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RIN: 0945-AA17 [Docket ID: HHS-OS-2022-0012]
Nondiscrimination in Health Programs and Activities, HHS proposed rule on Section 1557 of the Affordable Care Act (ACA)

I am a California board-certified family physician with a strong interest and involvement in supporting gender integrity, particularly in young people. I co-chair sexuality and gender identity committees for two national organizations, work with major national First Amendment freedom legal organizations, and advise legislatures at home and abroad on such issues.

The proposed Section 1557 rule imperils already at-risk gender dysphoric youth with experimental and unproven hormonal and surgical gender/transition affirming therapy (G(T)AT) – aka gender/transition affirming health care (GAHC) - which medicalizes prematurely and permanently. G(T)AHC is neither proven effective nor safe long term, 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. The lawsuits over the harms of G(T)AHC have begun. The proposed Section 1557 rule is far out of step with science and the law as I shall demonstrate.

Sex differences are real, highly consequential, and cannot be ignored without peril.

- Sex is an important biological variable in medicine and scientific studies.[1]
- Male and female sexes demonstrate significant differences in "genetics, epigenomic modifiers, hormonal milieu, immune function, neurocognitive aging process, vascular health, and response to therapeutics."[2]
- According to the NIH: "There is growing recognition that the quality and generalizability of biomedical research depends on appropriate consideration of key

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[1] Aditi Bhargava, Arthur P Arnold, Debra A Bangasser, Kate M Denton, Arpana Gupta, Lucinda M Hilliard Krause, Emeran A Mayer, Margaret McCarthy, Walter L Miller, Armin Raznahan, Ragini Verma, Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Scientific Statement, *Endocrine Reviews*, Volume 42, Issue 3, June 2021, Pages 219–258, https://doi.org/10.1210/endrev/bnaa034
[2] Bartz D, Chitnis T, Kaiser UB, et al. Clinical Advances in Sex- and Gender-Informed Medicine to Improve the Health of All: A Review. *JAMA Intern Med* 2020.

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biological variables, such as sex."… "Failure to account for sex as a biological variable may undermine the rigor, transparency, and generalizability of research findings."[3]
- "Diseases that affect both sexes often have different frequencies, presentations, and responses to treatments in males and females; therefore, different preventative, diagnostic, and treatment approaches may be required for males and females."[4]
- The proposed Section 1557 rule would ignore biological reality and therapeutic risk in favor of subjective ideological demand.

It is erroneous and unhelpful to lump the objective physical diagnoses of Intersex/disorders of sex development (DSD) with the subjective identifications such as non-binary, transgender, etc..

- DSD are established at conception for the 0.02% of people who have them.[5] [6]
- DSDs are definable medical problems. Something someone has.
- DSDs have two requirements:
    - "… a diverse group of congenital conditions where the development of the reproductive system is different from what is usually expected."[7]
    - DSDs usually impair fertility.[8]
- DSDs are not a third sex. There are 2 sex cells (gametes), sperm and ova. There is no third. Intersex is not an extrasex.
- People with DSD usually do not identify as transgender.
    - "Importantly, the vast majority of affected children with CAH historically did not experience self-perceived transgender identity or gender dysphoria (Zucker et al. 1996)."[9]

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[3] NIH at https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable-sabv/questions-answers

[4] Cretella, Michelle A.,Rosik, Christopher H.,Howsepian, A. A. Sex and gender are distinct variables critical to health: Comment on Hyde, Bigler, Joel, Tate, and van Anders (2019). American Psychologist, Vol 74(7), Oct 2019, 842-844.

[5] "Intersex. What It Is And Is Not," CMDA The Point Blog, May 2, 2019.

[6] Sax L, How common is intersex, Journal of Sex Research, Aug 1, 2002. http://www.leonardsax.com/how-common-is-intersex-a-response-to-anne-fausto-sterling/

[7] Beale JM, Creighton SM. Long-term health issues related to disorders or differences in sex development/intersex. *Maturitas*. 2016;94:143-148. doi:10.1016/j.maturitas.2016.10.003

[8] Słowikowska-Hilczer J, Hirschberg AL, Claahsen-van der Grinten H, et al. Fertility outcome and information on fertility issues in individuals with different forms of disorders of sex development: findings from the dsd-LIFE study. *Fertil Steril*. 2017;108(5):822-831. doi:10.1016/j.fertnstert.2017.08.013

[9] Hruz, P. W. (2020). Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. *The Linacre Quarterly*, *87*(1), 34–42. https://doi.org/10.1177/0024363919873762

- Conversely, in the trans-identified, there is no inherent defect in sex organ development, function or fertility.
    - UK GIDS Tavistock study 2020: In 44 gender dysphoric youth "All had normal karyotype and endocrinology…"[10]
- Thus, DSDs (Intersex) and gender dysphoria are two very different things requiring different approaches, not the Section 1557 proposed rule.

Regarding Minors with Gender Dysphoria or trans-identification, desistance is the norm, resolving on its own for an average of 85% by adulthood, unless it is affirmed. Mandatory permanent medicalization of a child for a condition that usually goes away is unwarranted. It is malpractice, and the lawsuits are already mounting.[11][12]

- DSM-5 p.455: rates of persistence translate to rates of desistance in natal males of 70 to 97.8% and natal females of 50 to 88%. [13]
- American Psychological Association *Handbook on Sexuality and Psychology,V1,744*:[14]
    - "In no more than about one in four children does gender dysphoria persist from childhood to adolescence or adulthood…" That represents a minimum 75% rate of desistance.
- Singh, Bradley, Zucker, 2021. 87.8% desistance noted in the "largest sample to date of boys clinic-referred for gender dysphoria."[15]
- Cohen-Kettenis, 2008, J SexMed: 80-95% of gender dysphoric pre-pubertal children desist by the end of adolescence.[16]

Citing: Zucker, Kenneth J., Susan J. Bradley, Gillian Oliver, Jennifer Blake, Susan Fleming, and Jane Hood. 1996. "Psychosexual Development of Women with Congenital Adrenal Hyperplasia." Hormones and Behavior 30: 300–18. doi: 10.1006/hbeh.1996.0038.

[10] 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

[11] https://www.thetimes.co.uk/article/tavistock-gender-clinic-to-be-sued-by-1-000-families-lbsw6k8zd

[12] https://www.dailymail.co.uk/news/article-11101661/Tavistock-transgender-clinic-facing-mass-legal-action-1-000-families.html

[13] American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders (5th ed.). Arlington, VA: American Psychiatric Publishing. P.455.

[14] Bockting, W. (2014). Chapter 24: Transgender Identity Development. In Tolman, D., & Diamond, L., Co-Editors-in-Chief (2014) *APA Handbook of Sexuality and Psychology* (2 volumes). Washington D.C.: American Psychological Association, *1*: 744.)

[15] 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

[16] Cohen-Kettenis PY, et al. "The treatment of adolescent transsexuals: changing insights." J Sex Med. 2008 Aug;5(8):1892-7. doi: 10.1111/j.1743-6109.2008.00870.x. Epub 2008 Jun 28.

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- Ristori, et al Int Rev Psychiatry 2016: Finding a desistance rate of 61-98% of GD cases by adulthood.[17]
- The pro-affirmation Endocrine Society Guidelines admit: "… the large majority (about 85%) of prepubertal children with a childhood diagnosis (of GD) did not remain gender dysphoric in adolescence."[18]
- U of Toronto psychologist Dr. Ken Zucker summarizes and defends the numerous studies showing desistance is common in his 2018 paper, "The myth of persistence."[19]

Mental health issues, adverse childhood events, neuro-developmental problems like autism spectrum disorder, and family issues are found in the overwhelming majority of the gender dysphoric.

- Many studies show these problems come before any diagnosis of gender dysphoria or claim of transgenderism.
- A 2015 report from Finland's gender identity services found 75% of adolescents they saw were or had been undergoing psychiatric treatment for reasons other than GD. 26% had autism spectrum disorder.[20]
- A 2014 four nation European study found almost 70% of people with gender identity disorder had "a current and lifetime diagnosis."[21]
- A 2018 Kaiser-Permanente study, "Mental Health of Transgender and Gender Nonconforming Youth Compared with Their Peers,"[22] gleaned from electronic medical records of 8.8M members in Georgia and California, revealed:
    - High rates of psychiatric disorders and suicidal ideation before gender non-congruence in teens.
    - Rates (prevalence ratios/PR) in the 6 months before first findings of GNC compared to gender congruent peers: psychiatric disorders 7 times higher overall, psychiatric hospitalizations 22-44 times higher, self harm 70-144

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[17] Ristori J, Steensma TD. Gender dysphoria in childhood. Int Rev Psychiatry. 2016;28(1):13-20.

[18] 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.

[19] Zucker, K. J. (2018). The myth of persistence: response to "A critical commentary on follow-up studies and 'desistance' theories about transgender and gender nonconforming children" by Temple Newhook et al. International Journal of Transgenderism, 19(2), 231–245. Published online May 29, 2018. http://doi.org/10.1080/15532739.2018.1468293

[20] Kaltiala-Heino R, Sumia M, Työläjärvi M, Lindberg N. Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development. Child and Adolescent Psychiatry and Mental Health (2015) 9:9.

[21] 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.

[22] 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.

times higher, and suicidal ideation 25-54 times higher (Tables 3 & 4 of study).

- A 2021 Australian prospective study from a multidisciplinary pediatric gender service showed: [23]
    - High rates of comorbid mental health disorders: anxiety (63.3%), depression (62.0%), behavioral disorders (35.4%), and autism (13.9%).
    - High rates of adverse childhood experiences, with family conflict (65.8%), parental mental illness (63.3%), loss of important figures via separation (59.5%), and bullying (54.4%); and maltreatment (39.2%).
- A 2018 parental survey of Rapid Onset Gender Dysphoria found:[24]
    - 62.5% of gender dysphoric adolescents had "a psychiatric disorder or neurodevelopmental disability (before) the onset of gender dysphoria".
    - 12.3% prevalence of autism spectrum disorder.
    - (48.4%) had experienced a traumatic or stressful prior event
- Personality Disorders are common, especially narcissism.
    - Looking at 8 studies, Zucker reported most found 50–80% prevalence of lifetime comorbid psychopathology in adults with GD, including a 20–60% prevalence of personality disorders."[25]
- Autogynephilia ("…propensity of certain males to be erotically aroused by the thought or image of themselves as women.")[26] [27] is common for adult males with transgender identification.
- Affirming parents don't improve the mental health statistics, and an affirming government won't either.
  Schumm and Crawford found, "Whereas Olson et al. (2016b) and Durwood, McLaughlin, and Olson (2017) concluded that transgender children with strong parental support had, at worst, only slightly higher levels of anxiety with no differences in self-worth or depression; a reanalysis of their findings suggests otherwise, with slightly higher levels of depression but significantly and substantively meaningful differences in anxiety and self-worth, and with results

[23] 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

[24] Littman, L. "Rapid-onset gender dysphoria in adolescents and young adults: A study of parental reports," journals.plos.org, Aug. 16, 2018. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0202330

[25] Zucker, KJ, et al. Gender Dysphoria in Adults. Annu. Rev. Clin. Psychol. 2016. 12:217–47. (P. 227.)

[26] Blanchard, Ray. (2005). Early History of the Concept of Autogynephilia. Archives of sexual behavior. 34. 439-46. 10.1007/s10508-005-4343-8.

[27] Lawrence AA. Autogynephilia: An Underappreciated Paraphilia. In: Balon R, ed. Sexual dysfunction: beyond the brain-body connection: Karger Medical and Scientific Publishers; 2011: 135-48. https://doi.org/10.1159/000328921.

favoring cisgender children, even when the transgender children had high levels of parental support for their gender transitioning."[28]

The medical literature is clear: do not prematurely affirm. The proposed 1557 rule would ignore this and place sexual minorities in harm's way.

- *APA Handbook on Sexuality and Psychology*: "Premature labeling of gender identity should be avoided." "This approach runs the risk of neglecting individual problems the child might be experiencing …"[29]
- 2020 Nordic J of Psychiatry: "An adolescent's gender identity concerns must not become a reason for failure to address all her/his other relevant problems in the usual way." [30]
- Withers 2020, "trans-identification and its associated medical treatment can constitute an attempt to evade experiences of psychological distress."[31]

Gender (transition) affirming health care is not the "standard of care" for gender dysphoria or gender non-conformity.

- Gender (transition) affirming healthcare guidelines ultimately derive from activist groups like WPATH (World Professional Association for Transgender Health) which is neither a scientific nor a medical organization, and whose SOCs (Standards of Care) appear to be both internally inconsistent and window dressing that is ultimately not followed.
    - Just calling them "standards of care" do not make them so.
- The 2017 Endocrine Society Guidelines, the first from a medical organization, specifies this disclaimer on p. 3895: "The guidelines cannot guarantee any specific outcome, nor do they establish a standard of care." G(T)AHC is not the standard of

[28] Schumm, Walter & Crawford, Duane. (2019). Is Research on Transgender Children What It Seems? Comments on Recent Research on Transgender Children with High Levels of Parental Support. The Linacre Quarterly. 87. 002436391988479. 10.1177/0024363919884799.
Citing: (1) Olson, Kristina R., Lily Durwood, Madeleine DeMeules, and Katie A. McLaughlin. 2016b. "Mental Health of Transgender Children Who Are Supported in Their Identities." Pediatrics 137:e20153223.
and (2) Durwood, Lily, Katie A. McLaughlin, and Kristina R. Olson. 2017. "Mental Health and Self-worth in Socially Transitioned Transgender Youth." Journal of the American Academy of Child & Adolescent Psychiatry 57:116–23.
[29] W. Bockting, *Ch. 24: Transgender Identity Development*, in 1 American Psychological Association Handbook on Sexuality and Psychology, 750 (D. Tolman & L. Diamond eds., 2014).
[30] Riittakerttu Kaltiala, Elias Heino, Marja Työläjärvi & Laura Suomalainen (2020) Adolescent development and psychosocial functioning after starting cross-sex hormones for gender dysphoria, Nordic Journal of Psychiatry, 74:3, 213-219, DOI: 10.1080/08039488.2019.1691260
[31] Withers, R. (2020) Transgender medicalization and the attempt to evade psychological distress. *J Anal Psychol*, 65: 865– 889. https://doi.org/10.1111/1468-5922.12641.

care.

- Pro-G(T)AHC guidelines and statements (which are not standards of care) from medical and psychological organizations are almost always written by WPATH members or repeat such, are not voted on by the rank and file members, and represent the incursion of ideology posing as science. Be wary of them.
- WPATH and similar pro-G(T)AHC statements are based on "eminence" and not evidence.
- These pro-G(T)AHC decisions and policies are not voted on by the rank-and-file members, only by a small leadership.
- There is evidence of deliberate suppression of opposition to G(T)AHC on the part of major organizations like the Amer. Acad. of Pediatrics.
  - AAP Resolution 27.[32] [33] It noted growing international skepticism of G(T)AHC and requested that the AAP provide updated review and inform the members. Resolution 27 was silenced and condemned by leadership.
- Numerous organizations do not support transition in minors (American College of Pediatricians, Christian Medical & Dental Associations, Catholic Medical Association, etc.)

The international standard of care is watchful waiting, including psychological evaluation of the child and family both.[34][35]

- This is because (1) the overwhelming probability of underlying mental health issues, adverse childhood experiences, neurodevelopmental problems like autism spectrum disorder, and family dynamic issues, none of which go away with G(T)AHC (see related section) and (2) the probability of desistance by adulthood (see related section).
- U of Toronto Psychologist Dr. James Cantor "…almost all clinics and professional associations in the world use what's called the *watchful waiting* approach to helping GD children…." [36]
- Laidlaw, et al: "…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

[32] https://www.dailymail.co.uk/news/article-11099561/Leaked-internal-files-pediatricians-angry-professional-bodys-transgender-policy.html
[33] https://www.wsj.com/articles/the-american-academy-of-pediatrics-dubious-transgender-science-jack-turban-research-social-contagion-gender-dysphoria-puberty-blockers-uk-11660732791
[34] de Vries, A. L., and P. T. Cohen-Kettenis. 2012. Clinical management of gender dysphoria in children and adolescents: The Dutch approach. Journal of Homosexuality 59(3): 301–320.
[35] 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
[36] 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

gender affirmative therapy…"[37] [38]

- This primacy of mental health evaluation and support was emphasized in the UK's Cass Interim Report of 2022,[39] the UK's 2020 National Institute for Health and Care Excellence reviews of puberty blockers and cross-sex hormones,[40] the UK's NHS closure of the world's largest pediatric gender clinic,[41] the Swedish Agency for Health Technology Assessment and Assessment of Social Services' 2019 literature review,[42] Sweden's Karolinska Hospital (affecting Astrid Lindgren Children's Hospital's pediatric gender services) 2021 policy change,[43] Finland's COHERE 2020 policy reform,[44] and the French National Academy of Medicine press release.[45]

Minors cannot give truly informed consent.[46] They have developing brains, their minds change often, and they don't grasp long-term consequences.[47] [48][49]

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[37] 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

[38] de Vries, A. L., and P. T. Cohen-Kettenis. 2012. Clinical management of gender dysphoria in children and adolescents: The Dutch approach. Journal of Homosexuality 59(3): 301–320.

[39] https://cass.independent-review.uk/publications/interim-report/

[40] https://arms.nice.org.uk/resources/hub/1070871/attachment and https://arms.nice.org.uk/resources/hub/1070905/attachment

[41] https://www.bbc.com/news/uk-62335665

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

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

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

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

[46] Stephen B. Levine (2018): Informed Consent for Transgendered Patients, *Journal of Sex & Marital Therapy*, 22 Dec 2018. DOI:10.1080/0092623X.2018.1518885

[47] National Institute of Mental Health (2001). Teenage Brain: A work in progress. http://www2.isu.edu/irh/projects/better_todays/B2T2VirtualPacket/BrainFunction/NIMH-Teenage%20Brain%20-%20A%20Work%20in%20Progress.pdf.

[48] Pustilnik AC, and Henry LM. Adolescent Medical Decision Making and the Law of the Horse. *Journal of Health Care Law and Policy* 2012; 15:1-14. (U of Maryland Legal Studies Research Paper 2013-14).

[49] Stringer, H. (Oct. 2017) Justice for teens, *APA Monitor on Psychology*, pp. 44-49. http://www.apamonitor-digital.org/apamonitor/201710/MobilePagedArticle.action?articleId=1169604&app=false#articleId1169604

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- A UK High Court in Bell vs. Tavistock (2020) specified, "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."[50]
- Anthony Latham, chair of the Scottish Council on Human Bioethics, wrote in 2022, "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."[51]
- The Swedish Pediatric Society 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."[52]

Puberty blocking agents [PBA] have significant risks.

- PBAs chemically sterilize at the level of the brain,[53] and prompt infertility by blocking the maturation of sperm and eggs.[54] Following them with cross-sex hormones assures sterility.[55] [56]
- PBAs compromise bone mineral density at what should be the period of peak increase.[57]
- PBAs hinder brain development and compromise sexual function.
- The US FDA added a warning for pseudotumor cerebri (idiopathic intracranial hypertension) July 2022.[58]

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

[51] Antony Latham (2022) Puberty Blockers for Children: Can They Consent?, The New Bioethics, 28:3, 268-291, DOI: 10.1080/20502877.2022.2088048

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

[53] Lupron Depot-Ped Injection Label (August 2012) at 12.1 "Mechanism of Action" https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020263s036lbl.pdf.

[54] Michael K. Laidlaw, Quentin L. Van Meter, Paul W. Hruz, Andre Van Mol, and William J. Malone, Letter to the Editor: Endocrine Treatment of Gender-Dsyphoria/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline, JCEM, Online, November 23, 2018.

[55] Howard E. Kulin, et al., "The Onset of Sperm Production in Pubertal Boys. Relationship to Gonadotropin Excretion," American Journal of Diseases in Children 143, no. 2 (March, 1989): 190-193, https://www.ncbi.nlm.nih.gov/pubmed/2492750.

[56] https://transcare.ucsf.edu/guidelines/youth

[57] 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

[58] "Risk of pseudotumor cerebri added to labeling for gonadotropin-releasing hormone agonists" July 1,2022. https://www.fda.gov/media/159663/download

- Self-harm does not improve on PBAs.[59] [60]
- PBAs are not proven fully reversible, and long-term complications are known.[61]

Cross-sex hormones have numerous known risks.[62] [63] [64] [65] [66] [67] [68]

- Estrogen use in male biology strongly increases the risks of blood clots, heart attacks, strokes, breast cancer, insulin resistance and more. Risk increases with length of use.[69]
- Testosterone use in female biology strongly increases the risks of heart attacks, strokes, breast and uterine cancer, hypertension, severe acne and more.
- An 2019 international panel of endocrinology organizations concluded about testosterone use in women[70] "…the only evidence-based indication for testosterone therapy for women is for the treatment of HSDD [Hypoactive sexual desire disorder]…There are insufficient data to support the use of testosterone for the treatment of any other symptom or clinical condition, or for disease prevention.…The safety of long-term testosterone therapy has not been

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[59] Michael Biggs, The Tavistock's Experiment with Puberty Blockers, 29 July 2019, http://users.ox.ac.uk/~sfos0060/Biggs_ExperimentPubertyBlockers.pdf
[60] 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
[61] Gallagher, Jenny Sadler et al. Long-Term Effects of Gonadotropin-Releasing Hormone Agonist and Add-Back in Adolescent Endometriosis. Journal of Pediatric and Adolescent Gynecology, Volume 31, Issue 2, 190. (2018)
[62] 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.
[63] 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.
[64] Irwig MS. Cardiovascular Health in Transgender People. Rev Endocr Metab Disord. 2018 Aug 3 epub.
[65] Nota NM, et al. Occurrence of Acute Cardiovascular Events in Transgender Individuals Receiving Hormone Therapy. *Circulation*, 139(11), 2019, pp. 1461-1462.
[66] Getahun D, Nash R, Flanders WD, et al. Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study. *Ann Intern Med* 2018; 169(4): 205-13. doi: 10.7326/M17-2785.
[67] Journal of Clinical & Translational Endocrinology 21 (2020) 100230
[68] Diabetes Care 2020 Feb; 43(2): 411-417; World J Diabetes. 2020 Mar 15; 11(3): 66–77.
[69] Getahun D, Nash R, Flanders WD, et al. Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study. *Ann Intern Med* 2018; 169(4): 205-13. doi: 10.7326/M17-2785.
[70] Susan R Davis, et al, Global Consensus Position Statement on the Use of Testosterone Therapy for Women, *The Journal of Clinical Endocrinology & Metabolism*, Volume 104, Issue 10, October 2019, Pages 4660–4666, https://doi.org/10.1210/jc.2019-01603.

established." Note the absence of indication for G(T)AHC.

Many regret transition. Many claim their consent lacked information on G(T)AHC's known risks and available alternatives.[71]

- Studies downplaying rates of regret habitually show high rates of loss to follow up (20-60%) and set unreasonable strict definitions for regret. (D'Angelo, 2018)…"[72]
- Follow up periods are consistently too short, reporting comes from gender clinics, and those with regret or who detransition say they then avoid gender clinics.[73]
- Levine, Abbruzzese, and Mason (2022) observe regarding gender affirming interventions, "…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."[74]

Studies and surveys commonly cited to support G(T)AHC for gender dysphoria very often demonstrate the same fatal flaws:[75]

- Impressively high rates of loss to follow up, from over 20% to over 60%, which invalidate the findings.[76] Were those lost patients helped, hurt, or even still alive?[77]
- Unacceptably strict definitions for regret.

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[71] https://www.reddit.com/r/detrans/.

[72] D'Angelo, R., Syrulnik, E., Ayad, S. *et al.* One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav* (2020). https://doi.org/10.1007/s10508-020-01844-2
Citing: D'Angelo R. Psychiatry's ethical involvement in gender-affirming care. *Australasian Psychiatry*. 2018;26(5):460-463. doi:10.1177/1039856218775216

[73] Littman L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav*. 2021;50(8):3353-3369. doi:10.1007/s10508-021-02163-w

[74] 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

[75] Andre Van Mol, "Regretting Transition for Gender Dysphoria" 'The Point" blog, June 23, 2022. https://cmda.org/regretting-transition-for-gender-dysphoria/

[76] D'Angelo, R., Syrulnik, E., Ayad, S. *et al.* One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav* (2020). https://doi.org/10.1007/s10508-020-01844-2
Citing: D'Angelo R. Psychiatry's ethical involvement in gender-affirming care. *Australasian Psychiatry*. 2018;26(5):460-463. doi:10.1177/1039856218775216

[77] D'Angelo R. Psychiatry's ethical involvement in gender-affirming care. *Australasian Psychiatry*. 2018;26(5):460-463. doi:10.1177/1039856218775216

- Insufficient periods of follow up, usually only 6 months to 2 years post-transition, despite the existing evidence that post-surgical regret is known to manifest 8 years or so post-transition.[78] [79]
- Are not randomized controlled or long-term comprehensive follow-up studies.[80] [81]
- Convenience sampling, which "is to be avoided always in survey research" and from which we "cannot make statistical generalizations."[82]
- Sampling usually taken from gender clinics, to which those with regret repeatedly report they do not return. A 2021 survey of 100 detransitioners found that only 24% had informed their clinician of their detransition, thus 76% did not.[83]
- Data is gleaned from in-house satisfaction surveys lacking clear and uniform definitions, metrics, and follow up. This low-quality data then gets pooled to create low quality, unreliable results.
- Per pediatric endocrinologist and academic Paul Hruz's 2020 paper "Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria". "Limitations of the existing transgender literature include general lack of randomized prospective trial design, small sample size, recruitment bias, short study duration, high subject dropout rates, and reliance on "expert" opinion."[84]

G(T)AHC's suicide reduction claim is a myth, used as emotional blackmail.

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[78] Dhejne C, Öberg K, Arver S, et al. An analysis of all applications for sex reassignment surgery in Sweden, 1960–2010: prevalence, incidence, and regrets. Arch Sex Behav. 2014;43:1535–1545.

[79] Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam cohort of gender dysphoria study (1972–2015): Trends in prevalence, treatment, and regrets. J Sex Med. 2018;15:582–590.

[80] Levine, S.B. Reflections on the Clinician's Role with Individuals Who Self-identify as Transgender. *Arch Sex Behav* (2021). https://doi.org/10.1007/s10508-021-02142-1

[81] Hruz, P. Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. "Limitations of the existing transgender literature include general lack of randomized prospective trial design, small sample size, recruitment bias, short study duration, high subject dropout rates, and reliance on "expert" opinion."

[82] "An important note about convenience sampling is that you cannot make statistical generalizations from research that relies on convenience sampling." "Convenience sampling is to be avoided *always* in survey research."
Lior Gideon, editor. Handbook of Survey Methodology for the Social Sciences. New York: Springer, 2012. ISBN 978-1-4614-3875-5.

[83] Littman, L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav* **50,** 3353–3369 (2021). https://doi.org/10.1007/s10508-021-02163-w

[84] Hruz, P. W. (2020). Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. *The Linacre Quarterly*, *87*(1), 34–42. https://doi.org/10.1177/0024363919873762

- Many parents of gender confused youth report being asked by mental health and medical officials, “Do you want a live son or a dead daughter?” or “Would you rather be planning a transition or a funeral?”
- But G(T)AT is not proven to reduce suicides. In fact, the best studies show worsening of mental health long term for many.
- Bailey and Blanchard: “There is no persuasive evidence that gender transition reduces gender dysphoric children’s likelihood of killing themselves.[85]
- A 2011 Swedish study of all their post-sex reassignment surgery adults showed a completed suicide rate 19 times that of the general population 10 yearsw out, along with nearly 3 times the rate of overall mortality and psychiatric inpatient care.[86]
- A 2020 study by Bränström and Pachankis, claiming to be the first total population study of 9.7 million Swedish residents, ultimately showed neither “gender-affirming hormone treatment” nor “gender-affirming surgery” improved the mental health benchmarks.[87] [88]
- There is no one reason for suicide. The U.S. CDC/MMWR “Suicide Contagion and the Reporting of Suicide” recommendations against “Presenting simplistic representations of suicide. Suicide is never the result of a single factor or event, but rather results from a complex interaction of many factors and usually involves a history of psychosocial problems.”[89]
- Mental health issues exist:
    - About 96% of US adolescents attempting suicide demonstrate at least one mental illness.[90]

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[85] J. Michael Bailey and Ray Blanchard, “Suicide or transition: The only options for gender dysphoric kids?” 4thwavenow.com, Sept. 8, 2017. https://4thwavenow.com/2017/09/08/suicide-or-transition-the-only-options-for-gender-dysphoric-kids/

[86] 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.

[87] Bränström R, Pachankis JE: Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. Am J Psychiatry 2020; 177:727–734. https://doi.org/10.1176/appi.ajp.2019.19010080

[88] Kalin NH: Reassessing mental health treatment utilization reduction in transgender individuals after gender-affirming surgeries: a comment by the editor on the process (letter). Am J Psychiatry 2020; 177:765 https://doi.org/10.1176/appi.ajp.2020.20060803

[89] O’Carroll, P.W. & Potter, L.B. (April 22, 1994). Suicide contagion and the reporting of suicide: Recommendations from a national workshop. MMWR, 43(RR-6):9-18. https://www.cdc.gov/mmwr/preview/mmwrhtml/00031539.htm

[90] Nock MK, Green JG, Hwang I, McLaughlin KA, Sampson NA, Zaslavsky AM, Kessler RC. Prevalence, correlates, and treatment of lifetime suicidal behavior among adolescents: results from the National Comorbidity Survey Replication Adolescent Supplement. JAMA Psychiatry. 2013 Mar;70(3):300-10.

- 90% of adults and adolescents who completed suicide had unresolved mental disorders .[91]
- G(T)AHC does not resolve underlying mental health issues.

California and North Carolina have launched reparations programs for those sterilized by the state as part of the eugenics movement.[92] [93]States and the United States will get to pay reparations again, this time due to G(T)AHC for minors and adults with gender dysphoria or other gender non-conformity, should the proposed 1557 rule pass.

Non-Discriminatory. Refusing to provide gender/transition affirming health care is actually non-discriminatory and appropriate both professionally and scientifically.

- G(T)AHC has not been proven safe, effective, or of more benefit than harm. This was emphasized in the 2020 UK High Court Bell v Tavistock case,[94] the UK's Cass Interim Report of 2022,[95] the UK's 2020 National Institute for Health and Care Excellence reviews of puberty blockers and cross-sex hormones,[96] the UK's NHS closure of the world's largest pediatric gender clinic,[97] the Swedish Agency for Health Technology Assessment and Assessment of Social Services' 2019 literature review,[98] Sweden's Karolinska Hospital (affecting Astrid Lindgren Children's Hospital's pediatric gender

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[91] Cavanagh, J., Carson, A., Sharpe, M. & Lawrie, S. (2003), Psychological autopsy studies of suicide: a systematic review, Psychological Medicine, 33: 395–405, Cambridge University Press, DOI: 10.1017/S0033291702006943.

[92] https://sacramento.cbslocal.com/2021/12/31/california-program-state-sponsored-sterilization-survivors/
More indepth prior report:
https://ktla.com/news/california/california-to-pay-victims-forced-coerced-into-sterilization-because-state-deemed-them-unfit-to-have-children/

[93] https://abcnews.go.com/Health/WomensHealth/north-carolina-compensate-victims-eugenics-program-sterilized/story?id=15328707

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

[95] https://cass.independent-review.uk/publications/interim-report/

[96] https://arms.nice.org.uk/resources/hub/1070871/attachment
and https://arms.nice.org.uk/resources/hub/1070905/attachment

[97] https://www.bbc.com/news/uk-62335665

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

services) 2021 policy change,[99] Finland's COHERE 2020 policy reform,[100] and the French National Academy of Medicine press release.[101]

- Physicians take an oath to do no harm, and G(T)AHC is documented to lead to much harm without proof of compensatory benefit.
- Withholding unproven interventions is non-discriminatory.
- The problem of diagnosis: "There are no laboratory, imaging, or other objective tests to diagnose a "true transgender" child." … "There is currently no way to predict who will desist and who will remain dysphoric."[102] Withholding unproven treatments for uncertain diagnostic or ideological identifications is non-discriminatory and simply wise medical practice protecting both the patient and physician.
- There are alternative treatments of mental health natures which are at least as effective and without the harms of hormonal and surgical interventions.

Regarding pronoun mandates, government cannot compel people to speak or support messages they disagree with or that violate their convictions.

SCOTUS has ruled:

- In *Janus v. American Federation of State, County, and Municipal Employees, Council 31*, 138 S. Ct. 2448, 2463 (2018), the Court reaffirmed that the government cannot compel individuals to mouth support for views they find objectionable. It undermines the right to free speech.
- In *National Institute of Family and Life Advocates (NIFLA) v. Becerra*, 138 S. Ct. 2361, 2371 (2018), the Court ruled that the pro-abortion notice requirement imposed on pregnancy resource clinics by the California law was an unconstitutional content-based restriction on speech. Justice Kennedy (joined by Roberts, Alito, and Gorsuch) offered a forceful opinion that the California law "is a paradigmatic example of the serious threat presented when government seeks to impose its own message in the place of individual speech, thought, and expression."
- Practical Impact: Requiring use of preferred pronouns, as an example, is compelled speech and violates the First Amendment.

The US Fifth Circuit Court of Appeals ruled a court cannot require anyone to refer to "gender-dysphoric litigants with pronouns matching their subjective gender identity." [103]

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

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

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

[102] 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.

[103] http://www.ca5.uscourts.gov/opinions/pub/19/19-40016-CR0.pdf.

104

- It is a clear First Amendment violation to force speech content.
- They also astutely asserted: "ordering use of a litigant's preferred pronouns may well turn out to be more complex than at first it might appear." … "In reality, a dysphoric person's [e]xperienced gender may include alternative gender identities beyond binary stereotypes." … "If a court orders one litigant referred to as "her" (instead of "him"), then the court can hardly refuse when the next litigant moves to be referred to as "xemself" (instead of "himself"). Deploying such neologisms could hinder communication among the parties and the court. And presumably the court's order, if disobeyed, would be enforceable through its contempt power."

Regarding the mandating of gender/transition affirming health care and professional participation therein, the proposed Section 1557 rule violates established law and legal precedent.

- The Church Amendments to the 1973 Public Health Service Act, Public Law 93-348, § 214.[105]
  - It applies to and prohibits discrimination against or coercion of healthcare professionals and hospitals who object to performing abortions, sterilizations, assisted suicide, and other procedures or services due to religious or moral convictions.
    - Sterilization is precisely what puberty blockers, cross-sex hormones, and genital surgery on healthy bodies directly incur.
  - The Church Amendment protects personnel who object to performing or assisting with *any lawful health service* based on a person's religious beliefs or moral convictions.
    - Healthcare professionals are protected from being mandated and coerced into providing G(T)AHC even when the care is legal.
- Religious Freedom Restoration Act of 1993**.**[106] [107] Beginning at 42 U.S.C. § 2000bb.
  - It enforces the First Amendment's protection of religious freedom from government interference.
  - The federal government cannot force a healthcare professional's engagement in activities that substantially burden religious exercise without an exception "of the highest order."
  - The "highest order" exception must prove two points:
    1) That there is a "compelling government interest" involved in enforcing this requirement.
    2) That the government cannot accomplish this goal in a manner less burdensome to your religious beliefs.

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[104] Patricia Barnes, "'Xemself,' 'Eirself,' and 'Verself': U.S. Appeals Court Nixes Gender Neutral Pronouns," forbes.com, Jan. 15, 2020.
[105] ADF's "A Legal Guide for Healthcare Professionals. 2016. http://tinyurl.com/wtnybnn.
[106] http://tinyurl.com/webhr36.
[107] ADF's "A Legal Guide for Healthcare Professionals." 2016. http://tinyurl.com/wtnybnn.

    - The Section 1557 proposed rule fails both requirements: there is no compelling government interest in enforcing therapy that is neither proven safe nor effective, and there are other far less burdensome means to accomplish the goal of assistance for the sexual minorities in question.
- Franciscan Alliance v. Azar struck down the Federal Transgender Mandate of 2016 which would have required doctors to perform gender affirming procedures on any patient, adult or minor, even against professional judgment.
    - The Fifth Circuit Court of Appeals upheld the judgment of the District Court in all respects except the Administrative Procedure Act (Aug. 26, 2022).[108] The Court delivered a detailed refutation of the claims of HHS/Sec. Becerra.

Thank you for the opportunity to address and oppose RIN: 0945-AA17 [Docket ID: HHS-OS-2022-0012] Nondiscrimination in Health Programs and Activities, HHS's proposed rule on Section 1557 of the Affordable Care Act (ACA).

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[108] https://becketnewsite.s3.amazonaws.com/20220826221641/Eighth-Circuit-Franciscan-Opinion.pdf