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.
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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.

[7] Hembree, Wylie C, et al. "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline." The Journal of Clinical Endocrinology & Metabolism, vol. 102, no. 11, 2017, pp. 3869–3903., doi:10.1210/jc.2017-01658.

[8] Alzahrani, Talal, et al. "Cardiovascular Disease Risk Factors and Myocardial Infarction in the Transgender Population." Circulation: Cardiovascular Quality and Outcomes, vol. 12, no. 4, 2019, doi:10.1161/circoutcomes.119.005597.

[9] Getahun D, Nash R, Flanders WD, Baird TC, Becerra-Culqui TA, Cromwell L, et al. Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study. Ann Intern Med. [Epub ahead of print 10 July 2018]169:205–213.doi: 10.7326/M17-2785.

[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