The Federal Rights And Protections of Conscience Should Apply To The Medical Transition Of Minors

Introduction:

For the reasons set forth below, we believe that "gender affirming" procedures for children and adolescents constitute a "sterilizing procedure" for the purposes of the protections from discrimination contained in 42 U.S.C. 300a-7 (collectively known as the "Church Amendments") and enforced by the Office of Civil Rights ("OCR"). Consequently, clinicians should have the right to refuse to provide such treatments on the basis of sincerely held moral and ethical convictions.

1. "Gender affirming" Procedures Sterilize Minors

The recommended "gender affirming" treatment paradigm for children and adolescents with gender incongruence includes an initial phase where puberty blocking agents (gonadotrophin releasing hormone analogues - GnRHas - hereinafter "Puberty Blockers") are introduced at Tanner Stage 2 (usually ages 10-12) to arrest puberty development before menarche in girls and before spermarche in boys - when they begin the maturation process to physiologically develop reproductive capacity. This phase of the medical protocol is then followed by cross-sex hormones at ages 14-16 that continues throughout the patient's lifetime as adults. (See the Endocrine Society and WPATH practice guidelines.)

As explained by endocrinologist, Michael Laidlaw, M.D., "continued suppression of the pituitary gonadal axis by [puberty blocking agents] will maintain a state of immaturity of the male and female gonads…[T]he gonads and entire pelvic genitalia will remain stunted at Tanner stage 2. The addition of cross sex hormones will not change this condition."[1]

Consequently, children and adolescents who are administered puberty blocking agents and cross-sex hormones in accord with the recommended treatment paradigm will be infertile and permanently unable to reproduce as adults. Whether it is at all possible under specific scenarios for children and youth to regain their reproductive capacity after cessation of the treatment paradigm has not been studied and is not known. However, the intention of the treatment paradigm is to permanently prevent the patient's

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[1] 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

reproductive capacity from developing and for cessation of the cross-sex hormones to be rare.

2. The Purpose of Gender Affirming Procedures Is To Neutralize Reproductive Capacity

As outlined above, the specific purpose of the recommended gender affirming treatment paradigm for children and adolescents is to disrupt and neutralize natural appropriately timed and healthy physiological maturation of the child's reproductive organs and capacity. This is not a side-effect related to the treatment of diseased organs or other biological disease processes. This is the treatment paradigm's stated aim.

For this reason, the Endocrine Society guidelines acknowledges that fertility disruption needs to be explained to the child and their parents prior to initiating Puberty Blockers.

> We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation **prior to initiating puberty suppression in adolescents** and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. (Emphasis Added) (Evaluation of Youth and Adults - Recommendation 1.5.[2])

3. 93-98% of Children Put On PBs Go Onto Cross-sex Hormones.

Puberty Blockers are neither a diagnostic tool nor a "pause." The recently published long term study in the Netherlands by clinicians who introduced the use of Puberty Blockers followed by cross-sex hormones to treat children and adolescents with gender incongruence (known as "the Dutch Protocol") determined that 93% of those who were treated under the protocol over a 20 year period subsequently went on cross-sex hormones.[3] This percentage does not include those treated with Puberty Blockers who went onto cross-sex hormones at another gender clinic or who were given Puberty Blockers but had not yet started cross sex hormones. These percentages have been

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[2] Hembree et al Guidelines on Gender-Dysphoric/Gender-Incongruent Persons J Clin Endocrinol Metab, November 2017, 102(11):3871, 3869–3903. See also WPATH SOC8 (2022) "Recommendation 6.10 - We recommend health care professionals working with transgender and gender diverse adolescents…inform them, prior to initiating treatment, of the reproductive effects including the potential loss of fertility.…"

[3] Maria A T C van der Loos, MD, Daniel T Klink, MD, PhD, Sabine E Hannema, MD, PhD, Sjoerdje Bruinsma, MSc, Thomas D Steensma, PhD, Baudewijntje P C Kreukels, PhD, Peggy T Cohen-Kettenis, PhD, Annelou L C de Vries, MD, PhD, Martin den Heijer, MD, PhD, Chantal M Wiepjes, MD, PhD, Children and adolescents in the Amsterdam Cohort of Gender Dysphoria: trends in diagnostic- and treatment trajectories during the first 20 years of the Dutch Protocol, *The Journal of Sexual Medicine*, Volume 20, Issue 3, March 2023, Pages 398–409, https://doi.org/10.1093/jsxmed/qdac029

confirmed by shorter studies in the United Kingdom where 98% went onto cross-sex hormones.[4]

While Puberty Blockers taken alone and discontinued can be used as a diagnostic tool for establishing the criteria of "persistence" necessary for the intervention of cross-sex hormones and may be reversible, practically that is not how they are used or how they function. In light of the fact that in 93 - 98% of cases they are followed by cross sex hormones, the prescribing physician ethically can not view them as merely an reversible diagnostic tool the minor can assent to, but must acknowledge that the recommended gender affirming treatment paradigm purposefully sterilizes the minor - neutralizes their reproductive capacity. This raises the moral and ethical issues as to the demonstrated medical necessity of the procedures and the minor's capacity to consent to them.

4. Gender Affirming Procedures Are Not Proven Medically Necessary

A. Unproven Curative Care

The Endocrine Society's guidelines for the gender affirming treatment paradigm is based on the necessity to medically treat gender dysphoria/incongruence in children and adolescents. However, this position is not supported by the available scientific evidence. No long-term studies demonstrate that gender affirming treatments for children and adolescents leads to better mental health outcomes. A recent comprehensive independent review of clinical studies commissioned by Florida (May 2022) found that the evidence in support of gender affirming treatment was of "low" and "very low" GRADE, i.e., certainty, because of small sample sizes, biased samples, limited follow-up, and inconsistent outcome measures. The Florida evidence review concluded that "[d]ue to the limitations in the body of evidence, there is great uncertainty about the effects of puberty blockers, cross-sex hormones and surgeries in young people with gender dysphoria." (See 2022 Florida Literature Review, AHCA, Attachment C, p.5.) Gordon Guyatt, distinguished professor in the Department of Health Research Methods, Evidence, and Impact at McMaster University, Ontario, who co-developed the GRADE system of evidence analysis, found "serious problems" with the Endocrine Society guidelines, as they did not look at the effect of the interventions on gender dysphoria itself, only their impact on the patient's physiology.[5]

Similarly, several recent European systematic reviews of evidence on gender affirming treatments came to similar conclusions. Public health authorities in the UK, Finland, and Sweden all concluded that there is insufficient evidence to support the claim that either

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[4] Carmichael P, Butler G, Masic U, Cole TJ, De Stavola BL, Davidson S, Skageberg EM, Khadr S, Viner RM. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. PLoS One. 2021 Feb 2;16(2):e0243894. doi: 10.1371/journal.pone.0243894. PMID: 33529227; PMCID: PMC7853497.

[5] Block J., Gender dysphoria in young people is rising—and so is professional disagreement, *BMJ* 2023;380:p382 doi: https://doi.org/10.1136/bmj.p382

puberty blockers or cross-sex hormones provide mental health benefits for gender incongruent children and adolescents. In other words, the gender affirming treatment paradigm has not been proven medically necessary curative care.

B. Unproven Preventative Care

Further, there are no randomized control group or long-term comparative approach studies demonstrating showing that the gender affirming treatment paradigm for children and youth reduces suicidality or experience better long-term outcomes than gender dysphoric/incongruent or transgender-identifying minors who do not undergo the treatment paradigm or who are treated with psychotherapy only.

An accurate rate of completed suicide in trans-identifying young people seeking gender affirming treatment based on data from the largest pediatric gender clinic in the world, the UK's Tavistock, has been estimated at 0.03% over 10 years. While higher than average relative to age matched non-gender dysphoric peers, it is far from the epidemic of transgender suicides portrayed in some academic literature and general media reports that conflate suicidal ideation with suicide. Self-report surveys must be interpreted with caution.

While recognizing an association between trans-identification and suicidality, causality is unclear. Specifically, there is no evidence that suicidality is caused by gender dysphoria nor is it reduced, in the long term, by gender affirming hormones or surgeries. Further, suicidality is a well-documented symptom of depression, anxiety, personality disorders, identity issues and autism spectrum disorder, all of which are over-represented among trans-identifying adolescents. Consequently, there is no clear evidence that gender affirming treatments are medically necessary to prevent suicidality.

5. "Gender Affirming" treatments are voluntary patient-directed palliative care.

In the absence of evidence to show that "gender affirming" procedures are "medically necessary" to relieve the condition of gender dysphoria/incongruence described in the DSM-5R or prevent suidicality, the treatment paradigm is best described as palliative, which merely reduces symptoms and improves the individual's quality of life. Palliative measures are based solely on the patient's personal desires and comfort. A clinician's ethical convictions objecting to the purposeful sterilization of a minor, under these circumstances, are legitimate.

This viewpoint is reflected in the new WPATH Guidelines (SOC8) and ICD-11 classification of diseases (effective 2022). WPATH states that the guideline's purpose is to assist "transgender and gender diverse" people in developing and accessing individualized "care plans" to provide them "lasting personal comfort with their gendered selves" and optimum "self-fulfillment."[6] Under WPATH SOC8 guidelines, "medical

[6] See World Professional Association for Transgender Health Standards of Care for Transgender and Gender Diverse People, Version 8 Frequently Asked Questions (FAQs)

necessity" is determined on the basis of patient-directed subjective self-concepts that **may** cause clinically significant distress or impairment. The role of the medical provider is not treatment in either the curative or preventative sense, but to "support and serve" the individual in this personal endeavor to actualize their "true selves."[7]

The WPATH SOC8 assessment for medical interventions for gender incongruence refers to the ICD-11's New Chapter on "Conditions Related to Sexual Health" and its definition of "Gender Incongruence" - and not to the American Psychiatric Association's DSM-5-TR. No longer is there reference to a mental health condition, but rather the new ICD chapter deals with sexual dysfunctions (syndromes and disorders. Placement in this chapter is for the purpose of "acknowledg[ing] the links between gender identity, sexual behaviour, exposure to violence and sexually transmitted infections" and to ensure "transgender people's access to gender-affirming health care, as well as adequate health insurance coverage for such services."[8] A diagnosis of "medical necessity" no longer requires the presence of clinical gender dysphoria, but only a "marked and persistent" incongruence[9] between one's "experienced gender and assigned sex,"and, where medical interventions for gender incongruence are simply to "affirm" the individual's "gender identity" "as much as desired, to the extent possible."[10]

6. 20-30% May Regret Medically Transitioning.

There are no large scale, long term studies to show the rate of regret associated with the "gender affirming" treatment paradigm for children and adolescents. However, two recent studies indicate that as many as 20-30% of patients may discontinue hormone treatment within a few years.[11] Even if this mounting rates are on the high end, they are

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[7] Ibid.

[8] World Health Organization, Gender incongruence and transgender . https://www.who.int/standards/classifications/frequently-asked-questions/gender-incongruence-and-transgender-health-in-the-icd

[9] WPATH SOC8 Appendix D. Treatment criteria for Adults and Adolescents - "Gender diversity/ incongruence is marked and sustained over time." See also, Chapter 6.12.a "the adolescent meets the diagnostic criteria of gender incongruence as per the ICD-11 in situations where a diagnosis is necessary to access health care. In countries that have not implemented the latest ICD, other taxonomies may be used although efforts should be undertaken to utilize the latest ICD as soon as practicable."

[10] See ICD-11 HA60 Gender incongruence of adolescence or adulthood.

[11] Boyd I, Hackett T, Bewley S. Care of Transgender Patients: A General Practice Quality Improvement Approach. *Healthcare (Basel)*2022;10:121. doi:10.3390/healthcare10010121; Roberts CM, Klein DA, Adirim TA, Schvey NA, Hisle-Gorman E. Continuation of Gender-affirming Hormones Among Transgender Adolescents and Adults. *J Clin Endocrinol Metab*2022;107:e3937-43. doi:10.1210/clinem/dgac251. pmid:35452119

comparable to rates of sterilization regret found in women 21-30 years old (12-24%)[12] and raise legitimate moral and ethical issues of conscience for physicians asked to provide gender affirming treatments.

7. Children Are Not Competent To Consent To Sterilization

All states impose age restrictions (18-21 years old) on voluntary sterilization procedures based on the minor's lack of capacity to fully appreciate and comprehend their physical, psychological and social implications. For these reasons, Medicaid restricts coverage to those over 21 and requires a specific informed consent form for the procedure.[13] In the present case, there is likewise a genuine issue as to whether children and adolescents can consent to gender affirming procedures,[14] and, similarly, clinicians may have legitimate ethical convictions that without it they are violating the medical precept of "first do no harm."

8. Failure to Protect Health Providers from Discrimination Will Have a Detrimental Effect on Services Provided to Minors.

For the reasons described, clinicians may have conscientious objections to providing sterilizing procedures under the "gender affirming" treatment paradigm to children and adolescents on the basis of their moral and ethical convictions. Such convictions are protected under the Church Amendments (42 U.S.C. 300a-7). Clinicians should not be forced either by law, governments or their employers to provide "gender affirming" sterilizing procedures against their moral convictions; and, accordingly, the OCR should protect their rights from discrimination. Failure to acknowledge and protect them as required, will result in fewer clinicians providing endocrine services to minors.

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[12] One-in-four (24.6%) sterilized women sampled reported that they "probably" or "definitely" would want to have their tubal sterilization procedure reversed, if they could do so safely. Eeckhaut MCW, Sweeney MM. Understanding Sterilization Regret in the United States: The Role of Relationship Context. J Marriage Fam. 2018 Oct;80(5):1259-1270. doi: 10.1111/jomf.12500. In a 2015 study, the regret rate was 12.6% for women who underwent sterilization at age 21-30 years. Danvers AA, Evans TA. Risk of Sterilization Regret and Age: An Analysis of the National Survey of Family Growth, 2015-2019. Obstet Gynecol. 2022 Mar 1;139(3):433-439. doi: 10.1097/AOG.0000000000004692.

[13] 42 CFR Section 441.253(a)-(d); https://www.govinfo.gov/content/pkg/CFR-2021-title42-vol4/pdf/CFR-2021-title42-vol4-sec441-253.pdf

[14] Levine SB, Abbruzzese E, Mason JW. Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults. J Sex Marital Ther. 2022;48(7):706-727. doi: 10.1080/0092623X.2022.2046221.