair.

Q. Okay. Do you yourself ever prescribe puberty blockers or cross-sex hormones?

A. Only in the context of youth seen in this team for the purpose of gender dysphoria.

Q. And you yourself in some occasions write that prescription?

A. Sometimes.

Q. Okay.

MR. BROOKS: Let me ask the reporter to mark as Ladinsky Exhibit 2 the transcript of May 5, 2022, one of the days of the preliminary injunction hearing in this matter.

(Whereupon, Ladinsky Exhibit 2 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) And I will tell you

that the days that constitute your testimony -- we have the whole day here, but you don't care too much about most of it. The days that constitute your testimony are behind Tab Number 12.

MS. EAGAN: Is this the redacted version or do we need to put this under the protective order? Because there was one version that's protected under the protective order because of Ms. Poe's testimony.

MR. BROOKS: Ms. Poe's testimony is which pages?

MS. EAGAN: 151 to 170.

MR. BROOKS: Let me have the --

MS. EAGAN: Can we remove those pages?

MR. BROOKS: Let me simplify and remove those pages from the marked exhibit.

MS. EAGAN: If you're just looking at her testimony, can we just mark whatever you put into this notebook that's just her testimony?

MR. BROOKS: Yes.

MS. EAGAN: That will simplify things.

MR. BROOKS: Okay. That's fine.

MS. EAGAN: So why don't we replace what you previously identified as Exhibit 2 with the transcript of just her testimony.

MR. BROOKS: Okay. Remark Exhibit 2.

What we're now marking as Ladinsky Exhibit 2 is a portion of the mini-script transcript from May 5, 2022, including a cover page and then commencing on Page 89 and continuing up to Page 152. That comprising the testimony of Dr. Ladinsky.

(Whereupon, a discussion was held off the record.)

Q. (BY MR. BROOKS) Dr. Ladinsky, I don't want to make this a -- I don't want to waste time going to the transcript all the time. I also don't want to make it a memory test. You testified at the hearing that you had, you said -- and I'm referring to Page 96 if you want to find this -- "Since our clinic's opening, we have

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touched the lives of some 400 to 450 youth." Is that consistent with your recollection generally?
A. That's consistent with my recollection.
Q. And you testified also -- and I quote from Page 128 Line 24. Quote, "No more than a third of them, though, have received medication relative to gender dysphoria."
A. I recall that statement.
Q. And is that generally consistent with your recollection of the facts?
A. It's generally consistent, yes.
Q. And so that takes us to something in the neighborhood of 125 to 150 who over the years have been -- have received medication, either puberty blockers or cross-sex hormones from your clinic; am I correct?
A. That's a fair statement as an approximation, sure.
Q. Do you believe that all of those minors who received puberty blockers or cross-sex hormones from your clinic had, in fact, been diagnosed as suffering from gender dysphoria

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according to the criteria of DSM-5?
A. I believe so.
Q. And does your clinic make an effort to ensure that all minors under their care who are receiving hormones or puberty blockers are also receiving supporting counseling and psychotherapy?
A. We do. It's just not fair to say that as an every single one 100 percent. This is a huge range of youth. But when appropriate, absolutely.
Q. What I asked was: Do you make an effort to ensure that everybody who's receiving puberty blockers or cross-sex hormones is also receiving counseling and psychotherapy?
A. Yes.
Q. Now, the gist of what we've just been through is that two-thirds of those minors who are referred to your clinic do not end up receiving a prescription for puberty blockers or cross-sex hormones; am I right?
A. That's fair.
Q. And why is that? What sorts of situations result in children having enough

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difficulty that they're referred to your clinic but they ultimately don't receive a prescription?
A. There are segments of the youth for whom we see and provide care who are prepubertal. In those younger kids, there's absolutely no indication for any medical treatment or intervention. There's a sizable population of youth presenting to us who are already very far into or have completed a puberty aligned with their natal sex. Those youth are not eligible for medication as well at the time we see them.
Q. Is it your testimony that individuals who have completed puberty aligned with their natal sex are not under any circumstances eligible for cross-sex hormones?
A. They may well be eligible for cross-sex hormones or hormonal therapy with sustained dysphoria and meeting all of the other criteria that our team -- that our team necessitates and mandates before those medications are begun.
Q. Do some young people who come to your clinic who are referred to your clinic, in

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your experience, cease to experience gender dysphoria over -- during the course of counseling and psychotherapy?
A. That's always possible.
Q. Has it happened sometimes? Does that account for some of these children who are referred to your clinic who don't receive a prescription?
A. Good question. For some we'll never know. Some of those 450 may come to see us once and never come back or twice and never come back, and we don't know why. Others -- we have one that I can think of that during the course of work on puberty blockers aligned -- decided in the context of family and therapy that it wasn't necessary.
Q. I appreciate that. That's -- and I recall your testimony about that individual.
Among young people who have been referred to your clinic who have not yet received any prescription for either puberty blockers or cross-sex hormones, does it sometimes happen that in the course of the psychotherapeutic support that your clinic provides or recommends that they

cease to experience gender dysphoria without ever receiving any prescription?
A. It's possible but not to my knowledge.
Q. Okay. Do you have a sense -- let me just take the year 2022 as the most recent completed year -- of what proportion of minors referred to your clinic were natal female versus natal male?
A. I can give you only an approximation, and it matches the approximation of our previous years.
Q. What is that?
A. We see a very close to half/half, very close.
Q. Tab 11. This was your PI declaration, earlier declaration.
MR. BROOKS: I'll ask the reporter to mark this as Exhibit 3.

(Whereupon, Ladinsky Exhibit 3 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) And Dr. Ladinsky, do you recall preparing and signing this declaration prior to the preliminary injunction hearing in this matter?
A. Yes, sir.
Q. In Paragraph 6 -- and this is dated April 20, 2022. In Paragraph 6, you state that, "Since starting at the gender clinic at UAB, I have treated approximately 250 transgender young people for gender dysphoria."
And earlier we looked at testimony in which you had mentioned a number of 400 to 450. Here you said you've treated approximately 250. Can you explain to me what the 250 number represents?
A. At that time it was an approximation of youth that had come through our doors and I believe may have received some form of medication. It was an approximation.
Q. So as the number that have received medication, your testimony now is that it's closer to one-third of that 400ish number; am I correct?

A. That's fair.
Q. And you're going to want to start a stack of paper off to the side somewhere.
MR. BROOKS: Let me mark as Ladinsky Exhibit 4 a set of responses and objections to document request interrogatories served by the University of Alabama System on March 3, 2023.

(Whereupon, Ladinsky Exhibit 4 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) Dr. Ladinsky, did you play any role in -- to your knowledge, in preparing answers, responses and objections, or just the responses to certain questions on behalf of the University of Alabama System?
A. I played a role.
Q. Without getting into conversations that you had with counsel, would you describe for me what that role was?
A. Of course. Together with my colleague, my partner at the Gender Health Clinic,

UAB Pediatric, Dr. Abdul-Latif, we worked together to provide answers and provide documents to the subpoena request. Also to clarify, especially to counsel, the differences between what's called the UAB Gender Health Clinic where the subpoena was sent, the adult team, as we call it. And a separate multi-disciplinary clinical care team providing care within the UAB Pediatrics Department of Endocrinology.
Q. And just to make sure we're clear on the record, the so-called Gender Health Clinic serves adults; am I correct?
A. It starts at age 18 and up.
Q. Age 18 and up?
A. Yes, sir.
Q. And in Alabama, the legal age of majority is 19 which is different than many states?
A. That's correct.
Q. And the UAB Pediatric Endocrinology Department is the clinic that you are associated --
A. That's correct.

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Q. -- with that serves minors up to --
A. That's correct.
Q. -- the age of 18?
MS. EAGAN: Let him finish his answer before you speak. She has a hard time taking this down.
THE WITNESS: My apologies.
Q. (BY MR. BROOKS) Let me ask you to turn to Page 5 and the objection and response to Number 11. And in this response three lines from the bottom, three, four lines from the bottom, it says, "UAB states that since 2017 the UAB Pediatric Endocrinology Department provided 17 minor patients with puberty blockers and the Gender Health Clinic did not provide any minor patients with puberty blockers." Do you see that?
A. I see that.
Q. Now, earlier you testified that something in the neighborhood of a third of something in the neighborhood of 400 to 450 minors have been treated by the UAB Pediatric Endocrinology Department, if I understand correctly, with either puberty blockers or

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cross-sex hormones, correct?
A. Approximately, yes.
Q. And is it the case -- is it consistent with your knowledge that only 17 of those minors have received puberty blockers?
A. That is correct.
Q. So the overwhelming number of minors who have received any sort of hormonal prescription from your department have received only a prescription for cross-sex hormones?
A. That's fair.
Q. Okay. I just wanted to understand the relationship between those numbers.
And is that reflective of the fact that the overwhelming majority of minors who present at your clinic are already well into puberty at the time you first see them?
A. That is what we see.
Q. Is it fair to say that the majority of minors who present at your clinic are 14 or older the first time you see them?
A. That's a fair statement.
Q. Are the majority 15 or older?

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A. I would not be able to make that distinction for you without --
Q. Okay.
A. -- a records deep dive.
Q. All right. I'm in the right neighborhood, 14 or over?
A. I think that's -- that's the right neighborhood.
Q. In your preliminary injunction declaration which is --
MR. BROOKS: What was the exhibit number on that?
MS. EAGAN: 3.
Q. (BY MR. BROOKS) Let me ask you to turn to Paragraph 11. And there you said, quote, "Most of our patients are in the care of the gender clinic for one to three years before initiating medical treatment for gender dysphoria." Do you see that?
A. I do.
Q. Is that a policy that is written anywhere?
A. I don't believe it's written

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anywhere, but it's very consistent with guideline-driven standards of care longitudinally.
Q. In your professional view, why is it important that patients be in the care and under the observation of your clinic from one to three years before you initiate any medical treatment?
A. Realizing each young person is an individual and is looked at in an individual way. But it's important to -- for us that sustained dysphoria over a longitudinal period of time remains present before initiating such medications. In addition, it gives that youth in the context of, you know, family environment to live in that identity and reflect back from it.
Q. I think you testified that in all of your experience, very few youth who presented with gender dysphoria have desisted from that dysphoria prior to receiving medication, correct?
A. To my knowledge.
Q. And, therefore, why do you believe it to be important to have this extended period of observation before prescribing puberty blockers or cross-sex hormones?

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A. As I said, each youth is unique, and it's very supported of observation not just of the youth but the family. But, again, to ensure to be sure that mental health is optimized, that the youth sustains that dysphoria over a longer period of time.

Q. In your expert report, which is behind Tab 13 in your binder, and is Exhibit Number --

MR. BROOKS: Let me mark as Exhibit 5 the expert report of Dr. Morissa Ladinsky submitted in this matter.

(Whereupon, Ladinsky Exhibit 5 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) Dr. Ladinsky, you're looking at the copy, which, I believe, is a complete copy in the binder. And do you recognize this as the expert report you prepared and submitted?

A. That's correct.

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Q. Let me ask you to turn to page 11. And there towards the bottom of the page, you wrote, quote, "The WPATH SOC 8 advises that 'it is important to establish the young person has experienced several years of persistent gender diversity/incongruence prior to initiating less reversible treatments such as gender-affirming hormones.'" Closed quote. Do you see that?

A. I do.

MS. EAGAN: I think you said WPATH 7. Should be SOC 8.

MR. BROOKS: Did I say 7? I apologize. It does say 8.

A. There's reference to both in the paragraph, but 8 in the last sentence.

Q. Let me read it again for clarity of the record. Quote, "The WPATH SOC 8 advises that 'it is important to establish the young person has experienced several years of persistent gender diversity/incongruence prior to initiating less reversible treatments such as gender-affirming hormones.'" Closed quote.

In the case of patients who are

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presenting at, for instance, age 14, what steps do you take to ensure that those patients experience several years of persistent gender diversity before your clinic prescribes less reversible treatments such as cross-sex hormones?

A. For clarification, I heard you to say gender diversity. Did you mean that or did you intend to say dysphoria?

Q. I use the term that was in -- that you quoted from WPATH SOC 8.

A. Okay.

Q. I can re-ask the question.

A. I'm just making sure. I got you.

Q. They said gender diversity slash incongruence, and I didn't mean anything different.

A. Perfect. No problem. Thank you. That clarifies it for me.

Q. My question was -- it's been a little while -- what steps do you take to make sure that that patient who walks in the door at age 14 or 15 has experienced several years of persistent gender diversity or incongruence before

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your clinic prescribes any sort of less reversible treatment such as gender-affirming hormones?

A. So that would be obtained -- the first step is a very robust and comprehensive history not just from the youth but the family members or household members that have come to us. We look at records sent from the referring primary care physician or provider as well as taking into account anything that we may have documented or learned from a mental health professional or provider that youth had been seeing in community.

Q. And then, in addition, you, as a general practice, make sure that your clinic sees that youth for at least a year or between one and three years before you prescribe cross-sex hormones?

A. Generally. It depends on the age. This is a 14 year old? Quite likely.

Q. And the reason that you're willing to require several years of observation and mental healthcare before you will prescribe cross-sex hormones is in order to safeguard against something reversible and later regretted mistake;

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am I correct?
MS. EAGAN: Object to the form.
A. That's part of. But I would prefer the term they use right here of "less reversible".
Q. (BY MR. BROOKS) Less reversible than what?
A. What do you mean?
Q. Less is a comparative word. I asked you less reversible than what?
A. Permanent. That was what you said that -- I was just clarifying in WPATH's language.
Q. Do some parents or patients, in your judgment, sometimes walk in the door more certain than they should be that that child needs cross-sex hormones?
A. Great question. And that they should be is probably a value judgment made by -- that may be different for every person in that room. But if we are seeing a youth who may not, you know, fall into our guideline-driven care, that's even more reason for extended support and time with us.
Q. Now, the process of having -- making

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sure the child goes through several years of gender incongruence or gender dysphoria before receiving a hormonal prescription that's advocated by WPATH in the language that you just -- that you quoted in your report may require that child to endure distress as DSM-5 says, clinically significant distress, for an extended period of years before receiving medical treatment; am I right?
MS. EAGAN: Object to the form as to the use of the term "several years of gender dysphoria as opposed to gender diversity."
Q. (BY MR. BROOKS) Are you able to answer my question?
A. If you meant several years of sustained gender dysphoria, I would disagree with that because a youth in that age and stage who manifests gender dysphoria and intense affective possible harmful behavior or thought processes, they will be supported in many different ways through that time both through mental health and through medicine, not including the initiation of hormones, though.

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Q. Ultimately you will decide to prescribe hormones only if you believe that that will relieve distress being suffered by a young person, correct?
A. Among other indicators.
Q. But that's a necessary requirement, correct?
A. An important one.
Q. Is there any circumstance in which you would prescribe cross-sex hormones for a minor where you don't -- where you haven't reached a professional conclusion that that is going to lessen distress suffered by the minor?
A. No, sir.
Q. Okay. Then let me circle back.
A. Okay.
Q. The process of requiring a child to go through several years of gender diversity or incongruence and at least one year of close observation by your clinic before receiving a hormonal prescription means that child will have to endure distress for a significant period before receiving medication; am I right?

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A. No. We don't see it that way.
Q. How am I not right?
A. Well, first and foremost, depending on the age that that youth comes to us, we could stay with the hypothetical 14 year old or extend it to the youth that come to our space for visits. They may be as old as 18. And who may have lived some of this for years before being able to get to us. That's one section. But for youth who, on an ongoing period of work with our team as necessary, they will be very well supported during that time, mental health, possibly other medications.
Q. Other medications appropriate to other mental health indications that you determine this child has?
A. Both that and there are other medications that are used to weigh components of dysphoria. For example, I mean, if you want an example of supportive medication. For a trans male, someone who was female at birth who's through a full female puberty, we can very, very safely reversibly delay menstruation for that person. That's what I meant by supportive

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medication and care.
Q. Is it the experience of your clinic that for these young people who come in diagnosed with or receiving diagnosis of gender dysphoria that you are able to significantly alleviate their suffering during this interim period by means of other medications such as you've described and the mental health support that you've described?
A. Family support, yes.
Q. Let me ask you to turn to Page 16 of your expert report, Exhibit 5. And there at the bottom of the page and running into the next page, it reads, "I prescribe puberty-delaying treatments starting at the Tanner 2 or early Tanner 3 stages of puberty. For people assigned as male at birth, these stages of puberty are typically between ages 9 and 15. And for people assigned female at birth, typically between ages 8 and 13." Do you see that language?
A. I do.
MR. BROOKS: It's Exhibit 5, the expert report submitted.
MS. EAGAN: Thank you.

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Q. (BY MR. BROOKS) Why is the age at which you will initiate puberty blockers for children different for those who are born female than for those who are born male?
A. Remember it's a very individualized decision-making process. And it's based far more upon the physiologic Tanner staging, the physical manifestations of puberty aligned with the natal sex than the age of any individual patient.
Q. Well, Dr. Ladinsky, I started by just quoting language from your report where you noted a typical age difference between when you would begin for someone born female versus someone born male. And my question is: Why that difference?
A. On a population level, the secondary sex characteristic emergence or physical stigma that show us hormonal puberty is starting, right. On a population level, it's earlier for folks assigned female at birth.
Q. And that in your experience is true regardless of their gender identity?
A. Yes.

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Q. And even for earlier maturing patients and taking this on an individual basis, why not nevertheless wait until age 11 or 12 consistent with the original Dutch protocol procedures instead of starting at 8 or 9?
A. If -- like I said, each, you know, each youth is an individual. We have not, in our clinic population, seen the need for what you just hypothetically elucidated in 8- or 9-year-olds. The majority of our youth beginning -- assigned female at birth beginning blockers are 11 or 12.
Q. Why then did you write in your expert report that the stages at which you prescribe are typically between -- begin at age 9 in the case of males and age 8 in the case of females?
A. To reinforce the population level data around entry into puberty.
Q. And, in fact, across the now eight years since you started your clinic, your clinic has prescribed puberty blockers for a grand total of 17 children?
A. That's correct, sir.

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Q. So your clinic experience really doesn't actually even take us to a kind of statistically significant experience and sample; am I right?
MS. EAGAN: Object to the form.
A. I could not answer that. I can only comment on our own experience.
Q. (BY MR. BROOKS) Well, my question had to do with your own experience.
A. Okay.
Q. In your professional judgment, seeing 17 patients who are treated this way across eight years is not a sample large enough to -- from which to draw statistically significant conclusions, is it?
MS. EAGAN: Object to the form.
A. It would completely depend on the question as the population studied. The metrics desired to then calculate what we know as statistical significance.
Q. (BY MR. BROOKS) Have you attempted any systematic study of outcomes for the 17 patients who received puberty blockers from your

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clinic?
A. We have not undertaken or commissioned a systematic study, no. In fact, three of them have relocated out of state under the pressure of this law. It's now 14.
Q. Your clinic has not, as a result of this law, refused to treat any patient, have you?
A. In the way that we had been practicing, that's correct. With the exception of the week that the law was in effect, we most certainly did not undertake anything that would have broken it.
MS. EAGAN: We've been going about an hour. Whenever you get to maybe a stopping point or a change in point, if we could take a short break.
MR. BROOKS: I agree. Let me take us back, and we'll break shortly.
Q. Let me take you again to what's Tab 17 in --
A. I'm sorry. I don't think I have a 17.
Q. You're right. 17 is the responses

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and objections, which is Exhibit 4. I apologize.
Let me take you to the response to Number 15, which is on Page 7. And the very last sentence of this response to Number 15 at the top of Page 7 reads -- sorry. The next to last sentence. "UAB does not track a patient once that patient leaves the care of UAB."
So I just want to ask you about that. What proportion of the patients who enter your clinic do you continue to provide care for through age 18?
A. The majority who -- the majority who continue to return to us and clearly those who are receiving medication.
Q. Of those who have received prescriptions for cross-sex hormones from your clinic, what proportion continued under your care through age 18?
A. The majority unless they relocated out of state.
Q. Well, I'll ask a flip-side question. What proportion of minors received a prescription for cross-sex hormones from your clinic for

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whatever reason terminated contact with your clinic before they reached age 18?
A. None to my knowledge.
Q. None?
A. To my knowledge.
Q. You have had, in your experience, no patients who received prescriptions for cross-sex hormones who are, to use the term, "lost to follow-up" who just ceased contact with your clinic?
A. To my knowledge, no.
Q. Your clinic has been in operation for approximately eight years; am I correct?
A. Correct.
Q. The majority, the substantial majority of patients that you see, you first see at age 14 or 15 or even older, correct?
A. That's correct.
Q. Is it the case that the majority of patients that you have provided prescriptions for over the years have now been adults and outside the care of your clinic for several years?
A. A small cohort, sure. Those that

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were older when we first opened and began and initiated.
Q. Well, those who came in at age 15 just three years ago --
A. Right.
Q. -- are now outside the care of UAB -- I want to use the right term -- Pediatric Endocrinology Department; am I correct?
A. Well, they would be 18 or 19, some. They may be away at college.
Q. The 19-year-olds you don't see. Those are treated in the adult clinic?
A. For the most part. There are exceptions.
Q. Let me take you back to your testimony at the preliminary injunction hearing, which is in the binder, Tab 12.
MR. BROOKS: I'm sorry. We'll take a break that I promised you first.
MS. EAGAN: Okay.

(Whereupon, a brief recess was taken.)

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Q. (BY MR. BROOKS) Let me ask you to take you to the exhibit of your responses and objections to requests of UAB and turn there to Page 6 if you would. And there midway down the page towards the end of the objections and responses to request Number 13, it reads, quote, "Since opening in July 2020, the Gender Health Clinic has conducted one transitioning surgery for an 18-year-old, but no longer provides such treatment to 18-year-olds." Do you see that language?

A. I do see that language, sir.

Q. When was the surgery that's referenced in that response conducted?

A. Sir, I have no knowledge of that because this applies to the Gender Health Clinic at UAB Medicine, what we know as the adult team.

Q. But you have literally no knowledge about this surgery whatsoever?

A. That is correct, sir. I have absolutely no knowledge of this.

Q. Do you know what surgery procedure

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was performed?

A. I do not.

Q. And you don't know when it was performed?

A. No, I do not know that either. That was not performed -- I mean, that was not a patient under the care of the UAB Pediatric Gender Health team of which I'm a part of.

Q. Now, that patient was, in fact, according to this description a minor, 18-year-old. Were you consulted in any way in connection with that patient?

A. I do not recall. That was -- I really don't.

Q. The Gender Health Clinic, the adult clinic was founded in July of 2020 it says. Did you have -- were you consulted in any way in connection with the founding of the Gender Health Clinic?

A. I attended one meeting in -- a good deal before its opening as they were conceiving of it, and they asked my partner and I to attend one meeting long before they opened.

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Q. Okay. The response that I just read includes the statement that the Gender Health Clinic, quote, "no longer provides such treatment to 18-year-olds."

Have you been part of any discussions about that decision to no longer provide such treatment to 18-year-old?

A. No, sir, I'm not. I can only infer they're talking about the law.

Q. Are you aware of any written policy prepared by anyone associated with your clinic or any other part of the UAB medical system, any written policy relating to when surgeries will or will not be provided to legal minors as a treatment for gender dysphoria?

A. I am not.

Q. When did you first become aware that UAB medical system had performed a transition surgery on an 18-year-old?

A. The moment you referred me to this statement.

Q. You never before read this document in its entirety?

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A. No, sir, not -- I don't recall.

Q. And when I read that statement to you, was that inconsistent with what you had previously believed to be true?

A. No.

Q. That is, you previously believed that the UAB Health System had performed surgeries on legal minors as a treatment for gender dysphoria?

A. I was not aware as to whether they were or were not in the particular narrow scope of an 18-year-old. I had no knowledge of policy or action.

Q. Does the Pediatric Endocrinology Department have a policy with respect to recommending surgery for minors as a treatment for gender dysphoria?

A. It is not part of our regular treatment protocol.

Q. Do you have any policy on that written anywhere?

A. I don't believe we have a written policy, but we have a very, very, very long track

record of such.
Q. And why is surgery on minors not part of your protocol?
A. Well, it's currently illegal. But prior to the VCAP law being passed and the surgery section, that being joined, it had not been provided in Alabama nor was it our practice to do such.
Q. And my question is why?
A. We felt -- we align in our thinking very much with the WPATH Standards of Care as well as the Endocrine Society. They do carve out a very, very narrow scope of individually viewing older teens with severe and unrelenting chest dysphoria that they may be candidates for masculinizing chest surgery. That is part of the standards of care and guideline-driven treatment. Beyond that, they do not endorse it and we concur.
MR. BROOKS: Let me mark as Ladinsky 6 the WPATH Standards of Care Version 8.

(Whereupon, Ladinsky Exhibit 6 was marked and copy of same is attached

hereto.)

Q. (BY MR. BROOKS) And Dr. Ladinsky, do you recognize this document as a document that you are well familiar with?
A. I'm familiar with it, yes.
Q. Let me ask you to turn to Page 133 or S133 as they number these things for reasons best known to themselves.
MS. EAGAN: Hold on a second. 133?
MR. BROOKS: Yes.
MS. EAGAN: My copy must have missed that.
THE WITNESS: Mine does too. It goes from 120 to something and then 157.
MS. EAGAN: It's missing that part. It goes from 127 to S156.
THE WITNESS: Mine as well.
MR. BROOKS: Never mind.
Q. I'm going to read you -- let me ask you this first, Dr. Ladinsky. You can put that down since it doesn't have the pages I intended.
MS. EAGAN: Can we get a copy if

you're going to start asking questions about a particular section or language. I would like for her to have copy of it to review. I can make a quick copy of it if that's okay.
MR. BROOKS: You can make a copy of this page.
MS. EAGAN: Are you going to ask her about other sections of this?
MR. BROOKS: I don't know that I will. Let's just get that.
MS. EAGAN: It's fine if you want to ask her a question and hand to her.
MR. BROOKS: I'll do that and then we'll mark the page.
Q. When SOC 8 came out, did you make an effort to familiarize yourself with its contents?
A. With relevant sections, yes.
Q. And did you, in fact, participate in any way in the development of the WPATH SOC 8?
A. No, sir.
Q. I'm going to read you a quote from Statement 13.7 on Page S133 and then hand you the text. It says, quote, "We recommend surgeons

consider gender-affirming surgical interventions for eligible transgender and gender diverse adolescents when there is evidence of a multidisciplinary approach that includes mental health and medical professionals has been involved in the decision-making process."
MR. BROOKS: Let me ask the reporter to mark this single page as Ladinsky Exhibit 7 and hand it to her.

(Whereupon, Ladinsky Exhibit 7 was marked and copy of same is attached hereto.)

MR. BROOKS: If you're wanting to identify what section it's in, we do have the table of contents.
MS. EAGAN: It looks like it's not in the section is what she was raising.
MR. BROOKS: That may be the case.
Q. My initial question is: Are you familiar with the recommendation 13.2 that is contained in Exhibit 7?

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A. You mean 13.7?
Q. I do.
A. It aligned with Chapter 13 in its applicability to adults, yes.
Q. Well, do you see the language that I read to you that pertains to adolescents specifically?
A. I do see that. That's correct.
Q. And were you familiar before I showed you this that recommendation from WPATH?
A. I was.
Q. All right. And in the Exhibit 6, let me ask you to turn to Page 66, which I believe you'll find is in the section relating to adolescents. 66.
A. Yeah. Okay.
Q. And there in the first column about 3 inches from the bottom, it says, "Chest masculinization surgery can be considered in minors when clinically and developmentally appropriate."
A. Right here, yeah.
Q. So WPATH, you would agree,

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recommends that chest masculinization surgery can be considered in minors; am I correct?
A. Correct.
Q. And that -- another term for that would be a mastectomy. It's removal of the breasts of a natal female; am I correct?
A. I'm not a surgeon to comment on that exact detail.
Q. You are a doctor. Do you understand the surgery that's referred to to consist of removing the female breasts?
A. Yes.
Q. And let me ask you to look at second column on the same page.
A. Okay.
Q. And about 2 inches down is a sentence that begins, "Limited data are available on the outcomes for youth undergoing vaginoplasty." Do you see that?
A. I do, yes.
Q. And a little farther below it says, While the sample sizes are small, these studies suggest there may be benefit for some adolescents

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to having these procedures -- that is vaginoplasty -- performed before the age of 18. Do you see that?
A. I see that.
Q. And am I correct -- do you have an understanding of what vaginoplasty as the term is used by WPATH refers to?
A. I do.
Q. It's a procedure performed on natal males; am I correct?
A. Correct.
Q. And it includes --
A. In this context.
Q. -- removal of the penis?
A. That's correct.
Q. And it includes castration; am I correct?
A. I believe so.
Q. And it is, in your understanding, absolutely and completely irreversible, is it not?
A. I view it that way.
Q. And you were aware, were you not, that WPATH says that that surgery may be

Page 65

appropriate before age 18?
MS. EAGAN: Object to the form.
A. I'm seeing it in front of me here.
Q. (BY MR. BROOKS) Well, you testified earlier that once the Standards of Care 8 came out, you took care to familiarize yourself with the sections dealing with adolescent health, right?
A. Correct.
Q. And you were aware before you sat down for this deposition today that WPATH is stating to the world that this procedure, including castration and removal of the penis, may be appropriate for natal males younger than 18?
A. That is what they're saying right here.
Q. And you were aware of that shortly after the Standards of Care 8 came out; am I right?
A. Aware, yes.
MR. BROOKS: Let me mark as Ladinsky Exhibit 8 the Endocrine Society --
MS. EAGAN: Hold on one second,

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Roger.
A. This is what I take with me when I review this chapter, the line just a few sentence -- at the end of that long paragraph on the right-hand side. Given the complexity -- da, da, da -- "it is not recommended this surgery be considered in youth under 18 at this time."
Q. (BY MR. BROOKS) And then it says, "see Chapter 13-Surgery and Postoperative Care," correct?
A. Correct.
Q. And earlier I directed your attention to language in Chapter 13, correct, where we discussed the recommendation to surgeons. Do you recall that language?
A. I do.
Q. All right.
MR. BROOKS: Let me mark as Ladinsky Exhibit 8, the Endocrine Society Guidelines 2017 edition. This is in your binder behind Tab 37.

(Whereupon, Ladinsky Exhibit 8 was marked and copy of same is attached hereto.)

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Q. (BY MR. BROOKS) Let me call your attention -- and I should ask: Is this a document that you consider yourself to be well familiar with?
A. I'm familiar with it, yes.
Q. And have you consulted it with some regularity in your practice since it issued in 2017?
A. We're aware of it, yes.
Q. Is it a document that you rely on as an important source of standards in your profession?
A. It's an important document, yes.
Q. Let me ask you to turn to 3894. I see you checking the section heading, which is appropriate. 2 inches from the bottom of the first column of 3894, it reads, quote, "Because some transgender male adolescents present after significant breast development has occurred, they may also consider mastectomy two years after they begin androgen therapy and before age 18 years."

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Closed quote. Do you see that?
A. I do see that.
Q. And in fact many of the natal females who present at your clinic have already experienced significant breast development; am I correct?
A. That's correct.
Q. And therefore according to the Endocrine Society Guidelines, they would be candidates for mastectomy before the age of 18?
A. The endocrine -- the guidelines suggest that, yes, it may be considered for that narrow population.
Q. Dr. Ladinsky, you actually described that in your other testimony not as a narrow population but as the primary population presenting at your clinic; am I correct?
MS. EAGAN: Object to the form.
A. By narrow, sir, I meant the small group of older teens assigned female at birth.
Q. (BY MR. BROOKS) Let's be clear. Most girls by age 14 have some significant breast development, correct?

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A. That's fair.
Q. And I believe you've testified that the majority of girls consenting at your clinic are 14 or older when you first see them?
A. That's true.
Q. And therefore it follows that majority of girls who present at your clinic, according to the Endocrine Society Guidelines, are candidates for mastectomy before age 18, correct?
A. If you read it as such.
Q. Do you read it differently?
A. It simply says may be considered. The clinician should individualize treatment based on the physical and mental health status of the individual. It's a guideline. Yeah.
Q. Are you aware of any guidelines that you consider to be respected in your field that do not approve mastectomies for natal females younger than 18?
A. I am not.
Q. And yet in your clinic, you do not perform or refer natal females for mastectomies younger than 18, correct?

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A. Correct.
Q. Is that because you disagree with the medical views expressed by WPATH and the Endocrine Society?
A. No, sir, does not.
Q. Do you think it is appropriate or inappropriate to perform mastectomies on minors?
A. Are you asking for my opinion?
Q. Yes. You're an expert offering opinion evidence.
A. I think the guidelines read very accurately and very fairly in that there is a small group of older teens assigned female at birth who manifest severe chest related dysphoria. And for those teens, I agree with the guidelines that it could be considered.
Q. But you don't consider it in your clinic and you never have?
A. Consider is a relative term. Is it discussed? At times when patients bring that up. The procedure itself has not been assessable in the state of Alabama and is now illegal.
Q. To your knowledge, clinics in

Page 71

multiple states are in fact performing irreversible mastectomies on natal females under the age of 18 in numerous cases each year, correct?
MS. EAGAN: Object to the form.
A. I could not comment on the numerous part of it. I don't know how many are being performed in centers around the country, but I am aware that that does occur.
Q. (BY MR. BROOKS) Well, based on your reading the literature and your conversation with colleagues, you are aware, are you not, that mastectomies are being performed on hundreds of girls around the country each year as a treatment for gender dysphoria?
MS. EAGAN: Object to the form.
A. Again, I could not comment on numbers, sir.
Q. (BY MR. BROOKS) You have no knowledge?
A. I don't have knowledge of numbers. I'm aware it happens.
Q. If the Endocrine Society and WPATH

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recommend that mastectomies be considered as a treatment for natal females who are minors, do you think it's medically reasonable for your clinic to never approve such procedures among your several hundred patients?
MS. EAGAN: Object to the form.
A. I mean, the guidelines speak to a very, very small group of exception, older trans masculine teenagers. Now to your question, it's never been part and parcel of the surgical work performed at my hospital, and my hospital is the only tertiary referral hospital in the state of Alabama.
Q. Have you ever referred a natal female for chest surgery to a medical center outside of Alabama?
A. Tell me what you mean by refer.
Q. Well, let me ask you if that is a term that has a technical meaning to you as a doctor?
A. It does.
Q. What does it mean to you?
A. As a primary care doctor, it means

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we are identifying and securing for the patient the source of care, and then we're discussing with the accepting physician, providing records and such, et cetera. So that is -- no, it has not been part of our practice to do so in that way.
Q. You have not done that?
A. I have not, sir, no.
Q. Okay. Let me ask you to find your transcript from the preliminary injunction hearing, which is 12. It's in the binder. Tab 12, your transcript.
MS. EAGAN: Did you say a page?
MR. BROOKS: I didn't yet.
Q. I'm going to direct your attention to Page 122.
A. I don't have 122.
MS. EAGAN: Here.
Q. (BY MR. BROOKS) I'll regularly refer only to the little page numbers. If you look at Line 22.
A. Okay.
Q. You were asked, "Did you review any studies or literature reviews or other research in

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putting together the declaration?" Referring to your PI declaration. And you respond, "We're continually doing that. It's part of our job." Do you see that testimony?

A. I do see that.

Q. Can you describe for me the steps you take to make sure that you are continually reviewing and current with the literature in your field?

A. Sure. The steps we take are this: We're always reviewing and re-reviewing guidelines. So, for example, the WPATH SOC 8, which are fairly new, so there's review of those as it pertains to patients we care for. There's continually reading published studies in this area. As well as national meetings and conferences where we're discussing with colleagues.

Q. And the guidelines -- so, for instance, the WPATH SOC 7 came out in 2012, correct?

A. Correct.

Q. So it was 11 years between Version 7

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and Version 8; am I correct?

A. Roughly. A decade apart.

Q. So the guidelines wouldn't necessary make you aware of the latest research in your field, would they?

A. Not necessarily because findings or studies may be published subsequent to it.

Q. And the Endocrine Society Guidelines, the current version, was published in 2017, correct?

A. Correct.

Q. How do you go about making sure that you are identifying and reading important new research papers in your field?

A. Those of us that do this work are united on multiple different lists. As colleagues, we're always elevating for each other anything new that may have come out. So we work as a team throughout the nation.

Q. Let me ask you to find your CV, which is Exhibit 1. Let me ask you to turn to Page 8.

A. Okay.

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Q. And there you listed major research interests. Do you see that?

A. Yes, sir.

Q. Nothing relating to the effects of puberty blocker or hormones on the body or brain of children or adolescents is one of your major research interests, correct?

A. That's correct.

Q. And nothing relating to the long-term physical and mental health outcomes of children or adolescents who are subjected to puberty blockers or cross-sex hormones are among your research interest, correct?

A. Very interested in them, but I'm not doing that research myself.

Q. If you turn to Page 11, again it's a list of manuscripts. And just to avoid any confusion, by manuscripts, do you mean papers submitted to peer-reviewed journals?

A. Papers published in peer-reviewed journals.

Q. You don't have any peer-reviewed paper that relate to any issue of transgender

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medicine, diagnosis, therapy, or outcomes, do you?

A. That's correct. I'm not a researcher. I'm a clinician.

Q. Let me ask you to look again at your transcript, Tab 12, and turn with me to Page 121 if you would. And at 121 beginning at Line 9, you testified, quote, "An experimental treatment will be a drug or a medical intervention that is part of a very, very tightly controlled clinical trial, a trial that has been granted, you know, granted a yes or no, granted the ability to do so by an institutional review board which strictly upholds the ethical rights of human subjects." Closed quote. Have I read that more or less correctly?

A. You have.

Q. Are you familiar with the term "case study"?

A. I am.

Q. And do you consider a case study to report on, in some cases, to report on an experimental treatment?

A. Not generally.

Q. Based on your definition of

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experimental treatment as given in your preliminary injunction testimony, am I correct that you yourself in the course of your work at the UAB Pediatric Clinic have never engaged in any experimental treatments?

A. As defined in this way, that's fair.

Q. And you have never in fact undertaken any experimental work in the field of pediatric treatment of gender dysphoria?

A. Personally, no.

Q. Have any of your colleagues, to your knowledge, at UAB participated in any experimental work relating to treatment of minors for gender dysphoria?

A. I'm not aware of that.

Q. You would agree, would you not, that before full clinical trials are undertaken that clinicians may in some cases try novel drugs or therapies on individual patients separate and apart from a tightly controlled clinical trial?

MS. EAGAN: Object to the form.

A. I'm not sure what you mean.

Q. (BY MR. BROOKS) In some cases,

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drugs that have not been subjected to a formal clinical trial are nevertheless prescribed to patients on an experimental basis, would you agree?

A. I'm not sure I use the word "experimental" in the same way, though. That's where I'm getting stuck.

Q. Well, if it hasn't -- if a drug has not been proven to be efficacious or it has not been proven to be safe, wouldn't you agree that its use on a human subject is experimental?

MS. EAGAN: Object to the form.

A. I don't know that we use the -- we don't use the word "experimental" in that way.

Q. (BY MR. BROOKS) That would be more pre-experimental?

A. No. I've not heard that term either.

Q. Well, when a drug is used in a context for which the type of formal experiment you described in your testimony has not yet been done, we don't have that information. We don't have the results of that type of carefully

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controlled clinical trial. How would you describe -- what terms would you use to describe that usage of the thus far untested pharmaceutical?

A. Well, it's not part and parcel of my regular practice, but I would assume that a medical provider engaging in what you describe would first and foremost explain to the patient and family in a detailed way what is known, what may not be known, and what they hope to achieve and how they will monitor for it.

Q. Well, my question for you is: What term would you use for the use of a drug for an indication or in a population for which it has not yet been tested and proven efficacious through the type of very, very careful clinical trial that you described in your testimony?

A. I think clinicians have a variety of terms if they're engaging in this that they would use. It's not part of my regular practice.

Q. What do you consider to be terms that clinicians would use for that type of use prior to proof of efficacy through a carefully

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controlled clinical trial?

A. I think the word that would come to mind would be novel.

Q. Do you know whether any of your colleagues at UAB are currently enrolling minors in any experimental research relating to treatment of gender dysphoria?

A. I'm not aware. That doesn't mean it's not happening in other divisions.

Q. Let me ask you to find your expert report, which is 5. Let me ask to you turn to Page 21. At the top of Page 21, you write in your expert report, quote, "In addition to my patients with intersex traits, I regularly manage non-transgender patients receiving the same hormones that are provided to transgender patients." Closed quote.

Given that you're not an endocrinologist, can you describe to me your professional responsibilities at UAB associated with non-transgender patients and the administration of hormones?

A. I'm a primary care pediatrician, and

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I see patients as well as teach in our pediatric primary care clinic. So we have adolescents who may have indications for hormonal therapy for reasons that -- for indications that don't involve gender dysphoria. Patients in that top paragraph, hypogonadotropic hypogonadism, the endocrinologist may have those patients on hormonal therapy. As a primary care physician, I am sort of -- I'm their, you know, I have a deep understanding of the medication and am helping endocrinology monitor for, you know, for that.

Q. You yourself have never prescribed hormones for any non-transgender patient; am I correct?

A. What do you mean by -- like right here, hormonal birth control?

Q. Well, let me be more specific.

A. Okay.

Q. You yourself have never prescribed testosterone suppression for any non-transgender patient, correct?

A. I have not.

Q. And you yourself have not prescribed

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estrogen for non-transgender girls for the type of use that you describe in the middle of that paragraph?

A. For which use, the hypothalamic, pituitary issues?

Q. I'm glad you said that. You say, and I'll quote, "For example, non-transgender girls with hypogonadotropic hypogonadism (delayed puberty due to lack of estrogen caused by a problem with the pituitary gland or hypothalamus) may be treated with estrogen to initiate puberty." Closed quote. Have I read that accurately?

A. You have.

Q. And have you yourself ever prescribed estrogen to a non-transgender girl for that purpose?

A. For that indication, I have not. But I do help manage them.

Q. What do you mean by manage?

A. As a primary care physician, we see our patients fairly frequently, and they know how to find us. So I will continue to review potential side effects, potential

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contraindications. I see you're taking estrogen, we're not smoking or vaping, that kind of thing. That's what I mean.

Q. You don't consider yourself a specialist in intersex conditions, do you?

A. I do not.

Q. And, indeed, that is not a topic on which you've ever made any publications, correct?

A. No, sir.

Q. Nor have you ever given a presentation on intersex condition at any professional meeting, am I correct?

A. Not on that as a primary reason, no.

Q. Colleagues do not consult you for your expertise in intersex conditions, correct?

A. No, sir. Not for the medical management of them.

Q. How much of your professional time -- you've mentioned that you have a role as a primary care physician?

A. Correct.

Q. How much of your professional life is occupied with your work with the UAB Gender

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Clinic?

A. Percentage? Fraction? Which would you like me to?

Q. Whatever you're comfortable with.

A. Maybe 25 percent.

Q. And do you receive separately identified compensation from the UAB System in connection with your work with the Gender Clinic?

A. No, sir. I'm salaried.

Q. And within the last five years, have you received any other compensation beyond your UAB salary of any sort related to gender dysphoria or treatment for gender dysphoria?

A. Not for medical management or anything thereof.

Q. Have you received speaker fees for talks given on that topic?

A. I think I once got a $25 honorarium.

Q. Have you received any sort of compensation or reimbursement for any pharmaceutical company relating to treatment for gender dysphoria?

A. No, sir.

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Q. You were named as a plaintiff in a lawsuit in 2022: Ladinsky versus Ivy, correct?
A. Correct.
Q. And did you carefully review the complaint in that action and satisfy yourself that everything in it that fell within your scope of knowledge was true and correct?
A. I believe so.
Q. In that lawsuit, you were not attempting to fill the role of a disinterested and impartial expert, but rather you were a plaintiff personally suing the State of Alabama; am I correct?
A. That's correct.
MR. BROOKS: Let me mark as Ladinsky Exhibit 9 a press release that appears to be dated March 8, 2021. Titled City of Birmingham's LGBTQ plus Advisory Board Issues Statement on HB1/SB10.

(Whereupon, Ladinsky Exhibit 9 was marked and copy of same is attached hereto.)

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Q. (BY MR. BROOKS) Dr. Ladinsky, do you recognize this document?
A. I do.
Q. I see that your name is the first of several signators?
A. Correct.
Q. Are you the primary draftsman of the document?
A. One of them. The first reviewer.
Q. Who was the initial drafter?
A. That's an excellent question. I believe it was one or a combination of my colleagues on the mayor's task force advisory firm.
Q. Who specifically?
MS. EAGAN: If you remember.
A. Yeah, I don't recall.
Q. (BY MR. BROOKS) That's always a fine answer.
MS. EAGAN: It's the truth.
A. It is the truth. That was a few years back.
Q. (BY MR. BROOKS) I understand.

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Towards the bottom of the text, the sentence that reads, quote, "The medicine in question follows a standardized evidence-based gender affirmative model of pediatric care." Do you see that?
A. I do.
Q. Can you explain to me what you understand the term "evidence-based" to mean?
A. Meaning simply consensus bodies of experts in the area have and are continually reviewing the best available evidence in the issue standards of care guidelines for practice and are continually reviewing and revising them.
Q. Do you understand evidence-based to be a term of art?
A. I do not. I've not viewed it that way.
Q. Have you ever received any training in what is referred to formally as evidence-based medicine?
A. I have.
Q. And describe to me the context in which you've received that training.
A. Through not just my medical training

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but more so during my fellowship training. We work with -- we spent a lot of time in the distillation of different studies, validity consistency, how to read the literature and understand science in the most empirical form relative to the issue in question.
Q. Are you aware that there is now a whole field developed of evidence-based medicine?
A. I am aware of that.
Q. And do you believe you have an understanding of how evidence-based medicine is defined within that field?
A. I will -- I have an understanding of it, but I could not give you the exact verbiage of their vision and how they see it.
Q. You continue in the sentence that -- I read a partial sentence into the record, and it continues that this model of pediatric care is, quote, "endorsed by the American Academy of Pediatrics and its 67,000 members nationwide." Closed quote. Do you see that language?
A. I do.
Q. Is it your understanding that the

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AAP membership, which you refer to, was ever given any opportunity to vote on any standard or statement relating to medical care for gender dysphoria in minors?

A. I believe there are processes that involve that.

Q. You believe there was a process that involved an opportunity for the entire membership of the AAP to vote on whether or not to endorse any statement or standard relating to medical care of gender dysphoria in minors?

A. The process does not, you know, does not solicit individual votes from all 67,000 members prior to the issuance of a policy statement or a set of guidelines. However, there are processes that entail the ability for feedback and for local regional, you know, executive leadership in so many domains to bring that input. It's sort of a small democracy basically.

Q. But a democracy in which the 67,000 members that you refer to never get an opportunity to vote, correct?

A. Through their sections councils, et

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cetera. They don't, you know, take a vote on every single policy statement, but they are given time to elevate input and questions, absolutely.

Q. You stated in the previous paragraph that, quote, "The bill further demands that school personnel out students who are trans or gender-diverse to their parents or guardians." Closed quote. Do you see that?

A. I do see that.

Q. And am I to understand that you support policies under which a child's adult authority figures at school may actively participate in a social transition of a child without first obtaining parental consent?

MS. EAGAN: Object to the form.

A. Tell me what you mean by participate in a transition.

Q. (BY MR. BROOKS) Sure. Addressing a child with a transgender name or cross-sex pronoun, for example.

A. Okay. Now tell me your question relative to that.

Q. Should I take it from the statement

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in this press release from 2021 that you support policies under which a child's adult authority figures at school may actively participate in the social transition of a child without first informing the child's parents and obtaining parental consent?

MS. EAGAN: Object to the form.

A. I'm not sure I can answer it in the way that you've asked it. I think the sentence gets to the heart of what could be a safety issue for some students in Alabama.

Q. (BY MR. BROOKS) Dr. Ladinsky, do you or do you not believe that schools in Alabama should be permitted to actively participate in the transition of children without the consent of their parents?

A. I'm confused by this actively participate in the transition --

Q. I explained what I meant by that because you asked me for an explanation.

A. Because I don't see that -- I don't see that the same as simply affirming a child or an adolescent in the school setting in the name or

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identity they've asked to be identified with.

Q. Then let me make my question more precise.

A. Okay.

Q. Do you or do you not believe that schools in Alabama should have policies that allow the child's adult authority figures at school to participate in the social transition of a child by addressing the child with a cross-sex name or pronouns without first obtaining parental consent?

A. I believe that lies within the purview of educators in that school, period. They know what's best for their youth.

Q. Your testimony here today is that it's your professional opinion that the educators in this field of gender dysphoria know what's best for youth more than the parents?

MS. EAGAN: Object to the form.

A. No, sir.

MS. EAGAN: Misstates her testimony.

A. No, that is not my testimony at all.

Q. (BY MR. BROOKS) Then explain better what you just tried to tell me.

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A. What I meant to say is that it is purview of the schools, the district, the school setting to set policy relative to how educators address and possibly affirm students.

MR. BROOKS: I'd like to mark as Ladinsky Exhibit 10 an excerpted chapter from a book entitled "Users' Guide to the Medical Literature, Essentials of Evidence-Based Clinical Practice" by Gordon Guyatt and others, Third Edition.

(Whereupon, Ladinsky Exhibit 10 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) Dr. Ladinsky, let me first ask whether you're at all familiar with the name and reputation of Dr. Gordon Guyatt?

A. I'm not.

Q. And let me ask whether you have ever seen this book in any edition: Essentials of Evidence-Based Clinical Practice?

A. I have not.

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Q. Have you ever attended -- taken a course or attended a seminar in principles of formal evidence-based clinical practice?

A. I have not.

Q. Let me ask you to turn to Page 15. And there Figure 2.3 or 2 dash 3 is headed Hierarchy of Evidence. And let me ask whether you believe you have any familiarity with the concept of a hierarchy of evidence as a characteristic of evidence-based medicine?

A. I'm familiar with that.

Q. And when you look at Figure 2-3, are these categories of evidence that you believe you understand?

A. Yes.

Q. What do you understand the observational study to be?

A. When a researcher identifies a sort of new population of patients or patients with a specific entity or characteristic and also metrics that would underlie patient important outcomes. They follow that group for a period of time.

Q. And what do you understand to be the

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difference between an observational study and a multi-patient randomized trial?

A. Both would be to an extent prospective, meaning they start at time zero and study population going forward. However, the second one, the randomized trial assumes what they call equipoise, meaning that if you're looking at the -- wondering about outcomes relative to this population, we really do not know that an intervention or that an outcome can be modified by something. We want to find out. And so you would randomly select, and there are procedures for that. In a randomized trial, two different groups of patients, following them forward.

Q. Are you able to explain why a multi-patient randomized trial ranks higher in the hierarchy of quality of evidence than an observational study?

A. Because when you have two different groups whose characteristics are tightly controlled from the beginning, it's easier to factor out what we call preponderance or extraneous factors impacting your metrics, what

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you want to learn about at the end.

Q. Let me ask -- were you finished?

A. Yes, sir.

Q. Let me ask you to turn to -- it's a long preface. If you would turn to Page 27 in the preface.

A. Here's 27.

Q. We're going to -- so if you look earlier in the preface, you will find Roman numerals pagination rather than arabic. And I said 27, but I meant 26.

A. Okay. I'm confused. We're going back to Roman numeral areas?

Q. Yes, we are.

A. Okay. So that's going to be closer to the beginning.

Q. It is. Page 26. And there's a paragraph I want you to read that begins, "Awareness of the importance of the pre-appraised evidence and evidence-based recommendations." And then it says, quote, "We have added a fundamental principle to the hierarchy of evidence and the necessity for value and preference judgments: that

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optimal clinical decision-making requires systematic summaries of the best available evidence."

A. Okay.

Q. Are you familiar with the concept of systematic review of medical evidence in your field?

A. I am. Not in a, you know, deep dive detailed researcher way, but yes.

Q. Have you ever participated in performing a systematic review?

A. No, I have not.

Q. Have you ever had occasion to carefully study a systematic review done by some outfit or group of analysts?

A. I've certainly read them.

Q. Are you able to tell me as you sit here today any specific systematic reviews relating to literature relevant to your field that you have consulted?

A. Explicitly, not -- I mean, the guideline documents themselves include systematic reviews, and there are papers and a number of

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papers on literature relative to the topic at hand that include this as part of what they're discussing.

Q. Is your understanding that the Endocrine Society Guidelines themselves include or -- include a systematic review?

A. I believe that's incorporated into it.

Q. Have you ever consulted the systematic review that you believe those guidelines made use of?

A. I've not explicitly reviewed every single one.

Q. Have you explicitly reviewed a single systematic review relied on by the Endocrine Society 2017 Guidelines?

A. I would have to go back and look at the guidelines to see which ones they referenced and cross it with which ones I read.

Q. And do you know, as you sit here today, whether in comparing WPATH SOC 8, WPATH, or anybody associated with WPATH performed any systematic guideline of any systematic review of

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literature on any topic?

A. I do not explicitly know the answer to that question.

Q. A little father down in the paragraph that begins, "This principle has led," is a reference to GRADE, G-R-A-D-E, Grading of Recommendations Assessment, Development, and Evaluation. At which it refers to as providing, quote, "an assessment of the confidence that one can place in the estimates of effect emerging from the review and meta-analysis."

Are you familiar with the GRADE system of evaluating the strength of evidence?

A. I'm familiar with it, yes.

Q. And have you ever received any training in how to apply the GRADE system to evaluate the strength of particular published evidence?

A. Not formally but it is part and parcel of the work that we do as clinicians and especially as educators in academic centers.

Q. Have you yourself ever attempted to apply the criteria specified by the GRADE system

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to arrive at a conclusion about the reliability of a particular experimental result reported in the literature?

A. I take it into account as I read each recommendation, yes.

Q. You believe that you are on an ongoing basis familiar with the criteria specified in the GRADE system for evaluating strength of evidence?

A. I'm familiar with it. It's generally reviewed to in studies.

Q. On Page 15 of this document, which I had you look at Figure 2-3 on previously. Page 15.

A. Okay.

Q. It reads toward the bottom of the page, quote, EBM, evidence-based medicine, places the unsystematic observations of individual clinicians lowest on the hierarchy. Closed quote. Do you see that language?

A. I do.

Q. Is it consistent with your professional understanding that the unsystematic

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observations of an individual clinician such as yourself is the least reliable form of evidence?
MS. EAGAN: Object to the form.
A. I would infer they are referring to a published case report or case collection in the literature, not my own personal commentary or observation.
Q. (BY MR. BROOKS) Is it your opinion that your own personal unpublished observation is a more reliable source of evidence than published observations of clinicians?
MS. EAGAN: Object to the form.
A. I don't think that plays into what is being discussed in this document. This is about medical literature and a hierarchy of study design.
Q. (BY MR. BROOKS) And in the hierarchy of evidence in Figure 2-3, clinical experience is the lowest least reliable form of evidence; am I correct?
A. In the setting in which they describe study design and type, that is what they've got here.

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Q. And is it consistent with your understanding as a scientist that clinical experience is the least -- provides the least reliable evidence when it comes to potential treatments and outcomes?
MS. EAGAN: Object to the form.
A. I don't think the clinical experience of one clinician plays into what they're evaluating here. How to understand evidence is presented in a formal published study or a prospective trial.
Q. (BY MR. BROOKS) And why is it that you don't believe that the clinical experience of an individual clinician such as yourself fits into the hierarchy of evidence specified by evidence-based medicine and principles?
A. Because I think -- it's my impression in this context, having not read the document, but in this context, that they refer to clinical experience -- right here, "either your own or that of a colleague." As a reference point to understand evidence there all the way up to what you refer to as a randomized trial.

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Q. In fact, it's your understanding, is it not, that opinions and clinical decisions simply based on a clinician's experience is exactly the problem that evidence-based medicine was developed to solve?
A. I do not know the answer.
Q. In the seven or now eight years since UAB Pediatric Gender Clinic was founded, your clinic has never published -- no one associated with your clinic has published any systematic observational studies of the outcomes in children as a function of the selection or timing of treatment options, correct?
A. That's correct.
Q. And you don't cite anywhere in your report any quantitative data from your own clinic or your own years of experience practicing in this field, correct?
A. Correct.
Q. You don't cite anywhere in your report any systematic review of literature relating to your field, do you?
A. I'd have to look back to see. I

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know that there are references in some.
Q. You know that there are references to systematic reviews in your expert report?
A. I would have to look back at the many, many that -- the studies that I referenced there.
Q. Did you make an effort to identify relevant systematic reviews of evidence relevant to your field in the course of preparing your expert report?
A. I believe so.
Q. You would agree, would you not, that the seminal and most cited research relating to the treatment of gender dysphoria in minors came out of the Netherlands and Vrije University research team in particular?
A. The earliest ones leaned on the foundation for care provided, yes.
Q. And prominent researchers and clinicians associated with that clinic include Dr. Cohen-Kettenis, Dr. de Vries, Dr. Steensma, Dr. van Goran, correct?
A. I know those names, yes.

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Q. Over the years you've read many papers published by researchers associated with the Vrije University clinic, have you not?
A. Several.
Q. Is it consistent with your understanding that that university team is the most respected source of research in your field in the world?
A. I think that's a subjective question.
Q. It is, and I asked your opinion.
A. I never -- I mean, are they highly respected, absolutely. Are they highly experienced, absolutely.
Q. And important publications are still being put out by the Vrije University research team up to the present, correct?
A. Correct.
Q. And they're published in English to your knowledge, right?
A. Those that I've read certainly are.
Q. Have you met any of these four doctors that I just mentioned at conferences or

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any professional context?
A. I have not.
Q. As part of the continual work that you mention to stay current in research relating to the treatment of gender dysphoria in minors, you attempt to stay abreast of publications from the Vrije University research team, do you not?
A. I do my best.
Q. It's not your opinion that peer-reviewed research coming out of Europe is somehow less relevant to you as an American doctor, is it?
A. Tell me what you mean by less relevant. Do you mean unimportant or not relevant to what I do?
Q. Is it your opinion that peer-reviewed research coming out of Europe is somehow less relevant to your clinical decision-making than research coming from American researchers?
A. It would depend on the topic being evaluated. If they're looking purely at systems of care, possibly. But if they're looking at

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valid results of certain elements of care, possibly. Of course we're going to take that into strong consideration.
Q. In fact, it continues to be the case that much of the important research relevant to your practice as a clinician comes from European authors, is it not?
A. I can't agree with that statement.
Q. No. Is it your opinion that the bodies of children in Europe respond differently to puberty blockers or cross-sex hormones than the bodies of children in America?
A. I can't imagine that being a truthful statement.
Q. And likewise, it's not your opinion that the minds of children in Europe would respond differently to puberty blockers or cross-sex hormones than the minds of children in America?
A. It's a pretty absolute statement with subjectivity. It's confusing. They're different environments.
Q. Well, is it your opinion that the minds of children in Europe respond differently to

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puberty blockers or cross-sex hormones than the minds of children in America?
A. I have not seen evidence to that.
Q. Of any such difference?
A. Correct.
Q. You would agree, would you not, that any responsible clinician needs to stay current on the latest research results and systematic analysis from North America, Europe, and the UK?
MS. EAGAN: Object to the form.
A. I agree they should -- all of us do our best to stay current with relevant research. We also do so with an eye to the various factors that impact the patients including the study.
Q. (BY MR. BROOKS) Are you aware of the Karolinska Institute in Sweden as a respected source of research in your field?
A. I've heard of such.
Q. Are you familiar with a Dr. -- I'm not going to say her name correctly -- D-h-e-j-n-e, Dhejne as a researcher whose literature you have seen?
A. I've seen that name.

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Q. Are you aware that another author with a substantial number of peer-reviewed papers relating to treatment of gender dysphoria in children is Professor Michael Biggs of Oxford University?
A. I'm not aware of that name, no.
Q. Let me take you to the Endocrine Society Guidelines which are tab 37 in your binder and Exhibit 8 and ask you to turn to Page 3872. Do you have 3872?
A. I do.
Q. Column 2. Down below the heading Method of Development.
A. Okay.
Q. It states five lines down, the task -- quote, "The task force followed the approach recommended by the Grading of Recommendation, Assessments, Development, and Evaluation group." GRADE. And it says a little farther down, "The task force used the best available research evidence to develop the recommendations." Do you see that?
A. Correct.

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Q. Do you know whether the Endocrine Society either -- whether the authors, I should say, of these guidelines, either performed or commissioned any systematic review of available science in connection with preparing the guidelines?
A. I would hope so.
Q. Do you know whether they did?
A. In the way that you're defining it, I don't. Right here it talks about it, though. "The task force commissioned two systematic reviews to support this guideline."
Q. Do you know what the subject of those two systematic reviews was? And I don't -- I'm not -- I don't want to trick you. There is a description --
A. It's right here.
Q. -- 3873 if you look in Column 1.
A. Right.
MS. EAGAN: Take the time to read that. If he's going to ask you questions about this commissioned systematic review, take your time if you need to and read through it, Dr.

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Ladinsky.
THE WITNESS: I will.
A. Just this section, sir, commissioned systematic review?
Q. (BY MR. BROOKS) I understand that to be the paragraph that you just read to be a description of the two systematic reviews that are referred to.
A. Well, right here --
MS. EAGAN: I'm not sure there is a question, though, on the table.
Q. (BY MR. BROOKS) And let me -- before calling your attention to this paragraph, did you have any recollection as to what the Endocrine Society had sought systematic reviews of?
A. It was my impression there were several different entities within this field.
Q. And what this paragraph tells us is that there was, quote, first review that focused on the effect, quote, the effect of steroid use in transgender individuals on the cardiovascular outcomes, correct?

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A. That's what it says.
Q. And at the top of the next column, it says that, "The second review summarized the available evidence regarding the effect of sex steroids on bone health in transgender individuals."
Do you have an understanding of how lipids and cardiovascular outcomes are potentially relevant to your field?
A. I do as in long-term risk factors, but I would be curious as to -- I would want to know the populations involved here. Were these adults?
Q. Do you have an understanding of what relevance bone health has to your field?
A. Of course.
Q. And what is that relevance?
A. That relevance is the laying down and then retaining supporting of bone mineral density, the strength of the cortical bone.
Q. And why is that an issue of potential concern in connection with treatment of transgender individuals?

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A. Any time you're discussing a hormonal impact relative to adolescents, bone density may be involved.
Q. Because bone density develops in the course of adolescence?
A. Because it develops more rapidly during certain periods of adolescence.
Q. Did you ever attempt to locate and study the two systematic reviews that the Endocrine Society says they relied on in preparing these guidelines from 2017?
MS. EAGAN: Just to be clear, you're talking about has she gone back and looked at more detail at the two that are mentioned in this section, Commissioned Systematic Review on Page 3873; that's what you're asking?
MR. BROOKS: That's exactly what I mean.
Q. Have you attempted to locate -- determine whether those are published and locate them and review them?
A. Well, I may have reviewed them. I have not intentionally done that relative to this

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paragraph in the last couple of weeks.
Q. Do you know whether you've ever read the systematic reviews referred to in this paragraph?
A. If I saw the reference or the exact paper, I might.
Q. But the Endocrine Society didn't give us a reference, so my question stands: Do you know whether you have ever read the systematic reviews referred to by the Endocrine Society in this paragraph?
A. Given only this paragraph to look at, I do not. But I've reviewed many, so.
Q. Are you familiar with an organization called the Cochrane Library?
A. I'm familiar with it.
Q. And are you aware of its reputation as a respected source of systematic reviews of medical evidence?
A. Cochrane reviews have been around for a long time, and they're a respected organization.
MR. BROOKS: Let me mark Ladinsky

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Exhibit 11 a document with the Cochrane Library logo on it titled "Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women (Review)." The first author being Haupt.

(Whereupon, Ladinsky Exhibit 11 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) My first question will be, Dr. Ladinsky, whether you think you've ever seen this document before today?
A. I don't believe I've seen or reviewed this particular document.
Q. Is it consistent with your understanding that antiandrogen or estradiol are hormone therapies used in treatment of natal males who desire to pursue a feminine gender identity?
A. I am.
Q. And, indeed, those are cross-sex hormones in that application that your clinic sometimes prescribes; am I right?

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A. That's correct.
Q. Does it surprise you that you have not previously seen this 2020 systematic review of cross-sex hormones prescribed in your clinic that was issued by a respected source of medical systematic reviews?
MS. EAGAN: Object to the form in your phrase couch -- excuse me. How you've couched this document. She said she's never reviewed this document. If you're going to ask her questions about the document and what it is, I would ask that we would be able to take a break so she can review it and she have time to familiarize herself with the document.
MR. BROOKS: Well, I'm not yet and I may not ask questions about the detailed contents.
Q. But given your early testimony about the reputation of the Cochrane Library and your testimony that part of your job is to stay current in the literature, let me ask a slightly different question.
Isn't a systematic review from the Cochrane Library of the use of antiandrogen or

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estradiol treatments in transitioning in transgender women a source of information that you would want to be aware of in the course of your professional duties?

MS. EAGAN: Object to the form.

A. Only if it were relevant and timely. Relevant with regard to the group of patients that I study and work with, not that I work with.

Q. (BY MR. BROOKS) Well, you've testified that these are cross-sex hormones that you use on minors, correct?

A. That's correct.

Q. And this study down in the left-hand corner of the first page shows a date of 2020, correct?

A. It does. But if we look at when the records that they analyzed were obtained was that well before 2020 in addition --

MS. EAGAN: I think it's best if you're going to ask her questions about the document, whether it's something she would be -- important to her, it's only fair to give her time the read the document. We can take a break for

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that or -- but I don't want her to answer questions without knowing what this document is.

MR. BROOKS: We won't take a break, and I'm not asking questions about the substance of the document.

Q. It's your understanding, Dr. Ladinsky, is it not, that a continued thorough systematic review is going to consider papers across the span of time up until the systematic review is performed?

MS. EAGAN: Object to the form.

A. Researched studies up to 19 December 2019.

Q. (BY MR. BROOKS) I didn't ask you a question about this document.

MR. BROOKS: Would you read the question?

MS. EAGAN: He's asking you about just in general. Listen to his question.

MR. BROOKS: Let me ask you to read the question back.

(Whereupon, a portion of the testimony was read by the court reporter.)

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A. I mean, to my recollection, Cochrane reviews focus more on type of studies that have been reviewed and analyzed, less of content.

Q. (BY MR. BROOKS) It's your understanding that Cochrane reviews, Cochrane systematic reviews are not applying GRADE criteria to evaluate the strength of evidence in medical fields?

A. I know they weight strength of evidence relative to study designs systematically. I'm not aware if they use the exact GRADE system or not.

Q. Are you familiar with antiandrogen that is referred to commonly as CTA? I'm not asking you a question about the document.

A. I'm not.

Q. All right. Would you agree that before prescribing antiandrogens or estradiol as a therapy for gender dysphoria, it would be important to have reliable information as to

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results including outcomes of feminization, sexual function, and reduction of gender dysphoria?

A. Best available evidence, sure.

Q. Well, before prescribing body-altering hormones, is it not your opinion that you would want to have reliable evidence on those topics?

A. I believe so.

Q. It's information that you want to the maximum extent it's available, correct?

A. Correct.

Q. Are you able to point to any randomized control study or what you consider to be a methodologically statistically reliable cohort study that, in your opinion, sufficiently establishes the efficacy and safety of hormonal treatments for males transitioning to female gender identities?

A. I think there are a compilation of studies that were taken together analyzed by consensus opinion as you see done in WPATH in the Endocrine Society's guidelines. There is, you know, solid evidence on that.

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Q. What do you consider to be the most statistically reliable cohort study relevant to establishing the efficacy and safety of hormonal treatments for male transitioning to female gender identities?

MS. EAGAN: You're asking here to identify one specific study?

MR. BROOKS: I am.

MS. EAGAN: Object to the form unless -- I mean --

MR. BROOKS: Counsel, I have been relaxed about it, but you're supposed to say objection and stick with that.

MS. EAGAN: Not in Alabama. You object to the form.

MR. BROOKS: Exactly. You object to the form, but I'm hearing a lot more than that.

MS. EAGAN: I don't think I said anything more than that. But, I mean, she can answer if she has an opinion on what particular study. I will say, you know, when you look at her expert disclosure, you really are going in areas that are not really what we are tendering her

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specifically for as an expert. If she has an opinion, she's welcome to talk about it. But when it comes to all these studies and all that --

MR. BROOKS: Counsel --

MS. EAGAN: -- our other experts will talk about that.

MR. BROOKS: Counsel, lectures, no. And she's offered views on safety and efficacy. And I'm asking questions about the foundation, and I am utterly within the zone.

MS. EAGAN: I'm allowing you to ask your question. I just want to make clear that there will be another expert that will address some of these studies and data in more detail than she as a clinician. But if she has an opinion, she certainly is welcome to offer that.

Q. (BY MR. BROOKS) Dr. Ladinsky, you offered opinions in courts previously that hormonal treatments were safe and efficacious. And my question for you is: What specific studies -- study or studies do you consider to provide the most statistically reliable evidence of the efficacy and safety of hormonal treatments

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for males transitioning to a female gender identity?

A. I think the body of studies coming out in the last two years, preliminary data from study in the Journal of Medicine. But it's a compilation of such tendered with expert scientific consensus and oversight that gives us as clinicians on the ground the information to not just treat our patients and see -- but what -- in addition, what to always be sure we're discussing with patients.

Q. Is it the case that as a clinician you primarily rely on what you refer to as consensus opinion as reflected in the WPATH and Endocrine Society Guidelines rather than attempting to form your own opinion based on the peer-reviewed literature as to what is or is not safe and efficacious?

A. We utilize all of it together in the context of cost, benefit for each patient in front of us.

Q. Correct. Then let's go back to the literature. You mentioned Chen's recent paper.

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Is there any other paper that you want to identify as providing what, in your opinion, is reliable evidence of the safety and efficacy of cross-sex hormonal treatments for males seeking to transition to a female gender identity?

A. Not at this time when it comes to specific details of specific studies.

Q. You testified preliminary injunction hearing that you were -- you were asked. I'll refer you to Page 125 of that testimony. It is 12.

You were asked about a statement from Sweden's National Board of Health. And what I want to ask you now is: What you said was, "I'm not imminently apprised of that." I'm going to ask you a little bit more about Sweden.

At the time of that testimony, were you aware of the policy statement put out by Sweden in February of 2022?

A. I was not.

Q. So the question on the stand was the first you had heard of that?

A. I believe so.

Q. Have you since then gone and reviewed at least the official English language summary put out by the Swedish health authority?
A. Not in immense detail.
Q. Have you read it?
A. I'm not sure we're referring to the same document. If you have the document, I'll be happy to look at it and tell you if I've seen it before.
MR. BROOKS: Let me mark this Ladinsky Exhibit 12 the document "Care of children and adolescents with gender dysphoria. Summary."

(Whereupon, Ladinsky Exhibit 12 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) My question at this point is simply whether you believe you've read this document before today?
A. I've skimmed it.
Q. How did you obtain it?
A. It's on the Internet. If it's the

same document.
Q. Have you made any efforts to obtain documents related to the systematic review of the literature relating to treatment of gender dysphoria in minors that was commissioned by the Swedish health authority?
A. No, I have not. I've simply skimmed what they have in the public domain.
MR. BROOKS: I want to mark as Ladinsky Exhibit 13 what is titled "Appendix 3. Characteristics of included studies: Extracted data." Dated 2022.

(Whereupon, Ladinsky Exhibit 13 was marked and copy of same is attached hereto.)

MR. BROOKS: I want to mark as Ladinsky Exhibit 14 a document titled "Appendix 2 Studies excluded due to high risk of bias." Also dated 2022.

(Whereupon, Ladinsky Exhibit 14 was

marked and copy of same is attached hereto.)

Q. (BY MS. EAGAN) Dr. Ladinsky, these documents are in the public domain and with modest exceptions are in English. Are these documents that you've obtained and reviewed before today?
A. Certainly not exhaustively. I do believe I've skimmed some of them.
Q. Exhibit 14 is the excluded studies taken.
A. Okay.
Q. Is this a document that you've reviewed before today?
A. No, sir.
Q. So you don't have any -- they're described as "excluded due to high risk of bias." Do you see that language?
A. I see that.
Q. Do you have an understanding of a formal or technical meaning of bias relevant to medical research literature?
A. I believe that these are studies

whose methodology is quite dissimilar from a randomized double-blind placebo-controlled study.
Q. Do you have an understanding of the technical meaning of bias when it comes to discussion of the results of research studies?
A. To a superficial extent.
Q. What is that extent?
A. Simply that there can be confounders. There can be elements influencing the results that may not have been controlled for in the same way they could have in an RCT, randomized controlled trial. It does not mean the results are insignificant or should be adopted or not adopted. It simply refers to study methodology and the ability to eliminate confounders.
Q. And aspects of methodology that create a high risk of bias, am I correct, can result in the results being unreliable or I should say unpredictive of results that would be obtained in other patients?
A. I don't agree with that. As a clinician I see that term as perhaps the study

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findings are less generalizable.
Q. Do you believe that you have previously reviewed the document that I've marked as Ladinsky Exhibit 13 which is a list of included studies?
A. I do not. I've not seen this. It's just extracted --
MS. EAGAN: I think the question was: Have you seen or recall seeing DX 13?
A. No.
MR. BROOKS: Let me mark as Ladinsky Exhibit 15 a document entitled "Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria." Dated October 2020.

(Whereupon, Ladinsky Exhibit 15 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) And Dr. Ladinsky, this document says in its opening paragraph, quote, "This document will help inform Dr. Hilary

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Cass' independent review into gender identity services for children and young people." And it goes on.
But is this a document that you have studied before today?
A. No, sir.
Q. Are you familiar with a report issued by Dr. Hilary Cass to the English health service in 2022?
A. I believe it's an interim report.
Q. It is titled "Interim report." Have you studied that document with some care?
A. Not studied it but I'm familiar with it.
Q. And given your desire to stay current in the scientific knowledge in your field, why have you not before today reviewed the analysis and conclusions of this evidence review prepared by the NICE organization in England?
MS. EAGAN: Object to the form.
A. I've read it but I'm not going to say I read every single page and every single word in deep deep detail. These are Dr. Cass' interim

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recommendations.
Q. (BY MR. BROOKS) I'm sorry. Let me be clear in my question because we're confusing documents.
Back to Exhibit 15, which is the evidence review, not the interim report. We talked earlier in the context of evidence-based medicine about the role of systematic reviews. And my question is: Given the testimony you have given about your desire to stay current and knowledgeable about the scientific knowledge in your field, why have you not studied the analysis and conclusions of this systematic review of puberty blockers as a treatment of gender dysphoria in children and adolescents?
MS. EAGAN: Object to the form.
A. This document that I'm looking at was never elevated to my attention in the form it is right here.
Q. (BY MR. BROOKS) Do you have any knowledge as to whether this particular systematic review has been cited by healthcare authorities in other European countries?

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A. I do not. I have no knowledge.
Q. Do you have any knowledge as to whether it's been cited by healthcare authorities in various states of the United States?
A. I do not.
Q. Do you have any knowledge as to whether this systematic review is the most comprehensive and detailed systematic review of the literature relating to use of puberty blockers in minors that have been performed to date?
A. I do not.
Q. As a clinician, it is important to you to have the best available knowledge with regard to the clinical effectiveness of treatment of children and adolescents with puberty blockers compared with treatment relying solely on psychological support, correct?
MS. EAGAN: Object to the form and the term "best available".
MR. BROOKS: Let's hear the question back.

(Whereupon, a portion of the

testimony was read by the court reporter.)

MS. EAGAN: Object to the form.

A. I would think it's important to all clinicians, but I'm not sure really what you're asking.

Q. (BY MR. BROOKS) I'm asking: Don't you want to be aware of the latest information and best analysis with regard to the safety and efficacy of puberty blockers as a treatment for gender dysphoria in minors as compared to the alternative of psychological support and psychotherapy alone?

A. Like I said, I'm not sure what you're trying to ask.

Q. What part of my question is unclear to you?

A. The idea of comparing those two groups.

Q. Well, you testified earlier that in your own clinic you're able to significantly ameliorate distress by means of psychotherapy and

support prior to administration of hormones, correct?

MS. EAGAN: Object to the form. Misstates previous testimony.

A. Only -- it's not that that's -- I mean --

THE WITNESS: Should I answer that?

MS. EAGAN: I mean --

MR. BROOKS: That's how it works. I will ask the court reporter to read the question.

(Whereupon, a portion of the testimony was read by the court reporter.)

A. Okay. So youth who are not currently receiving puberty blockers or hormones, okay, either because they're too young or not quite eligible for such are not simply set out with psychotherapy alone. These youth by and large have made a social transition and are living in their identity. They're not a homogeneous

group of patients. Each one is unique and different. But for these youth with significant gender dysphoria in our space and having been referred to us, they're not a case-controlled group. They're -- those eligible for puberty blocking medication may receive it. Individual cases. Each one is looked at. Others may not yet be eligible or may be of an age that they're no longer eligible. However, they are living in their identity. Family, work is going on, therapy is going on. And they see down the line that they may become eligible for hormonal therapy. Those are taken together what can allay the dysphoria. Not a single intervention. So I guess where I had trouble with that one is that I don't see these two groups -- eligible for puberty blockers, you get them, you don't. Let me compare them. I don't see that as a safe or realistic description of the use for hormonal care.

Q. Well, let me ask, I guess, a simpler question.

A. Okay.

Q. Isn't it important to you as a

clinician to know how the effectiveness for reducing gender dysphoria of puberty blockers or cross-sex hormones compares in outcomes to psychological support and psychotherapy alone without medical intervention?

A. I believe we have a wide body of research that helps us understand that. I don't believe that those two hypothetical groups would be eligible for a prospective randomized controlled trial to understand that.

Q. Nor did I ask you that.

A. Okay. Just making sure.

Q. What I asked you was: Don't you believe it's important to you as a clinician to have the best available information about the relative efficacy for relieving gender dysphoria in minors of hormonal interventions on the one hand and psychotherapeutic interventions without medical intervention on the other?

MS. EAGAN: Object to the form.

A. And I believe a wide body of research does discuss that.

Q. (BY MR. BROOKS) I didn't ask that.

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I asked whether it's important to you as a clinician to have the best available information on that question?
A. It's important to have the best available information on anything that pertains to my patients.
Q. And it would likewise be important to parents of a child facing medical choices for a gender dysphoric child to have that information?
MS. EAGAN: Object to the form.
A. It's important for parents to have all of the available information.
Q. (BY MR. BROOKS) And it's important for medical health policy-makers to have that information?
MS. EAGAN: Object to the form.
A. When you say policy-makers, do you mean governments, institutions, consensus bodies issuing recommendations?
Q. (BY MR. BROOKS) I mean any organization that is making recommendations or making decisions about reimbursement or making decisions about availability, making decisions

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about medical policy?
A. On a very general level, it would be relative to any proposed treatment or any proposed medical intervention.
Q. And likewise, I was asking about efficacy. It's important to you as a clinician to have the best available information about both short-term and long-term safety of hormonal interventions on the one hand and psychotherapeutic support and counseling without medical interventions on the other?
MS. EAGAN: Object to the form.
A. The former, absolutely. The latter, there's a wide body of evidence as well as clinical experience which shows us that that is not a population I would propose to study.
MR. BROOKS: Let me ask you to read back the question.

(Whereupon, a portion of the testimony was read by the court reporter.)

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MS. EAGAN: Object to the form.
Q. (BY MR. BROOKS) And you can try to answer the question.
A. I thought I just did.
Q. And I think you -- is it your testimony that you don't consider it important to have the best available information about short and long-term safety of psychotherapy and counseling support as a treatment for gender dysphoria in minors?
A. I think the relevant research and clinical experience to date informs us very well in those spheres. We are always evaluating ongoing work as it's done and comes in.
Q. Dr. Ladinsky, is it important to you as a clinician to have the best available evidence about the safety, both short and long term, of both hormonal interventions for gender dysphoria in minors and, on the other hand, treatments that rely on psychotherapy and counseling support, short and long term?
MS. EAGAN: Object to the term "available evidence" and the form. You can

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answer.
A. I don't -- I mean that's information that is very helpful, but I don't see a prospective study looking at those two groups as a safe ethical practical or doable entity. That would put people in harm's way.
MR. BROOKS: Let's take a break.

(Whereupon, a lunch recess was taken.)

Q. (BY MR. BROOKS) Let me ask you, Dr. Ladinsky, if you can find your expert report Tab 13 in the binder, and turn to Page 19 if you would.
And at the end of the only full paragraph on the page, it reads, "Suicidality is of particular concern for this population because the estimated lifetime prevalence of suicide attempts among transgender people is as high as 40 percent." Do you see that language?
A. I see it.
Q. And let me ask you first: Do you

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consider yourself an expert in suicide and suicidality?
A. I am not an expert in that area, no.
Q. And do you have any understanding as to whether the 40 percent number -- and I think in the Ivy complaint, actually you have a 45 percent number -- refers to actual attempts or intents or suicidal ideation?
A. I stated here, suicide attempts among transgender people as high as 40. And I agree with what's written right there.
Q. And --
A. Attempts.
Q. I just want to get clear on that before we went elsewhere.
I want to ask you some questions about suicide. Have you ever made any efforts to find research that reports information about actual completed suicide among gender dysphoric individuals, minors either before or after transition?
A. I've read a bit about that.
Q. And what studies are you aware of

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that provide information about actual suicide among that population either before or after transition?
A. I mean, again, as a clinician, sir, I'm not going to be encyclopedic on specific studies, who wrote them, when were they published, et cetera, but more in that generalized body of knowledge. So there are many that discuss this topic.
Q. There are many that discuss actual suicide rates is your testimony?
A. There are several that discuss suicide rates similar to what's quoted here.
Q. Are you -- what you've quoted here is not a suicidal rate. It's --
A. No.
Q. -- an attempt rate, correct?
A. It's a prevalence of suicide attempt. That's correct.
Q. While you're not an expert in suicide and suicidality, you understand that there is a very wide large difference between suicide attempts and actual completed suicide, correct?

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MS. EAGAN: Object to the form.
A. I'm not an expert. I think all of it -- all of it is inordinately concerning and front and center in care for this population.
Q. Do you know whether it is the case that the vast majority of suicidality among minors does not lead to suicide?
A. Your definition of suicidality is?
Q. It's a term I believe you used. Do you have a definition that you prefer to work with?
A. We consider it suicidality to -- it's a broad term to sort of encompass thoughts of actual intent to pursue, intent with a plan, failed action, completion. It's a very wide range group of thoughts or behaviors.
Q. Are you aware of any evidence of suicide by any prepubertal child believed to be the results of gender dysphoria?
MS. EAGAN: You said prepubertal?
MR. BROOKS: I did.
A. Am I aware of or have I read about; is that your question?

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Q. Are you aware of any evidence of actual completed suicide by any prepubertal child that's believed to be due to gender dysphoria?
A. I am not personally, but that doesn't mean it hasn't happened.
Q. All I can ask you about today is what you know.
A. Sure.
Q. You would agree with me, would you not, that evidence relating to actual completed suicide whether before -- among gender dysphoric minors whether before or after transition could be quite important for considerations of clinical decisions, informed consent?
A. Yes.
Q. Are you aware of any study that demonstrates that medical transition of any type reduces the rate of completed suicides among any gender dysphoric population whether adult or minor?
A. I cannot speak to specific studies, but I believe the body of literature helps us in showing that transgender people who are afforded

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the ability to live, present, you know, consistent with their identified gender will have less suicide attempts completion.

Q. And my question was not about suicide attempts. So let's -- I want to talk about suicide, people who die.

Do you believe -- have you ever read any study that concluded that medical transition of any type reduced the rate of suicide among gender dysphoric population?

A. As I've said, I'm not, you know, the researcher that knows every single study in its isolation. But I believe there's a body of evidence that helps us affirm that.

Q. When you refer to a body of evidence, what are you referring to?

A. Collections of data.

Q. What collections of data?

A. I mean --

Q. Dr. Ladinsky, if the answer is I don't know, then that's the answer. I want you to identify for me what you're referring to as a body of evidence.

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A. I cannot point to specific study or a specific compilation of studies.

Q. Would you agree that the long-term effects of hormones on suicide, completed suicide is at least as important to a meaningful evaluation of the beneficence of such procedures as are measures of short-term happiness?

A. That was a mouthful.

MR. BROOKS: She can read it back.

(Whereupon, a portion of the testimony was read by the court reporter.)

A. I'm not a medical ethicist, and I will not render an opinion on that.

Q. (BY MR. BROOKS) All right. Let me ask a slightly more general question. Would you agree that the long-term effects of hormones on health and mental health into the adult years are at least as important to the meaningful evaluation of the ethics of administering those treatments to children as are the short-term effects?

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Long-term effects --

A. Right.

Q. -- need to be considered at least as important as short-term effects; would you agree with that?

A. We're talking about long-term and short-term effects. I'm happy to do so with one caveat. Those treatments are never administered to children. But if we're talking about adolescents going forward, that's a little bit clearer.

Q. To be clear on the record, I accept your making it more precise.

A. Thank you. So I'm not going to make a value statement about care in adolescents versus quality of life in adulthood. It's critically important that we are well aware of -- and we discuss with families -- potential long-term effects of these medications on their young person in adulthood.

Q. That is you as a clinician. It's not appropriate for you to focus with the family, with the child just on short-term mental health

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and happiness?

A. Agree. It's a comprehensive discussion.

Q. And do you have any view as to whether data as to whether hormones increase or decrease death by suicide in the long term would be relevant to whether a doctor can ethically prescribe such medications to adolescents?

A. I don't believe I can answer that in a yes or no, you know, using the principles of ethics that our medical ethicists use because I'm not one. I do think the discussion of what is known about long-term effects must come into and is part and parcel of the discussions we have with families around the care we provide.

Q. You're a doctor who has obligations under medical ethical principles; am I correct?

A. That's correct.

Q. And yet you're unable to tell me whether, in your view, data about whether hormones increase or decrease death by suicide in the long term is relevant to the question of whether you can ethically prescribe those hormones to an

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adolescent?
MS. EAGAN: Object to the form.
A. It's extremely difficult to draw a linear relationship between one medication or one course of medical therapy in adolescents and suicide in adulthood because there's so many different factors and life trajectories that impact one to the other.
Q. (BY MR. BROOKS) Does your clinic maintain contact and records with your patients that enable you to know with confidence how many of those for whom your clinic has prescribed cross-sex hormones as adolescents or its young adults have subsequently committed suicide?
A. We do not have a formal mechanism around, you know, obtaining that data going forward in the same way as in my primary care pediatric clinic. We don't have a systematic way of tracking parameters of health and well-being once our patients graduate from our space and go on into college or adulthood. One would hope we would be apprised of a tragedy like that through families. Because we get to know our families

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very well, and we have fortunately never received that phone call.
MR. BROOKS: Let me mark as Ladinsky Exhibit 16 a paper entitled "Psychosocial Functioning in Transgender Youth after 2 Years of Hormone." By Diane Chen and many other authors. From 2023.

(Whereupon, Ladinsky Exhibit 16 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) Dr. Ladinsky, am I correct that this is a paper that you referred to in testimony this morning?
A. I have reviewed this document, yes.
Q. And you referred to it specifically in testimony this morning, correct?
A. Uh-huh. As a study that gives us time zero going forward prospective.
Q. And is Diane Chen or these other coauthors respected researchers in your field to your knowledge?

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A. I do not know all of them. But those whose names I've seen, the answer is yes.
Q. What names stand out that you are able to direct us to?
A. Drs. Rosenthal, Hidalgo, Ehrensaft, Olson-Kennedy.
Q. Is Dr. Chen among those whose reputation you know?
A. Quite possibly. I just -- remember I'm not a researcher. I'm a clinician. I'm not --
Q. But this is a paper that you studied for some care after it came out?
A. I've read it. I don't know that I could quote you exact details of any given anything, but I'm happy to --
Q. Well, I couldn't either. But just a few details I want to ask you about.
A. Let's do it.
Q. Sticking with the first page where things are simplified a bit. Under results, it refers to a total of 315 transgender and nonbinary participants. That seems to be -- you understand

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that to be the study size?
A. Study population.
Q. Study population?
A. Correct.
Q. Thank you. And it says that they have a mean age of 16 when they were enrolled. Standard deviation of 1.9, right?
A. I would have to look at methods to find out if that 16 reflects when they were enrolled or when the evaluative analysis was done.
Q. Okay. It says with mean age of 16 were enrolled.
A. Perfect.
Q. But I don't know the math terms on that so I won't take time.
A. No worries.
Q. And the study covers -- if you look at conclusions or the title of the study, it covers two years following the beginning of hormone treatments for adolescents, correct?
A. I believe so.
Q. If you turn with me to Page 243, it tells us -- about 3 or 4 inches down in the first

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column in 243 -- that two participants died by suicide during the study, one after 6 months of follow-up and the after 12 months of follow-up. Do you see that?

A. Yes, I do.

Q. And so for one, that was 6 months after beginning hormonal treatment; and for the other, it was approximately a year after beginning hormonal treatment, correct?

A. That's correct. That's what it says.

Q. And that is -- across the span, that is of the study population of 315, two committed suicide within a year of beginning cross-sex hormonal treatments, right?

A. That's correct.

Q. And if you turn with me to Page 245 and Table 2, the authors identify death by suicide. There's two deaths by suicide as adverse events associated with this study, correct?

A. That's what they state in this chart. I would have to go back to see exactly how they -- what they -- what the conclusion criteria

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were for an adverse.

Q. The authors --

A. That's what they say.

Q. The authors label those suicides as adverse events in this study?

A. Absolutely.

Q. Are you aware of -- so that's 2 out of 315 in the course of a year. That's a rate of something more than one-half percent mortality in a year, agree? 2 is more than half a percent of 315?

A. The most. Okay. I'm not doing math in my head right now.

Q. You know what, I'm going to represent to you that 2 divided by 315 is about .6 percent?

A. Not even 1 percent, okay.

Q. Well you said not even 1 percent. But are you able to point me to any study or any compilation or any body of information anywhere that found that high a rate of death by suicide among gender dysphoric adolescents who had not received cross-sex hormones?

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A. I think my first question is this, and I don't know the answer.

Q. I ask the questions, but you can go ahead.

A. Where my brain is going to be able to answer your question is what is the prevalence of suicide in the general population if we took a group of people who are 16 plus or minus 1.9 years.

Q. That is because we don't have a control here, you can't attribute causation?

A. No, I did not say that.

Q. Wouldn't you say it?

A. No. I only -- all I said was in order to answer that question, I would love to know the answer to my first thought: What is the population prevalence relative to this group -- this age group of young adults currently in America.

Q. Without being an expert in suicide, you know, do you not, that the general adolescent population does not exhibit an annual suicide rate of half a percent?

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A. I don't know what the exact number is.

Q. But let me ask again whether you're aware of any study or summary or body of knowledge that found a rate of suicide as high as half a percent per year among gender dysphoric adolescents who had not been subjected to cross-sex hormones?

A. I cannot point you to a singular study. But my inference from my own clinical experiences, it would be higher. And given the youth I see in the hospital, I would imagine it would be higher.

Q. You would imagine that?

A. I would imagine that. I don't have an exact study to point you to.

Q. Dr. Ladinsky, would you not agree that in this paper, Dr. Chen and Olson-Kennedy and others report what is in fact a catastrophic suicide rate?

MS. EAGAN: Object to the form.

A. I would only say that they report that using that adjective if they stated that in

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the study. Can I look through and see if that's in their conclusion?
Q. They don't use that word.
A. Okay.
Q. I'm asking for your opinion.
A. Okay.
Q. Isn't this a stunningly high suicide rate, 2 out of 315 in just one year?
A. I would not call that catastrophic.
Q. All right. Do you believe that the rate of suicide that they experienced amongst their study population is unexpectedly high among a population receiving cross-sex hormones?
A. No, sir, I don't.
Q. Do you think that a reasonable parent considering whether to approve cross-sex hormones for their adolescent child would want to know that this recent study by Chen, et al., observed a completed suicide rate deaths of 2 out of 315 in just a year?
MS. EAGAN: Object to the form.
A. I've never had a parent ask for that figure as we discuss use of these medications for

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their own individual young person.
Q. (BY MR. BROOKS) And if they don't ask, you don't tell?
MS. EAGAN: Object to the form.
A. I don't think that's an appropriate statement to say what we do or don't do in counseling families relative to these medications.
Q. Let me re-ask my original question. Don't you believe that a parent considering whether or not to approve cross-sex hormones for their adolescent child would want to know that this recent and prominent study experienced an actual death rate of 2 out of 315 adolescents in just one year?
A. I can't speak for what any parent would or would not want to know.
Q. Are you a parent?
A. I am.
Q. Wouldn't you want to know that?
A. I would want to know -- and I'm kind of bringing with you the framework that many of the parents come to us with. They are aware of very high suicide rates or rates of suicidal

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ideation among transgender people who have not had the opportunity or even those who may have to live in accordance with their identity. Most parents are very aware of that. They also may have experienced it in their child. So would they want to know, is there data that suicide can still happen even while my child is receiving medication? I can't tell you if they would want to know that or not. But I'm saying it's -- I can't put myself in the place of any one parent. It's a very complex interplay in these rooms with each individual patient.
Q. When you read the Chen, et al., study just out this year, am I correct in assuming that you noticed the data about the two suicides?
A. I did.
Q. So you're aware of that?
A. That's for sure. I'm sorry. Yes, I am aware of that.
Q. You can say that's for sure.
A. No. It's more of an expression than a statement of empirical fact.
Q. Are you aware of any data from any

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source that reports an equally high rate of suicide per year among an untreated gender dysphoric population?
A. I am not aware of any specific data set.
MR. BROOKS: We'll mark as Ladinsky 17 an article by Dutch name Wiepjes, W-i-e-p-j-e-s, and others dated 2020. Titled "Trends in suicide death risk in transgender people: results from the Amsterdam Cohort of Gender Dysphoria study (1972 to 2017)."

(Whereupon, Ladinsky Exhibit 17 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) Dr. Ladinsky, you cite at least one different paper by Wiepjes in your expert report, but I don't recall whether you cited this one. Is this a paper that you're familiar with?
A. I'm not.
Q. Are you familiar with the existence

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of a number of papers over the years coming out of the so-called Amsterdam cohort?
A. Peripherally.
Q. And looking at the authors here, you see Wiepjes, Steensma, and others?
A. Uh-huh.
Q. And do you have any knowledge as to the reputation of those researchers?
A. The final author. Steensma appears throughout the literature.
Q. If you look in the methods summary on the first page, it describes this as a chart study including all -- just on the very first page where it says methods.
"A chart study, including all 8,263 referrals to our clinic since 1972." Do you see that?
A. I do.
Q. Do you have an understanding of what a chart study is?
A. Retrospective chart review, yes, sir, I do.
Q. Can you describe briefly what a

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chart study is?
A. It's where researchers at time, a certain fixed point in time review backwards information simply from what is documented in the medical record looking at a certain population around a certain study metric.
Q. And these -- this team had perhaps due to the medical record structures of the Netherlands a very large study population, correct?
A. It's a good number.
Q. They claim that it's everybody who has been referred to their clinic since 1972, correct?
A. That's what they claim.
Q. And this is one of the world's preeminent gender clinics?
A. Certainly one of the earliest.
Q. Are you not willing to concede that to this day it's one of the world's preeminent gender clinic?
A. I think preeminent is a valuating term. So what one person may call preeminent,

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someone else may not.
Q. It is. But you're a professional in the field, and I want your opinion as to whether this is recognized as one of the preeminent gender clinics in the world?
A. It's a fair statement. Some would recognize it that way.
Q. How about you?
A. Honestly, I've never -- it's not something that I've said, oh, yeah, they're preeminent. I've just said, they were certainly one of the earliest and have phenomenal data and can be very instructive in how others do what they do.
Q. Let me take you to Page 489, the second column. And down to the very bottom crossing over into 490, I want to read a sentence to you. It says, quote, "In our cohort, both trans women and trans men show a three- to four-fold elevated risk of suicide compared with the population rate in the Netherlands and can therefore be considered a high risk group." Do you see that language?

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A. I do.
Q. And is that consistent with your general understanding of the -- strike that.
On Page 490 second column, these authors, including Dr. Steensma state in the first full paragraph, "An important finding was that the incidence for observed suicide deaths was almost equally distributed over the different stages of treatment." And if you go down another inch and a half is a sentence --
MS. EAGAN: Where are you reading?
THE WITNESS: Right there.
Q. (BY MR. BROOKS) And down an inch and a half is a sentence that reads, quote, "This indicates that vulnerability for suicide occurs similarly in the different stages of transition." Closed quote. Do you see that?
A. I do.
Q. If it's true that suicide occurs similarly both before and after transition, is that an important fact for clinical decisions about medical transition?
MS. EAGAN: Object to the form.

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A. That statement in isolation that risk of suicide for transgender people before, during, within, and after transition remains elevated. That's an important element to know. It underscores a longitudinal mental health that's provided along the way. I think it's hard to generalize any statement from this cohort study, though, because it involves 1972 to 2017 in The Netherlands where social norms and acceptance of transgender people may not have been the same as what it is today because there are many factors that impact suicide from marginalized populations such as trans people.

Q. Dr. Ladinsky, if it's true as these authors report that the incidence of observed completed suicide deaths was almost equally distributed across the different stages of treatment; that is, before and after hormonal interventions, surgeries, the works, is that potentially an important consideration in deciding the clinical appropriateness of prescribing cross-sex hormones for minors?

A. In this study the mean age was 28,

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so these are adults going forward. But if you want to -- do you want to rephrase that relative to minors?

Q. No. I'll let the question stand as it is.

A. Can you --

Q. Do you believe -- I'll restate it to save time. If it's the case as these authors report that the actual rate of completed suicide is closely similar before and after medical intervention for gender dysphoria, is that potentially an important consideration for you as the clinician in deciding when or whether it's appropriate to prescribe cross-sex hormones?

MS. EAGAN: Dr. Ladinsky, if you need to read this document that you've never read to understand the context of that statement, she certainly is entitled to do so before answering that question, so.

MR. BROOKS: I didn't ask a question about the document and I disagree.

MS. EAGAN: Well, you've asked her about a conclusion that is stated in the document

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wouldn't that be an important consideration. She certainly should understand the context of the statement.

Q. My question -- and I'm happy to just take the document away so it's not a question about the document.

A. Okay. These is median age of first visit 28 years.

Q. If it is true that the rate of completed suicide is closely similar before and after hormonal interventions in individuals suffering with gender dysphoria, isn't that, in your opinion, an important fact you need to consider as a clinician in deciding whether to prescribe cross-sex hormones to adolescents?

A. Can I presume that you're asking that as a theoretical?

Q. Yes.

A. Okay. That helps. If that were true -- and I am not positing it as true. I don't believe it to be true. But if it were true, it would be an important thing not just to know, but it would also help govern the robust mental health

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oversight that's already very robust but further discussions would be had relative to that.

MR. BROOKS: I'm going to mark as Ladinsky Exhibit 18. A title of -- an article entitled "A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones" from 2011 with authors including Asscheman, Gooren, and others.

(Whereupon, Ladinsky Exhibit 18 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) Dr. Ladinsky, this is a -- you'll see up at the top another article coming out of Vrije University or VU Center. And let me ask whether you believe you've seen this article before today?

A. I have not seen this article before today, sir.

Q. Have you ever made any organized effort to find literature that addressed actual suicide among gender dysphoria individuals?

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A. I've read a good bit about it in the literature I read. But have I, you know, done a Google search putting those terms together, no.
Q. Isn't it important to you to know what the literature knows about actual suicide among gender dysphoric individuals?
A. It's important to know what we know. This is an area where there is -- numbers may be higher than we know.
Q. In the abstract of this paper under design, it says this is "a cohort study with the median follow-up of 18.5 years at a university gender clinic." Do you see that?
A. I see that.
Q. In terms of the information available in your field, that's a very long follow-up study, correct?
A. It's hard because we're not comparing apples to apples again. This is a cohort study with a median follow-up at 18.5 years that enrolled adults at 31.4 and 26.1 mean age respectively. It may yield important information, but 18.5 years isn't something that's -- isn't

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fully generalizable to the adolescent. We take this for what it's worth.
Q. My only question at this point is: Compared to what's available in the literature, an 18.5 year follow-up is one of the longest studies that you're aware of; am I correct?
A. I do not know comparatively. I think it's a good length of follow-up.
MS. EAGAN: I would like for her to have time to get herself familiar with this document.
MR. BROOKS: Well, let's see what I have to ask.
MS. EAGAN: At this point she --
MR. BROOKS: I understand.
MS. EAGAN: We don't know what this document is you're asking.
MR. BROOKS: Suicide.
MS. EAGAN: Before questioning about the document, I would like for the witness to have an opportunity to familiarize herself with the document.
Q. (BY MR. BROOKS) Let me ask you to

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turn to Page 638.
A. Okay.
Q. Where we are within the results section if you turn back. In the second column towards the bottom is a paragraph that begins, "External causes of death were increased almost eightfold due to suicide and illicit drug use. The suicide rate in males to female was increased sixfold." Do you see that?
A. I do.
Q. And if it's the case that the suicide rate among post-transition transsexuals is eightfold or sixfold depending on which number we look at, is that a number that you think that parents considering whether to authorize medical transition of their child would want to know?
A. I would not use data produced from this particular study in my counseling of families in Birmingham, Alabama, in 2023. These are adults when they transitioned. They also transitioned in the 90s and early 2000s at a time when there were very, very different forces impacting the world in which they lived. HIV, AIDS was still very real

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in The Netherlands at that time as you see here. And what I glean from this that I will continue to use and counsel with families is that transgender people, regardless of transition, remain at risk for discrimination, of marginalization. And we will always work with that in the population we care for.
Q. I'm sorry. Remain at risk for what?
A. Marginalization, discrimination, societal challenges. That's what you'll see through here.
Q. Do you think that you take away from this also advising families that after transition, transgender individuals remain at high risk for actual completed suicide?
A. I would not draw that conclusion from this document, but that is something we -- that is within the sphere of the counseling we provide, the oversight, the work that we do.
Q. That is your disclosure to the parents for purposes of informed consent tells them that according to the available data, transgender individuals remain at high risk of

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completed suicide after transition?
MS. EAGAN: Object to the form.
A. I would have to look and see if that is a line item on our extensive informed consent document. But it is within the anticipatory guidance and counseling that's had with families that most all appointments relative to the importance of mental health, of coping, et cetera.
Q. (BY MR. BROOKS) Do you have an opinion as to whether data about suicide rates among individuals who have undergone transition surgeries is something you should consider as you decide whether to recommend or whether to authorize transitioning hormones?
A. It's not part and parcel of a discussion because we're looking -- when we're talking about initiation of hormonal therapy and the criteria that goes into that, we're not extrapolating years and years and years into the future presuming and assuming that every patient will one day have gender-affirming surgery. That's a very individualized decision made by adults.

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Q. In counseling families and adolescents about transition options, isn't it, in fact, part of your job to envision and help them envision life and outcomes years and years and years in the future?
A. Those are discussions that are always had.
Q. Is it part of your job?
A. I wouldn't say it's a line item in anything, but these are discussions that are had with -- by pediatricians in all contexts of the work that we do, not just gender health.
Q. To the extent that you as a gender specialist counsel parents and adolescents about transition, about medical transition, don't you consider that you have an ethical obligation to help them foresee outcomes and life years and years and years into the future?
A. I don't think anyone has a crystal ball. Your pediatrician doesn't foresee your children's life in the future but certainly helps and guides with medical decision-making around current health, sustained health, and health going

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forward. We do so to optimize the future.
Q. Do you believe that as a doctor participating and advising parents and adolescents about medical transitions that you have an ethical obligation to help them think about not just the short term but about how this will affect their life and mental health years and years and years into the future?
A. I'm not sure I would say we have an ethical obligation to predict their health years and years and years into the future because we don't. No one does. But we certainly can talk about how to optimize that.
MR. BROOKS: Let me mark as Exhibit 19 a paper entitled "Suicide by Clinic-Referred Transgender Adolescents in the United Kingdom" by Michael Biggs dated 2022.

(Whereupon, Ladinsky Exhibit 19 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) Dr. Ladinsky, are

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you familiar with the clinic that's referred to in some cases as the Gender Identity Development Services or GDIS or the Tavistock Clinic in England?
A. I'm well aware of it, yes.
Q. And I'll represent that this is a study of actual suicide rates based on extensive data from the Tavistock Clinic. My question right now simply is: Do you believe that you have seen this paper before today?
A. I don't.
Q. Would it be consistent with the understanding that the Tavistock Clinic has over the years served a large number of adolescents and would have a large dataset?
A. It would certainly have the largest dataset in the UK.
Q. And if a study of suicide among those referred to the Tavistock Clinic was published in 2022 and you had earlier testified about the various listservs and other things you rely on to bring relevant literature to your understanding, do you have an understanding how it

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could be that until now you're unaware of this paper from just last year about suicide at the Tavistock Clinic?

MS. EAGAN: Dr. Ladinsky, I would ask that you actually take the time to review the paper before you begin answering questions as to the paper's contents.

MR. BROOKS: And I haven't asked any questions about the paper's contents.

MS. EAGAN: Well, you have. That's what you're implying.

MR. BROOKS: I have not asked questions about the paper's contents nor do I intend to.

MS. EAGAN: Well, she still can review it.

MR. BROOKS: If you want to go off the clock since I'm not asking questions about it, we can go off the clock. But she cannot take my clock time reading a paper I'm not asking her questions about.

MS. EAGAN: That's fine. We can go off the clock. But I think before you're asking

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questions as to why she wasn't aware of this paper, she's certainly entitled to understand the contents of the paper and the context.

MR. BROOKS: Off we go.

(Whereupon, a brief recess was taken.)

Q. (BY MR. BROOKS) Have you heard or read the catchphrase "Would you rather have a living daughter or a dead son"?

A. I've heard that said.

Q. Or vice versa as the case may be. And are you aware that that catchphrase circulates on social media to a considerable extent?

A. I'm not.

Q. You're not?

A. I'm not a social media person.

Q. Me neither. And do you believe that you or your colleagues ever use that phrase in counseling parents or adolescents?

A. I do not and I have not heard it said in my clinic space when counseling parents.

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Q. And as you sit here today, you can't point to any specific data or paper that shows that hormonal intervention reduces actual rates of death by suicide among gender dysphoric adolescents, correct?

A. This one helps to assuage that concern.

Q. And you refer to?

A. The conclusion, "The proportion of individual patients who died by suicide was 0.03 percent, which is orders of magnitude smaller than the proportion of transgender adolescents who report attempting suicide when surveyed. The fact that deaths were so rare should provide some reassurance to transgender youth and their families."

Additionally, two of the patients who committed suicide known to the Tavistock Clinic included here were patients on the waiting list. That's important. They did not have the opportunity to get gender-affirming care or to even be considered eligible for some. Hope can save lives.

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Q. Dr. Ladinsky, are you aware of -- I won't take time to ask you what else you found. I wouldn't have pulled that out if that was all you found.

Are you aware of any data that shows that administration of cross-sex hormones or puberty blockers for adolescents or children reduces the actual rate of death by suicide?

A. I cannot refer you immediately in this instance.

Q. And absent that data, it's not scientifically supported to refer to those treatments as lifesaving, is it?

MS. EAGAN: Object to the form.

A. I don't think that's a fair statement at all. It does not describe what's in the literature. It's kind of an editorial comment that is not like an impaired statement.

Q. (BY MR. BROOKS) Well, you yourself have referred to those treatments as lifesaving, have you not?

A. If I have referred to them in any of these documents, then I have.

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Q. Putting aside documents created for litigation, you have from time to time referred to those treatments as lifesaving, have you not?
A. I'm not aware of that.
Q. Okay.
A. If you have evidence to that from a presentation I've made, then I guess I did. But in this moment, I don't recall it.
Q. In your opinion in counseling a parent given what we know and what we don't know, it would not be ethical to use that phrase, "Would you rather have a living daughter or a dead son," would it?
A. That is not a phrase I use in the counseling I provide.
Q. And you consider it to be unethical to say that to a parent, don't you?
A. I could not make a value judgment on it.
Q. Why not?
A. Because it's not appropriate.
Q. You as a doctor don't have to make value judgments as you counsel parents?

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A. Of course I make value judgments.
Q. Ethical judgments?
A. Ethical judgments within structure around framework. But to ask me if a certain idiomatic phrase is ethically just or not is not something I could answer. Most importantly it's not a phrase I use.
Q. Why not?
A. It's -- I mean, it's not the way that I talk or think, if that makes sense. When I emphasize -- when we talk about counseling families is data that reinforces the positive mental health impacts of transgender people being allowed to live in ways that are most aligned with their gender identity at each stage.
Q. Have you ever had a parent ask you, in essence, whether that's the choice they face, having a live daughter or a dead son?
A. I have not.
MS. EAGAN: Can we take like a five-minute bathroom break?
MR. BROOKS: Yes.

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(Whereupon, a brief recess was taken.)

Q. (BY MR. BROOKS) Let me ask you to find Exhibit 5, your expert report, which is in a binder. Turn to Page 29 if you would. In the middle of the page is a short paragraph that reads, "Dr. Hurz's suggestion that 'alteration of normal adolescent brain maturation' may be another 'possible side effect' of puberty blockers is not accurate. I have not seen this in my practice and science does not support this statement." Do you see that?
A. I do.
Q. And you cite a single paper in reference to your statement about science by Dr. Staphorsius, correct?
A. Correct.
Q. When you say "I have not seen this in my practice," let me ask whether in your practice you systematically make any tests of cognitive capability of your patients before and after treatment?

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A. No, sir. That is not part and parcel of standards of care in what we do. I assume you're implying neuropsychological evaluative examinations?
Q. Yes.
A. Okay.
Q. So when you say "I have not seen this in my practice," all you mean is that you haven't seen any effect on brain maturation that was dramatic enough for you just to notice it in ordinary interactions with the child?
A. More importantly, parents noticing elements of cognitive decline, academic decline that, you know, was --
Q. Well, your understanding as a pediatrician is that adolescence is -- healthy adolescence is a period of positive development and mental capability, correct?
A. In a general sense, yes.
Q. And you say "science does not support the statement." Did you have anything in mind in addition to the Staphorsius paper that you referenced?

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A. This is -- this paper is referenced because it directly addresses this from a neuropsychological perspective using what they identify as validated -- validated evaluations, executive functioning.

MR. BROOKS: Let me mark as Ladinsky Exhibit 20 an editorial by de Vries and Hannema from The New England Journal of Medicine dated 2023 entitled "Growing Evidence and Remaining Questions in Adolescent Transgender Care."

(Whereupon, Ladinsky Exhibit 20 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) And I believe you've testified earlier that de Vries is a researcher of strong reputation; am I correct?

A. That's fair.

Q. And this paper is -- this editorial, I should say. This is not a research paper. But The New England Journal of Medicine in which it was published is an extremely prestigious medical

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journal; am I correct?

A. It is.

Q. One of the premier journals in the world?

A. I believe that's fair.

Q. And on the next -- on the second page, 276, Column 2, writing in 2023, de Vries states -- and I'm 3 inches from the bottom. A paragraph that begins, quote, "Finally, benefits of early medical intervention, including puberty suppression, need to be weighed against possible adverse effects. For example, with regard to bone and brain development and fertility." Closed quote. Do you see that?

A. I do.

Q. Now, writing in 2023, Dr. de Vries thought that possible adverse effects of medical intervention in gender dysphoric youth and children were adverse effects on brain development. Do you agree that that's what's accurately described in what Dr. de Vries says?

A. I'm sorry. I'm going to have to ask you to repeat that because I was finishing reading

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that paragraph.

Q. Writing in 2023, Dr. de Vries listed as among possible adverse effects from medical intervention in children and adolescents negative impact on brain development, correct?

A. I believe Dr. de Vries posed this here as a question, not as a statement of fact.

Q. And do you disagree or agree with Dr. de Vries that as of 2023, it is an open question whether medical interventions in minors affect brain development in an adverse manner?

A. In her editorial or opinion commentary on the Chen article, her job is to do what physicians do. We work hard to elevate potential research questions. Dr. de Vries does state in that same paragraph, right, "that adolescents' educational achievements are as expected given their pretreatment status, which is reassuring." In other words, we do not have evidence of this. But as a research question, Dr. de Vries seems to find it merits asking.

Q. Well, indeed, Dr. de Vries says it merits weighing against possible benefits of

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medical intervention, does she not?

A. She does say that, and I take that to mean again she is probing. Because in her last paragraph, she continues that, Despite uncertainties that call for further study, current information shows that mental health improves with gender-affirming hormone, GAH, whereas withholding treatment may lead to, da, da, da, adversely affect psychological functioning.

Q. And mental health is a different question from brain development, do you agree?

A. She raises them as different questions, however, they are not inextricable.

Q. Endocrine Society is Tab 37. Let me ask you to turn to Ladinsky Exhibit 8, which is Tab 37 in the binder I gave you. And if you would turn to Page 3882. And under side effects in Column 1, the Endocrine Society, Guidelines, state that, "The primary risks of pubertal suppression in GD/gender incongruent adolescents may include" and she -- and then they list a number of things. One of which is, quote, "unknown effects on brain development," period, closed quote. Do you see

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that?
A. I see that.
Q. And I think you've testified you're not a neurologist, and you haven't done research in this area. Do you agree or disagree with the Endocrine Society Guidelines when they state that the effect of pubertal suppression on brain development in adolescents is unknown?
A. That is what they state right there. We must take some comfort in generalizing from the extended longitudinal data on young people treated with the same medication for central precocious puberty who are well into adulthood, and it does not show a decrement in cognitive development.
Q. Are you aware of studies of the effect of pubertal suppression or central precocious puberty that specifically measured cognitive development?
A. I am not aware of studies that may have measured cognitive development with neuropsychological tests.
Q. All right.
A. It doesn't mean they don't exist.

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Q. Let me ask you to turn to Page 3883, the next page there. And at the top of the first column, the first full paragraph reads, "Limited data are available regarding the effects of GnRH analogs." That's puberty blockers, correct?
A. Correct.
Q. "On brain development. A single cross-sectional study demonstrated no compromise of executive function."
A. Right.
Q. "But animal data suggest there may be effect of GnRH analogs on cognitive function." Closed quote. Do you see that?
A. I see that.
Q. And do you yourself have any knowledge concerning what animal data may -- does or does not show about the effect of blocking puberty on cognitive function?
A. I have no knowledge of this.
Q. Do you consider information from animal data to be at all relevant to reasonable inferences about effect on humans?
A. Less so when there is available data

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on humans, especially humans that are relevant to the population for which I work.
Q. Now, the Endocrine Society Guidelines that are focused -- the committee that is focused specifically on puberty blockers and cross-sex hormones chose to warn here that animal data suggests that puberty blockers may have an effect on cognitive function. Do you consider that this committee or you have a more informed view on that question?
MS. EAGAN: Object to the form as to the term "warn".
A. I'm not sure what you're asking. Can you help me with that?
Q. (BY MR. BROOKS) I can ask it again. The Endocrine Society committee that prepares the guidelines state in the text that I read that animal data suggest there may be an effect of puberty blockers on the development of cognitive function, correct?
A. Relative to animal data, that's what they say right here, yes.
Q. And presumably, it's fair to say

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that they would not have included that information unless they thought it was at least potentially relevant to humans, correct?
A. I can not infer why they chose to include it or not. I do -- what my read as a frontline physician is this sentence is a testament to their robustness. They're inordinately thorough. They're not telling us what to do or not with this.
Q. Certainly you have no basis to disagree with the statement of the committee that animal data suggest that there may be an effect of puberty blockers on cognitive function, do you?
A. If that's what they state. I have no knowledge of it or knowledge to negate it.
MR. BROOKS: Let me mark as Exhibit 21 a paper entitled "Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Pubertal Suppression in Transgender Youth" from 2020. Lead author is Diane Chen.

(Whereupon, Ladinsky Exhibit 21 was

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marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) Dr. Ladinsky, you understand Diane Chen to be one of the lead investigators in the ongoing prospective study that's reported on by the Chen paper that we looked at previously, correct?

A. I would assume so given her position at Lurie which is one of the forecenters.

Q. Which is one of the?

A. One of the forecenters involved in this prospective data collection.

Q. And here from three years earlier, 2020, is a paper specifically directed at research methodologies for evaluating the effect of puberty suppression on neurodevelopment or brain development. And my first question for you is: Have you seen this paper before?

A. I have not, sir.

Q. Are you familiar with something called a Delphi consensus procedure?

A. Not in detail but I'm familiar with

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its existence and what it is around obtaining expert consensus when asking a question in a scientific or a systematic way.

Q. Okay. Is it consistent with your understanding or is it outside your expertise that the adolescent period is associated with profound neurodevelopment including increase in capabilities for distraction and logical thinking?

A. That is outside my area of expertise to comment on it any quantitative way.

Q. Okay. And is it consistent with your understanding as a doctor or outside your expertise to say that several neurodevelopmental processes occur during adolescence including myelin development and changes in neural connectivity?

A. I think we're talking about -- I'm not -- not being a neurologist or neuroscientist, I could not give you, for example, the functional MRI components of which pathways are being pruned and fine-tuned.

Q. Well, then let me ask a more behavioral question. Is it consistent with your

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understanding or outside your expertise to say that the puberty process in humans has been linked to developmental changes in social and emotional processing as well as emotional control?

A. That's a generalization that, again, a two-part generalization that I don't have the capability -- I'm not a neuroscientist or neurologist to give you quantitative backing for either part of those.

Q. Okay. I always tell my witnesses, I don't know, is the quickest way out of some topics.

Let me take you however to Page 254.

MS. EAGAN: We can go off the record, but I would like for her to have a chance to review this report.

MR. BROOKS: I'll take her to the particular language, and then she can see what she wants to review around that.

MS. EAGAN: Okay.

Q. (BY MR. BROOKS) In 254, Column 1, these authors state -- and this is not a research paper. They are not reporting on data?

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A. Right.

Q. They state under discussion in the second sentence, I believe, 254.

A. Okay.

Q. 254 under discussion, second sentence reads, quote, "puberty is a major developmental process and the full consequences, (both beneficial and adverse) of suppressing endogenous puberty are not yet understood." Closed quote.

So my question for you -- and, again, this is -- there's no date reported in this paper. It's not a study. Do you agree or disagree with these authors when they state that "the full consequences of suppressing endogenous puberty are not yet understood?"

A. That's a statement that they make and have convened sort of a consensus -- group of experts to work on how to best evaluate that.

Q. And do you agree or disagree or is it outside your expertise to say the full consequences of suppressing endogenous puberty are not yet understood?

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A. Outside of my expertise to know how quantitatively, qualitatively, that's a fair statement.
Q. Let me ask you to turn to Page 249.
A. Okay.
Q. And the second column -- this isn't even a statement by the author. It's a question by the author. 249 second column. Towards the top it says, first full paragraph, "We employed a two-round Delphi procedure to obtain expert consensus regarding the most efficacious research design elements to address the following research question: What, if any, real-world impact does pubertal suppression have on transgender children's cognitive and neural development?" Closed quote. Do you see that?
A. I do.
Q. And do you agree that learning the answer to that question could have important clinical implications?
A. I think it's a research question that merits asking.
Q. Do you agree or disagree that

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knowing the real-world impact of pubertal suppression on cognitive and neural development could have important clinical implications?
A. In theory, it could.
Q. And the answer to that question could be important to you as a clinician, to parents, and to health policymakers, correct?
MS. EAGAN: Object to the form.
A. I think the results of a multi-center methodologic study, should it be undertaken, could have clinical ramifications, but that would depend completely upon the methodology, the possible confounders, the length of time. And just as they say there may be a larger database if more was available that the cohort could be compared to. In other words, validating the comparison groups. I would be interested also in youth who received the same medication at the same physiologic stage for central precocious puberty.
Q. So far as you know since this article was published in 2020 in the Transgender Health Journal, no researchers have undertaken the type of careful study that's described -- that

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you've just described to attempt to measure the real-world impact, if any, of pubertal suppression on children's cognitive and neural development?
A. I do not know.
Q. Let me ask you to turn to 248.
A. They do say here, the real -- it's on the record. "The real world clinical care considerations may well be undeveloped in the proposed research design."
MS. EAGAN: I don't think there is a question on the table right now.
THE WITNESS: I was just finishing up.
Q. (BY MR. BROOKS) I'll take your attention to Page 248.
A. Yes, sir.
MS. EAGAN: Dr. Ladinsky, if you need more time -- if you need any more time to review this document more robustly, we can go off the record and you can review it if you need to.
THE WITNESS: Well, if I'm going to be asked about the content of 248, which is probably the intro.

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Q. (BY MR. BROOKS) Again, I'm going ask you a question rather than a content question. Towards the bottom of 248 about an inch up is a sentence that begins animal studies.
A. Okay.
Q. 2 inches up.
A. I see it.
Q. It reads, "Animal studies demonstrate pubertal hormones exert broad neural influence, including effects on neurogenesis, differentiation, apoptosis, dendritic branching, spine density, and regional gray and white matter volumes," period. I'm afraid to ask whether I read that correctly?
A. You did pretty well.
Q. So Chen and these many authors also mention animal studies, as would you agree, suggestive or as flagging questions that need to be investigated?
A. I don't read this as suggestive. I read this as simply making a statement relative to findings on rodents and monkeys and projecting.
Q. In fact, medical research often

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begins by studying the effects of procedures or pharmaceuticals on rodents or monkeys before moving on to humans, correct?

A. It can definitely.

Q. Indeed, ethical principles often require that experiments be done on animals before they're done on humans, correct?

A. Completely depends on the nature of what's being studied.

Q. Let me ask you to turn to Page 253. Talk a little bit more about rodents. Column 2, 3 inches down. Says, quote, "studies in rodents show ovarian hormones, acting during puberty, program cognitive flexibility by exerting long-lasting effects on excitatory-inhibitory balance in the prefrontal cortex." Period. Do you see that?

A. I do.

Q. Do you have any reason to agree with that or is it simply outside your expertise that rodents studies have shown that ovarian hormones can have long-lasting effects in brain development?

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A. It is outside my area of expertise to comment on this finding and any semblance of generalized ability to higher-order animals and humans.

Q. You would agree, however, would you not, that a scientist who is faced with animal studies that report long-lasting effects, to use the phrase from the paper, of pubertal hormones on animal brain development should conclude at least that there is some possibility that pubertal hormones may also have broad influence on brain development in humans?

A. I don't agree with that statement. I don't know. I don't have the knowledge base to understand how the effect of pubertal hormones on brains; ergo, observed behavior in rodents are generalizable to that same impact in people or even primates with their higher-order brain functioning that takes into account so many environmental messages.

Q. Does data -- and I admit I'm curious as to what kind of intelligence test you would give to a rat, but that's another question.

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Before I showed you this Chen, et al., 2020 article, were you aware of references in literature relating to gender dysphoria and treatment for gender dysphoria to animal research and its potential in patients relating to brain development?

A. No, not in that way.

Q. And having seen these references in the Endocrine Society Guidelines and in the Chen, et al., paper, does that cause you as a clinician to want to know the answer to the question of whether puberty blockers in humans have long-lasting effects on a child's brain development?

A. You're asking from what I'm seeing here about findings relative to animals?

Q. Correct. And my question is: What you've seen just today -- and that's why I ask you before. You didn't know that before. From what you've seen today, does that make you as a clinician want to know the answer to the question of whether puberty blockers administered during the time of endogenous puberty have long-lasting

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effects on the neural development of that child?

A. I appreciate and have an eye to ongoing research. Does what I've read here about rodents concern me greatly, just the animal related information? For me personally as a frontline provider, it does not.

Q. Turn to Page 252 if you would. In the first column on 252, inch and a half from the bottom, the sentence begins, quote, "The effects of pubertal suppression." I'll give you a moment to find it.

A. Got it.

Q. "The effects of pubertal suppression may not appear for several years. Any GnRHa-related difference in brain structure is likely to be observed over the long term, rather than immediately." End of quote. Do you see that?

A. I do.

Q. And so Dr. Chen, the lead investigator in the currently ongoing NIH-funded prospective study, writes here that effects of puberty suppression on brain structure is, quote,

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"likely to be observed over the long term, rather than immediately." Closed quote. And my question for you is given that you're not a neurologist: Do you agree, disagree, or consider it beyond your expertise to comment on Dr. Chen's statement there?

A. So this one sentence, Dr. Chen's conjecture that the effects of pubertal suppression may not appear for several years. That?

Q. Yes.

A. Does it -- what was the question?

Q. My question is: Do you agree, disagree, or consider it outside your expertise to comment on that statement by Dr. Chen?

A. The latter. It's outside my expertise to comment on. Here it's really posed -- I see it posed as a research question, and I look forward to any data.

Q. Let me ask you to turn to Page 255. And in the first column almost halfway down the page, sentence begins, "Yet evidence suggests." Not quite halfway down the page.

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A. I'll get there.

MS. EAGAN: Take your time and read through the section.

A. I'm bringing the previous page's context into what you asked me to look at if it's okay.

Q. (BY MR. BROOKS) Of course it is.

A. Thanks.

Okay. I have a better context now. Thank you, sir.

Q. Okay. Back in the middle of the first column of 255.

A. Okay.

Q. There is statement that says, quote, "evidence suggests an overoccurrence of neurodiversity characteristics (especially related to autism) among gender-referred youth." It continues, "The neurodevelopmental impacts of pubertal suppression on neurodiverse, gender-diverse youth might well be different than in neurotypical gender-diverse youth, given variations in neurodevelopmental trajectories observed across neurodevelopmental conditions."

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Period. Closed quote.

Is it consistent with your own clinical observation that young people with neurodiversity characteristics, including autism, are disproportionally represented than those referred to your clinic as compared to the general population?

A. I think it is consistent subjectively with our experience.

Q. And before reading this, have you given any consideration to the question of whether the effect of puberty blockers on those types of young people might be different than it is on, I'll say, a clinically normal --

A. Neurotypical.

Q. Neurotypical youth?

A. Well, in fact, I was looking for a paragraph that addressed that and was grateful to find it.

Q. Okay. That is -- this is a question you have given some thought to in your professional work?

A. I think we all have but not in a

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negative way.

Q. Well, I take it that simply finding out the answer to the question of what impact it may have is not a negative or a positive question, correct?

A. I haven't even gone that far. I was just -- as this consensus article is looking at how to study the trajectory of neurodevelopment in patients who receive puberty blockers. It's to me important that it takes into account those with neurodiverse processing. Methodologically how will you make sure that any evaluation, to answer the question, is talking about takes the breadth and depth of the youth we see into account.

Q. And so far as you know, when it comes to the effect of puberty blockers on neurodevelopment, nobody has yet attempted any study to determine how, if at all, those effects differ on neuro atypical adolescence versus neuro typical adolescence?

A. Not that I'm aware of. It doesn't mean it doesn't exist.

Q. I know that I've looked enough

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that --
A. Yeah.
Q. -- I know it doesn't exist.
MR. BROOKS: I'm going to mark as Ladinsky Exhibit 22 a document entitled "The Cass Review, interim report" February 2022. This is in your binder behind Tab 55.

(Whereupon, Ladinsky Exhibit 22 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) And Dr. Ladinsky, I believe you testified earlier that sometime after this interim report was issued that you read it?
A. I have. I've reviewed it.
Q. And --
A. I can't quote intimate detail, though.
Q. I understand.
A. It's pretty long.
Q. It's pretty long. Do you have any knowledge as to the reputation of Dr. Hilary Cass?

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A. Not in detail. I believe that she's a retired psychologist, if that's correct, who had considerable experience in the GIDS.
Q. That's not correct.
A. Okay.
Q. She's a pediatrician. Whether she's retired or not, I couldn't say. She obviously had some time.
A. I believe she's retired.
Q. Is this a document that you have discussed with colleagues in your clinic?
A. It is not.
Q. Are you aware that this document has been cited with respect to health authorities in multiple countries?
A. I'm not aware of that.
Q. When you read the document, was it generally your opinion that it raised legitimate questions and concerns or did you think it was scientifically unreliable?
A. That's a tall ask because I believe more importantly the focus of Dr. Cass' immensely robust work is with an eye to evaluating capacity,

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competence capability to decentralize this care given by multi-disciplinary teams but with an eye to the need to do so in more than one location throughout the Kingdom looking towards Sweden. And so she took into account and continues to, the input from many, many, many providers in Britain's NHS at many levels.
Q. Let me ask you to -- let me ask you to turn to Page 38 of this document.
A. Okay.
Q. And there under -- this document is easy to refer to. It has these nice numbered paragraphs. Call your attention to 3.32.
A. Uh-huh.
Q. Where Dr. Cass writes, quote, "A closely linked concern is the unknown impacts on development, maturation, and cognition if a child or young person is not exposed to the physical, psychological, physiological, neurochemical and sexual changes that accompany adolescent hormone surges." Do you see that language?
A. I do.
Q. And do you agree that up to the

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present, the impacts of blocking, preventing puberty at its natural or endogenous time on development of maturation and cognition of that child is unknown?
MS. EAGAN: I'm sorry. Read back that question. I was reading the document and I missed the question.

(Whereupon, a portion of the testimony was read by the court reporter.)

A. I believe it's what level you're asking the question on. You know, myelination, dendrites, pruning on a very very physiologic level or robust development in how that individual's interacting in accordance with age-related expectations, meaning biological or sociologic. Is it unanswered?
Q. (BY MR. BROOKS) If I -- and indeed, the paragraph here speaks broadly to development and maturation, so let me narrow the question.
Do you agree that the impact of

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puberty blockers on the child's developmental cognition is up to the present unknown?
A. I don't know. It's beyond my expertise to answer that because it can be answered on different levels, as I said, by different specialists.
Q. Okay. Toward the bottom of that section, that column. Dr. Cass writes, "If pubertal sex hormones are essential to these brain maturation processes, this raises a secondary question of whether there is a critical time window for the processes to take place, or whether catch-up is possible when estrogen or testosterone is introduced later." Closed quote.
And my question for you is: Are you aware of any study that addresses the question of whether any negative impact on brain maturation due to puberty blockade can be made up if a child is later exposed to either endogenous or cross-sex hormones?
A. I am not aware if that has been systematically studied in the way you ask it.
Q. And in any context, are you aware of

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development processes -- strike that.
Dr. Cass refers to a critical time window. And let me ask whether in any context as a doctor you're aware of developmental processes that have to happen at a particular time in the sequence of a child's development or they cannot happen properly?
A. In a general sense in pediatrics, yes. Thinking of visual input during an infant's first six months kind of thing.
Q. That is if they don't get the appropriate visual input, there are certain neurodevelopmental things that don't add up?
A. They may have some visual impairment.
Q. Okay. But visual impairment has to do with nerves, right?
A. Well, that's -- when you talk about a critical window of development, there are some anatomic structures. There are some areas in the developing person that that has applicability.
Q. All right.
MR. BROOKS: I'm going to mark as

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Ladinsky 23 a paper entitled "Puberty suppression and executive functioning: An fMRI-study in adolescents with gender dysphoria" by Staphorsius and others dated 2015.

(Whereupon, Ladinsky Exhibit 23 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) Dr. Ladinsky, this is the paper that you cited in your expert report in connection with cognitive development; am I correct?
A. It's correct, sir.
Q. And you believe that you studied it with some care and are reasonably familiar with its contents?
A. Reasonably familiar.
Q. And would you agree with me that when it comes to impact of puberty suppression on executive functioning, to use the term that they use, that the results reported in the Staphorsius and Cohen-Kettenis paper are mixed?

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A. There are some sentences that might lead you to believe that. However, I'm not sure I completely agree.
Q. Well, needless to say, we'll look at it in more detail.
A. Okay.
Q. Just for context, this is dated 2015. It is again out of the Vrije University research clinic in Amsterdam, correct?
A. That's correct.
Q. And we saw earlier that in 2023, Dr. de Vries, in that clinic, stated that one possible effect of puberty blockers could be adverse effects on brain development, but I won't ask you about that again.
Let's look at what Staphorsius says about that. Now, the methodology here was to use the so-called Tower of London test. Can you -- do you have any understanding of how that is used to measure cognitive development?
A. It actually to my knowledge -- and remember I'm not a neuropsychologist or a neuroscientist, but this is a test that can be

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done on a computer. And it looks at, to an extent, visual spatial but more importantly what they're looking at is a part of the brain on the executive function which has to do with planning and organizing. I don't believe that test elucidates somebody's cognitive development which is more like age appropriate or even IQs.

Q. So, and I used the wrong term obviously. I don't -- I'm learning. Executive functioning?

A. Right.

Q. Describe for me again what executive functioning refers to?

A. Well, Reader's Digest version is it's part of the brain's ability in an age appropriate way to plan, to organize, to quickly incorporate information learned in one setting to another one.

Q. Okay. That sounds important for maturation to adult life; you would agree?

A. I would agree.

Q. And just so I can picture this a little more. Is the Tower of London test

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basically like this child's toy that I've seen that you're rearranging disks to try to get them in a -- you don't know?

A. I'm not a neuroscientist or a neuropsychologist. I do know it can be done on the computer which is not going to be the same thing as hand-eye coordination.

Q. Now, this was -- so that we don't kind of over read it. If you turn to Page 192, it says that there were 41 adolescents with gender dysphoria in the study, 22 female to males. Some of whom had been subjected to puberty suppression and some who had not. And 18 male to females of which some had been subjected to puberty suppression and some had not. So all in all, it's a sample of 41; am I correct?

A. It's a very small sample, yes.

Q. And the mean time, if we turn to Page 194 at Column 1 at the end of the little Paragraph Number 3.1. It says the duration of suppression for male to females was 1.8 years. With the standard of deviation show ing it for female to males, it was 1.4 years. Do you see

Page 220

that?

A. I do.

Q. So would you consider that to be a long, short, or kind of standard length puberty suppression?

A. Fairly standard.

Q. And this is, if I understand correctly, not a longitudinal study. That is, it's a one-time study. Some of the subjects have been subject to suppression and some have not. But it's not a prospective study. It's not a longitudinal study, correct?

A. I believe so.

Q. Okay. If you look at 194, Column 1, towards the beginning of Section 3.1. It says, control boys, i.e., those who had not had puberty suppression, had significantly higher IQ scores than the suppressed male to females.

A. Okay.

MS. EAGAN: Roger, show me where you are.

MR. BROOKS: Paragraph 3.1, second sentence.

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MS. EAGAN: Thank you.

Q. (BY MR. BROOKS) And it's not longitudinal. But whatever report that those who had not experienced puberty suppression among the boys had higher IQ scores as measured by whatever test they use than males who had had puberty suppressed, correct?

A. That's what this sentence indicates, yes.

Q. And based on the nature of this study, that could be cause and effect or it could be a random variation between the control group and the study group, we can't tell?

A. It certainly could. What it indicates is that the case and control groups at the start may not have been equal for reasons we don't know.

Q. And if you turn back to Page 191 which is the -- not quite the first page.

A. Okay.

Q. In the abstract up top -- the abstract continues over from the previous page, and you certainly are free to refer to that part.

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It says on the first full sentence at the top of Page 191, it says, the suppressed male to females, if I may translate, had significantly lower accuracy scores than the control groups and the untreated female to males. Do you see that?

A. I do.

Q. And again, that potentially could be reflecting a negative impact of puberty suppression, but it could be reflecting other factors. We can't tell?

A. Correct. I read that the same way you do.

Q. Now, in a technical paper when the authors write that the accuracy scores of those boys who had been subjected to puberty suppression was, quote, significantly lower, that significantly is a term of art and refers to statistical significance, correct?

A. Correct, which is interpreted lightly with these very small numbers.

Q. Well, with small numbers, you would have to have a larger difference for it to be statistically significant, correct? That's how it

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works.

A. That may be how stats work, but it leaves someone reading a paper like this with -- you take it for what you see. But with very very small numbers, it may not be generalizable to an entire population.

Q. What do you understand to be the statistical -- the formal meaning of statistically significant?

A. It's been a long time.

Q. Something to do with P values?

A. Has to do with P values, greater than .05, less than -- depends on the test involved. But the question is the sample size, et cetera.

Q. Let me turn -- ask you to turn back to Page 194. In 3.2, which is headed Tower of London performance data. You're on the right page, 3.2.

A. Okay.

Q. 3.2, ToL, Tower of London performance data. It states that in the second sentence, Post hoc analyses show the suppressed

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male to females had significantly lower accuracy scores than the control groups and the untreated female to males. Have I read that correctly? I left one out. Let me try again.

Quote, Post hoc analyses showed that the suppressed male to females had significantly lower accuracy scores than the control groups, open paren, p equals .02 compared to control boys and p equals .04 compared to control girls, closed paren, and the untreated female to males. Closed quote. Do you see that?

A. I do.

Q. And again, the report here is that the treated subjects; that is, treated with puberty blockers had significantly lower accuracy scores on the Tower of London test than two different control populations, right?

A. That's what they're saying here.

Q. Well, you cited this paper. I assume that's because you thought it was a reliable scientific source?

A. I think it's the only source available at the time that has asked this question

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and done a bit to evaluate it.

Q. And by saying that the puberty suppressed boys, male to females had significantly lower accuracy scores, what that means is they just got the puzzle wrong more often than the control groups, correct?

A. I do not know. I've never administered a Tower of London test.

Q. I'm going to go home this evening and take one online and see how I do.

A. Let me know.

Q. If you look a little farther in that paragraph, it states, quote, even after correcting for IQ -- and we looked at IQ earlier -- a significant effect of group on accuracy remained. Closed quote.

A. Right.

Q. Do you think you understand that sentence?

A. Somewhat, yeah.

Q. What do you understand it to be telling us?

A. That even if you -- you can use

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statistical equations to control for the fact that one of these groups had an overall lower IQ. The findings can't. They didn't do as well on the Tower test.

Q. Let me call your attention to Table 1 on the next page, 193. And first I'll ask whether you studied this table of key results before you cited this paper in your expert report?

A. Not in intense depth.

Q. One of the things that's measured by the Staphorsius authors is reaction time; am I correct?

A. That's correct.

Q. And is that something that you understand generally improves across pubertal development?

A. I could not comment on that.

Q. Okay.

A. I've never administered a neuropsychological test to accept that point.

Q. I have watched my small children and my older children and as a layman, I suspect it's true, but I also don't claim to know.

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MS. EAGAN: Boys don't react real fast when they have to do something.

MR. BROOKS: That's a different question.

Q. The final column on this is RT which, am I correct you -- well, below the table it says RT, reaction times in seconds. So it's not a guessing game. RT is reaction time in seconds to whatever the test is. And if you look, we have the male to female suppressed and untreated. And do you see that the reaction time -- and pardon me. Let me ask a background question.

It is consistent with your understanding that when you're measuring reaction times, longer is worser?

A. Again, I'm not a neuropsychologist.

Q. Dr. Ladinsky, you cited this paper to say that there are no negative effects of pubertal suppression. Do you not know, quite apart from being a neuropsychologist, that a lower reaction time is less advantageous?

A. That's a generalized statement. I'm

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not sure I can generalize from the data presented here in the small groups information that may impact at this time in our history of clinical decision-making.

Q. Understood. It's a small sample?

A. Uh-huh.

Q. It's a one time rather than prospective?

A. Correct.

Q. But what they found in Staphorsius, et al., is that the reaction time of the puberty suppressed boys was slower than the untreated male to female boys and slower than the control's non-transgender boys, correct?

A. That is what they report.

Q. Which is, again, causation can't be determined from an experiment like this, but it's -- to the extent papers like this do anything, it raises a concern, does it not, that the puberty blockade may have, within the time period we have here, a negative effect on the development of reaction time?

MS. EAGAN: Object to the form.

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A. I don't read it that way.

Q. (BY MR. BROOKS) Why not?

A. My take from this is in the narrow scope of how it is conducted and carried out. It raises investigative questions, but it -- I don't see in it generalizability to come to the statement you made.

Q. If you don't see in this paper generalizability for all the reasons you explained, why did you cite it as evidence that Dr. Hruz was wrong in the concern that he raised?

A. "In conclusion, our results suggest that there are no detrimental effects of GnRHa on EF."

Q. I took you to data. If you don't believe the data is generalizable, why did you cite this paper as disproving Dr. Hruz' concern about potential impact on brain development from puberty blockers?

A. I put a bit more -- I utilized the authors' interpretation of their own data relative to the research question they asked. And the conclusion that they glean is what I took with me.

Q. All right.
A. That sentence I read and, "We found no evidence for this and if anything, we found that puberty suppression even seemed to make some aspects of brain functioning more in accordance with natal sex."
MR. BROOKS: I'd like to mark as Exhibit 24 a scientific statement from the Endocrine Society dated 2021 entitled "Considering Sex as a Biological Variable in Basic and Clinical Studies."

(Whereupon, Ladinsky Exhibit 24 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) Dr. Ladinsky, you've repeatedly referred to the Endocrine Society Guidelines relating to treatment of gender dysphoria. This is a different document from the Endocrine Society. And I'll ask first whether you think you've ever seen it before?
A. I do not recall seeing this document

before.
Q. I am going to ask you about one scientific proposition that it states. If you would turn to Page 238. Before that let me ask: Are you generally aware of a requirement from the NIH, the National Institute of Health, that studies that they fund must consider sex as a biological variable; that is, they need to separately record data with respect to male or female individuals or even male or female cells in whatever the experiments are?
A. I'm not aware of that, sir. I'm not a researcher.
Q. Would you look on Page 238, Column 2. And 3 inches down from the bottom -- 3 inches up from the bottom -- pardon me -- is a sentence that begins "Recent evidence." It's a buried sentence. "Recent evidence has revealed."
A. Okay.
Q. Let me read that into the record. Quote, "Recent evidence has revealed that molecular sex differences in the brain are more widespread than initially thought and such

seemingly small-scale differences can have a large impact on physiology and behavior. Neurons typically communicate with each other via neurotransmitters and neuropeptides, which are released presynaptic neurons and travel across a synapse to bind receptors on the postsynaptic neuron to exert downstream cellular effects. There are sex differences in production and release of many neurotransmitters and neuropeptides that can result in behavioral changes."
First, let me ask at a high level: Is it within your knowledge that in recent years science has discovered more and more differences down to the cellular levels between male and female brains?
A. I'm not aware of that.
Q. You're not aware of that?
A. But again I'm not a --
Q. I understand.
A. -- psychologist or researcher.
Q. And you don't have any knowledge as to whether it's true or not true that sex-based

differences in human brains go even to the level of neurotransmitters and neuroreceptors?
A. Not in detail, no.
Q. It is within your knowledge, is it not, that every brain -- every cell in a human brain contains either XY male chromosomes or XX female chromosomes in a normal healthy human?
A. Unless there's a genetic or receptor based disorder of sexual development.
Q. Hence my qualification, normal healthy human.
A. Okay.
Q. You would agree with the statement?
A. I guess.
Q. Well, every cell in your brain is female in the sense of having an XX chromosome, and every cell in my brain is male in the sense of having an XY chromosome, correct?
A. If you say so, yeah.
Q. No. I'm asking you. You're the witness.
A. I believe so.
Q. And are you aware of any study ever

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of the effect on brain function and health of flooding a male brain with estrogen levels that never occur in a healthy male and could never naturally occur in that brain?

A. Again, I'm certainly -- I'm not a researcher, and I'm not encyclopedic in the literature relative to basic science studies.

Q. If you have no knowledge as to the effect of flooding a male brain with female hormones at levels that could never naturally occur in that brain, on what basis do you assert that administering cross-sex hormones is safe?

A. If we take a step back -- and I think why this question was so difficult for me even though it seems easy is that as physicians we don't -- pediatricians we don't think about brains as male brains or female brains. They're just that child's brain. So that's why it was hard for me to answer this question. Even outside of gender health, we don't think of child development as boy brain, girl brain. We think of it as that child's brain. So with that caveat, it's a little hard -- that's why it was harder to answer that one.

Q. Is it your professional opinion that experts in child development don't think and don't research in terms of boy brain and girl brain?

A. Those are just not terms that are familiar to me nor have I seen them in the literature I read.

Q. In fact, you're well familiar with literature that documents that boy brains and girl brains follow different developmental trajectories and are well recognized in repeatable fashions, are you not?

A. Give me some examples.

Q. No. I ask questions only.

Are you or are you not familiar with such literature?

A. That boy brains and girl brains develop differently at different times?

Q. Yes.

A. That's not --

Q. Indeed that they develop in physically different ways identifiable by MRI scans?

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A. I'm not aware of it on the level that you're discussing.

Q. Let me ask you to turn in your expert report to Page 7, where in the first full sentence on the page you wrote, quote, "All the major medical professional groups in the United States, including the American Academy of Pediatrics, the American Medical Association, and the American Academy of Child and Adolescent Psychiatry, agree that this care is safe, effective, and medically necessary treatment for the health and wellbeing of children and adolescents suffering from gender dysphoria." Closed quote. Do you see that?

A. I do see that.

Q. And in writing that, did you go check and ascertain that these organizations had actually represented that these treatments were, quote, "safe"?

A. I believe -- not sure how you're defining safe or how they're defining, but I know that all three of these organizations -- three here -- endorse this care --

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Q. Did you --

A. -- as safe, effective, and medically necessary for the health and wellbeing.

Q. You cite the Endocrine Society Guidelines?

A. Right.

Q. Let me ask you to turn to that which is Tab 37 in your binder.

A. Okay.

Q. Do you believe that you found any representation from the Endocrine Society in this document that either puberty blockers or cross-sex hormones are safe when administered to adolescents?

A. If you give me your definition of safe that would be great --

Q. No.

A. -- to help me.

Q. You represented in your expert report that these organizations had stated that it was safe. So we'll work with your -- whatever you meant when you said that.

Do you think you looked for and

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found any such representation before making that statement in your report?
A. I think endorsing a specific line of treatment carries that notion within it. In other words, everything in medicine is a cost-benefit evaluation application to an individual patient, but I certainly did not see in any of these guidelines a statement that this treatment is unsafe.
Q. You did see statements in the Endocrine Society Guidelines raising concerns that puberty blockers could affect brain development, did you not? We looked at that earlier.
A. Yeah. They raise it as a possibility, though they don't cite solid evidence. And they raise it as a question for research.
Q. And you did see reference in the Endocrine Society Guidelines to a number of other known or potential adverse effects of both puberty blockers and cross-sex hormones for adolescents, did you not?
A. Correct.

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Q. And what you didn't see anywhere in the Endocrine Society Guidelines was a statement that either of those treatments was safe when administered to adolescents, did you?
A. We think about that term in a clinically relevant way. In other words, when weighing risk versus benefits for an individual patient, there is a level of safety. And we have data, the use of these medications in similar ages for other indications.
Q. That's you. But what you can't do is point me to anything in the Endocrine Society Guidelines that represent to the world that these treatments are safe when administered to children or adolescents; is that correct?
A. I'm not sure that that sentence exists in here.
Q. All right.
MR. BROOKS: Let me mark as Exhibit 25 a paper by Rafferty headed "Ensuring Comprehensive Care and Support For Transgender and Gender-Diverse Children and Adolescents" dated 2018.

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(Whereupon, Ladinsky Exhibit 25 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) Dr. Ladinsky, this is the AAP statement that you cited in support of your representation that the AAP has asserted that the use of puberty blockers and cross-sex hormones are, quote, "safe"; am I correct?
The question on the table is --
A. This is the policy statement to which I referred, yes.
Q. Okay. I have searched with the benefit of an online search key --
A. Tool.
Q. -- and I can't find any assertion by Rafferty, the AAP, that either puberty blockers or cross-sex hormones are safe when administered to children. Do you believe that you found such before making that representation in your expert report?
A. When endorsing -- again, when a

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consensus body endorses a modality or a treatment protocol or paradigm, within that is data reflecting on relative safety that doctors take into consideration in the cost-benefit analyses with patients. You will not find that single sentence in there.
Q. Have you yourself participated in developing such a medical association statement?
A. This? No, I have not.
Q. Any such?
A. No, sir.
Q. How do you know how -- and by the way, do you have any knowledge as to who participated in preparing the AAP statement?
A. So not only Dr. Rafferty, but you had a lot of input from members of two different, what we call, AAP heads, bodies, sections, and committees. So you had a number of people from the committee on psychosocial aspects of child and family health, the adolescent health, and then the section on LGBTQ.
Q. Do you have any personal knowledge as to what input, if any, any of those individuals

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had?
A. I do.
Q. And on what bases?
A. I'm a member of the section on LGBTQ health and wellness. I'm also a member of the minority health equity and inclusion subcommittee, and so --
Q. Prior to 2018, you --
MS. EAGAN: Were you through with your answer? I thought you interrupted her. I. Wasn't sure if you were you through with your answer because you said, "and so -- ".
A. But I was going to say I know the processes by which these policy statements are arrived at. There is a lot of member input.
Q. (BY MR. BROOKS) In general, multiple members would review such policy statements? Multiple members would have a hand in revising it perhaps?
A. That's correct.
Q. It would have to be approved by the entire committee or multiple committees?
A. That's correct, yes.

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Q. All right. But just to be clear, your citation of -- so far as you recall, your citation of the Rafferty paper was not based on finding any representation in Rafferty that puberty blockers or cross-sex hormones were safe as administered to adolescents, but rather you inferred that from the endorsements of those procedures?
A. That's a relative sort of inference, but that is inherent in how physicians interpret, align with, utilize policy statements like these and other standards of care and guidelines.
MR. BROOKS: Let me mark as Exhibit 26 a document headed "AACAP Statement Responding to Efforts to Ban Evidence-Based Care For Transgender and Gender Diverse Youth" dated November 2019.

(Whereupon, Ladinsky Exhibit 26 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) Did you review this

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document preferably before citing it for the proposition that the AACAP had stated that use of puberty blockers and cross-sex hormones was, quote, "safe"?
A. AACAP being the American Academy of Child and Adolescent Psychiatry, correct?
Q. I take your word for it, yes.
A. No. I've not seen this document, but I'm well aware of the endorsement from this organization.
Q. Well, let me ask: You cited in your footnote a November 8, 2019 statement from the AACAP. This is a November 8, 2019 statement. I'm sorry. Maybe I misspoke. This is the date you cited in your footnote, and yet you say you've never seen it before?
A. I'm sure I've seen it in putting this together, yes. Actually, yes.
Q. Did you or did you not review this document before citing it in your expert report?
A. I did review it.
Q. And did you find any statement from the AACAP that these hormonal interventions in

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minors are, quote, "safe"?
A. I do not see a sentence that states that.
MR. BROOKS: Let me mark as Exhibit 27 a document headed "AMA, State Advocacy Update". March 26, 2021.

(Whereupon, Ladinsky Exhibit 27 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) And is this a document that you cited in your footnote in support of the proposition that medical organizations had endorsed hormonal interventions as, quote, "safe"?
A. Quite honestly, possibly. I know that there are other -- and that's perhaps yes.
Q. Well, I didn't --
A. There are other AMA documents that go into more detail.
Q. If it's -- I don't want to make a mistake on this. So behind Tab 13 is your expert

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report. Let's double-check whether that's what you cited.
A. That's a fair statement.
Q. Okay.
A. It's a summary of -- what I'm seeing in my head is a more lengthy document.
Q. And you are not expressing the view that this advocacy update is something that was voted on by the membership or by any formal committee of the AMA, are you?
A. I'm sorry. Can you restate that?
Q. Yes. You don't have any opinion as to whether this advocacy update was voted on by any committee of the AMA, do you?
A. I'm not aware of the details within the AMA. I'm quite aware of the AMA's disdain for criminalizing health for transgender minors.
Q. And do you believe that you can point me to any statement in this document from the AMA that hormonal interventions in minors are, quote, "safe"?
A. No, sir. And that's not the point of this document.

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MS. EAGAN: Roger, when you get through with this line of questioning, can we take a break? We've been going for a long time.
MR. BROOKS: Let's do a break. I'm at the end of that line of questioning.

(Whereupon, a brief recess was taken.)

Q. (BY MR. BROOKS) New topic.
A. New topic. Okay.
Q. Would you agree with me that biologically a key, almost defining, aspect of puberty is development into fertility. That is the individual becoming potentially fertile? It's not a mysterious question.
Would you agree with me that a key, almost definitional, aspect of the pubertal process is a child sexually maturing to become potentially fertile?
A. That is a longitudinal aspect of the physiologic changes that happen during puberty.
Q. And specifically, puberty includes

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gonadal and hormonal changes that are necessary to achieve fertility?
A. In today's world not necessarily, but.
Q. I'll ask a more precise question. Natural healthy puberty includes gonadal and hormonal changes necessary to achieve fertility, correct?
A. Ideally.
Q. Let's go back to the Rafferty paper, Exhibit 25. And you cited this in your expert report because you believe it to be a generally reliable document?
A. Generally reliable, what do you mean?
Q. In your opinion is the description of the science a description that you can rely on as a clinician?
A. I think that's fair.
Q. Let me ask you to turn to Page 6. And there is a Table 2 at the top of the page that says -- titled "The process of gender affirmation may include one or more of the following

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components."
A. Right.
Q. And puberty blockers -- one of the columns is reversibility, right? You see that?
A. Right.
Q. And puberty blockers, it says reversible and then has a little footnote.
A. Little C.
Q. If we follow that C, what it says is, quote, "The effect of sustained puberty suppression on fertility is unknown." Do you see that?
A. I see that. It's Footnote C.
Q. Footnote C?
A. Yeah.
Q. And do you agree or disagree with the American Academy of Pediatrics or is it outside your expertise to say that the effect of sustained pubertal suppression on fertility of the adolescent is unknown?
A. I think the remainder of that and then Footnote 6 of 68, and they refer, yeah, right back to the Endocrine Society Clinical Practice

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Guidelines. So I think that's the way that it's stated here. And in Footnote C, I don't have any problem with that.

Q. That is, you don't disagree with the statement that the effects of sustained puberty suppression on fertility is unknown?

A. I don't have any -- I agree with that statement. The question is: What does the Endocrine Society and Dr. Rafferty and our clinical judgment mean by sustained?

Q. Let's look at what the Endocrine Society has to say since you mentioned that, and that is in your binder, Tab 37. And I'm going to call your attention to Page 3880, but you're going to want to look back and see what recommendation this discussion pertains to which is on the previous page, 1.5. And what that recommendation says is, quote, "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

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affirmed gender in both adolescents and adults." Closed quote. Do you see that?

A. I do.

Q. And do you have any understanding if puberty suppression is simply a pause why the Endocrine Society recommends counseling regarding options for fertility preservation prior to administering puberty suppression?

A. I do believe that section -- this recommendation Number 1.5, "The task force placed a high value on avoiding harm with gender-affirming hormone therapy in prepubertal children with GD/gender incongruence." That's -- so that's the sentence that proceeds it.

Q. Yes.

A. Meaning prepubertal children are not prescribed medication. That is the standard of care. They're talking in generalizable terms, puberty suppression and prior to treating with hormonal therapy. They're talking about the entire manuscript there.

Q. Well, they speak specifically about providing counsel for options fertility

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preservation prior to initiating puberty suppression in adolescence. Do you see that?

A. I do.

Q. And if puberty suppression just acts as a pause, do you have any understanding why the Endocrine Society recommends that clinicians provide counseling on fertility preservation prior to administering puberty blockers?

A. I can only infer. But for youth who begin puberty blocker medications and then over a period of time maintain sustained significant dysphoria becoming eligible for hormonal therapy, okay, that discussion must be had because there is a possible decrement to fertility in that group.

Q. For a child who's put on puberty blockers at, let's say, 10 or Stage 2 and proceeds without interruptions onto cross-sex hormones, there are in fact no options for fertility preservation, are there?

A. There are.

Q. What demonstrated options for fertility preservation in that context are there?

A. If that young person were to allow

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for a little bit of space in between, it can be obtained.

Q. That is if the child -- that's contrary to my hypothetical, so let's break it down.

My hypothetical was a child is put on puberty blockers at 10 or Stage 2 and proceeds without interruption to cross-sex hormones at whatever age you generally consider to be clinically appropriate, for that individual, there are no fertility preservation options, are there?

A. I'm not -- remember I'm not a reproductive endocrinologist. However, in the future that person, if they, you know, cease their treatment for a little while, may be able to procure gametes. But I think the Endocrine Society makes this recommendation in a very general way here, and it's a sound board.

Q. Now, they mentioned in the little heading, values of preferences, that you just stated, that -- I take it from the way they stated, that all the evidence relating to fertility is, quote, what they call "low-quality

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evidence", correct?
A. Everything, all of it throughout the whole document?
Q. Everything on which they base their recommendation they describe as low-quality evidence; am I right?
A. They say right here, okay, "This justifies the strong recommendation in the face of low-quality evidence." But I think it's important to understand the context around this term "low quality", "lesser quality", et cetera. That does not refer to utilizing, not utilizing, negating the recommendation. That term "low-quality evidence" simply refers to the studies that undergird that recommendation and how their methodology aligns with randomized prospective double-blind placebo-controlled. These are terms that physicians and clinicians use in interpreting evidence. The notion of low quality is more of a technical term referring to study methodology. Not bad, good, horrible, yucky.
Q. Technical terms, right?
A. Yes, sir.

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Q. So if we turn over the page, we're still on the discussion of the remarks about use of puberty blockers.
A. Okay.
Q. And at the top of Column 388 -- of Column 1 of 3880, the first full sentence reads -- and we're talking here about males as will be obvious. "Note that there are no data in this population concerning the time required for sufficient spermatogenesis to collect enough sperm for later fertility." Do you see that?
A. Right here. I do see that.
Q. And this is -- that population refers to boys who have been on puberty suppression for a period of time and then ceased puberty suppression for a period of time, correct?
MS. EAGAN: Dr. Ladinsky, I would ask that you read -- I would like for her to read all these remarks leading up to it because you're asking about one sentence.
MR. BROOKS: That's fine. I already thought she had, basically.
MS. EAGAN: I'm not sure she has.

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A. I've read it, but, I mean, it's important to know that this is in a section, recommendations for those involved in the gender hormonal treatment of individuals. It's not a single section on puberty blockers.
MS. EAGAN: What I would ask, though -- read the remarks, Dr. Ladinsky. Take your time to read the remarks and then answer his question about the context of that one sentence, please.
A. Okay.
Q. (BY MR. BROOKS) All right. At the -- referring to the population of natal males who have been on puberty blockers, it says at the top of Column 1, quote, "There are no data in this population concerning the time required for sufficient spermatogenesis to collect enough sperm for later fertility." Closed quote. Do you see that?
A. I see that.
Q. So far as you know, is it still true that there is no data on that topic?
A. While I am not a researcher --

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remember this was 2017.
Q. That's why I asked.
A. There is considerable work ongoing not just in the field of gender health but more importantly in pediatric oncology where nothing to do with gender, this population may need to enter into chemotherapeutic regimens that could later impair fertility. And there is a good amount going on right now to find, you know, to give us a better idea. But you see right there .7 to 3 years.
Q. I'm sorry. What was -- I see.
A. In the next sentence because --
Q. This is in a different use case; that is, in adult men --
A. No. In males treated for precocious puberty.
Q. Pardon me. Yes.
A. Spermarche means the ability to obtain viable sperm from a sample from that patient. 0.7 to 3 years after cessation of GnRH analogs.
Q. So --

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A. Puberty blockers.
Q. So far as you know, there's been no study of how long it takes or whether an individual whose puberty -- whose ordinary endogenous puberty has been blocked can generate enough sperm to use the language here, quote, "for later fertility," closed quote?
A. I think you see it right here. 0.7 to 3 years after cessation, after stopping the blockers.
Q. That doesn't make any representation about whether there was enough to achieve fertility, does it?
A. Well, spermarche implies that.
Q. Is that your understanding of the literature?
A. No. Looking at the term.
Q. I understand.
A. The ability to collect viable sperm.
Q. Do you know whether in the literature spermarche implies actually fertility?
A. I do not, but.
Q. And as to another use case; that is,

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adult men with gonadotropin deficiency, it notes that sperm numbers were quote, "far below the normal range", correct?
A. I don't take care of adult men with gonadotropin deficiency.
Q. You don't prescribe puberty blockers for children with precocious puberty either, do you?
A. My endocrinology colleagues do.
Q. And what the Endocrine Society says is that in the case of adult men who have for whatever medical reason been subjected to blockade, after some period of time it remains true that their sperm numbers are, quote, "far below the normal range", right?
A. That's referring to this unique population of men. That's how I read it.
Q. And you wouldn't want to extrapolate from that population to adolescents who have had puberty blocked at its normal healthy time, correct?
MS. EAGAN: Object to the form.
A. Let me just look at -- if you don't

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mind, 70 and 71, I'd like to look at this footnote.
Okay. Both of these studies were looking at a different population of adult men who for exactly as you said, reasons we don't know, are gonadotropin deficient.
Q. And my question was simply: You don't think it's appropriate to extrapolate from the experience of that population to what the experience may be of adolescents who have normal healthy puberty blocked?
A. Not in a clinically significant way for me on a frontline.
Q. And for similar reasons, it would also not be appropriate to extrapolate from a population that suffered from precocious puberty and had puberty blocked -- and had puberty occur at -- postponed until, I should say, a normal time period for puberty?
MS. EAGAN: Object to the form.
A. On the contrary, I think that's immensely helpful. It gives me information about pediatric patients who began the same treatment at

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the same physiologic stage.
Q. (BY MR. BROOKS) So let me ask you about physiologic stage. It's not your testimony, is it, that children who suffer from precocious puberty are at the same brain developmental stage as children to whom your team prescribes puberty blockers as a treatment for gender dysphoria?
A. Some may be. I can't state, you know, that's a yes or a no.
Q. I would have thought you could.
A. It's a wide range.
Q. So let me ask: Precocious puberty, how do you understand that to be defined?
A. Precocious puberty in a natal male is the development of secondary sex characteristics or adrenal ketones under androgen before the age of 9; and in a girl, before the age of 8. Again, androgenic, not breast buds, but other elements.
Q. And if that was happening, for instance, in a boy at age 8 and a girl at age 7, would your hospital potentially prescribe puberty blockers?

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A. They may.
Q. For that small advance?
A. They may.
Q. It is not your testimony, is it, that on average children who suffer from precocious puberty are at a level of neurological development comparable to the average level of development of children for whom you prescribe puberty blockers as a treatment for gender dysphoria?
A. If by brain development you mean they're a few years on average younger, that's true.
Q. And to your knowledge, important aspects of brain development routinely occur during those few years, correct?
A. Important aspects of brain development occur at all ages.
Q. And it's not your testimony, is it, that on average children who are prescribed puberty blockers as a treatment for precocious puberty have physical size and body development comparable to children for whom you prescribe

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puberty blockers as a treatment for gender dysphoria?
A. On the contrary they often may. They may have the same height.
Q. I didn't ask may. I said on average.
A. I think it's quite common. Precocious puberty puts them at a physiology, including size, on par with someone who may be eligible to receive puberty blocking medication for significant gender dysphoria in early adolescent Stage 2.
Q. A little farther down in the column on 3880, it says in the next paragraph, "In girls, no studies have reported long-term, adverse effects of pubertal suppression on ovarian function." However, in the next sentence it says, "Clinician 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." Do you see that language?

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A. I see it.
Q. And is it still consistent with your understanding that there is no data out there about how long after cessation of puberty blockers a girl may resume ovulation?
A. At the moment, there are no data available at the time of this report. And if there are data looking specifically at the timing of eventual ovulation for someone assigned female at birth that was placed on GnRH analog for central precocious puberty or for gender dysphoria. I do not know if there have been data since that. I do know that there's long-term data in cisgender females treated with GnRH analogs for central precocious puberty that report normal pregnancy, ultimate fertility, et cetera.
Q. So as far as you know, there are no data with regard to females treated with puberty blockers to prevent normal healthy timed puberty as to when, if ever, those girls can achieve healthy levels of fertility?
A. It would -- I mean, to me that's a two-part question that would also -- are we

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looking at a population of theoretical girls that did begin puberty suppression at 10 or 2 or early 10 or 3 and then took a pause to maturation before beginning hormonal therapy; or are we talking about girls that go straight.
Q. In neither case is there any data to your knowledge as to when or whether those girls can ever achieve healthy levels of fertility?
A. As to whether I believe, there may be. There's some data showing that if they stop -- stopping testosterone or decreasing, fertility is quite possible.
Q. Well --
A. There's also --
Q. Go a little bit further down here.
A. -- many cases of trans men becoming pregnant, intended and unintended.
Q. It says -- at the end of the paragraph -- it says in the third paragraph, restoration -- and now we're talking about cross-sex hormones. "Restoration of spermatogenesis after prolonged estrogen treatment has not been studied." Period. Do you see that?

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A. At the timing here, it had not been studied.
Q. And so far as you know, it has still not been studied, correct?
A. I believe -- I'm no expert and I'm not an endocrinologist, a reproductive endocrinologist. But there is some data showing that even after prolonged estrogen treatment, restoration of spermatogenesis, quite possible.
Q. Do you have any study in mind when you say that or a statement from any organization?
No consulting with counsel on that.
A. All right. I would need to look into it.
Q. As you sit here now, you don't recall?
A. I'm telling you anecdotally, I can't give you an exact reference.
Q. Do you have a specific case from your clinic's experience in which a natal male who underwent prolonged cross-sex hormone treatment has subsequently become a father?
A. No, sir. Our clinic hasn't been

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around long enough for that to have taken place.
Q. Are you aware of any report of such a case in the literature?
A. Not that I can specifically direct you to.
Q. And anybody that you've treated in your clinic -- and if you started at 15 perhaps, they would be --
A. 23.
Q. -- 23. Just old enough. Are you aware of any case in which a natal female who underwent prolonged treatment with endogenous testosterone has later conceived and born a healthy child?
A. Yes.
Q. In one of your patients?
A. No, sir. Our patients aren't that old. Our first cohort are in college.
Q. And what case did you have in mind when you said yes, sir?
A. This is a case of an adult male, an adult trans man, that a colleague of ours -- not -- in a different state. A colleague of ours

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had brought to our attention where this man, transgender man became pregnant unintentionally but very happily and gave birth to a very healthy baby boy.
Q. What do you know about what hormonal or puberty blocking treatments that natal female had been subjected to prior to that pregnancy?
A. I do not know that gentleman's entire medical history. This was a case that a colleague had elevated in a discussion section with many of us, so I do not know a thing about that gentleman's history nor is it my business to know. However, he is far from the -- he's far from the only one.
Q. All right. Tell me another one.
A. Many adult trans men do carry their own children.
Q. Many adult trans men, natal females don't in fact choose to undergo cross-sex hormones, correct?
A. I couldn't speak to any individual's preference choice or how they manage their gender care.

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Q. General question.
A. Right.
Q. Many natal females who choose -- who live in a transgender male identity choose not to take cross-sex hormones; am I correct?
A. I think it's fair to say that transgender adults as a group may or may not choose to take or to continue hormonal therapy.
Q. So when we see a news item about a transgender man who has conceived and borne a child, we just don't know anything about whether that individual ever was subjected to prolonged testosterone, exogenous testosterone treatment, do we?
A. We don't know each individual man's medical history.
Q. And you're not aware of any published case study that documents a natal female who has been subjected to prolonged exogenous testosterone who has conceived and borne a healthy child?
MS. EAGAN: Object to the form.
Q. (BY MR. BROOKS) You can answer the

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question.
A. If you give me a computer, I can find you one, but I can't point you to one right now. That does not mean it has not been studied or that case collections have not been assembled.
Q. I understand. Part of my function today is just to get clear what you know and what you don't, and others may know other things. We put puzzle pieces together.
MR. BROOKS: I'm going to mark as Ladinsky Exhibit 28 a transcript of the PI, preliminary injunction hearing testimony of Dr. Antommaria from May 6, 2022.

(Whereupon, Ladinsky Exhibit 28 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) On Page 231 of this transcript, Dr. Antommaria was asked, "Would you agree that some of the risks of puberty blockers and cross-sex hormones would be loss in fertility?" And Dr. Antommaria answered, "There

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is a risk of impaired fertility."
Let me just ask you: Do you agree with Dr. Antommaria on that point, do you disagree, or do you think it's really outside your expertise?
A. If we are allowed to start at Sentence 8, I fully agree with Dr. Antommaria's bolded 8 through 11. And then as it continues with reference to some of the risks of puberty blockers and cross-sex would be loss of fertility. I agree with Dr. Antommaria's statement of, "There is a risk of impaired fertility."
Q. All right. Let's look at a very recent statement because you referred to a number of times of the possibility of more recent research. And I will take you to Exhibit 20 which is the de Vries editorial in the New England Journal of Medicine if we can find that. And I'm just going to take you back to language that we actually read into the record earlier, but we were focusing on brain development. The second page, the second column, two-thirds of the way down, it reads, "Finally, benefits of early medical

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intervention, including puberty suppression, need to be weighed against possible adverse effects, for example, with regard to bone and brain development and fertility." Period. Closed quote.
A. Right.
Q. And if Dr. de Vries of Vrije University team, writing in 2023, expresses the view that adverse effects on fertility are still possible effects of puberty suppression and early medical intervention, then do you agree, disagree, or think that you lack information to form an opinion on Dr. de Vries' statement?
MS. EAGAN: Object to the form.
A. Dr. de Vries is simply, to me, articulating what is done clinically on the frontlines which is weighing no risks, unknown risks, known benefits in the context of each individual patient.
Q. (BY MR. BROOKS) And one of the risks that Dr. de Vries thinks as of 2023 needs to be weighed is the risk of impairing fertility, correct?

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MS. EAGAN: Object to the form.
A. Correct. That is what Dr. de Vries says right here.
Q. (BY MR. BROOKS) Let me ask you to turn to your expert report to Paragraph 21. Maybe it's Page 21. You don't have numbered paragraphs. Page 21. Tab 13.
You state four lines from the bottom, quote, "Many people undergo fertility preservation before any treatment that could compromise fertility."
Of -- and you've said that the preponderance of the patients who present at your clinic are 14 years or older?
A. Correct.
Q. And among natal girls, what proportion who are age 14 have experienced menarche and are producing potentially fertile eggs?
A. Many.
Q. Many?
A. Yeah.
Q. What proportion of young people who

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come to your clinic into adolescence -- we'll talk about those 17 that you've given puberty blockers to. What proportion of those who arrive late enough that that's not an issue in fact undergo fertility preservation techniques before you administer cross-sex hormones to them?

A. Similar to Dr. Antommaria, I'd like to desegregate my trans ladies, natal males, from my trans men, natal females.

Q. Please.

A. Okay. And with reference to the former.

Q. Natal males?

A. Natal males identify female and those who go on to begin cross-sex hormones as older teens, those trans ladies. Following, you know, lengthy discussions leading up to that, more than half --

Q. Okay.

A. -- do bank gametes.

Q. And now for the natal females?

A. For the natal females, so those assigned male -- assigned female at birth identify

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male --

Q. I'm glad you get confused too.

A. -- that are beginning testosterone therapy. The preponderance of the evidence is such that as adults they are not as likely to experience impaired fertility should they want to, you know, one day have their own biologic children. So again, medicine, cost-benefit rate, the evidence showing that should they want to as adults either stop testosterone; if they have a uterus, carry their own child; relative to the procurement of eggs, which is extremely costly and quite invasive. It's cost-benefit given the family, the information we have, but it's not common that that's chosen.

Q. I think we saw earlier in the Endocrine Society document their representation that there was in fact no data on recovery of fertility by natal females after prolonged exposure to testosterone. You recall that?

A. That was a statement in 2017.

Q. And when I asked for more recent information, you referred to things you had seen

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in the news rather than anything in the scientific literature?

A. I didn't say that, sir.

Q. I thought you did?

A. Something I'd seen in the news?

Q. Then let me --

A. No, sir.

Q. Then let me ask: Are you aware of any peer-reviewed report, whether a study or a case study, of a natal female who has conceived and borne a healthy child after an extended period of years on cross-sex testosterone?

A. I have reason to believe that data exists. I cannot encyclopedically procure it for you out of my head, though.

Q. Despite the fact that you can't identify any such study, you advise natal females that fertility preservation is not so urgent for them because they will be able to have a better chance of recovering fertility later in adulthood if they change their minds?

A. It is not said exactly like you said that in counseling family.

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Q. How do you say it?

A. We talk about the risks of impaired fertility as adults should they maintain a uterus and want to carry their own biologic children and the possible need for fertility -- assisted fertility should that occur. We talk about the banking of ova and what is involved. And families weigh that and make their decision accordingly.

Q. When you say assisted fertility, what do you refer to?

A. The need to visit a reproductive endocrinologist later in life.

Q. But again, up to the present, you haven't seen a specific case study of any natal female who has been on cross-sex testosterone for a period of years who has conceived and borne a healthy child even with the assistance of a reproductive endocrinologist, correct?

MS. EAGAN: Object to the form.

Q. (BY MR. BROOKS) Unless she instructs you not to answer, you still have to answer.

A. I'll just restate what I just told

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you.
Q. Then let me ask her to read the question first, and then you can decide whether that's what you need to do.

(Whereupon, a portion of the testimony was read by the court reporter.)

A. I cannot point you to such a study. It does not mean it is nonexistent in the literature, the popular literature as well as the medical literature.
Q. (BY MR. BROOKS) Let me ask you to turn to Page 27 in your expert report. And you say -- there's a paragraph, full paragraph here that leads into the discussion of bone density. Do you see that?
A. I do.
Q. And you say towards the end, quote, "we know from excellent data that bone density catch-up ensues. This is well documented and matches our own clinical experience." Do you see

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that?
A. I see that.
Q. And for well documented -- well, let me ask you first about your clinical experience; that is, do you routinely measure the bone density of young people in your practice before and after they take cross-sex hormones or puberty blockers?
A. We do not routinely unless they have -- remember, we use puberty blockers for short durations of time. If they have other medical indications or other medical challenges that could interfere with calcium metabolism, vitamin D metabolism, or bone density, we do. But at this point, there is not -- it's not for these brief periods of time.
Q. In your clinical experience, you haven't compiled quantitative data about bone density, correct?
A. No, sir.
Q. So now let's look at what you say in Footnote 20 which is van der Loos.
MR. BROOKS: Let me mark as Exhibit 29. I think this will be called a research

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report, a short thing by van der Loos.

(Whereupon, Ladinsky Exhibit 29 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) And this is titled "Development of hip bone geometry in transgender adolescents resembles the experienced gender if GnRHa treatment is started in early, but not late, puberty." Do you see that?
My initial question is: Am I correct that this is what your Footnote 20 refers to?
A. I am -- but I believe that if you see that the original publication was in the Journal of Bone and Mineral Research, and this is in The Journal of the Endocrine Society. I believe that this is sort of a concise summary of that article as sort of abridged and published in the Journal of Endocrine Society, not the original.
Q. That's probably right and I'll have

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to follow that link there for the exciting --
A. Sorry.
Q. -- completion of this installment. Okay. I will not take your time on what's not the right document.
MR. BROOKS: Why don't we take a five-minute break while I kind of do a final scan.

(Whereupon, a brief recess was taken.)

Q. (BY MR. BROOKS) Let me ask a process question. As you prepared your expert report, did -- and without going into the substance, did counsel assist you, by for instance, in identifying articles that you might find useful to cite?
A. I think that's fair.
Q. And did counsel provide any editorial suggestions to the text?
A. It was a sort of back-and-forth if that makes sense.
Q. That does make sense.

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A. Okay.
Q. And did you ever take care that by the end everything in this report reflects your opinion rather than the opinion of counsel?
A. Yes, sir.
MR. BROOKS: Let me mark as Ladinsky Exhibit 30 a document entitled "Patient information for informed consent feminizing medications for transgender clients," which was apparently marked as Plaintiff's Exhibit 41 at the preliminary injunction hearing.

(Whereupon, Ladinsky Exhibit 30 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) And Dr. Ladinsky, I read the title that you see here. It's several pages in, you will see also the document -- it's probably in -- sometimes a separate document -- client information for informed consent, testosterone for transgender clients. I just want you to understand what we have here.

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A. So I'm assuming I have both -- okay.
Q. And I've just marked it as it was used as an exhibit at trial. I just want you to be aware that both of those are in here.
And does this -- do these two documents, if I may, are these still the forms that you're using in your clinic today?
A. They are.
Q. And when was the last time any change was made to these documents?
A. I believe they were reviewed, reformatted in the lead-up to the PI hearing.
Q. Was the substance changed as far as you know?
A. No, sir.
Q. And any of the specific disclosures changed in the lead-up to the PI period?
A. Not to my knowledge.
Q. So the first document refers to feminizing medication, and then the second one refers to testosterone for transgender clients. Neither of those categories include puberty blockers; am I correct?

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A. Correct.
Q. And do you have a different informed consent form that you use prior to administering puberty blockers?
A. So we actually do not use a written informed consent form for puberty blockers, and that's in line with the practice in many centers around the country. We at our center view them as a reversible but sort of pause button. We do in each patient's chart have, you know, basically a summary of what we discussed with the patients relative to potential side effects, intended effects, et cetera, of puberty blockers.
Q. Well, do you have any script that you or people associated with your clinic use to make sure that they have raised all potential side effects of puberty blockers in those oral conversations?
A. We do.
Q. And what does that look like? How long a document is it?
A. It's -- I'm visualizing it sort of as a phrase in the medical record. But it's a

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paragraph like that (indicating).
Q. It's not more than a page long?
A. That's fair.
MR. BROOKS: Counsel, I will say that I believe that that document is clearly called for by the document request, and we will request that it be produced following up.
MS. EAGAN: Well, I'll say I'm not UAB's lawyer, so you'll have to take that up with UAB's lawyer.
MR. BROOKS: Quite so.
Q. We will follow up on that.
A. Sure, absolutely.
Q. I appreciate your assurance.
A. Remember that the UAB Gender Health Clinic --
MS. EAGAN: There is no question on the table.
THE WITNESS: Okay.
Q. (BY MR. BROOKS) I like to think the Gender Health Clinic is not using puberty blockers, but that's a separate question.
A. Ditto.

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Q. All right. Let me just ask you about Page 3 of this document. And I'm looking at the information for feminizing.
A. Okay.
Q. You specifically require -- at the bottom of this page it states, "I know that there may be mood changes with these medicines, and I agree to continue therapy with a qualified therapist." Do you see that?
A. Uh-huh.
Q. So as a requirement to receiving cross-sex hormones from your clinic, you actually require that the patient agree to continue psychotherapy with a qualified therapist, correct?
A. That's what it says right there.
Q. Well, and do you know that to be your actual practice?
A. It is our practice.
Q. Okay. Let's look at your expert report Page 31. And there you say in the final paragraph, "If my clinic is barred from providing this care, it is foreseeable and certain that transgender youth in Alabama will suffer medical

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and mental health consequences, including declining mental health, suicide ideation, suicide attempts, and possibly completed suicides." Do see that language?
A. I see that language.
Q. And if in your view it is foreseeable and certain that these negative effects will happen if you do not provide hormonal care for the puberty blockers, is it your professional opinion that these harms will be avoided if you are able to provide hormonal interventions?
A. These medical interventions are part of gender affirmation required by transgender, gender incongruent young people to live in accordance with their identified gender in a robust way. Will it -- we've talked about this today. Will it in a linear way prevent, we cannot say that. But we know that the inability to provide it will accelerate these negative effects.
Q. Well, on the proposition that it is certain that the absence of these treatments will cause worsening condition, you cite nothing. And

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part of what your expert report is to do is to provide us not only your opinions but the basis for those opinions. And I would like you to tell me what the basis of that opinion is.
A. There's a wealth of literature that comes together to underscore improved mental health, improved physical health for young people who are able to access this care. If this care is not available -- and I'm going to bifurcate that as well. Okay. Let's talk about youth who are gender incongruent who are at high risk for gender dysphoria and what comes with it who have no ability to receive this care. We know the outcomes will be lessened. Mental health alone has not been shown to alleviate some of the downstream serious negative effects of untreated gender dysphoria.
Q. Is it your testimony that studies which you believe to be a sufficiently large size and sound methodology have shown that hormonal interventions will alleviate these harms?
A. Alleviate is a strong word. Okay.
Q. I thought it was a weak word.

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A. Will mitigate.
Q. All right.
A. Okay. When, you know, taken together with all of the other factors, family support, et cetera. But the bifurcation that is also very very important in this statement is if my colleagues and I are forced to cease care for youth receiving it currently, okay, to just stop it, that's not only medically contraindicated, but it's an ethical breach, and it has been shown to be associated with these harms.
Q. That is ceasing care, ceasing hormonal care for those already receiving it has been shown?
A. Well, first of all, in the case -- in the unique case of testosterone, that's medically contraindicated regardless. Anyone receiving testosterone for any number of medical indications, including gender dysphoria. That's medication that medically you don't stop. It's medically contraindicated to just cease that, but.
Q. Let me ask you a question about that if I may.

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A. Okay.
Q. You've talked throughout the day about the fact or the possibility of the young people have a choice to cease cross-sex hormones if they choose to?
A. That's correct.
Q. Do you tell them before prescribing testosterone that it would be medically indicated not to stop it once they begin it?
A. We tell them and we talk at each visit that our patients have the freedom and ability to change their mind. In the unique case of testosterone, we tell them, we don't want you to simply stop the medication. But should you decide that taking the medication is not warranted for you, we will do this together under a medically supervised taper. We have yet to see this specific situation. But yes, we have those discussions.
Q. You referred earlier to children who were suffering gender incongruence and were at risk for gender dysphoria. Do you recall that?
A. I do.

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Q. Does your clinic prescribe either puberty blockers or cross-sex hormones for children who have not received a diagnosis of gender dysphoria?
A. We do not.
Q. Then what were you talking about when you talked about children who are gender incongruous and at risk for gender dysphoria if they don't receive treatment?
A. I was speaking of a group of young people who may be in the phase of developing or understanding a gender incongruent identity, meaning as it's evolving. Should they evolve into teens with a transgender identity and for many the accompanying dysphoria, to know that the standard of care medicine is not available to them could accelerate mental health -- negative mental health outcomes.
Q. Let me ask for your unbigoted testimony under oath as to whether your clinic ever provides puberty blockers or cross-sex hormones for any young person who has not received a formal diagnosis of gender dysphoria by a

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qualified mental health professional?
A. Are you asking: Is it conceivable the diagnosis could have been made by physician or others?
Q. Has your clinic ever prescribed puberty blockers or cross-sex hormones for a young person who has not received a formal diagnosis of gender dysphoria by an appropriately qualified medical or mental health provider?
A. No, sir.
Q. Okay.
A. We have not.
MR. BROOKS: Let me mark as Ladinsky Exhibit 31 a document entitled "Advancing knowledge of transgender medical intervention effects" by Joshua Safer, from the Urology Journal.

(Whereupon, Ladinsky Exhibit 31 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) Let me ask first

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whether you've ever had any professional interactions with Dr. Safer?
A. I have not.
Q. Do you -- have you heard of his professional reputation?
A. I have not.
Q. Are you familiar with the gender clinic at the Mount Sinai Medical Institute in Manhattan?
A. I know that they have one.
Q. Okay. But you had no interactions?
A. No, sir.
Q. Then this will be quick. Writing in 2019 in the very first paragraph, Dr. Safer says the following: When assessing the risks and benefits of transgender hormone therapy, the evidence base to guide decision-making is thin. Although transgender hormone treatment seems to be generally safe when prescribed under medical supervision, the data that exist are mostly from medical record review of convenience samples with dozens or hundreds of patients." And he goes on a little bit later in that same paragraph to say,

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quote, "The nature of these studies has been to show minimal harm rather than to show benefit." Do you see the language that I've read?

A. I'm sorry. I was reading the --

Q. Feel free to read the entire paragraph.

A. I was reading the sentence before that.

MS. EAGAN: Look through the whole document. You're not familiar with this document.

THE WITNESS: Not at all.

MS. EAGAN: Let's take time to --

Q. (BY MR. BROOKS) Let me ask a fairly simple question. If Dr. Safer concluded in 2019, November of 2019, that the studies available up to that point tended to show minimal harm rather than to show benefit from cross-sex hormone therapy for gender dysphoria, do you simply disagree with Dr. Safer?

A. I'm struggling with this because I -- my first glance is that Dr. Safer is commenting on an article that's similar to --

Q. That's correct. And up front he's

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summarizing the state of the science.

A. As he sees it.

Q. That's right. And my question for you is very simple. If, as he sees it, the state of the science is to show minimal harm rather than to show benefit from cross-sex hormones, do you simply disagree with his evaluation of the science?

A. I cannot in any way comment on Dr. Safer's impressions relative to this. This is a group -- the study involves and the analysis here involves a group of adults. These may well have been adults who transitioned as adults. Therefore, physiologically the changes they experienced from those hormones may be quite different than those experienced by an adolescent. In addition, it's tempered by their expectations, their perception of their own bodily feelings, pain, discomfort, or comfort. So that's what I'm seeing here if that helps.

Q. All right.

MR. BROOKS: Let me mark as Ladinsky Exhibit 32 a paper entitled "Psychological

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Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared With Cisgender General Population Peers" by authors including van der Miesen, Steensma, de Vries, and others with Dutch names. That's dated 2020.

(Whereupon, Ladinsky Exhibit 32 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) My first question to you, Dr. Ladinsky, will be whether this is an article that you have read before today?

A. I recall seeing this article. I cannot -- I don't recall detail.

MS. EAGAN: Take your time.

Q. (BY MR. BROOKS) I want to ask you not so much about the results but about a couple of cautions the authors authored. Page 703.

MS. EAGAN: Dr. Ladinsky, do you want to review the article?

Q. (BY MR. BROOKS) Well, let me ask the question before you review the whole article.

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If you turn to Page 703, an inch and a half from the bottom in the first column, maybe 2, is a sentence that reads, "It should be acknowledged that the care provided in the present study also involved the offering of appropriate mental health care." Period. Closed quote. Do you see that?

A. Hang on.

MS. EAGAN: What page?

MR. BROOKS: It's 703, the first column.

Q. And you're in the second column right now?

A. Okay.

Q. An inch and a half from the bottom of the first column.

A. Do you mind if I read the discussion quickly?

Q. Let me ask you a question first, and then you can decide what you need to read. What the authors here say is, "It should be acknowledged that the care provided in the present study also involved the offering of appropriate

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mental health care." Inch and half from the bottom of that column, maybe 2.
A. I got you.
Q. So let me ask: That's consistent with your clinic's practice where we saw you --
A. That's correct.
Q. -- require your patients to be receiving appropriate mental health care concurrently with whatever medical care you provide, correct?
A. That's correct. It is our practice.
Q. Does that -- just speaking general methodology, does that create what you early refer to as a confound when you attempt to analyze the significance of improvements or lack of improvements on the part of patients? I think you used the term. Do you understand what a confound is?
A. I do. I'm trying to put it into the context of what you're asking relative in addition to this.
Q. So let's put this study aside for a moment because just generally it studies gender

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dysphoric youths who are receiving medical intervention of some type?
A. Right.
Q. And you're measuring outcomes. If they are concurrently receiving mental healthcare, does that in your understanding create a confound that stands between you and formed conclusion about the effect of the medical care on the one hand versus the mental health care on the other?
A. No.
MS. EAGAN: Object.
Q. (BY MR. BROOKS) Why is that?
A. First of all, I'm not actively engaged in research. Are you insinuating, meaning when I'm evaluating --
Q. Exactly so.
A. -- successive treatment with an individual patient?
Q. Or when you're evaluating literature?
A. That's very different. Okay. When I'm evaluating literature as in this study?
Q. Or any study whether there's medical

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care and mental health care delivered concurrently?
A. In this -- in gender health, especially in work with adolescents, you know, to -- the mental health piece is standard of care for good reasons. I'm not a researcher, but I would not see it as a confounding variable because it's being received before, during, and ongoing, their receipt of these individual transitioning therapies. It shouldn't confound our analysis of success around the role of medication.
Q. Let me ask a question unrelated -- entirely unrelated to this paper. I don't think anything in the paper mentions this.
You testified that the large majority of your patients who come in are age 14 or above when you first see them, correct?
A. Many, yes.
Q. And is it the case that at least most young people who come to you at that stage in life are experiencing distress or mental health difficulties of one type or another?
A. Many.

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Q. And do you have any knowledge as to whether -- putting aside gender dysphoria in young people -- young people who are, let's say, at age 15 suffering mental health issues are on average in a better place, in the same place, or in a worse place two years later? In other words, does maturation in that age period, simple process of getting older, provide a statistical improvement in mental health?
A. I'm sorry. Were you talking about youth who experience gender dysphoria or the general population of just, say, cisgendered teenagers experiencing anxiety, depression?
Q. The latter.
A. The latter. Okay.
Q. My question is: Do you have any knowledge about whether such a trend either getting worse or getting better in that age period exists?
A. In my clinical experience as a primary care provider for children and adolescents, it is my experience that adolescents who have mental health challenges and are not

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provided therapeutic programming pharmacology around them, they do not get better. They can get far worse.

Q. Back to our friends at the Vrije University clinic in the second column of 703. The authors state 2 inches -- everything I call out is an inch or 2 from the bottom. So 2 inches from the bottom. The sentence that begins, "The present study can." Do you see that?

A. Got it.

Q. Let me read that in the record. "The present study can, therefore, not provide evidence about the direct benefits of puberty suppression over time and long-term mental health outcomes. Conclusions about long-term benefits of puberty suppression should thus be made with extreme caution needing prospective long-term follow-up studies with a repeated measure design with individuals being followed over time to confirm the current findings." Do you see that language?

A. I see that language.

Q. And do you agree that up to the

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present, conclusions about the long-term benefits -- this is what they specifically speak to -- of puberty suppression need to be made with extreme caution?

A. Without putting it into the context of the entire study, I don't know what they mean by "with extreme caution".

A clinical implication of these findings is the need for worldwide availability of gender-affirming care including puberty suppression to alleviate mental health problems.

MS. EAGAN: Dr. Ladinsky, you probably answered his question. He asked if you agree with that statement, and you said you can't do it without the context of the document. So I think it's time for another question.

MR. BROOKS: Well testified.

THE WITNESS: She's professional.

MR. BROOKS: Let me mark as Exhibit 33 a paper by Polly Carmichael dated 2021 entitled "Short-term outcomes of pubertal suppression in a selected cohort of 12-to-15-year-old young people with persistent gender dysphoria in the UK."

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(Whereupon, Ladinsky Exhibit 33 was marked and copy of same is attached hereto.)

Q. (BY MR. BROOKS) You'll see at a glance that this is research coming out of the Tavistock Clinic --

A. We do.

Q. -- that we spoke about earlier. Have you encountered professionally any of the authors of this article?

A. I have not.

Q. And is this article one that you believe that is part of your process of staying abreast of the literature in the field that you read sometime soon after it was published?

A. I vaguely recall it being published.

Q. They list in the methods paragraph certain metrics that they followed including youth self-report, CBCL, YSR. Are those metrics that you're familiar with?

A. The YSR, I'm not familiar with.

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I've heard of the CBCL. But these are, you know, as you see by the spelling of behavior, these are British tools.

Q. You know that to be the case? You don't believe that the CBCL and the YSR are used by American researchers as well?

A. They may well be used by American researchers as well, but I am not familiar with them, put it that way.

Q. And you see that this article is from February 2021. Do you see that?

A. It was published then, that's correct.

Q. Presumably the work done was earlier than that?

A. Yes, exactly.

Q. Do you recall -- you said you recall this being published. Obviously coming from a large and prestigious institute, correct?

A. The Tavistock/Portman Clinic is a very very well, you know, longstanding institutional source of care, yes.

Q. Was this, in your opinion, an

important piece of research information when it came out?

A. It was sort of an observational study looking at 44 young people receiving puberty blockers with persistent severe gender dysphoria. Their observations are always going to be of interest to anybody working in this field. Do I remember it as sentinel, I can't -- I don't recall.

MR. BROOKS: Well, with a minute or two to go, I will cede my time. I have no further questions for the witness.

MS. EAGAN: I do not have any questions.

COURT REPORTER: Do you want a copy of the transcript?

MS. EAGAN: Absolutely. We're going to read and sign.

(Whereupon, a discussion was held off the record.)

MR. BROOKS: The defendants are

withdrawing from the record Exhibit 2, which was as transcript of the May 5, 2022 session of the preliminary injunction hearing.

MS. EAGAN: And plaintiff is in agreement with that withdrawal, so it will not part of this deposition transcript.

(Whereupon, the deposition ended at 5:56 p.m.)

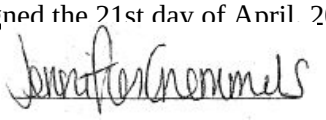
C E R T I F I C A T E

STATE OF ALABAMA)
JEFFERSON COUNTY)

I hereby certify that the above and foregoing proceeding was taken down by me in stenotype, and the questions and answers thereto were transcribed by means of computer-aided transcription, and that the foregoing represents a true and correct transcript of the testimony given by said witness upon said hearing.

I further certify that I am neither of counsel, nor of kin to the parties to the action, nor am I in anyway interested in the result of said cause.

Signed the 21st day of April 2023.



Jennifer Madaris
ACCR 585
My license expires September 30, 2023
My Commission expires January 4, 2026

To: Melody H. Eagan, Esq.
Re: Signature of Deponent Morissa J. Ladinsky, M.D.
Date Errata due back at our offices: 30 days

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I, the undersigned, do hereby certify that I have read the transcript of my testimony, and that

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___ The following changes are noted:

Pursuant to Civil Procedure, Rule 30. ALA. CODE § 5-30(e) (2017). Rule 30(e) states any changes in form or substance which you desire to make to your testimony shall be entered upon the deposition with a statement of the reasons given for making them. To assist you in making any such corrections, please use the form below. If additional pages are necessary, please furnish same and attach.

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DEPONENT'S SIGNATURE

Sworn to and subscribed before me this ___ day of

_____, _____.

_____

NOTARY PUBLIC / My Commission Expires:_____