Appendix Attachment

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

AUGUST DEKKER, et al.,

Plaintiffs,

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

SIMONE MARSTILLER, et al.,

Defendants.
_____/

DECLARATION OF QUENTIN L. VAN METER, MD

I, Quentin L. Van Meter., hereby declare and state as follows:

1. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this declaration and would testify completely to those facts if called to do so.

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

3. I did my Pediatric Endocrine fellowship at Johns Hopkins Hospital from 1978-1980. The faculty present at that time had carried on the tradition of excellence established by Lawson Wilkins, M.D. Because of the reputation of the endocrine program as a center for exceptional care for children with disorders of sexual differentiation, I had well-above average exposure to such patients. As a

Pediatric Fellow, I was also exposed to adults with Gender Identity Disorder, then called Trans-Sexuality, and received training from John Money, Ph.D., in his Psycho-hormonal Division. Over the past 44 years, I have closely followed the topic of incongruent gender in children adolescents and adults.

4. I am the author of a report attached to the Florida Agency for Healthcare Administration's Generally Accepted Professional Medical Standards on the Treatment of Gender Dysphoria. A copy of my report is attached and incorporated by reference as Exhibit "A" to this declaration.

5. I have been retained by the Defendants in this case to respond to statements of Johanna Olsen-Kennedy about my report.

6. I have testified in deposition or at trial in the following cases within the last four years: Siefert *v.* Hamilton County, Ohio, Grahm *v.* Gloucester County Schools, Virginia, Ray et al *v.*Himes et al, U.S. District Court for the Southern District, Ohio, A.Loughman *v* .C. Loughman 311th Judicial District Court, Harris County TX, L.C. Cauthen *v.* J.B. Cauthen Cobb Country Superior Court, Georgia, and LL Spahr *v.* R.S.Spahr, St. Louis County Court, MO.

7. A list of my publications is included in my curriculum vitae, which is attached.

8. I was compensated $350 per hour for preparing my initial report ("Exhibit "A")I am being compensated at an hourly rate of $450 per hour for my time preparing this declaration. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

7. In paragraph 63 of her declaration, Dr. Olsen-Kennedy states that I "incorrectly allege that an increase in numbers of youth presenting for care related to GD provides support for the social contagion theory." In doing so, she summarily dismisses the fact that the numbers of children and adolescents presenting with gender identity incongruence (GII) has increased because of social

contagion and asserts that the "old numbers" were from the time when the diagnosis was for Gender Identity Disorder (GID), not Gender Dysphoria. She categorizes GID as a completely separate disorder from Gender Dysphoria, which is patently wrong. GID was banished from the DSM-V because the committee that was in charge of revising the DSM-IV threatened its chairman, Kenneth Zucker, with loss of his position at the prestigious clinic in Toronto where so much work had been done with children and adolescents using counseling therapies to bring about desistance of the gender identity incongruence. Zucker, in order to protect his patients from losing all health care funding for their counseling therapies, pleaded that erasing GID would leave the patients with no diagnosis at all and that, at least Gender Dysphoria would allow these patients to seek the care they needed and not have to pay out of pocket. His efforts still got him fired.

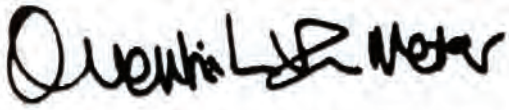
8. It flies in the face of reality that online communication is the not the first and foremost place where the patient with GII searches. If you search transgender on Google, you find 513,000,000 entries, with Planned Parenthood at the top of the list. This is social contagion by definition. At 5000% increase in clinic consultations over 10 years in the Tavistock clinic does not happen with resolution of the minority stress theory.

9. In paragraphs 89-91 of her declaration, Dr. Olson-Kennedystates that "[b]oth the GAPMS Memo and Dr. Van Meter repeatedly express concern that the U.S. Food and Drug Administration (FDA) has not approved puberty blockers or hormone therapy for the treatment of gender dysphoria." In doing so, she argues that many drugs are used off label and therefore the use of off-label drugs for gender dysphoria is no different. Those drugs that are used off-label are either not shown to have any significant adverse outcome, or they are used in a very limited fashion until it can be proven they are safe and efficacious. An example of this is the use of aromatase inhibitors in adolescent males to stall off epiphyseal closure in hopes of achieving a better final height. This class of drugs was brought under scrutiny by the Pediatric Endocrine Society Committee on

Pharmacotherapeutics, and very strict safety monitoring standards were proposed. There are unquestionable issues with adverse outcomes using GnRH analogs in adolescents: bone density, interruption of gonadal maturation, inhibition of brain development are just a few. There is no ongoing, centralized unbiased assessment of these issues, despite the clear call by the Endocrine Society Guidelines of 2009 and revised Guidelines of 2017. Because the necessary, RECOMMENDED controlled studies are not being done, proceeding with the use of GNRH agonists is unquestionably experimenting on children.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 2nd day of October, 2022.

Respectfully submitted,



Quentin L. Van Meter, MD

QUENTIN L. VAN METER, M.D. **updated 29 April, 2022**
1800 Howell Mill Road NW, Suite 475
Atlanta, Georgia 30318 **(678) 961-2100**

PERSONAL

Home Address:	1080 Peachtree St. NE #3507, Atlanta, GA 30309
Home Phone:	(404) 963-5618
Date of Birth:	September 13, 1947
Place of Birth:	Laramie, Wyoming
Citizenship:	USA

EDUCATION:

Undergraduate:	College of William & Mary, 1969 B.S. – 1969
Medical School:	Medical College of Virginia, 1973 M.D. – 1973

CLINICAL TRAINING:

Institution:	The University of California, San Francisco
Hospital:	Naval Regional Medical Center, Oakland
Position:	Pediatric Intern – 1973 – 1974 Pediatric Resident – 1974 – 1976
Institution:	Johns Hopkins University
Hospital:	Johns Hopkins Hospital
Position:	Fellow, Pediatric Endocrinology 1978 – 1980 Fellowship Program Director: Claude Migeon, M.D.
Current Position:	Pediatric Endocrinologist Van Meter Pediatric Endocrinology, P.C. 1800 Howell Mill Road, Suite 475 Atlanta, Georgia 30318

PROFESSIONAL CERTIFICATION & SOCIETIES:

Diplomate, National Board of Medical Examiners, 1974

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

Fellow:	American Academy of Pediatrics, Georgia Chapter 1975 -present President, Uniformed Services West Chapter, 1987 – 1990 District VIII member, AAP Committee on Awards for Excellence in Research, 1990-1994 Editor, The Georgia Pediatrician, 1994 – 1998 Chairman, Georgia Chapter Legislative Committee, 1996 – 2006
Fellow:	The American College of Pediatricians, 2007 – present Member of the Board of Directors, 2008- present President, 2018-present
Member:	Pediatric Endocrine Society, 1989 – present
Member:	American Diabetes Association Professional Section, 1988 – present
Member:	Endocrine Society, 1994-present
Member:	Southern Pediatric Endocrine Society, 1992 – Present
Member:	American Association of Clinical Endocrinologists, 2005 – present
Licensure:	Georgia, #34734

FACULTY POSITIONS:

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

MILITARY SERVICE:

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

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

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

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

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

OTHER PROFESSIONAL ACTIVITIES:

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

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

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

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

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

Pediatric Endocrinologist Peer Reviewer 2006 – present
MCMC, LLC, Boston, MA
IMEDECS, Lansdale PA

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

PUBLICATIONS: (Articles in Peer Reviewed Journals)

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

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

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

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

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

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

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

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

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

ABSTRACTS/LETTERS:

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

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

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

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

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

G.M. Bright[1], W.V.Moore[2], J.Nguyen[3], G. Kletter[4], B. S. Miller[5], Q. L. Van Meter[6], E. Humphriss[1], J.A. Moore[7] and J.L. Cleland[1] Results of a Phase 1b Study of a new long-acting human growth hormone (VRS-317) in pediatric growth hormone deficiency (PGHD). PAS 2014 May 2014

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

Wayne V. Moore[1], Patricia Y. Fechner[2], Huong Jil Nguyen[3], Quentin L. Van Meter[4], John S. Fuqua[5] , Bradley S. Miller[6], David Ng[7], Eric Humphriss[8], R. W. Charlton[8], George M. Bright[8], Safety and Efficacy of Somavaratan (VRS-317), a Long-Acting rhGH, in Children with Growth Hormone Deficiency (GHD): 3-Year Update of the VERTICAL & VISTA Trials, presented at the 2017 Endocrine Society meeting in Orlando FL

Bradley S. Miller[1], Wayne V. Moore[2], Patricia Y. Fechner[3], Huong Jil Nguyen[4], Quentin L. Van Meter[5], John S. Fuqua[6], David Ng[7], Eric Humphriss[8], R. W. Charlton[8], George M. Bright[8], 3-Year Update of the Phase 2a and Long-term Safety Studies (VERTICAL and VISTA) of Somavaratan (VRS-317), a Long-acting rhGH for the Treatment of Pediatric Growth Hormone Deficiency, presented at the 2017 IMPE meeting in Washington D.C.

ADDITIONAL PRESENTATIONS/LECTURES:

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

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

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

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

Pediatric Grand Rounds, Tanner Medical Center, October 1997

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

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

Pediatric Grand Rounds, Columbus Regional Medical Center, January 2004

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

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

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

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

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

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

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

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

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

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

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

Southern Pediatric Endocrine Society, Orlando FL, Feb 2019

Matthew Bulfin Conference, Indianapolis IN April 2019

CMDA annual conference, Ridgecrest NC, May 2019

Support 4 Family conference, London, UK June 2019

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

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

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

CURRENT HOSPITAL APPOINTMENTS:

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

PAST AND CURRENT CLINICAL RESEARCH:

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

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

LEGAL EXPERT WITNESS:

2017	North Carolina Legislature- transgender bathroom bill
2018	Jessica Siefert transgender case, Cincinnati, OH
2018	Alberta, Canada school system transgender case
2018	Decatur GA School Board transgender case
2019	British Columbia transgender case
2019	Gavin Grimm transgender case, Gloucester County, VA
2019	Rowe vs Isle of Wight School Board, UK
2019	Younger transgender case, Dallas, TX
2020	Alabama State House and Senate committee hearings
2020	Pennsylvania State House Health Subcommittee hearings
2020	Iowa State House committee hearing
2020	California State House committee hearing
2020	Harris Count TX custody case
2021	Missouri State House committee hearing
2021	NAACP *v* State of Arkansas

EXHIBIT "A"

Concerns about Affirmation of an Incongruent Gender in a Child or Adolescent

Quentin L. Van Meter, M.D.
May 17, 2022

Qualifications

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

I did my Pediatric Endocrine fellowship at Johns Hopkins Hospital from 1978-1980. The faculty present at that time had carried on the tradition of excellence established by Lawson Wilkins, M.D. Because of the reputation of the endocrine program as a center for exceptional care for children with disorders of sexual differentiation, I had well-above average exposure to such patients. As a Pediatric Fellow, I was also exposed to adults with Gender Identity Disorder, then called Trans-Sexuality, and received training from John Money, Ph.D., in his Psycho-hormonal Division. Over the past 44 years, I have closely followed the topic of incongruent gender in children adolescents and adults, but I am focusing in this document on working with children and adolescents. To get a more solid understanding of how male and female human beings develop in utero, it is important to start at the point when a sperm meets an egg.

Differentiation in the Fetus

From the moment of conception, a fetus is determined to be either a male (XY), female (XX), or in rare cases, to have a combination of sex-determining chromosomes, many of which are not compatible with life, and some of which are the cause of identifiable clinical syndromes. The presence of a Y chromosome in the developing fetus directs the developing gonadal tissue to develop as a testicle. The absence of a functional Y chromosome allows the gonadal tissue to develop as an ovary. Under the influence of the mother's placental hormones, the testicle will produce testosterone which directs the genital tissue to form a penis and a scrotum. Simultaneously, the testicle produces anti-Müllerian Hormone (AMH) which regresses development of the tissue that would otherwise develop into the uterus, fallopian tubes, and upper third of the vagina. This combination of actions in early fetal development is responsible for what we subsequently see on fetal sonograms, and what we observe at birth as male or female genitalia. It is only when the genital structures are ambiguous in appearance that sex determination is withheld until a thorough expert team evaluation has occurred.

For reasons most often occurring as random events, there are malfunctions of the normal differentiation. These aberrations of normal development are responsible for what we classify as Disorders of Sexual Differentiation (DSD), and they represent a very small fraction of the human population. The incidence of such circumstances occurs in 1:4500 to 1:5500 births.[1] Sex is binary, male or female, and is determined by chromosomal complement and corresponding reproductive role. The exceedingly rare DSDs are all medically identifiable deviations from this sexual binary norm. The 2006 consensus statement of the Intersex Society of North America and the 2015 revision of the Statement do not endorse DSD as a third sex.[2] DSD outcomes range from appearance of female external genitalia in an XY male (complete androgen insensitivity syndrome) to appearance of male external genitalia in an XX female (severe congenital adrenal hyperplasia).

As one would expect, there are variations of the degree of hormonally driven changes that create ambiguous genital development that prevent assigning of a specific classification as either male or female at birth. DSD patients are not "transgender"; they have an objective, physical, medically verifiable, physiologic condition. Transgender people generally do not have intersex conditions or any other verifiable physical anomaly. People who identify as "feeling like the opposite sex" or "somewhere in between" do not comprise a third sex. They remain biological men or biological women.

In some DSDs there exist more than one set of chromosomes. When there is a divergence of the appearance of the external genitalia from the chromosomally determined sex due to the presence of both an ovarian and testicular cell lines in a patient simultaneously, the patient is classified as having ovo-testicular DSD (formerly termed a true hermaphrodite). When there is a disruption in the development of genital structures but there is solely testicular tissue present in the chromosomal male or solely ovarian tissue in the chromosomal female, the term 46 XY DSD or 46 XX DSD is used instead respectively (formerly termed male pseudohermaphrodite or female pseudohermaphrodite).

The decision to assign a sex of rearing is complex and is specific to the diagnosis. Patients with complete androgen insensitivity (CAIS) are XY DSD but are never reared as a male. Because testosterone never influences development, they become happy, functional female adults with infertility. Females with severe congenital adrenal hyperplasia (CAH) are XX DSD but are not reared as males despite the male appearance of the genitalia at birth. Although these girls may show a tendency for male play behaviors as children, they generally assume a female sexual identity. Therapeutic interventions in the DSD individuals from infancy onward are aimed at what function can be expected from their disordered sexual anatomy in terms of function and fertility. Most often, the chromosomal sex aligns with the sex of rearing.

Gender Identity

"Gender" is a term that refers to the psychological and cultural characteristics associated with biological sex. It is a psychological concept and sociological term, not a biological one. The term gender possessed solely a linguistic meaning prior to the 1950s. This changed when sexologists of the 1950s and 1960s co-opted the term to conceptualize cross-dressing and transsexualism in their psychological practice. "Gender identity" is a term coined by my former endocrine faculty member John Money in the 1970s and has come to refer to an individual's mental and emotional sense of being male or female. The norm is for individuals to have a gender identity that aligns with one's biological sex.

Gender discordance (formerly Gender Identity Disorder) is used to describe a psychological condition in which a person experiences marked incongruence between his experienced gender and the gender associated with his biological sex. He will often express the belief that he is the opposite sex. Up until 2010, gender discordance occurred in 0.001% of biological females and in 0.0033% of biological males.[3] Exact numbers are hard to document since reporting is often anecdotal. Gender discordance is not considered a normal developmental variation.

"Gender Dysphoria" is a diagnostic term to describe the emotional distress caused by gender incongruity.[4] John Money played a prominent role in the early development of gender theory and transgenderism. He understood gender to be "the social performance indicative of an internal sexed identity."[5] He joined the Johns Hopkins faculty in 1951 specifically to have access to children diagnosed with DSD, hoping to prove his theory that gender was arbitrary and fluid. Money experimented with DSD infants by assigning them to the opposite biological sex through surgical revision, counseling, and hormonal manipulation during puberty. His mode of operation was to have a theory and then experiment with patients to see how his theory worked.

Ethics in Clinical Research on Human Subjects

It is important to discuss the need for ethics to play a role in the design of clinical studies involving human patients. To have a hypothesis, as did John Money, is not at issue. However, to clearly elucidate the potential for harm and balance that knowledge with the potential benefits is key and essential. After the travesties of open-ended experimentation in the Nazi concentration camps, international guidelines were established to protect human subjects from just such experimentation.[6] John Money ignored these guidelines as he assigned genders to infants and toddlers with ambiguous genitalia. There was no informed consent of the patients, who were infants and toddlers, and their parents were just told to follow the advice of Dr. Money and to trust that he had the correct information. There was no standardized protocol to follow, and no known outcome that could be guaranteed. This kind of endeavor did not anticipate or prevent adverse outcomes and was the antithesis of ethical science. Money never submitted his research proposals for review by an independent external review board. This left the patients unprotected and vulnerable to harm, and, indeed, in the case of the Reimer twins, to death due to drug addiction/overdose in one brother to and suicide in the other.[7]

Near the end of my fellowship training at Johns Hopkins, a male infant was sent to our clinic to assess the cause of his very small penis and testicles. My attending physician and I laid out a diagnostic work-up based on the known science which would help us understand whether the problem was due to a pituitary deficiency or an inability of tissue response to hormones. We purposely left John Money off the care "team," having some serious concerns about his tendency to dismiss science and to experiment. We sent the family home with their son and were quite surprised when the mother returned six weeks later with a baby wearing a pink dress and an eyelet bonnet. Without our knowledge, Dr. Money had intervened and told the family that our protocol was nonsense and the baby needed to be reared as female. On physical exam, there was clear evidence that not only was the baby able to produce testosterone, but his penis responded well, as expected, to the hormone production by his own body. The family was relieved but had not been spared suffering under the experimentation by Dr. Money. They had suffered deeply when they divulged to their extended family that their baby boy was actually a baby girl, and then they suffered even more when they recanted and resumed calling him a boy.

Because of his experience with infants, Money initially garnered support from endocrine colleagues and surgical colleagues, and Johns Hopkins became a renowned center for care of patients with DSD in the 1970s, receiving referrals from around the world. Follow-up studies on these infants later showed, however, that altering their natal sexual identity via social intervention could lead to severe psychological harm. Clinical case reports of children with DSD have revealed that gender identity is indeed not immune to environmental input.[8]

Meanwhile, Money had expanded into the field of adult patients with persistent gender identity disorder. This very small group of patients chose voluntarily, as adults, to enter a very precise protocol which began with living socially as the opposite sex for a year, eventually receiving hormonal therapy to change their physical appearance to some extent. The final step was surgical revision of the body structures that would otherwise be at odds with their desired gender identity. This small group of patients was followed for a number of years past their final surgical procedures and required continuous counseling. These patients expressed some degree of subjective satisfaction but showed no objective improvement in overall wellbeing.[9] The legacy of John Money fell into disrepute and the transsexual treatment program at Johns Hopkin was closed in the 1980s based on the lack of evidence that this protocol produced an effective cure.

Etiology of Gender Disorders

Transgender affirming professionals claim transgender individuals have a "feminized brain" trapped in a male body at birth and vice versa based upon various brain studies. Diffusion-weighted MRI scans have demonstrated that the pubertal testosterone surge in boys increases white matter volume. A study by Rametti and colleagues found that the white matter microstructure of the brains of female-to-male (FtM) transsexual adults, who had not begun testosterone treatment, more closely resembled that of men than that of women.[10] Other

diffusion-weighted MRI studies have concluded that the white matter microstructure in both FtM and male-to-female (MtF) transsexuals falls halfway between that of genetic females and males.[11] These studies, however, are of limited clinical significance due to the small number of subjects and failure to account for neuroplasticity.

Neuroplasticity is the well-established phenomenon in which long-term behavior alters brain microstructure. For example, the MRI scans of experienced cab drivers in London are distinctly different from those of non-cab drivers, and the changes noted are dependent on the years of experience.[12] There is no evidence that people are born with brain microstructures that are forever unalterable, but there is significant evidence that experience changes brain microstructure.[13,14] Therefore, any transgender brain differences would more likely be the result of transgender behavior than its cause.

Furthermore, infants' brains are imprinted prenatally by their own endogenous sex hormones, which are secreted from their gonads beginning at approximately eight weeks' gestation.[15,16,17] There are no published studies documenting MRI-verified differences in the brains of gender-disordered children or adolescents. The DSD guidelines also specifically state that current MRI technology cannot be used to identify those patients who should be raised as males or raised as females.[18] Behavior geneticists have known for decades that while genes and hormones influence behavior, they do not hard-wire a person to think, feel, or behave in a particular way. The science of epigenetics has established that genes are not analogous to rigid "blueprints" for behavior. Rather, humans "develop traits through the dynamic process of gene-environment interaction. ... [genes alone] don't determine who we are." [19]

Regarding transgenderism, twin studies of adults prove definitively that prenatal genetic and hormone influence is minimal. The largest twin study of transgender adults found that only 20 percent of identical twins were both transgender-identified.[20] Since identical twins contain 100 percent of the same DNA from conception and develop in exactly the same prenatal environment exposed to the same prenatal hormones, if genes and/or prenatal hormones contributed to a significant degree to transgenderism, the concordance rates would be close to 100 percent. Instead, 80 percent of identical twin pairs were discordant. This difference would indicate that at least 80 percent of what contributes to transgenderism as an adult in one co-twin consists of one or more non-shared post-natal experiences including but not limited to non-shared family experiences. These findings also mean that persistent GD is due predominately to the impact of nonshared environmental influences. These studies provide compelling evidence that discordant gender is not hard-wired genetically.

Gender Dysphoria vs. Gender Identity Disorder

Up until the recent revision of the DSM-IV criteria, the American Psychological Association (APA) held that Gender Identity Disorder (GID) was the mental disorder described as a discordance between the natal sex and the gender identity of the patient. Dr. Kenneth Zucker, who is a highly respected clinician and researcher from Toronto, carried on evaluation and

treatment of GID patients for forty years. His works, widely published, found that the vast majority of boys and girls with GID identify with their biological sex by the time they emerge from puberty to adulthood, through either watchful waiting or family and individual counseling.[21] His results were mirrored in studies from Europe.[22,23]

When the DSM-V revision of the diagnosis of GID was proposed by the APA committee responsible for revision, Dr. Zucker strongly opposed the change to the term Gender Dysphoria, which purposefully removed gender discordance as a mental disorder apart from the presence of significant emotional distress. With this revision, Gender Dysphoria describes the mental anguish which is experienced by the gender discordant patient. The theory that societal rejection is the root cause of Gender Dysphoria was validly questioned by a study from Sweden which showed that the dysphoria was not eliminated by hormones and sex reassignment surgery even with widespread societal acceptance.[24]

Treatment of Gender Dysphoria

The treatment of children and adolescents with gender discordance and accompanying gender dysphoria should include an in-depth evaluation of the child and family dynamics. This evaluation provides a basis on which to proceed with psychologic therapy. The entire biologic and social family should be involved in psychological therapy designed to assist the patient, if at all possible, to align gender identity with natal sex. Psychological support by competent counselors with an intent of resolving the gender conflict should be provided as long as the patient continues to suffer emotionally. Given the high degree of eventual desistance of gender discordance/dysphoria by the end of puberty, it would be ethical and logical to counsel the patient and family to rear the child in conformity with natal sex.

There should be no interruption of natural puberty. Natural pubertal maturation in accordance with one's natal sex is not a disease. It is designed to carry malleable, immature children forward to be healthy adults capable of conceiving their own progeny by providing either a sperm or an egg. Puberty affects physical changes, some of them painful, unique to the natal sex to reflect the laws of nature. Interruption of puberty has been reserved for children who begin puberty at an age much younger than normal in an effort to preserve final height potential and avoid the social consequences of precocious maturation.[25]

There are a number of physical changes that are a consequence of normally timed puberty that could be classified as disadvantageous: changes in body proportions can alter success with dance and gymnastics; acne can be severe and disfiguring; a boy soprano can suddenly hardly carry a tune. It has not been the ethical standard of care to stop puberty so that these changes can be circumvented. Erikson described the stage of adolescence as "Identity versus Role Confusion" during which the teen works at developing a sense of self by testing roles then integrating them into a single identity.[26] This process is often unpleasant regardless of the presence or absence of gender identity conflicts. The major benefit of enduring puberty in a GD patient is that it provides a strong likelihood of alignment of his gender identity with his

natal sex. There is no doubt that these patients need compassionate care to get them through their innate pubertal changes.

The light at the end of the tunnel is the proven scientific evidence that 80%- 95% of pre-pubertal children with GD will come to identify with their biological sex by late adolescence. Some will require lifelong supportive counseling while others will not.[27] Intervention at a young age with gonadotropin releasing hormone analogs (often referred to as puberty blockers) to either stop puberty early on or prevent it from starting before it naturally occurs is suggested by guidelines developed by WPATH without scientific basis. These guidelines are essentially nothing more than an open-ended experiment in the manner of John Money. They represent the ideas of their authors with clear admission that there is no long-term evidence that harm will exceed benefits as these patients grow to old age. There is evidence that bone mineral density is irreversibly decreased if puberty blockers are used during the years of adolescence.[28] To treat puberty as a pathologic state of health that should be avoided by using puberty blockers (GnRH analogs) is to interrupt a major necessary physiologic transformation at a critical age when such changes can effectively happen. We have definite evidence of the need for estrogen in females to store calcium in their skeleton in their teen years. That physiologic event can't be put off successfully to a later date. It is very difficult to imagine ethical controlled clinical trials that could elucidate the effects of delaying puberty until the age of consent.

The use of cross-sex hormones during this same time frame has no basis of safety and efficacy. The use of such treatment in adults raises scientifically valid concerns that were amply expressed in the 2009 Endocrine Society Guidelines on Transgender treatment. The next step in WPATH-recommended intervention is to use cross-sex hormone therapy during the time when the patient would naturally be experiencing endogenous pubertal changes. This too is not based on scientifically proven theories. The use of cross-sex hormones can cause permanent infertility.[29]

The final recommended step is so-called "sex reassignment surgery," which can include surgical removal of the breasts in natal females, or removal of the penis and scrotum in natal males. Each of these steps has adverse outcomes, some reversible and others not. Mastectomies leave scars, and there is great difficulty in creating a functional vaginal-like orifice, and certainly no success in creating an innervated erectile penis where none existed previously. Sex reassignment surgery is, by nature, permanent.

Recurrent Themes that Are Repeatedly Published

Puberty blockers are stated to be completely reversible in their effects on the adolescent who has entered puberty based on clinical studies in young children with precocious puberty who have been treated with these drugs. This is comparing apples to oranges. Precocious puberty, by definition, is defined as puberty which starts before the 8th birthday for a female child or the before the 9th birthday in a male child. The end of treatment is carefully timed so that resumption of puberty occurs at the average age for females (10.5 years) and males (11.5

years). This allows the necessary functions of puberty to prepare the body for reproduction and affects the bones, gonads, and brain, among other body systems. On the other hand, blocking puberty at the age of normal puberty prevents the needed accretion of calcium into the skeleton and prevents the maturation of the gonads. There is no long-term data that compares bone, gonad, and brain health in pubertal-aged patients who have had puberty interrupted and those who have not, as was noted as a concern in the Endocrine Society Guidelines. There are no such ongoing studies completed that guarantee the full reversibility of blocking puberty in this age group, but there is evidence that normal bone density can't be fully reestablished. Without any verifiable safety data, using the puberty blockers for interrupting normal puberty is not a sanctionable off-label use of these drugs and is therefore to be considered uncontrolled, non-consentable experimentation on children.

Advocates for the social, medical and surgical affirmation of gender incongruent children insist that they are only following established standards of care. There are no standards of care for transgender health. Standards of care established by broad consensus are reached by inclusion of the whole spectrum of opinions, clinical experience and published science in the formation thereof. The guidelines published by WPATH[30], the Endocrine Society,[29,31] the American Academy of Pediatrics[32], and the Pediatric Endocrine Society[33] are solely the opinions of like-minded practitioners who excluded any contrary opinion. The Endocrine Society Guidelines, as mentioned before, clearly stated that they are not to be considered standards of care. Before true consensus-driven standards of care are established for the treatment of transgender patients of all ages, following the current guidelines is risky experimentation in a manner reminiscent of John Money's tactics.

What We Do Know and Do Not Know

We do know that social affirmation of an incongruent gender tears the fabric of the patient's life into pieces- pitting family members against each other, ruining child friendships and it introduces the child to a fantasy world, much of it on the internet. Kenneth Zucker aptly documented the detrimental effects of such affirmation and the immense amount of work it takes to undo these effects when the child does come to realize they can't change their sex and wants to go back to identifying with their sex[34]. We do not know that social affirmation does anything other than push the child away from the proven, 80-90% effective, so-called watch-and wait treatment option. Embarrassingly unscientific short term convenience sample studies purport to show that all gender incongruent children who are socially affirmed have improved mental health and are therefore better off than those children who are not allowed to socially transition.[35]

We do know that blocking puberty during the age when puberty naturally happens lessens accretion of calcium into the skeleton and that this can't be regained by allowing puberty to resume or by using cross sex hormones. We do know that the ovary and testicle cease to mature with treatment. What we do not know is whether allowing puberty to resume will allow the ovary and testicle to fully mature and have full function in terms of fertility. We do

not know if brain development that is halted with puberty blockers can return to full function once puberty is allowed to resume.

We do know that elevated levels of testosterone in females and of estrogen in males create significant medical morbidity. This knowledge comes from the evaluation and treatment of naturally occurring disease states in children and adults. Treatment of these conditions is aimed at returning hormone levels to normal, thereby avoiding cancers, heart disease, and stroke. We do not know that elevating testosterone in females and estrogen in males to levels ten-fold higher than these known disease states is safe, but common sense would say it can't possibly be safe.

The Myth of Increased Suicide

The affirmation advocates repeatedly refer to the established increased risk of suicide if any of the affirmation strategies are not followed to completion. They point to their own published studies touting dramatic improvement in mental health status of patients who are affirmed in all three ways, but they cite data from convenience sampling, which never should be sued to prove anything other than association, at best. Such studies can never prove causation. There are only two total population studies in the peer-reviewed medical literature.[24,36,37] They show that when every recorded case in the population of Sweden was analyzed, neither medical affirmation nor medical affirmation followed by surgical affirmation improved the mental health of the patients in the long run.

What of the Nearly Logarithmic Increase in Incidence of Gender Incongruence?

Data collection in this regard is subject to estimates based on surveys, which can easily alter the numbers upward or downward, depending on who designed the survey and to whom it was presented. Fear, self-loathing or suicide will necessarily lower the numbers of survey participants whose lives are made miserable by the choice to affirm an incongruent gender. Instant gratification, payback to strict parents, and current celebrity will draw survey participants to express euphoric satisfaction with their decision to affirm their incongruent gender, especially when the surveys are circulated by trans-activist organizations, such as the Trevor Project. What had been in 2010 a nearly invisible fraction of adults who admitted to living with an incongruent gender has exponentially increased in frequency to as many as one out of five students in a suburban Pittsburgh school district in 2021. After I completed my fellowship at Johns Hopkins in 1980, it was not until 1993 that a biologic male presented to my private practice office with a desire to be treated with estrogen to feminize his body so that he could appear to be a female and identify as such. There was nothing in published medical literature that I could find to guide my treatment options. I canvassed my broad contact pediatric endocrinology network across the United States, and nobody had heard of such a clinical case, and none had any suggestions about what I should do. In the ensuing 19 years, the number of transgender treatment centers have burgeoned from zero to several hundred between university-based centers and Planned parenthood. Minority stress theory is frequently used to cover this explosion in numbers, but that is utterly impossible. What does

explain this increase is online recruiting and grooming of vulnerable children and adolescents by a generously funded political movement aimed at dissolving the reality and birthright of biologic sex. This will not end well. By the time a plethora of legal action against those who promoted and engineered the social, medical, and surgical affirmation of incongruent gender knocks down this house of cards, millions of children and adolescents will have been medically, surgically, and mentally maimed as well sterilized.

Endnotes

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Appendix Attachment

6

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

AUGUST DEKKER, et al.,

Plaintiffs,

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

SIMONE MARSTILLER, et al.,

Defendants.
_____/

DECLARATION OF ANDRE VAN MOL, MD

I, ANDRE VAN MOL, MD am submitting this declaration in support of the Agency for Healthcare Administration's (AHCA) response in opposition to the Plaintiffs' motion for preliminary injunction.

1. This declaration provides the following expert opinions, which are explained in further details below:

a. The expert declaration of Dr. Armand H. Matheny Antommaria is in error regarding his stated primary objections to the Florida Agency for Health Care Administration (AHCA) Medicaid's Generally Accepted Professional Medical Standards Determination of Treatment of Gender Dysphoria (GAPMS

Report) specified in his assertions that Florida AHCA "mischaracterizes":

i. "individuals as diagnosing themselves with gender dysphoria,"

ii. "treatments for gender dysphoria and "off-label" treatments as experimental,"

iii. "treatments of gender dysphoria as "eminence-based medicine" and

the evidence base supporting many medical treatments, and"

iv. the informed consent process for the treatment of gender dysphoria

BACKGROUND AND QUALIFICATIONS

2. I am a board-certified family physician in full-time practice in California where I am licensed to practice.

3. In 1986 I received my medical degree from the Medical College of Wisconsin. I completed flight surgeon training in the US Navy in 1988 at the Naval Aerospace Medical Institute in 1988. My family medicine residency was completed in 1992 at Charleston Naval Hospital in South Carolina.

4. I have been licensed to practice medicine in California since 1988 and have been certified by the American Board of Family Practice since 1993.

5. My practice of family medicine is entirely clinic based, caring for patients from neonates to the elderly. I have no academic appointments.

6. I serve the American College of Pediatricians, with whom I am a fellow, as Co-chair of the Council on Adolescent Sexuality and the Christian Medical & Dental Associations as Co-chair of the Sexual & Gender Identity Task Force. I am a member of the American Academic of Family Physicians. I work with Alliance Defending Freedom in a coalition of professionals advising on policy matters addressing sexual orientation and gender identity, including serving as amicus curiae/friend of court in federal appellate and SCOTUS cases.

7. I am author or co-author of six peer-reviewed commentaries and letters, and author of numerous articles in professional and general publications in the USA and abroad.

8. I am an active peer reviewer for several medical journals.

9. I previously offered an expert witness affidavit in 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. July 23, 2019.

10. I have served federal courts as a medical professional *amicus curiae* in:

Harris Funeral Homes, Inc. v. EEOC, No. 18-107 (U.S. Supreme Court, July 24, 2018); *Adams v. School Board of St. Johns County, Florida*, No. 18-13592 (11th Cir. Aug. 23, 2018); *Doe v. Boyertown Area School District*, No. 18-658 (3rd Cir. Nov. 21, 2018); *Meriwether v. Trustees of Shawnee State University*, No. 20-3289 (6th Cir. Mar. 12, 2020); *Hecox v. Little*, Nos. 20-35813 (9th Cir., Nov. 19, 2020); *Adams v. School Board of St. Johns County, Florida*, No. 18-13592 (11th Circuit, Oct. 26, 2021); and *Brandt v. Rutledge*, No. 21-2875 (8th Circuit, Nov. 14, 2021).

11. I have provided written reports, consultation by teleconferences, and/or written testimony to many state legislatures and several parliaments on proposed legislation concerning gender dysphoria and sexual minority issues. I have testified in legislative committees in both California (2018) and Ohio (2022) regarding gender dysphoria related legislation.

12. I have been contracted by the state of Florida Department of Medicaid, and continue to work with them as a registered vendor in the state of Florida, in the preparation of the GAPMS Determination on the Treatment of Gender Dysphoria and the General Medicaid Policy Rule 59G-1.050 rule exclusion (7) Gender Dysphoria.

13. I am being compensated at a rate of $350 an hour for preparation of expert declarations and reports, and $600 per hour for time spent preparing for or giving deposition or trial testimony. My compensation is independent of the outcome of said efforts and litigation, my stated opinions, or the content of my testimony.

GENDER DYSPHORIA AS A MEDICAL DIAGNOSIS BUT ALSO A SELF-DIAGNOSIS

14. The Matheny Antommaria declaration is correct that gender dysphoria is a medical diagnosis, which is not quite the point addressed when the GAPMS report notes that it arrives as a self-diagnosis. The Matheny Antommaria declaration then concedes on page 7, "The diagnosis of gender dysphoria in adolescents and adults, like many other common medical diagnoses, relies on individuals' self-report of symptoms." Yes, it does. The problem is that proper, extensive psychological evaluation and support of the gender dysphoric patient and family both is not assured or even consistent. And there is tremendous pressure on the clinician to affirm upon request. This deficiency is internationally recognized.

15. Psychiatry professor Stephen B. Levine observed that "Clinicians who have embraced the gender-affirmative model of care operate on the

assumption that children and teens know best what they need to be happy and productive (Ehrensaft, 2017)."[1] Self-diagnosis has limits, and the risk from it rises the further the self-diagnosis is allowed to mandate treatment options.

16. Professor Levine notes elsewhere that "The World Professional Association for Transgender Health's Standards of Care recommend an informed consent process, which is at odds with its recommendation of providing hormones on demand."[2] Again, the common practice of self-diagnosis leads to a common demand of medicalization.

17. The Interim Cass Review from the United Kingdom[3] resulted in the closure of the world's largest pediatric gender clinic, the National Health Service's Gender Identity Development service, or GIDS.[4] "The Cass Review specified on page 17, "1.14 Primary and secondary care staff have told us that they feel under pressure to adopt an unquestioning affirmative approach and that this is at odds with the standard process of clinical assessment and

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[1] Stephen B. Levine, E. Abbruzzese & Julia W. Mason (2022): Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults, Journal of Sex & Marital Therapy, DOI: 10.1080/0092623X.2022.2046221.
[2] Stephen B. Levine (2018): Informed Consent for Transgendered Patients, Journal of Sex & Marital Therapy, DOI: 10.1080/0092623X.2018.1518885.
[3] https://cass.independent-review.uk/publications/interim-report/
[4] NHS to close Tavistock child gender identity clinic" 7/28/2022. https://www.bbc.com/news/uk-62335665

diagnosis that they have been trained to undertake in all other clinical encounters." Page 17 states "1.15 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 that would normally be managed by local services can sometimes be overlooked." Thus, the very presence of gender-related distress resulted in other mental health concerns being pushed aside, or "overshadowed".

18. The UK NHS's GIDS experienced the resignation of thirty-five psychologists over a three year period due to the over-prescribing of the medicalization of minors with gender dysphoria "with psychologists unable to properly assess patients over fears they will be branded 'transphobic...'" It was added, "we fear that we have had front row seats to a medical scandal."[5]

19. A prospective study from an Australian multidisciplinary gender service in 2021 revealed "Key challenges faced by the clinicians included the following: the effects of increasingly dominant, polarized discourses on daily clinical practice; issues pertaining to patient and clinician safety (including pressures to abandon the holistic [biopsychosocial] model); the difficulties of

[5] "NHS 'over-diagnosing' children having transgender treatment, former staff warn," news.sky.com, 12 Dec. 2019. https://news.sky.com/story/nhs-over-diagnosing-children-having-transgender-treatment-former-staff-warn-11875624 .

untangling gender dysphoria from comorbid factors such as anxiety, depression, and sexual abuse; and the factual uncertainties present in the currently available literature on longitudinal outcomes."[6]

20. The Matheny Antommaria declaration furthermore states on page 7, "Like gender dysphoria, there is no confirmatory laboratory or radiographic study for the diagnosis of migraine headaches." But the approved and off-label treatments for migraines do not risk sterility, compromised sexual function, brain development, heart attacks, strokes, blood clots, or cancer in the way puberty blocking agents and cross-sex hormones do.[7][8][9][10]

21. One must weigh the risks against the benefits as well as alternatives, and the alternative of psychological treatment of patient and family is not proven inferior to gender (transition) affirming interventions, as

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[6] Kozlowska K, McClure G, Chudleigh C, et al. Australian children and adolescents with gender dysphoria: Clinical presentations and challenges experienced by a multidisciplinary team and gender service. *Human Systems*. 2021;1(1):70-95. doi:10.1177/26344041211010777.

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[10] Irwig MS. Cardiovascular Health in Transgender People. Rev Endocr Metab Disord. 2018 Aug 3 epub.

noted in Dr. Cantor's Attachment D in the GAPMS report. Extensive and continuing psychological intervention is a priority in the new guidelines for treatment of gender dysphoria now noted in the United Kingdom, Sweden, Finland, and France, as noted adeptly in Dr. Cantor's Attachment D.

22. Self-reporting is a low-certainty form of diagnosis when other more precise diagnostic tools exist, such as the Diagnostic and Statistical Manual (DSM) of the American Psychiatric Association. When affirmation on demand is common, clear diagnosis and addressing of underlying factors becomes uncommon, leaving the patient to suffer with unresolved psychological distress, adverse childhood experiences, neurodevelopmental disorders like autism spectrum, and possible poor family dynamics, as noted in the literature.[11][12][13]

23. The Matheny Antommaria declaration states on page 8, "Only licensed healthcare providers or teams of providers, based on patient reports and, in the case of minors, parent reports, make the diagnosis of gender

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[11] Kozlowska K, McClure G, Chudleigh C, et al. Australian children and adolescents with gender dysphoria: Clinical presentations and challenges experienced by a multidisciplinary team and gender service. *Human Systems*. 2021;1(1):70-95. doi:10.1177/26344041211010777

[12] Becerra-Culqui TA, Liu Y, Nash R, et al. Mental Health of Transgender and Gender Nonconforming Youth Compared with Their Peers. Pediatrics. 2018;141(5):e20173845

[13] Heylens G, et al. "Psychiatric characteristics in transsexual individuals: multicentre study in four European countries," The British Journal of Psychiatry Feb 2014, 204 (2) 151-156; DOI: 10.1192/bjp.bp.112.121954.

dysphoria and any subsequent treatment recommendations." Were that the case, Planned Parenthood clinics would not be one of the largest sources of gender (transition) affirming hormones in the USA, with their availability boldly advertised on their web page.[14]

GENDER (TRANSITION) AFFIRMING MEDICAL INTERVENTIONS ARE VIEWED AS EXPERIMENTAL BY MANY

24. The Matheny Antommaria declaration stated on page 9, "the GAPMS Memo uses the term "experimental" or "investigational" to convey that gender-affirming medical care is new, untested, or different, that suggestion is baseless." Yes, it is not new, but assertions and evidence abound of gender (transition) affirming medical care being insufficiently tested, still investigational, and experimental despite its age. I will discuss this further in the section on lack of evidence-basing for G(T)AMC, but note here that the declaration paragraph 4 lists the 2011 de Vries, et al study[15] as the inaugural example of the "Prospective observational trials of puberty blockers" supporting their use in gender dysphoria.

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[14] Planned Parenthood "Transgender Hormone Therapy" web page https://www.plannedparenthood.org/get-care/our-services/transgender-hormone-therapy .

[15] de Vries AL, Steensma TD, Doreleijers TA, Cohen- Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. J Sex Med. 2011;8(8):2276-2283.

25. Levine, et al, wrote that both the 2011 de Vries, et al, puberty blocking study and its sister study dealing with surgeries "suffer from a high risk of bias due to their study design, which is effectively a non-randomized case series— one of the lowest levels of evidence..." and that "In addition, the studies suffer from limited applicability to the populations of adolescents presenting today (de Vries, 2020). The interventions described in the study are currently being applied to adolescents who were not cross-gender identified prior to puberty, who have significant mental health problems, as well as those who have non-binary identities—all of these presentations were explicitly disqualified from the Dutch protocol." Levine, et al, conclude, "We contend that the Dutch studies have been misunderstood and misrepresented as providing evidence of the safety and efficacy of these interventions for all youth." And this appears to be the case with this point of the Matheny Antommaria declaration.

26. Prof. Michael Biggs of Oxford published a recent detailed critique of the Dutch Protocols in which he asserted "The Dutch clinicians chose incommensurable scales to measure gender dysphoria, which calls into

question their finding that dysphoria declined following cross-sex hormones and surgery."[16]

27. One of those Dutch clinicians, Thomas Steensma, co-author of the studies in question, reported to the Dutch media "Little research has yet been done on the treatment with puberty inhibitors and in young people. That is why it is also seen as experimental." [17] Dr. Steensma cautioned that "The rest of the world is blindly adopting our research."

28. The Matheny Antommaria declaration protests in paragraphs 24 and 25 that "off-label" does not mean experimental, untested, or unsafe, and further specifies, "Once the FDA has approved a medication for one indication,[12] thereby agreeing that it is safe (i.e., its benefits outweigh its potential risks) and effective for this intended use, as is the case with the medications at issue here, prescribers are generally free to prescribe it for other indications." But a more direct quote from the FDA Website warns: "If you and your healthcare provider decide to use an approved drug for an

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[16] Michael Biggs (2022): The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence, Journal of Sex & Marital Therapy, DOI: 10.1080/0092623X.2022.2121238.

[17] https://www.ad.nl/nijmegen/dringend-meer-onderzoek-nodig-naar-transgenderzorg-aan-jongeren-waar-komt-de-grote-stroom-kinderen-vandaan~aec79d00/ reported in "Dutch Doctor Who Pioneered Early Transgender Treatment Says World is "Blindly" Adopting His Approach," March 12, 2021, Minnesota Family Council The Family Beacon. https://www.mfc.org/familybeacon/dutch-doctor-who-pioneered-early-transgender-treatment-says-world-is-blindly-adopting-his-approach

unapproved use to treat your disease or medical condition, remember that FDA has not determined that the drug is safe and effective for the unapproved use."[18] Safe and effective for a given approved indication should not be assumed to mean safe and effective for any other.

29. The Matheny Antommaria declaration claims on page 13, "The GAPMS Memo misleadingly notes that testosterone is a Schedule III controlled substance because of its 'high probability of abuse.'" The US FDA does not support this Matheny Antommaria claim. An FDA statement from October 25, 2016 is titled, "FDA approves new changes to testosterone labeling regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS)."[19] It details "class-wide labeling changes for all prescription testosterone products" to this effect, "to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other AAS."

GENDER (TRANSITION) AFFIRMING MEDICAL CARE LACKS THE EVIDENCE BASE IT SHOULD HAVE AT THIS POINT

[18] https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label .
[19] https://www.fda.gov/drugs/drug-safety-and-availability/fda-approves-new-changes-testosterone-labeling-regarding-risks-associated-abuse-and-dependence .

30. Paragraph 29 of the Matheny Antommaria Declaration protests, "AHCA also incorrectly characterizes gender-affirming medical treatment as lacking sufficient evidence of safety and efficacy." This accusation does not hold up well to scrutiny.

31. The Matheny Antommaria Declaration repeats a false belief stated in para. 35, "Under the applicable ethical standards, randomized, placebo-controlled

trials that compare pharmacological treatment to no pharmacological treatment in gender dysphoria are currently unethical." Para. 31 states, "randomized controlled trials may not be feasible or ethical..."

32. Oxford's Michael Biggs' critique of what has been known as the Dutch Protocol derived from de Vries, et al. ("The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence")[20] targets this false claim and its pre-ordained conclusions, observing that the study authors excuse that ".. it would have been unethical to withhold GnRHa from the control group, because the clinicians believed the treatment to be beneficial—this rationale is circular because discovering whether a treatment is truly beneficial requires a randomized control trial." As a consequence of their choice, "The decision to

[20] Michael Biggs (2022): The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence, Journal of Sex & Marital Therapy, DOI: 10.1080/0092623X.2022.2121238

rely on uncontrolled studies was exacerbated by other decisions. The Dutch clinicians chose incommensurable scales to measure gender dysphoria, which calls into question their finding that dysphoria declined following cross-sex hormones and surgery."

33. Yet reproducibility is critical to the advancement of science. A 2005 PLOS Medicine article by Stanford's P.A. Ioannidis was titled "Why Most Published Research Findings Are False." Ioannidis asserted this was true "for Most Research Designs and for Most Fields," adding "...research findings may often be... accurate measures of the prevailing bias," and that the hotter the field, the more likely the error.[21] And the gender dysphoria field would be accurately described as "hot." A 2015 study in Science journal assembled teams of 270 scientists on 5 continents to repeat 100 studies in three major psychology journals. The results were that only one-third to one-half of the studies were reproducible, meaning one-half to two-thirds were not.[22] The National Association of Scholars published "The Irreproducibility Crisis of

[21] "Why Most Published Research Findings Are False,' John P. A. Ioannidis, August 30, 2005 PLOS Medicine. DOI: 10.1371/journal.pmed.0020124.
[22] "Estimating the reproducibility of psychological science," Science, 28 August 2015: Vol. 349 no. 6251. DOI: 10.1126/science.aac4716.

Modern Science" in 2018, calling detailed attention to the problem, a problem which is abundant in gender (transition) affirming medical care.[23]

34. There is no field of science or medicine so nailed down, so certain, so overwhelmingly proven as to rise above the continuing need for controlled studies under strict ethical supervision and ongoing critical review. Assertions of it being unethical to do so in G(T)AMC are premature, pre-emptive, and unmerited.

35. There is another factor for those insisting that undertaking randomized, controlled trials in gender care would be unethical, and that is the mistaken premise that the gender dysphoric control group would be denied any therapy. But in clinical trials only the independent variable – the intervention under study -- is different between the control and the experimental groups. This means all study participants could benefit from all other treatments and support indicated for the diagnosis, particularly psychological support. The study group is not left out to flounder. Controlled clinical trials are essential to medical science and medical care, and gender (transition) affirming medical care is severely deficient in them.

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[23] David Randall and Christopher Welser, "The Irreproducibility Crisis of Modern Science," April 09, 2018. https://www.nas.org/reports/the-irreproducibility-crisis-of-modern-science/full-report

36. The Matheny Antommaria Declaration references de Vries 2011 several times, and it is a weak study of questionable findings, as I have noted. Para. 33 of the declaration offers up as evidence of "ongoing, federally funded, prospective observational studies of gender-affirming healthcare for adolescents with gender dysphoria in the U.S." the controversial National Institutes of Health study led by J. Olson-Kennedy, who also has submitted a declaration to this case.[24]

37. A letter (included as Attachment A) was signed and sent by 28 members of the Congress and Senate to NIH Secretary Alex Azar May 28, 2020 "to express our deep concerns regarding the above-mentioned study… This study clearly violates sound medical ethics with its experimental interventions into the normal physical development of children before they are old enough to understand or consent to such procedures." Among the numerous problems they found with the study were "there is no control group." "The minimum age for participation in the cross-sex hormone cohort

[24] National Institutes of Health Reporter, The impact of early medical treatment in transgender youth. Accessed August 25, 2022. Available at http://reporter.nih.gov/search/lGJnh68uokiic97N2X00kA/project-details/8965408 ; Olson-Kennedy J, Chan YM, Garofalo R, et al. Impact of early medical treatment for transgender youth: Protocol for the longitudinal, observational trans youth care study. JMIR Res Protoc. 2019;8(7):e14434.

of the study was originally 13, but the age was decreased to 8 years old in 2017, mid-study." (Attachment B.)

38. An additional Congressional concern regarding the J. Olson-Kennedy lead study was that "it also appears that the Children's Hospital of Los Angeles used funds from its grant to study the effects of double-mastectomies on girls as young as 13." They specifically call attention to J. Olson-Kennedy's 2018 JAMA Pediatrics "Chest Reconstruction and Chest Dysphoria…" study.[25] Allow me to present suspect items of that study. "Chest dysphoria" is a neologism of convenience, not a DSM-5 diagnosis but an invention of the paper. The "chest dysphoria scale" measuring tool of the authors (p. 435) "is not yet validated," thus another unproven invention of convenience. Mastectomies were done on girls as young as 13 or 14 years of age, who lacking the capacity for mature decision making or informed consent (I will discuss in a later section of this declaration). J. Olson-Kennedy is elsewhere quoted at a 2018 California symposium regarding such a life-altering decision for adolescents, stating "If you want breasts at a later point

[25] Olson-Kennedy J, Warus J, Okonta V, Belzer M, Clark LF. Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. *JAMA Pediatr.*2018;172(5):431–436. doi:10.1001/jamapediatrics.2017.5440

in your life, you can go and get them."[26] No, in fact mastectomies are permanent. Implants can be acquired, functional breasts cannot. The highly consequential nature of these hormonal and surgical procedures should generate more pause and humility than the referenced comment or the documented procedures reflect.

39. Levine, Abbruzzese, and Mason note "the widely recognized deficiencies in the evidence supporting gender-affirmative interventions (National Institute for Health & Care Excellence, 2020a; 2020b)."[27] They add, "The evidence underlying the practice of pediatric gender transition is widely recognized to be of very low quality (Hembree et al., 2017). In 2020, the most comprehensive systematic review of evidence to date, commissioned by the UK National Health System (NHS) and conducted by the National Institute for Health and Care Excellence (NICE), concluded that the evidence for both puberty blocking and cross-sex hormones is of very low certainty (National Institute for Health & Care Excellence, 2020a; 2020b)." The Hembree 2017

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[26] "Watch This 'Transyouth' Doctor Downplay The Significance Of 'Life Altering' Chest Surgery For Young Girls," May 25, 2021, Daily Caller News Foundation. https://www.tampafp.com/watch-this-transyouth-doctor-downplay-the-significance-of-life-altering-chest-surgery-for-young-girls/

[27] Stephen B. Levine, E. Abbruzzese & Julia W. Mason (2022): Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults, Journal of Sex & Marital Therapy, DOI: 10.1080/0092623X.2022.2046221

citation is the Endocrine Society Guidelines for the treatment of "Gender Dysphoric/Gender-Incongruent Persons" and its recommendation of puberty blocking and cross-sex hormone administration for selected minors citing "low evidence" and genital surgery for selected adults citing "very low evidence."[28]

40. *British Medical Journal* editor in chief Carl Heneghan wrote in 2019, "The current evidence does not support informed decision making and safe practice in children."[29] A 2019 paper in *Archives of Disease in Childhood* by C. Richards, et al., carried the revealing title "Use of puberty blockers for gender dysphoria: a momentous step in the dark."[30]

41. The Cass Review Interim Report from the United Kingdom stated this on page 18 regarding the "Existing evidence base": "Evidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and

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

[29] Heneghan, Carl. "Gender-Affirming Hormone in Children and Adolescents." BMJ EBM Spotlight, 21 May 2019, blogs.bmj.com/bmjebmspotlight/2019/02/25/gender-affirming-hormone-inchildren-and-adolescents-evidence-review/.

[30] Richards C, Maxwell J, McCune N. Use of puberty blockers for gender dysphoria: a momentous step in the dark. *Archives of Disease in Childhood* 2019;104:611-612.

internationally."[31] On page 19 the report states "1.26. Internationally as well as nationally, longer-term follow-up data on children and young people who have been seen by gender identity services is limited, including for those who have received physical interventions; who were transferred to adult services and/or accessed private services; or who desisted, experienced regret or detransitioned."

42. James Cantor's report to the Florida Agency for Healthcare Adminstration's GAPMS report Attachment D, section 3, "Follow-Up Studies of Puberty Blockers and Cross-Sex Hormones" found "I[n] total, there have been 11 prospective outcomes studies following up gender dysphoric children undergoing medically induced suppression of puberty or cross-sex hormone treatment. Four studies failed to find evidence of improvement in mental health functioning at all, and some groups deteriorated on some variables.20 Five studies successfully identified evidence of improvement, but because patients received psychotherapy along with medical services, which of those treatments caused the improvement is unknowable.21 In the remaining two studies, both psychotherapy and medical interventions were provided, but the studies were designed in such a way as to allow the effects of psychotherapy

[31] Cass Review, Interim Report. https://cass.independent-review.uk/publications/interim-report/.

to be separated from the effects of the puberty-blocking medications.22" The body of scientific evidence supporting gender (transition) affirming medical care is far less convincing than the Matheny Antommaria Declaration repeatedly states.

43. There are, however, two higher quality studies with more robust follow-up periods regarding the impact on mental health of gender (transition) affirming medical care, and they show poor results. A 30-year population-based matched cohort study of all 324 sex-reassigned adult persons in Sweden was published in 2011 by Dhejne, et al., which revealed they demonstrated a completed suicide rate 19 times that of the general population 10 years post-transition, along with nearly 3 times the rate of all-cause (overall) mortality and psychiatric inpatient care.[32] A 2020 study by Branstrom and Pachankis was the first total population study of 9.7 million Swedish residents, and it ultimately showed that neither "gender affirming hormone treatment" nor "gender affirming surgeries" achieved improvement in the mental health service usages and endpoints assessed.[33]

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[32] Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Langstrom N, et al. (2011) Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden. PLoS ONE 6(2): e16885. doi:10.1371/journal.pone.0016885.
[33] Branstrom, R., & Pachankis, J. E. (2020a). Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: A total population study. American Journal of Psychiatry, 177(8),727–734. doi:10.1176/appi.ajp.2019.19010080

44. James Cantor's report to the Florida Agency for Healthcare Adminstration's GAPMS report Attachment D, Section IV "International Health Care Consensus" (pages 42-46) offers an excellent and concise summary of the dissatisfaction with the lack of convincing evidence for the effectiveness and long-term safety of hormonal and surgical interventions for gender dysphoria in minors and the resultant retreat from them in favor of strong emphasis on psychological evaluation and intervention currently underway in the United Kingdom, Sweden, Finland, and France.

45. Para. 38 of the Matheny Antommaria Declaration states, "One directly relevant example of a widely accepted and Florida Medicaid program covered treatment that is based on prospective observational studies is the use of puberty blockers to treat central precocious puberty." Furthermore, "There are no randomized controlled trials evaluating the adult height of treated and untreated individuals." The analogy to gender (transition) affirming medical care is a non sequitur in that precocious puberty is a disease state in a compromised body, whereas gender dysphoria is neither. The natural course of untreated precocious puberty involves lasting physical

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Branstrom, R., & Pachankis, J. E. (2020b). Correction to Br.nstr.m and Pachankis. (2020). American Journal of Psychiatry, 177(8), 734–734. doi:10.1176/appi.ajp.2020.1778correction

problems and complications, whereas the natural history of gender dysphoria in minors is desistance and a body with a healthy and intact endocrine system. The Endocrine Society Guidelines state, "... the large majority (about 85%) of prepubertal children with a childhood diagnosis (of GD) did not remain gender dysphoric in adolescence."[34] A 2021 study by Singh, Bradley, Zucker, 2021 found a desistance rate of 87.8% in "largest sample to date of boys clinic-referred for gender dysphoria."[35] The gender dysphoric usually carry no inherent defect in sex organ development, function, or fertility. A 2020 study from the UK's Gender Identity Development Service found that "All had normal karyotype and endocrinology" function in 44 GD youth.[36]

GENDER (TRANSITION) AFFIRMING MEDICAL INTERVENTION IS NOT THE STANDARD OF CARE

46. Para. 39 of the Matheny Antommaria Declaration notes, "Professional medical organizations develop evidence-based clinical practice guidelines to provide clinicians with helpful, evidence-based

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[34] Hembree, W., Cohen-Kettenis, et al., (2017) Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guildeline. J Clin Endocrinol Metab,102:1–35.
[35] Singh D, Bradley SJ and Zucker KJ (2021) A Follow-Up Study of Boys With Gender Identity Disorder. *Front. Psychiatry* 12:632784. doi: 10.3389/fpsyt.2021.632784
[36] Polly Carmichael, Gary Butler, 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. medRxiv 2020.12.01.20241653; doi:https://doi.org/10.1101/2020.12.01.20241653

recommendations and improve patient care and outcomes." But the declaration states repeatedly that the quality of said evidence, namely the "low" to "very low" quality recognized in studies supporting gender (transition) affirming medical interventions, is of little consequence to medical practice along with the invalid assertion that controlled trials of high quality would of necessity be unethical. This invites several observations. If the quality of the data is of limited consequence to practice, what is the point of grading systems and guidelines? What is the point of evidence at all if its quality is superfluous? And why is there such international pushback and retraction of gender (transition) medical interventions as noted in the United Kingdom, Sweden, Finland, and France, as notes previously in the declaration along with the GAPMS Report Attachment D from Dr. Cantor?

47. The Matheny Antommaria Declaration para. 42 states that "...none of the Endocrine Society's 84 recommendations in 2 of its other guidelines that focus on the pediatric population—guidelines on pediatric obesity and congenital adrenal hyperplasia—is based on "high quality" evidence. Twenty-four (29%) of the recommendations are based on "moderate," and 49 (58%) on "low" or "very low quality" evidence." This evades the fact that nearly all the Endocrine Society Guidelines for gender (transition) affirming interventions are graded as low to very low quality, not

a mixed bag. Also, pediatric obesity and congenital adrenal hyperplasia are disease states, whereas gender dysphoria and incongruence are not. The consequences of proposed medicinal and surgical interventions must continuously be viewed in that light.

48. Levine, Abbruzzese, and Mason observe, "It is common for gender-affirmative specialists to erroneously believe that gender-affirmative interventions are a standard of care (Malone, D'Angelo, Beck, Mason, & Evans, 2021; Malone, Hruz, Mason, Beck, et al:, 2021). Despite the increasingly widespread professional beliefs in the safety and efficacy of pediatric gender transition, and the endorsement of this treatment pathway by a number of professional medical societies, the best available evidence suggests that the benefits of gender-affirmative interventions are of very low certainty (Clayton et al., 2021; National Institute for Health & Care Excellence, 2020a; 2020b) and must be carefully weighed against the health risks to fertility, bone, and cardiovascular health (Alzahrani et al., 2019; Biggs, 2021; Getahun et al., 2018; Hembree et al., 2017; Nota et al., 2019).[37]

[37] Stephen B. Levine, E. Abbruzzese & Julia W. Mason (2022): Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults, Journal of Sex & Marital Therapy, DOI: 10.1080/0092623X.2022.2046221

49. The Levine, et al., clarification that "the endorsement of this treatment pathway by a number of professional medical societies" despite contradicting the "best available evidence" is precisely what is meant by the term "eminence-based" as opposed to "evidence-based" medicine. The weight of the organizational name is used as its own proof of concept. That is not evidence-based care.

50. Any mention of the Endocrine Society Guidelines merits squaring with these quotes from it on page 3985, "The guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others. The guidelines cannot guarantee any specific outcome, nor do they establish a standard of care. The guidelines are not intended to dictate the treatment of a particular patient." To reiterate, "The guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others[,]" "nor do they establish a standard of care."

51. The American Academic of Pediatrics appears in several declarations. Dr. Cantor's GAPMS Report Attachment D, Section V "Assessing Statements from Professional Associations" (pages 31-41) with its included Appendix 2 peer-reviewed "point-by-point check" of the American Academic of Pediatrics policy on "transgender and gender diverse children and

adolescents"[38] provides an excellent review of their policy contents, their misrepresentation, and where merited, their failures. In para. 108 of page 40 of Attachment D, Dr. Cantor asserts, "The policy of the American Academy of Pediatrics (AAP) 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. Although changes in recommendations can obviously be appropriate in response to new research evidence, the AAP provided none. 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."

52. Dr. Cantor's included 2019 peer-review article on the AAP policy concluded, "Rather, AAP's statement is a systematic exclusion and misrepresentation of entire literatures. Not only did AAP fail to provide *extraordinary* evidence, it failed to provide the evidence at all. Indeed, AAP's recommendations are *despite* the existing evidence."[39]

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[38] As Appendix 2 to attachment D Dr. Cantor included his peer-reviewed "point-by-point fact-check" of the AAP claims. (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)

[39] James M. Cantor (2019): Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy, Journal of Sex & Marital Therapy, DOI:10.1080/0092623X.2019.1698481

53. The international standard of care is watchful waiting, including psychological evaluation of the child and family both, not gender (transition) affirming therapy.[40] James Cantor asserts, "...almost all clinics and professional associations in the world use what's called the *watchful waiting* approach to helping GD children...."[41] Michael Laidlaw, et al., agree "...watchful waiting with support for gender-dysphoric children and adolescents up to the age of 16 years is the current standard of care worldwide, not gender affirmative therapy...."[42]

INFORMED CONSENT AND MINORS

54. The Matheny Antommaria Declaration para. 47 claims, "Adolescents generally possess comparable medical decision-making capacity to adults.39 There is evidence that most adolescents with gender dysphoria have sufficient medical decision-making capacity to make decisions regarding

[40] Michael Laidlaw, Michelle Cretella & Kevin Donovan (2019) The Right to Best Care for Children Does Not Include the Right to Medical Transition, The American Journal of Bioethics, 19:2, 75-77, DOI: 10.1080/15265161.2018.1557288
[41] James M. Cantor (2019): Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy, Journal of Sex & Marital Therapy, DOI:10.1080/0092623X.2019.1698481
[42] Michael Laidlaw, Michelle Cretella & Kevin Donovan (2019) The Right to Best Care for Children Does Not Include the Right to Medical Transition, The American Journal of Bioethics, 19:2, 75-77, DOI: 10.1080/15265161.2018.1557288

puberty blockers." Para. 48 adds, "The current standard of care for treating gender dysphoria in minors is

consistent with general ethical principles instantiated in the practices of informed consent and shared decision-making." There is much to object to in these assertions.

55. Levine, Abbruzzese, and Mason observe, "...the process of obtaining informed consent from patients and their families has no established standard. There is no consensus about the requisite elements of evaluations, nor is there unanimity about how informed consent processes should be conducted (Byne et al., 2012). These two matters are inconsistent from practitioner to practitioner, clinic to clinic, and country to country."[43]

56. The Swedish Pediatric Society issues a letter supporting the Swedish National Council for Medical Ethics' (SMER) proposed systematic review of gender dysphoria treatment in which they cautioned, "Giving children the right to independently make vital decisions whereby at that age they cannot be expected to understand the consequences of their decisions is not scientifically founded and contrary to medical practice."[44]

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[43] Stephen B. Levine, E. Abbruzzese & Julia W. Mason (2022): Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults, Journal of Sex & Marital Therapy, DOI: 10.1080/0092623X.2022.2046221

[44] http://www.barnlakarforeningen.se/2019/05/02/blf-staller-sig-bakom-smers-skrivelse-angaende-konsdysfori/

57. A United Kingdom High Court in Bell vs. Tavistock (December 12, 2020) ruled that gender (transition) affirming medical care in minors was experimental and could not, in most cases, be given to minors under 16 without court order, and that such was advisable for those 16-17. They added in para. 144, "There is no age appropriate way to explain to many of these children what losing their fertility or full sexual function may mean to them in later years."[45] In para. 141 it explained, "That adolescents find it difficult to contemplate or comprehend what their life will be like as adults and that they do not always consider the longer-term consequences of their actions is perhaps a statement of the obvious." Obvious, indeed.

58. Anthony Latham, family physician and chair of the Scottish Council on Human Bioethics, published a 2022 paper "Puberty Blockers for Children: Can They Consent?" in which he asserted, "The young brain is biologically and socially immature, tends towards short-term risk taking, does not possess the ability to comprehend long term consequences and is highly influenced by peers…" He concluded, "Children cannot consent, and therefore should not be asked to consent to being treated with puberty blockers for gender dysphoria. This does not deny the reality of GD or that future forms of

[45] https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf

treatment may be acceptable, but it does rule out such an experimental medication which has such profound and potentially very harmful irreversible consequences."

59. The Matheny Antommaria Declaration para. 48 states, "The current version of

guideline states clinicians should individualize decision-making for chest surgery in

transgender males (individuals assigned female at birth who identify as male) and

that chest surgery may be considered in some instances for individuals under 18

years old." Please review para. 38 of my declaration regarding J. Olson-Kennedy 's 2018 JAMA Pediatrics article "Chest Reconstruction and Chest Dysphoria..."[46]

Double-mastectomies, the "chest surgery" in question, are being performed on biological females as young as 13.

[46] Olson-Kennedy J, Warus J, Okonta V, Belzer M, Clark LF. Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. *JAMA Pediatr.*2018;172(5):431–436. doi:10.1001/jamapediatrics.2017.5440

60. The Matheny Antommaria Declaration notes in para. 50 that, "...Medicaid beneficiaries are provided coverage for comparable surgeries, such as those for gynecomastia." This is followed in para. 51 with the statement, "There is nothing unique about chest surgery for gender dysphoria that justifies singling out this and other medical treatments for gender dysphoria for noncoverage..." Yes, there clearly is. Gynecomastia is a disease state in biological males and the surgery for it removes the small amount of additional glandular breast tissue it represents. It is not a complete mastectomy on a biological female with total loss of healthy functional breasts.

THE FLORIDA MEDICAID RULE IS NON-DISCRIMINATORY

61. Implicit in the Matheny Antommaria Declaration, and explicit in some organizational complaints, against the Florida Medicaid rule excluding gender (transition) affirming medical interventions is the charge of discrimination.

62. Florida Medicaid rules state that "As a condition of coverage, sex reassignment treatment must be "consistent with generally accepted

professional medical standards (GAPMS) and not experimental or investigational" (Rule 59G-1.035, F.A.C....).[47]

63. The GAPMS report concludes: "Considering the weak evidence supporting the use of puberty suppression, cross-sex hormones, and surgical procedures when compared to the stronger research demonstrating the permanent effects they cause, these treatments do not conform to GAPMS and are experimental and investigational."

64. Declining to provide gender (transition) affirming health care is non-discriminatory and appropriate both professionally and scientifically.

a. G(T)AHC has not been proven safe, effective, or of more benefit than harm particularly long term. This was emphasized in the 2020 UK High Court Bell v Tavistock case,[48] the UK's Cass Interim Report of 2022,[49] the UK's 2020 National Institute for Health and Care Excellence reviews of puberty blockers and cross-sex hormones,[50] the UK's NHS closure of the world's largest pediatric gender clinic,[51] the Swedish Agency for Health Technology

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47 https://www.ahca.myflorida.com/Medicaid/review/General/59G_1035_Determining_Generally_Accepted_Professional_Medical_Standards.pdf

48 https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf

49 https://cass.independent-review.uk/publications/interim-report/

50 https://arms.nice.org.uk/resources/hub/1070871/attachment and https://arms.nice.org.uk/resources/hub/1070905/attachment

51 https://www.bbc.com/news/uk-62335665

Assessment and Assessment of Social Services' 2019 literature review,[52] Sweden's Karolinska Hospital (affecting Astrid Lindgren Children's Hospital's pediatric gender services) 2021 policy change,[53] Finland's COHERE 2020 policy reform,[54] and the French National Academy of Medicine press release.[55]

b. Physicians take an oath to do no harm, and G(T)AHC is documented to lead to significant harm without proof of compensatory benefit.

c. Withholding unproven interventions is non-discriminatory.

d. The problem of diagnosis: "There is currently no way to predict who will desist and who will remain dysphoric."[56] Withholding unproven treatments for uncertain diagnostic or ideological identifications is non-discriminatory and simply wise medical practice protecting both the patient and physician.

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[52] https://www.sbu.se/en/publications/sbu-bereder/gender-dysphoria-in-children-and-adolescents-an-inventory-of-the-literature/

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

[54] https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en.pdf/aaf9a6e7-b970-9de9-165c-abedfae46f2e/Summary_minors_en.pdf

[55] https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/

[56] Michael K Laidlaw; Quentin L Van Meter; Paul W Hruz; Andre Van Mol; William J Malone. 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, Online, November 23, 2018.

e. There are alternative treatments of mental health natures which are at least as effective and without the harms of hormonal and surgical interventions.

CONCLUSION

65. Gender (transition) affirming health care imperils already at-risk gender dysphoric youth with experimental and unproven hormonal and surgical interventions which medicalize prematurely and permanently. G(T)AHC is not proven effective, not proven to have long-term safety, does not reduce suicides, and is not the standard of care for gender dysphoria. Scientific and legal evidence is driving an international pushback against G(T)AHC in favor of intensive psychological evaluation and support, and the lawsuits over the harms of G(T)AHC have begun. Florida Medicaid is on solid ground in excluding gender (transition) affirming medical interventions from payment.

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

Executed on September 27, 2022

//s//Andre Van Mol, MD
ANDRE VAN MOL, MD