

**FLORIDA MEDICAID & G/TAT**

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## Sex

Is objective, identifiable, immutable, determined at conception (not “assigned at birth”), stamped on every nucleated cell, and highly consequential.<sup>1 2 3 4</sup>

- Per DSM-5, p. 829, sex is “Biological indication of male and female (**understood in the context of reproductive capacity**), such as sex chromosomes, gonads, sex hormones, and nonambiguous internal and external genitalia.”<sup>5</sup>
- There are 2 sex cells or gametes, sperm and ova. There is no third.
- It is biologically impossible to be born in the wrong body.
- Psychiatrist Stephen B. Levine: “**Biological sex cannot be changed.**”<sup>6</sup>

## What about intersex (disorders of sex development)?

- They are also established at conception for the 0.02% of people who have them.<sup>7 8</sup>
- DSDs are definable medical problems, not identities. Something someone has and not who they are.
- DSDs:
  - “... a diverse group of congenital conditions where the **development of the reproductive system is different from what is usually expected.**”<sup>9</sup>
  - DSDs **usually impair fertility.**<sup>10</sup>

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<sup>1</sup> Institute of Medicine (US) Committee on Understanding the Biology of Sex and Gender Differences; Wizemann TM, Pardue ML, editors. Exploring the Biological Contributions to Human Health: Does Sex Matter? Washington (DC): National Academies Press (US); 2001. 2, Every Cell Has a Sex. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK222291/>

<sup>2</sup> “Researchers Identify 6,500 Genes That Are Expressed Differently in Men and Women,” Weizmann Wonder Wander (Weizmann Institute of Science), May 3, 2017, online at: <https://wiswander.weizmann.ac.il/life-sciences/researchers-identify-6500-genes-are-expressed-differently-men-and-women>.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)* (Arlington, VA: American Psychiatric Association, 2013), p. 829.

<sup>6</sup> Stephen B. Levine (2018): Informed Consent for Transgendered Patients, *Journal of Sex & Marital Therapy*, DOI: 10.1080/0092623X.2018.1518885.

<sup>7</sup> “Intersex. What It Is And Is Not,” CMDA The Point Blog, May 2, 2019.

<sup>8</sup> 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/>

<sup>9</sup> 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

<sup>10</sup> Słowikowska-Hilczler J, Hirschberg AL, Claahsen-van der Grinten H, et al. Fertility outcome and information on fertility issues in individuals with different forms of disorders

- **Biological anomalies do not disprove** or undercut the reality of there being only two sexes, male and female, which are ordered to the purpose of reproduction.<sup>11</sup>
  - **DSDs are not a third sex.** There are 2 sex cells (gametes), sperm and ova. There is no third. Intersex is **not an Extrasex**.
- **DSD patients usually do not identify with transgender identity.**
  - “Importantly, the vast majority of affected children with CAH historically did not experience self-perceived transgender identity or gender dysphoria (Zucker et al. 1996).”<sup>12</sup>
  - UK GIDS Tavistock study 2020: “All had normal karyotype and endocrinology” function in 44 GD youth.<sup>13</sup>
- Why do some say the prevalence is 5%? They include conditions that fail the two-part definition.
- Conversely, **in the trans-identified, there is no inherent defect in sex organ development, function or fertility.**
- **DSDs (Intersex) and gender dysphoria are two different things.**

## Gender

- In popular usage, it’s an engineered term leveraging linguistics against biology.<sup>14</sup>
  - **Nouns have gender, people have a sex.**
  - Psychologist Dr. John **Money** of John Hopkins initiated its use in professional journals in **1955**, referring to “**the identity of the inner sexed self.**”<sup>15</sup>
- **Gender** (in current popular usage) is subjective, fluid and self-declared.
- **Sex is biology. Gender is ideology.**
  - If you cannot define or forbid defining a woman, you cannot protect her rights.
- **Gender identity** is a feeling, a self-perception, often a sex stereotype.

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of sex development: findings from the dsd-LIFE study. *Fertil Steril*. 2017;108(5):822-831. doi:10.1016/j.fertnstert.2017.08.013

<sup>11</sup> American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) (Arlington, VA: American Psychiatric Association, 2013), p. 829.

<sup>12</sup> 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>

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.

<sup>13</sup> 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>

<sup>14</sup> Quentin Van Meter, “Bringing Transparency to the Treatment of Transgender Persons,” *Issues in Law and Medicine* 34, no. 2 (Fall 2019): 147.

<sup>15</sup> John Money, “Hermaphroditism, gender and precocity in hyperadrenocorticism: psychologic findings,” *Bulletin of the John Hopkins Hospital* 95, no. 6 (1955): 253 – 264, <http://www.ncbi.nlm.nih.gov/pubmed/14378807>.

- Ideations cannot be “assigned at birth.”
- Per C. West: However, **“The root “gen”—from which we get words such as generous, generate, genesis, genetics, genealogy, progeny, gender, and genitals—means “to produce” or “give birth to.” A person’s gen-der, therefore, is based on the manner in which that person is designed to gen-erate new life. **Contrary to widespread secular insistence, a person’s gender is not a malleable social construct. Rather, a person’s gender is determined by the kind of genitals he or she has.**”**

Christopher West, *Our Bodies Tell God’s Story*, (Brazos Press, Grand Rapids), 2020. p. 28.

**Gender dysphoria** is a diagnosis.

- **It’s a psycho-social, neurodevelopmental issue.**
- Distress with one’s sexed body.
- The term is fading. What replaces it? **Gender incongruence?**
  - **Gender Anxiety** is an apt term for minors.

**Transgenderism is an overarching ideology.** (Dr. Ken Zucker’s term)

- Zucker: “The term “transgender identity” is hardly an objective label for a child’s gendered subjectivity.”<sup>16</sup>

TG & GD are **not the same**, save for now arriving to us as self-diagnoses.

- DSM 5 of the APA:<sup>17</sup>

“Transgender refers to the broad spectrum of individuals who transiently or persistently identify with a gender different from their natal gender.”
- Ken Zucker: “But a transgender identity is not isomorphic with a mental health diagnosis of gender dysphoria ...”<sup>18</sup>
- A gender-dysphoric youth experiences a sense of incongruity between the gender expectations linked to her or his biological sex and her or his biological sex itself.”<sup>19</sup>
- DSM-5 “Gender Dysphoria” terminology is soiled by ideology: “A marked incongruence between one’s experienced/expressed gender and assigned gender, of at least 6 months’ duration...” and “associated with clinically significant distress or impairment in social, occupational or other important areas of functioning.”

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<sup>16</sup> 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>

<sup>17</sup> American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing. P.451.

<sup>18</sup> K.J. Zucker, 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, 19(2) *INT’L J. TRANSGENDERISM* 231–45 (2018).

<sup>19</sup> Tomer Shechner, *Gender Identity Disorder: A Literature Review from a Developmental Perspective*, 47 *Isr. J. of Psychiatry & Related Sci.* 132-38 (2010.)

**Prevalence stats, DSM-5:** “For natal adult **males**, prevalence ranges from **0.005% to 0.014%**, and for natal **females**, from **0.002% to 0.003%**.”

- But surveys now say **2% of youths** claim they “may be trans.”<sup>20</sup>
- Something changed, and it wasn’t biology or genetics.

**Desistance is the norm for GD/GA, unless affirmed. Conservatively, 85% will desist by adulthood.**

- DSM-5 p.455: rates of persistence translate to rates of desistance in natal males from 70 to 97.8% and natal females from 50 to 88%.<sup>21</sup>
- American Psychological Assoc. *Handbook on Sexuality and Psychology*, V1,744:<sup>22</sup>
  - “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, *Front. Psychiatry*. 87.8% desistance in “largest sample to date of boys clinic-referred for gender dysphoria.”<sup>23</sup>
- Cohen-Kettenis, 2008, *J SexMed*: 80-95% of gender dysphoric pre-pubertal children desist by the end of adolescence.<sup>24</sup>
- Ristori, et al *Int Rev Psychiatry* 2016: Finding a desistance rate of **61-98%** of GD cases by adulthood.<sup>25</sup>
- 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.”<sup>26</sup>

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<sup>20</sup> Johns MM, Lowry R, Andrzejewski J, et al. Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students — 19 States and Large Urban School Districts, 2017. *MMWR Morb Mortal Wkly Rep* 2019;68:67–71. DOI: [http://dx.doi.org/10.15585/mmwr.mm6803a3external icon](http://dx.doi.org/10.15585/mmwr.mm6803a3externalicon)

<sup>21</sup> American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing. P.455.

<sup>22</sup> 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.)

<sup>23</sup> 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/fpsy.2021.632784

<sup>24</sup> 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.

<sup>25</sup> Ristori J, Steensma TD. Gender dysphoria in childhood. *Int Rev Psychiatry*. 2016;28(1):13-20.

<sup>26</sup> Hembree, W., Cohen-Kettenis, et al., (2017) Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*,102:1–35.

- 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.**”<sup>27</sup>

### **Brain development in minors** <sup>28 29 30 31</sup>

- Children have developing brain, their minds change often, and they don’t grasp long-term consequences.<sup>32</sup>
- The frontal lobe – brain’s judgment and inhibition center -- does not fully mature until approximately 23 – 25 years of age.
- The amygdala – brain’s emotion center -- is both immature and not fully connected to the frontal lobe in teens. So emotional thinking can prevail.
- AAP’s HealthDay reported (April 2017) U of Iowa study that kids younger than 14yo could not reliably cross a busy street safely. <sup>33</sup>
  - So how are they competent to choose gender affirming therapy/GAT?

### **Problem of Consent**

- Children have developing brain, their minds change often, and they don’t grasp long-term consequences.<sup>34</sup>

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<sup>27</sup> 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>

<sup>28</sup> National Institute of Mental Health (2001). Teenage Brain: A work in progress.

<https://studylib.net/doc/7268562/teenage-brain--a-work-in-progress--fact-sheet->

<sup>29</sup> 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).

<sup>30</sup> Blakemore, S.-J., Burnett, S. and Dahl, R.E. (2010), The role of puberty in the developing adolescent brain. *Hum. Brain Mapp.*, 31: 926-933. doi:[10.1002/hbm.21052](https://doi.org/10.1002/hbm.21052)

<sup>31</sup> František Váša, et al. Conservative and disruptive modes of adolescent change in human brain functional connectivity. *PNAS*, Jan 2020, 201906144; DOI:[10.1073/pnas.1906144117](https://doi.org/10.1073/pnas.1906144117).

<sup>32</sup> “Transing California Foster Children & Why Doctors Like Us Opposed It,” *PublicDiscourse.com*, October 28, 2018.

<sup>33</sup> <https://consumer.healthday.com/kids-health-information-23/child-safety-news-587/at-what-age-can-kids-safely-cross-the-street-721785.html>.

<sup>34</sup> Andre Van Mol, “Transing California Foster Children & Why Doctors Like Us Opposed It,” *PublicDiscourse.com*, October 28, 2018.

Cited therein:

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](http://www2.isu.edu/irh/projects/better_todays/B2T2VirtualPacket/BrainFunction/NIMH-Teenage%20Brain%20-%20A%20Work%20in%20Progress.pdf).

- Dr. Levine’s 2-part test for ethical tensions people of all ages requesting GAT: “Does the patient have a clear idea of the risks of the services that are being requested? Is the consent truly informed?”
  - “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.”<sup>35</sup>
- Informed consent requires full disclosure of risks and benefits, and recommendations where benefits clearly outweigh risks. G/TAT fails that test.
- A patient who undergoes gender transitioning will be a patient for the rest of their life. Lifelong need for sex hormones and management of their complications; surgeries, further surgeries and management of surgical consequences; and other shortcomings must be considered.<sup>36 37</sup>
- May 2, 2019 the Swedish Pediatric Society issues a letter of support for the Swedish National Council for Medical Ethics’ (SMER) proposal (for the Ministry of Social Affairs to systematically review treatment of youth with gender dysphoria) 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.**”<sup>38</sup>
- **UK High Court in Bell vs. Tavistock** Dec. 12, 2020 ruled that GAT/TAT 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, “**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.”<sup>39</sup>

### Ethical Considerations

- **Ethics of permanently medicalizing something with an 85% rate of desistance based on a self-diagnosis is highly suspect.**
- **Dr. Levine’s outstanding tables of concerns here.**

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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).

<sup>35</sup> Stephen B. Levine (2018): Informed Consent for Transgendered Patients, *Journal of Sex & Marital Therapy*, DOI: 10.1080/0092623X.2018.1518885.

<sup>36</sup> Moore E, Wisniewski A, Dobs A. Endocrine treatment of transsexual people: a review of treatment regimens, outcomes, and adverse effects. *J Clin Endocrinol Metab* 2003;88:3467-3473.

<sup>37</sup> Feldman J, Brown GR, Deutsch MB, et al. Priorities for transgender medical and healthcare research. *Curr Opin Endocrinol Diabetes Obes* 2016;23:180-187.

<sup>38</sup> <http://www.barnlakarforeningen.se/2019/05/02/blf-staller-sig-bakom-smers-skrivelse-angaende-konsdysfori/>

<sup>39</sup> <https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf>

Stephen B. Levine (2017): Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria, *Journal of Sex & Marital Therapy*, DOI: 10.1080/0092623X.2017.1309482.

- **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.”<sup>40</sup> And it is based on only a self-diagnosis.

#### Do Not Prematurely Affirm:

- **APA Handbook on Sexuality and Psychology** (APA, 2014)
  - **“Premature labeling of gender identity should be avoided.** Early social transition (i.e., change of gender role,...) should be approached with caution to **avoid foreclosing this stage** of (trans)gender identity development.”<sup>41</sup>
  - As for **premature affirmation:** “This approach runs the risk of **neglecting individual problems** the child might be experiencing and may involve an early gender role transition that might be challenging to reverse **if cross-gender feelings do not persist...**”<sup>42</sup>
- **2020 Nordic J of Psychiatry:**<sup>43</sup>
  - “Conclusion: **Medical gender reassignment is not enough to improve** functioning and relieve **psychiatric comorbidities** among adolescents with gender dysphoria. Appropriate interventions are warranted for psychiatric comorbidities and problems in adolescent development.”
  - **...“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.”**
- Withers 2020, “**trans-identification** and its associated medical treatment **can constitute an attempt to evade experiences of psychological distress.**” He cautions, “This puts young trans people at risk of receiving potentially damaging

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<sup>40</sup> 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.

<sup>41</sup> W. Bockting, *Ch. 24: Transgender Identity Development*, in 1 *American Psychological Association Handbook on Sexuality and Psychology*, 744 (D. Tolman & L. Diamond eds., 2014).

<sup>42</sup> W. Bockting, *Ch. 24: Transgender Identity Development*, in 1 *American Psychological Association Handbook on Sexuality and Psychology*, 750 (D. Tolman & L. Diamond eds., 2014).

<sup>43</sup> Riittakerttu Kaltiala, Elias Heino, Marja Työläjäarvi & 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](https://doi.org/10.1080/08039488.2019.1691260)



medical treatment they may later seek to reverse or come to regret, while their underlying psychological issues remain unaddressed.”<sup>44</sup>

### **GAT/TAT is Not the Standard of Care.**

- The **2017 Endocrine Society Guidelines** state their medical evidence rating for puberty blockers and cross-sex hormones in selected minors as “low” and adult genital surgery as “very low.”<sup>45</sup> Not evidence-based standards of care.
  - **Disclaimer p. 3895:** “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.”
- Zucker, 2019. “...the field suffers from a vexing problem: There are **no randomized controlled trials (RCT) of different treatment approaches**, so the front-line clinician has to rely on lower-order levels of evidence in deciding on what the optimal approach to treatment might be.”<sup>46</sup>
- Hruz, 2020. **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.”<sup>47</sup>
- Levine, 2020. “The fact that modern patterns of the **treatment of trans individuals are not based on controlled or long-term comprehensive follow-up studies** has allowed many ethical tensions to persist.”<sup>48</sup>
- JAMA 2017: “Potential longer-term medical and surgical **risks are currently not well defined...**”<sup>49</sup>

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<sup>44</sup> 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>.

<sup>45</sup> 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>

<sup>46</sup> Zucker, K. J. (2019), Debate: Different strokes for different folks. *Child Adolesc Ment Health*. doi:[10.1111/camh.12330](https://doi.org/10.1111/camh.12330)

<sup>47</sup> 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>

<sup>48</sup> 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>

<sup>49</sup> Radix A, Davis AM. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons. *JAMA*. 2017;318(15):1491–1492. doi:10.1001/jama.2017.13540

**The international standard of care is watchful waiting, including psychological evaluation of the child and family both, not gender affirming therapy (GAT).<sup>5051</sup>**

- 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...”<sup>52</sup>
- 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 gender affirmative therapy** (de Vries and Cohen-Kettenis 2012).”<sup>53 54</sup>
- Laidlaw, et al: “it has been clearly shown that children working in psychological therapy have been able to alleviate their GD, thus avoiding the radical changes and health risks of GAT [8].”<sup>55</sup>
- And there is strong international push back against GAT in minors in favor of mental health intervention underway in nations formerly leading the GAT-for-kids march.

**International questioning of the rush to gender affirmation therapy for minors:**

- The Australasian College of Physicians.<sup>56</sup>
- The Swedish National Council for Medical Ethics, 2019.<sup>57</sup>
- Swedish Agency for Health Technology Assessment and Assessment of Social Services’ 2019 literature review.<sup>58</sup> Found no scientific evidence to explain increase

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<sup>50</sup> 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.

<sup>51</sup> 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](https://doi.org/10.1080/15265161.2018.1557288)

<sup>52</sup> 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

<sup>53</sup> 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](https://doi.org/10.1080/15265161.2018.1557288)

<sup>54</sup> 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.

<sup>55</sup> Laidlaw MK, Van Meter QL, Hruz PW, Van Mol A, Malone WJ Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline". *J Clin Endocrinol Metab*. 2019 Mar 1;104(3):686-687. doi: 10.1210/jc.2018-01925.

<sup>56</sup> <https://www.binary.org.au/australians-demand-inquiry-into-child-puberty-blockers>.

<sup>57</sup> <https://www.transgendertrend.com/wp-content/uploads/2019/04/SMER-National-Council-for-Medical-Ethics-directive-March-2019.pdf>.

<sup>58</sup> <https://www.sbu.se/en/publications/sbu-bereder/gender-dysphoria-in-children-and-adolescents-an-inventory-of-the-literature/>

incidence of GD, the increase in minors seeking GAT, few studies on gender affirming surgery in minors, few studies on long-term effects, and **“Almost all” studies were observational and “no relevant randomized controlled trials in children and adolescents were found.”**

- Sweden’s Karolinska Hospital (affecting Astrid Lindgren Children’s Hospital’s pediatric gender services) issues a policy change effective April 1, 2021:<sup>59</sup> hormonal treatments (**PBA and CSH**) **will not be allowed under age 16**; patients **16-18 can only** receive hormonal treatment in a **clinical trial** setting; **psychological and psychiatric care** must continue **under 18**; and they cite both the UK High Court ruling in *Bell v Tavistock* and that “These treatments are potentially fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and thrombosis.”
- The Royal College of General Practitioners (UK).<sup>60</sup>
- **Professor Michael Biggs of Oxford** criticized the UK’s NHS GIDS having produced only a single study (at that time) from their trial of puberty blockers, and showed **no statistically significant difference in psychosocial functioning between the group given blockers and the group given only psychological support**. Furthermore, **unpublished** evidence showed **puberty blockers worsened gender dysphoria.**<sup>61</sup>
- **UK Tavistock Gender Identity Development Service (GIDS) Controversy.**
  - **35 psychologists resigned over 3 years.**<sup>62</sup>
  - **They cited the over-prescribing medicalization of kids with GD** “with **psychologists unable to properly assess patients** over fears they will be **branded ‘transphobic...’**”
  - **“we fear that we have had front row seats to a medical scandal.”**
- The UK’s N.I.C.E. reviews (The National Institute for Health and Care Excellence).<sup>63</sup>
  - 2020 N.I.C.E. **Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria.:**
    - Conclusion: “The results of the studies that reported impact on the critical outcomes of gender dysphoria and mental health (depression, anger and anxiety), and the important outcomes of body image and psychosocial impact (global and psychosocial functioning), in children and adolescents with gender dysphoria are **of very low certainty**

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<sup>59</sup> [Karolinska Policyförändring K2021-3343 March 2021 \(Swedish\).pdf](#);

[Karolinska Policy Change K2021-3343 March 2021 \(English, unofficial translation\).pdf](#)

<sup>60</sup> <https://www.rcgp.org.uk/-/media/Files/Policy/A-Z-policy/2019/RCGP-position-statement-providing-care-for-gender-transgender-patients-june-2019.ashx?la=en>

<sup>61</sup> Michael Biggs, *The Tavistock’s Experiment with Puberty Blockers*, 29 July 2019, [http://users.ox.ac.uk/~sfos0060/Biggs\\_ExperimentPubertyBlockers.pdf](http://users.ox.ac.uk/~sfos0060/Biggs_ExperimentPubertyBlockers.pdf)

<sup>62</sup> “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>

<sup>63</sup> <https://arms.nice.org.uk/resources/hub/1070871/attachment> and <https://arms.nice.org.uk/resources/hub/1070905/attachment>

- using modified GRADE. They suggest little change with GnRH analogues from baseline to follow-up.”**
- 2020 N.I.C.E. **Evidence review: Gender-affirming hormones for children and adolescents with gender dysphoria.:**
    - Conclusion: “Any potential benefits of gender-affirming hormones must be weighed against the **largely unknown long-term safety profile of these treatments in children and adolescents with gender dysphoria.**”
    - “Results from 5 uncontrolled, observational studies suggest that, in children and adolescents with gender dysphoria, gender-affirming hormones are **likely to improve** symptoms of gender dysphoria, and **may also** improve depression, anxiety, quality of life, suicidality, and psychosocial functioning. The impact of treatment on body image is unclear. **All results were of very low certainty using modified GRADE.**”
    - Very significantly: “**Adverse events and discontinuation rates** associated with gender-affirming hormones were **only reported in 1 study, and no conclusions can be made on these outcomes.**”
  - United Kingdom High Court case ruling in Bell vs. Tavistock Dec. 12, 2020.<sup>64</sup> Ruled that puberty blockers and cross-sex hormones constitute **experimental** treatments with **limited evidence for efficacy and safety** which cannot, in most cases, be given to children **under 16 years** of age without application to the **court**. Even for minors under aged 16-17, the High Court advised “clinicians may well regard these as cases where the authorisation of the court should be sought prior to commencing the clinical treatment.”
    - The ruling has been appealed.
  - **NHS** Dec 2020 amendments to service specifications for **Gender Identity Development Service (GIDS)** for children and adolescents:<sup>65</sup> children under 16 cannot be referred to pediatric endocrinology for PBA without Court order; those under 16 already on PBA need “full clinical review” and Court order to continue or start CSH; **GIDS must insure psychological support and therapies to both patients** being removed from hormones and their **families/care givers**; for those 16-17 who meet the quals, are competent, and with parental approval, “treatment may proceed,” but even then consider Court order is any doubt about ‘best interests” of patient.
  - **Finland** rejects routine “affirmation” pathway for minors with GD. From *Council for Choices in Health Care in Finland (COHERE Finland)* 2020.<sup>66</sup>

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<sup>64</sup> <https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf>

<sup>65</sup> <https://www.england.nhs.uk/wp-content/uploads/2020/12/Amendment-to-Gender-Identity-Development-Service-Specification-for-Children-and-Adolescents.pdf>

<sup>66</sup>

[https://palveluvalikoima.fi/documents/1237350/22895008/Summary\\_minors\\_en.pdf/aaf9a6e7-b970-9de9-165c-abadfae46f2e/Summary\\_minors\\_en.pdf](https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en.pdf/aaf9a6e7-b970-9de9-165c-abadfae46f2e/Summary_minors_en.pdf)

- **Significant reversal** of prior primarily pro-GAT position.
- **Strong emphasis on mental health** evaluation and treatment: “If a child or young person experiencing gender-related anxiety has other simultaneous psychiatric symptoms requiring specialised medical care, treatment according to the nature and severity of the disorder must be arranged within the services of their own region, as no conclusions can be drawn on the stability of gender identity during the period of disorder caused by a psychiatric illness with symptoms that hamper development.”
- Recognition of **childhood phases and fads**: “...if the variation in gender identity and related dysphoria do not reflect the **temporary search for identity typical of the development stage** of adolescence...”
- **Prohibits transition surgery**: “Surgical treatments **are not part of the treatment methods** for dysphoria caused by gender-related conflicts in minors.”

### **MAJOR BULLET POINTS.**

- Informed consent requires full disclosure of risks and benefits, and recommendations where benefits clearly outweigh risks. G/TAT fails that test.
- Ethics of permanently medicalizing something in minors with an 85% rate of desistance by adulthood based on a self-diagnosis is highly suspect.<sup>67 68 69 70</sup>
  - Someone can come to their senses later, but what’s gone is gone.
- Do Not Prematurely Affirm:
  - *APA Handbook on Sexuality and Psychology* (APA, 2014): “Premature labeling of gender identity should be avoided.” Why? “This approach runs the risk of neglecting individual problems the child might be experiencing...”<sup>71</sup>
  - 2020 *Nordic J of Psychiatry*:<sup>72</sup> ...“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.”

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<sup>67</sup> American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing. P.455.

<sup>68</sup> 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/fpsy.2021.632784

<sup>69</sup> Hembree, W., Cohen-Kettenis, et al., (2017) Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*,102:1–35.

<sup>70</sup> 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>

<sup>71</sup> W. Bockting, *Ch. 24: Transgender Identity Development*, in 1 *American Psychological Association Handbook on Sexuality and Psychology*, 750 (D. Tolman & L. Diamond eds., 2014).

<sup>72</sup> Riittakerttu Kaltiala, Elias Heino, Marja Työljärvi & Laura Suomalainen (2020) Adolescent development and psychosocial functioning after starting cross-sex hormones

- Withers 2020, “trans-identification and its associated medical treatment can constitute an attempt to evade experiences of psychological distress.”<sup>73</sup>
- Gender [transition] affirming therapy guidelines derive from activist groups like WPATH (World Professional Association for Transgender Health) which is not a scientific organization and whose SOCs (Standards of Care) appear to be window dressing that is ultimately not followed.
- The 2017 Endocrine Society Guidelines state their medical evidence rating for puberty blockers and cross-sex hormones in selected minors as “low” and adult genital surgery as “very low.”<sup>74</sup> Not evidence-based standards of care.
  - Disclaimer p. 3895: “The guidelines cannot guarantee any specific outcome, nor do they establish a standard of care.”
- Consensus is not a proxy for truth. The pro-GAT/TAT party line is in part a Castro consensus.<sup>75</sup>
- Gender [transition] affirming therapy is not the standard of care.
- The international standard of care is “watchful waiting,” including extensive psychological support and evaluation of the child and family both.<sup>76 77 78</sup>
  - Why? The probability of desistance.

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for gender dysphoria, *Nordic Journal of Psychiatry*, 74:3, 213-219, DOI: [10.1080/08039488.2019.1691260](https://doi.org/10.1080/08039488.2019.1691260)

<sup>73</sup> 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>.

<sup>74</sup> 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>

<sup>75</sup> Understanding the Role of Dependence in Consensus Formation. *Proceedings of the 2020 Truth and Trust Online (TTO 2020)*, pages 12–20, Virtual, October 16-17, 2020. <https://www.cs.hmc.edu/~montanez/pdfs/allen-2020-castro-consensus.pdf>

<sup>76</sup> 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.

<sup>77</sup> 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](https://doi.org/10.1080/15265161.2018.1557288)

<sup>78</sup> 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

- The overwhelming likelihood of mental health and other issues preceding the diagnosis of GD.<sup>79 80 81 82 83</sup>
- UK High Court *Bell v Tavistock*<sup>84</sup> Dec. 12, 2020 ruling that GAT/TAT in minors was experimental, not proven safe or effective, and required court order for those under 16 and that court order was advisable for those 16-17.
  - “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.”
- NHS issued amendments to Gender Identity Development Service specifications for minors Dec 2020.<sup>85</sup>
- Transgenderism as the catch-all explanation for distress, & transition is promoted as a cure-all solution (Littman study).<sup>86</sup>
- Skilled psychological investigation for underlying causes is shamed as “transphobic”.<sup>87</sup>
  - Those underlying causes and contributors – which are always there – don’t vanish with GAT, they are the seeds of regret, and they must be dealt with.
- There is international questioning of GAT/TAT for minors occurring on national levels in UK (NICE 1 & 2 -- National Institute for Health and Care Excellence,<sup>88</sup> *Bell v*

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<sup>79</sup> 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.

<sup>80</sup> 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.

<sup>81</sup> Kozłowska 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

<sup>82</sup> 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>

<sup>83</sup> 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.

<sup>84</sup> <https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf>

<sup>85</sup> <https://www.england.nhs.uk/wp-content/uploads/2020/12/Amendment-to-Gender-Identity-Development-Service-Specification-for-Children-and-Adolescents.pdf>

<sup>86</sup> 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>.

<sup>87</sup> “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>

<sup>88</sup> <https://arms.nice.org.uk/resources/hub/1070871/attachment> and <https://arms.nice.org.uk/resources/hub/1070905/attachment>

Tavistock, NHS GIDS protocol amendments), Sweden (Karolinska hospital no longer issuing hormones to minors under 16,<sup>89</sup> Swedish Agency for Health Technology Assessment and Assessment of Social Services' 2019 literature review.<sup>90</sup>), Finland COHERE,<sup>91</sup> Australia,<sup>92</sup> Brazil, etc. And now Florida Dept. of Health Guidelines (4/20/2022)<sup>93</sup>

- 4 levels of transition: social, puberty blockade, cross-sex (wrong sex) hormones, and sex reassignment (gender affirming/confirming) surgery.
  - Social transitioning by itself leads to persistence.<sup>94,95</sup>
- PBA use in precocious puberty and prostate cancer treat diseases where benefits outweigh risks.
  - PBA use in GD kids causes disease (hypogonadotropic hypogonadism) in otherwise healthy kids.<sup>96</sup>
  - Not FDA approved for this.
  - Puberty is not a disease state but a normal stage of life..
- The myth of PBAs as “pause buttons” that “buy time” to “wait and see.”
  - PBA are Gateway drugs, select persistence rather than natural desistance. Commits a child to CSH and SRS/GAS.

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<sup>89</sup> [Karolinska Policyförändring K2021-3343 March 2021 \(Swedish\).pdf](#);

[Karolinska Policy Change K2021-3343 March 2021 \(English, unofficial translation\).pdf](#)

<sup>90</sup> <https://www.sbu.se/en/publications/sbu-bereder/gender-dysphoria-in-children-and-adolescents-an-inventory-of-the-literature/>

<sup>91</sup>

[https://palveluvalikoima.fi/documents/1237350/22895008/Summary\\_minors\\_en.pdf/aaf9a6e7-b970-9de9-165c-abedfae46f2e/Summary\\_minors\\_en.pdf](https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en.pdf/aaf9a6e7-b970-9de9-165c-abedfae46f2e/Summary_minors_en.pdf)

<sup>92</sup> <https://www.binary.org.au/australians-demand-inquiry-into-child-puberty-blockers>.

<sup>93</sup> <https://content.govdelivery.com/accounts/FLDOH/bulletins/3143d4c>

<sup>94</sup> Hembree, W., Cohen-Kettenis, et al., (2017) Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*,102:1-35.

<sup>95</sup> Zucker, K. Debate: Different strokes for different folks. *Child and Adolescent Mental Health*. Accepted for publication: 18 March 2019.

<sup>96</sup> 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-Dysphoria/Gender-Incongruent Persons: An Endocrine Society\* Clinical Practice Guideline, *JCEM*, Online, November 23, 2018.



- 5 studies show PBA use results in persistence of trans identification 96.5-100%.<sup>97 98 99 100 101</sup>
- PBA Risk Summary.
  - Not fully reversible, long-term complications possible even if PBAs stopped early.<sup>102</sup>
  - Infertility risk (blocks maturing of sperm and ova)<sup>103 104 105 106</sup>
  - Genitalia arrested in underdeveloped stage
  - Sexual dysfunction

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<sup>97</sup> Michael Laidlaw, Michelle Cretella, Kevin Donovan, The Right to Best Care for Children Does Not Include the Right to Medical Transition, *American Journal of Bioethics*, 19 (2):75-77 (2019). <https://doi.org/10.1080/15265161.2018.1557288>

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<sup>98</sup> 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(4):582–590

<sup>99</sup> Brik T, Vrouenraets LJ, de Vries MC, Hannema SE. Trajectories of adolescents treated with gonadotropin-releasing hormone analogues for gender dysphoria [published online ahead of print March 9, 2020]. *Arch Sex Behav*. doi:10.1007/s10508-020-01660-8

<sup>100</sup> Kuper LE, Stewart S, Preston S, Lau M, Lopez X. Body dissatisfaction and mental health outcomes of youth on gender-affirming hormone therapy. *Pediatrics*. 2020;145(4):e20193006

<sup>101</sup> 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>

<sup>102</sup> 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)

<sup>103</sup> 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-Dysphoria/Gender-Incongruent Persons: An Endocrine Society\* Clinical Practice Guideline, *JCEM*, Online, November 23, 2018.

<sup>104</sup> 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>.

<sup>105</sup> Children's Hospital Los Angeles (2016). Children's Hospital Los Angeles Assent/Consent Forms to Participate in Research Study: "The Impact of Early Medical Treatment in Transgender Youth". Obtained Apr 17, 2020 via HHS Appeal 19-0093-AA; NIH FOIA Request 51365. [https://drive.google.com/file/d/1Q-zjCivH-QW7hL25idXT\\_jITfjZUUm1w/view](https://drive.google.com/file/d/1Q-zjCivH-QW7hL25idXT_jITfjZUUm1w/view)

<sup>106</sup> <https://transcare.ucsf.edu/guidelines/youth>

- Males: erectile, orgasmic and ejaculatory impairment
  - Females: menopausal state inducing<sup>107</sup>
- Mental health issues: mood swings, depression, suicidal ideation and attempts (Lupron package insert)<sup>108 109</sup>
- Bone mineral density compromise at its period of greatest growth.<sup>110</sup> Osteopenia/-porosis?
- Hindering of brain development milestones
- PBAs will interrupt the vital pubertal time-frame window for development of brain, bones and psychology with peers.<sup>111</sup> No one can have that window back.
- Cross-sex hormone risks.<sup>112 113 114</sup>
  - Following PBA's with cross-sex hormones (CSH) assures sterility.
  - Estrogen in biological males
    - Dyslipidemias
    - Thromboembolic disease (blood clots)
    - Cardiovascular and cerebrovascular disease (heart attacks and strokes).
      - Risk increases with length of use.<sup>115</sup>

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<sup>107</sup> Faubion SS, Kuhle CL, Shuster LT, Rocca WA. Long-term health consequences of premature or early menopause and considerations for management. *Climacteric*. 2015;18(4):483–491. doi:10.3109/13697137.2015.1020484.

<sup>108</sup> 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>

<sup>109</sup> Michael Biggs, The Tavistock's Experiment with Puberty Blockers, 29 July 2019, [http://users.ox.ac.uk/~sfos0060/Biggs\\_ExperimentPubertyBlockers.pdf](http://users.ox.ac.uk/~sfos0060/Biggs_ExperimentPubertyBlockers.pdf)

<sup>110</sup> 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>

<sup>111</sup> 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>

<sup>112</sup> Radix A, Davis AM. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons. *JAMA*.2017;318(15):1491–1492. doi:10.1001/jama.2017.13540.

<sup>113</sup> Michael Laidlaw, Michelle Cretella, Kevin Donovan, *The Right to Best Care for Children Does Not Include the Right to Medical Transition*, American Journal of Bioethics, 19 (2):75-77 (2019). <https://doi.org/10.1080/15265161.2018.1557288>.

<sup>114</sup> Hembree, W. C., P. T. Cohen-Kettenis, L. Gooren, et al. 2017. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An endocrine society clinical practice guideline. *The Journal of Clinical Endocrinology & Metabolism* 102(11): 3869–3903. doi: 10.1210/jc.2017-01658.

<sup>115</sup> 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.

- Breast cancer<sup>116</sup>
  - Weight gain
  - Insulin resistance
  - Cholelithiasis
- Testosterone in biological females
  - Cardiovascular and cerebrovascular disease (heart attacks and strokes)
  - Breast/uterine cancer
  - Liver dysfunction
  - Hypertension
  - Severe acne
  - Liver cancer? <sup>117</sup>
- International panel of endocrinology organizations concluded about testosterone use in women(10/2019)<sup>118</sup> “...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 established.
- Sex reassignment surgery (SRS)/gender affirming surgery (GAS)/gender confirming surgery (tops, bottoms, contouring, etc.):
  - Is cosmetic, creating poorly functioning pseudo-genitalia.
    - Usually no orgasms.
    - Sterility is guaranteed by absence of ovaries and testicles.
  - Rated by the Hayes Directory with the lowest possible rating for strength of evidence.<sup>119</sup> The Centers for Medicare & Medicaid did not issue a National Coverage Determination for it due to poor proof.
- 2011 Swedish study (Dhejne) of all their SRS patients over 30 years (324) showed 19 times the completed suicide rate 10 years out.<sup>120</sup>

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<sup>116</sup> Christel J M de Blok, et al. “Breast cancer risk in transgender people receiving hormone treatment: nationwide cohort study in the Netherlands..” *BMJ* 2019; 365.

<https://www.bmj.com/content/365/bmj.l1652>

<sup>117</sup> Lin, Alexander Justin et al. Androgen-receptor-positive hepatocellular carcinoma in a transgender teenager taking exogenous testosterone *The Lancet*, Volume 396, Issue 10245, 198. (July 18,2020.)

<sup>118</sup> 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>.

<sup>119</sup> Hayes, Inc., *Hormone Therapy for the Treatment of Gender Dysphoria*, Hayes Medical Technology Directory (2014).

<sup>120</sup> 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.

- 2019 (online) Bränström and Pachankis. First total population study of 9.7 million Swedish residents.<sup>121</sup> Ultimately showed neither “gender-affirming hormone treatment” nor “gender-affirming surgery” provided reductions of the mental health treatment benchmarks examined.<sup>122 123</sup>
- G[T]AT’s suicide reduction claim is a myth used as emotional blackmail.
  - Parents told, “Do you want to be planning a transition or a funeral?”
- Regret rates with GAT are not low, and studies underestimate them due to “overly stringent definitions of regret” “very high rates of participant loss to follow-up (22%-63%) (D’Angelo, 2018 )...”<sup>124</sup>
- The chemical sterilization/castration and surgical mutilation of normal sex organs in children is not healthcare.
- NC (2012)<sup>125</sup> and CA (2021)<sup>126</sup> passed laws to compensate surviving victims of the 20<sup>th</sup> century eugenics forced sterilization programs. With GAT, they will get to do it again.

### Social Transitioning

- **Social transitioning** by itself leads to persistence of GD:

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<sup>121</sup> 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>

<sup>122</sup> 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>

<sup>123</sup> Andre Van Mol, Michael K. Laidlaw, Miriam Grossman, Paul R. McHugh. Gender-Affirmation Surgery Conclusion Lacks Evidence. *Am J Psychiatry* 2020; 177:765–766; doi: 10.1176/appi.ajp.2020.19111130.

[Other six are found in the endnotes of Branstrom Response to Letters below. doi: 10.1176/appi.ajp.2020.20050599.]

<sup>124</sup> 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

<sup>125</sup> <https://abcnews.go.com/Health/WomensHealth/north-carolina-compensate-victims-eugenics-program-sterilized/story?id=15328707>

<sup>126</sup> <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/>

- From **the Endocrine Society guidelines** themselves, even **“Social transition is associated with the persistence of GD** as a child progresses into adolescence.”<sup>127</sup>
- Ken Zucker: **“Gender social transition** of prepubertal children will **increase dramatically the rate of gender dysphoria persistence** when compared to follow-up studies of children with gender dysphoria who did not receive this type of psychosocial intervention and, oddly enough, **might be characterized as iatrogenic.**”<sup>128</sup>

### Puberty Blockers and Long-Term Effects

- **Immature, developing brain meets ideology meets hormones.**
- **Not as reversible as advocates may say.**
  - Average age for spermarche was found to 14 years old, generally Tanner stage 3 - 4.<sup>129</sup>
  - If puberty blocking begins at Tanner stage II as Endocrine Society guidelines suggest, menarche and spermarche won't happen. Infertility.<sup>130</sup>
  - Administering cross-sex hormones with or right after puberty blockers means sperm and eggs won't mature. Infertility.<sup>131</sup>
  - **UCSF Transgender Care**, Health considerations for gender nonconforming children and transgender adolescents, subsection “Preparing for gender-affirming hormone use in transgender youth”:  
“The consent process for hormones should include a **conversation about fertility**. While options are being explored to preserve future fertility for transgender youth, the current reality is that cryopreservation is very expensive, in many cases prohibitively so for those with ovaries. **For youth whose pubertal process has been suspended in the earliest stages, followed by administration of gender-affirming hormones, development of mature sperm or eggs is unlikely** at the present time,

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<sup>127</sup> Hembree, W., Cohen-Kettenis, et al., (2017) Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*,102:1-35.

<sup>128</sup> Zucker, K. Debate: Different strokes for different folks. *Child and Adolescent Mental Health*. Accepted for publication: 18 March 2019.

<sup>129</sup> Schaefer F, Marr J, Seidel C, Tilgen W, Schäfer K. Assessment of gonadal maturation by evaluation of spermaturia. *Arch Dis Child*. 1990;65(11):1205-1207. doi:10.1136/adc.65.11.1205

<sup>130</sup> 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-Dysphoria/Gender-Incongruent Persons: An Endocrine Society\* Clinical Practice Guideline, *JCEM*, Online, November 23, 2018.

<sup>131</sup> 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>.

although it is noteworthy that there is active research developing gametes in vitro from the field of juvenile oncology. **The issue of future infertility is often far more problematic for parents and family members than for youth**, especially especially at the beginning stages of discussing moving forward with gender-affirming hormones.”

<https://transcare.ucsf.edu/guidelines/youth>

- **Children’s Hospital Los Angeles**, “PUBERTAL BLOCKERS FOR MINORS IN EARLY ADOLESCENCE, Parent or Guardian Consent, subsection “Risks of Puberty Blockers”:<sup>132</sup>

**“If your child starts puberty blockers in the earliest stages of puberty, and then goes on to gender affirming hormones, they will not develop sperm or eggs.** This means that **they will not be able to have biological children.** This is an important aspect of blocking puberty and progressing to hormones that you should understand prior to moving forward with puberty suppression. If your child discontinues the use of blockers, and does not go on gender affirming hormones, they will continue their pubertal development about 6-12 months after stopping the medication, and fertility would be maintained.”

[I find the last sentence contestable. Stopping at 4 months v 4 years will not have equivalent results.]

- Studies show that **fewer than 5% of adolescents receiving GAT even attempt fertility preservation.**<sup>133 134</sup>
- **Lupron package insert:**  
Under “ADVERSE REACTIONS”  
“In postmarketing experience, **mood swings, depression, rare reports of suicidal ideation and attempt, ...**”  
Under “6.5 Postmarketing”  
“Like other drugs in this class, mood swings, including depression, have been reported. There have been very rare reports of suicidal ideation and attempt. Many, but not all, of these patients had a history of depression or other psychiatric illness. **Patients should be counseled on the possibility of development or worsening of depression** during treatment with LUPRON.”
- **Professor Michael Biggs of Oxford**

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<sup>132</sup> Children’s Hospital Los Angeles (2016). Children’s Hospital Los Angeles Assent/Consent Forms to Participate in Research Study: “The Impact of Early Medical Treatment in Transgender Youth”. Obtained Apr 17, 2020 via HHS Appeal 19-0093-AA; NIH FOIA Request 51365. [https://drive.google.com/file/d/1Q-zjCivH-QW7hL25idXT\\_jITfjZUUm1w/view](https://drive.google.com/file/d/1Q-zjCivH-QW7hL25idXT_jITfjZUUm1w/view)

<sup>133</sup> Nahata L, Tishelman AC, Caltabellotta NM, Quinn GP. Low Fertility Preservation Utilization Among Transgender Youth. J Adolesc Health. 2017;61:40-44.

<sup>134</sup> Chen D, Simons L, Johnson EK, Lockart BA, Finlayson C. Fertility Preservation for Transgender Adolescents. J Adolesc Health. 2017 Jul;61(1):120-123.

Criticized the UK’s NHS GIDS produced only a single study from their trial of puberty blockers, “In fact, the initial results showed predominantly negative outcomes. The only tabulated data available, for 30 of the subjects after a year on triptorelin, showed that **children reported greater self-harm**; girls experienced **more behavioural and emotional problems** and expressed **greater dissatisfaction with their body**—so **drugs exacerbated gender dysphoria** (GIDS 2015).<sup>135</sup>

- **UK GIDS Tavistock study 2020.**<sup>136</sup>
  - **BMD and growth/height both showed “suppression of growth” precisely when they should be having the surge of the lifetime.**
    - “As anticipated, pubertal suppression reduced growth that was dependent on puberty hormones, i.e. height and BMD. Height growth continued for those not yet at final height, but more slowly than for their peers so height z-score fell. Similarly for bone strength, BMD and BMC increased in the lumbar spine indicating greater bone strength, but more slowly than in peers so BMD z-score fell.”
  - **Self-harm did not improve** and “no changes in psychological function,” meaning no improvement. (Also, “YSR [Youth Self Report] data at 36 months (n = 6) were not analysed.”)
    - “We found no differences between baseline and later outcomes for overall psychological distress as rated by parents and young people, nor for self-harm.”
    - “We found no evidence of change in psychological function with GnRHa treatment as indicated by parent report (CBCL) or self-report (YSR) of overall problems, internalising or externalising problems or self-harm. This is in contrast to the Dutch study which reported improved psychological function across total problems, externalising and internalising scores for both CBCL and YSR and small improvements in CGAS.”
- **Puberty blockers chemically castrate both sexes at the level of the brain**
  - Lupron Depot-Ped Injection Label (August 2012) at 12.1 “Mechanism of Action”  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/020263s0361bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020263s0361bl.pdf).
  - Myungsun Shim, et al., “Effectiveness of three different luteinizing hormone-releasing hormone agonists in the chemical castration of patients with prostate cancer: Goserelin versus triptorelin versus leuprolide” *Urological Oncology* (May 1, 2019);
  - Christina Jewett, “Drug used to halt puberty in children may cause lasting health problems” *Stat* (February 2, 2017),

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<sup>135</sup> Michael Biggs, The Tavistock’s Experiment with Puberty Blockers, 29 July 2019, [http://users.ox.ac.uk/~sfos0060/Biggs\\_ExperimentPubertyBlockers.pdf](http://users.ox.ac.uk/~sfos0060/Biggs_ExperimentPubertyBlockers.pdf)

<sup>136</sup> 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>

<https://www.statnews.com/2017/02/02/lupron-puberty-children-health-problems/>.

- Puberty blockers can also cause problems by **inducing early menopausal-like state in females**. Any form of premature menopause poses risks:
  - Faubion, et al: “The long-term consequences of premature or early menopause **include adverse effects on cognition, mood, cardiovascular, bone, and sexual health, as well as an increased risk of early mortality**. The use of hormone therapy has been shown to lessen some, although not all of these risks.”<sup>137</sup>
- **Bone mineral density** surges during normal puberty. But not with PBA on board. Osteoporosis in their 30s??
  - See UK GIDS Tavistock study 2020 above.
  - **One study boasted PBA did not reduce adolescent BMD.**<sup>138</sup> That’s bad. It is supposed to surge at that age.
- **2018 PBA Study “Conclusions: The majority of subjects reported long term side effects** extending beyond GnRHa use, while **almost 1/3 reported irreversible side effects** that persisted for years after discontinuing treatment.”<sup>139</sup>
- Christina Jewett, “Drug used to halt puberty in children may cause lasting health problems” *Stat* (February 2, 2017), <https://www.statnews.com/2017/02/02/lupron-puberty-children-health-problems/>.
- Induces a disease state, hypogonadotropic hypogonadism, in an otherwise healthy child, and with incumbent risks.<sup>140</sup>

This is not the same as using PBAs to delay puberty in a child with a disease state, namely precocious puberty, and even that carries risks.

#### **Cross-Sex Hormone Therapy Risks:**

- **With CSH: a biological female body experiences male levels of testosterone, something never seen outside of an androgen-secreting tumor. It’s a iatrogenic pathological state.**
- “The Endocrine Society’s guidelines recommend elevating females’ testosterone

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<sup>137</sup> Faubion SS, Kuhle CL, Shuster LT, Rocca WA. Long-term health consequences of premature or early menopause and considerations for management. *Climacteric*. 2015;18(4):483–491. doi:10.3109/13697137.2015.1020484.

<sup>138</sup> Tobin Joseph, Joanna Ting & Gary Butler. The effect of GnRHa treatment on bone density in young adolescents with gender dysphoria: findings from a large national cohort. *Endocrine Abstracts* (2018) **58** OC8.2 | DOI: [10.1530/endoabs.58.OC8.2](https://doi.org/10.1530/endoabs.58.OC8.2)

<sup>139</sup> 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)

<sup>140</sup> 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-Dysphoria/Gender-Incongruent Persons: An Endocrine Society\* Clinical Practice Guideline, *JCEM*, Online, November 23, 2018..



levels from a normal of 10 to 50 ng/dL to 300 to 1000 ng/dL, values typically found with androgen secreting tumors.”<sup>141</sup>

- **COMPLICATIONS OF CSH THERAPY:**<sup>142 143 144</sup>
  - Cross Sex Hormones (CSH)
    - Testosterone
      - Cardiovascular and cerebrovascular disease (heart attacks and strokes)
      - Breast/uterine cancer
      - Liver dysfunction
      - HTN
      - Severe acne
      - Liver cancer?<sup>145</sup>
    - Estrogen
      - Dyslipidemias
      - Thromboembolic disease (blood clots)
      - Cardiovascular and cerebrovascular disease (heart attacks and strokes)
      - Breast cancer<sup>146</sup>
      - Weight gain
      - Insulin resistance
      - Cholelithiasis
  - **Testosterone increases the risk of heart disease in women 4 fold,**

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<sup>141</sup> 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-Dysphoria/Gender-Incongruent Persons: An Endocrine Society\* Clinical Practice Guideline, JCEM, Online, November 23, 2018..

<sup>142</sup> Radix A, Davis AM. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons. *JAMA*.2017;318(15):1491–1492. doi:10.1001/jama.2017.13540.

<sup>143</sup> Michael Laidlaw, Michelle Cretella, Kevin Donovan, *The Right to Best Care for Children Does Not Include the Right to Medical Transition*, American Journal of Bioethics, 19 (2):75-77 (2019). <https://doi.org/10.1080/15265161.2018.1557288>.

<sup>144</sup> Hembree, W. C., P. T. Cohen-Kettenis, L. Gooren, et al. 2017. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An endocrine society clinical practice guideline. *The Journal of Clinical Endocrinology & Metabolism* 102(11): 3869–3903. doi: 10.1210/jc.2017-01658.

<sup>145</sup> Lin, Alexander Justin et al. Androgen-receptor-positive hepatocellular carcinoma in a transgender teenager taking exogenous testosterone *The Lancet*, Volume 396, Issue 10245, 198. (July 18,2020.)

<sup>146</sup> Christel J M de Blok, et al. “Breast cancer risk in transgender people receiving hormone treatment: nationwide cohort study in the Netherlands..” *BMJ* 2019; 365. <https://www.bmj.com/content/365/bmj.l1652>

- Estrogen increases the rate of deep vein thrombosis (blood clots) and stroke in men 3 to 5 fold, heart attacks 2 fold.**<sup>147 148 149 150</sup>
- The **increased risk of venous thromboembolism (VTE)** in biological males taking **estrogen increased further with duration of use from four-times greater after two years to over sixteen-times greater after eight years** of use compared to males not using estrogen.<sup>151</sup>
  - In a 2019 nationwide cohort study of the Netherlands, of 1129 trans women (natal males) who were taking estrogen, **the incidence of breast cancer “was 46-fold higher than in cisgender men”**.<sup>152</sup>
  - **Estrogen** (in MtF) can cause **increased weight gain**<sup>153</sup> and **insulin resistance**.<sup>154</sup>
  - “A pathological analysis of the genital tract of 112 FTM subjects who were given androgen for at least 6 months before hysterectomy was performed. In addition, 100 bilateral mastectomies were performed, allowing a study of the breast tissue.” ... “The present data confirms and expands the putative associations between long-term androgen administration and abnormalities in ovarian architecture with macroscopic and microscopic characteristics of PCO, increased risk of endometrial atrophy and fibrotic breast tissue with marked glandular reduction.”<sup>155</sup>
  - **Testosterone** in FtM can cause **severe acne**.<sup>156</sup>

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<sup>147</sup> 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.

<sup>148</sup> 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.

<sup>149</sup> Irwig MS. Cardiovascular Health in Transgender People. *Rev Endocr Metab Disord*. 2018 Aug 3 epub.

<sup>150</sup> Nota NM, et al. Occurrence of Acute Cardiovascular Events in Transgender Individuals Receiving Hormone Therapy. *Circulation*, 139(11), 2019, pp. 1461-1462.

<sup>151</sup> 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.

<sup>152</sup> Christel J M de Blok, et al. “Breast cancer risk in transgender people receiving hormone treatment: nationwide cohort study in the Netherlands..” *BMJ* 2019; 365. <https://www.bmj.com/content/365/bmj.l1652>

<sup>153</sup> *Journal of Clinical & Translational Endocrinology* 21 (2020) 100230

<sup>154</sup> *Diabetes Care* 2020 Feb; 43(2): 411-417; *World J Diabetes*. 2020 Mar 15; 11(3): 66–77

<sup>155</sup> Grynberg M, Fanchin R, Dubost G, Colau JC, Brémont-Weil C, Frydman R, Ayoubi JM. Histology of genital tract and breast tissue after long-term testosterone administration in a female-to-male transsexual population. *Reprod Biomed Online*. 2010 Apr;20(4):553-8. doi: 10.1016/j.rbmo.2009.12.021. Epub 2009 Dec 24. PMID: 20122869.

<sup>156</sup> *British Journal of Dermatology* (2019) 180, pp26–30

- **International panel of endocrinology organizations said about testosterone use in women**(10/2019)<sup>157</sup>  
 “The international panel concluded **the only evidence-based indication for testosterone therapy for women is for the treatment of HSDD [Hypoactive sexual desire disorder]**, with available data supporting a moderate therapeutic effect. **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 established.**
  - **They made no mention of gender affirming therapy [GAT].**
- **General problems of early menopause**, which PBA induce:  
 “The long-term consequences of premature or early menopause include adverse effects on cognition, mood, cardiovascular, bone, and sexual health, as well as an increased risk of early mortality. The use of hormone therapy has been shown to lessen some, although not all of these risks.”<sup>158</sup>
- **Children’s Hospital Los Angeles** “Informed Consent Form for Feminizing Medications (transfeminine individuals on GnRH analogs)”<sup>159</sup> (Obtained through FOIA)
  - “5. Taking feminizing medications after or while being on GnRH analogs will likely lead to infertility, particularly when GnRH analogs have been started in early puberty.
    - Sperm will not mature, leading to infertility. The ability to make sperm normally may or may not come back even after stopping taking feminizing medication.”
- **Children’s Hospital Los Angeles** “Informed Consent Form for Feminizing Medications” (Obtained through FOIA)
  - 5. Feminizing medications will make the testicles produce less testosterone, which can affect overall sexual function:
    - Sperm may not mature, leading to reduced fertility. The ability to make sperm normally may or may not come back even after stopping taking feminizing medication. The options for sperm banking have been explained. People taking estrogen may still be able to make someone pregnant.”

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<sup>157</sup> 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>.

<sup>158</sup> Faubion SS, Kuhle CL, Shuster LT, Rocca WA. Long-term health consequences of premature or early menopause and considerations for management. *Climacteric*. 2015;18(4):483–491. doi:10.3109/13697137.2015.1020484.

<sup>159</sup> Children’s Hospital Los Angeles (2016). Children’s Hospital Los Angeles Assent/Consent Forms to Participate in Research Study: "The Impact of Early Medical Treatment in Transgender Youth". Obtained Apr 17, 2020 via HHS Appeal 19-0093-AA; NIH FOIA Request 51365. [https://drive.google.com/file/d/1Q-zjCivH-QW7hL25idXT\\_jITfjZUUm1w/view](https://drive.google.com/file/d/1Q-zjCivH-QW7hL25idXT_jITfjZUUm1w/view)

**Sex-Reassignment/Gender Affirming Surgery:**

- **Sex reassignment (SRS)/gender affirmation surgery (GAS) is cosmetic, creating poorly functioning pseudo-genitalia.**
  - **Usually no orgasms.**
  - **Sterility is guaranteed in the absence of ovaries and testicles.**
- **1979:** A study from the **Johns Hopkins U** psychiatry department revealed the **mental and social health of patients undergoing sex reassignment surgery did not improve.** The program closed shortly thereafter.<sup>160</sup>
- A **2011 Swedish study** of **post-gender-reassignment adults showed a suicide rate 19 times** that of the general population 10 years out. Also nearly 3 times the rate of overall mortality and psychiatric inpatient care. This was a 30-year population-based matched cohort study of all 324 sex-reassigned persons in Sweden.<sup>161</sup>
- In 2019 (online) **Bränström and Pachankis** published the first total population study of 9.7 million Swedish residents titled, “Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study.”<sup>162</sup> Looking at three limited measures of mental health service usage, they claimed that although “gender-affirming hormone treatment” provided no improvement, “gender-affirming surgeries” did.
  - The online August 1, 2020 American J of Psychiatry edition contained seven critical letters,<sup>163</sup> a major “correction” paragraph from the editors retracting the studies main finding,<sup>164</sup> and a letter from the study authors conceding their “conclusion” “was too strong.”<sup>165</sup>

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<sup>160</sup> Meyer J.K. and Reter D. Sex Reassignment Follow up Arch. Gen Psychiatry 36; 1010-1015; 1979

<sup>161</sup> 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.

<sup>162</sup> 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>

<sup>163</sup> Andre Van Mol, Michael K. Laidlaw, Miriam Grossman, Paul R. McHugh. Gender-Affirmation Surgery Conclusion Lacks Evidence. Am J Psychiatry 2020; 177:765–766; doi: 10.1176/appi.ajp.2020.19111130.

[Other six are found in the endnotes of Branstrom Response to Letters below. doi: 10.1176/appi.ajp.2020.20050599.]

<sup>164</sup> 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>

<sup>165</sup> Richard Bränström and John E. Pachankis. Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and

- Ultimately, the Bränström and Pachankis study therefore demonstrated that neither “gender-affirming hormone treatment” nor “surgery” provided reductions of the mental health treatment benchmarks examined in transgender-identified people.
- A 2016 study of nearly all (98%; n=104) of Dutch patients who underwent **sex reassignment surgery** from 1978-2010 found no significant difference in **psychiatric morbidity or mortality** between male to female and female to male (FtM) “save for the total number of psychiatric diagnoses where FtM held a significantly higher number of psychiatric diagnoses overall.”<sup>166</sup>
  - “This suggests that generally SRS may reduce psychological morbidity for some individuals while increasing it for others.”
  - **SRS was not an agent of statistically significant net benefit.**
- **Mastectomies on minors, *JAMA Pediatrics*, 2018.**<sup>167</sup>  
**Questionable claim:** “Chest dysphoria was high among presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults.”  
**Problems:**
  - “Chest dysphoria” is a neologism of convenience, not a DSM-5 diagnosis.
  - The “chest dysphoria scale” was a measuring tool of the authors and “is not yet validated.” (p. 435)
  - Mastectomies were done on girls as young as 13 years old, lacking the capacity for mature decision making or informed consent.
  - Study seems flawed and unethical.
- The **Hayes Directory** reviewed all relevant literature on SRS treatments in 2014 and gave it the **lowest possible rating:** the research findings were “too sparse” and “too limited” even to *suggest* conclusions.<sup>168</sup>
- Rossi, 2012, *Brazil J of Urol*: “Our data show that **gender reassignment surgery, even if performed by trained surgeons in a qualified centre, is still associated with important complication rates.**”<sup>169</sup>

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Transgender Individuals’ Mental Health: Response to Letters. *American Journal of Psychiatry* 2020 177:8, 769-772 doi: 10.1176/appi.ajp.2020.20050599.

<sup>166</sup> Simonsen, R. K., Giraldi, A., Kristensen, E. & Hald, G. M. Long-term follow-up of individuals undergoing sex reassignment surgery: Psychiatric morbidity and mortality. *Nord J Psychiatry* 70, 241-247, doi:10.3109/08039488.2015.1081405 (2016).

<sup>167</sup> 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

<sup>168</sup> Hayes, Inc., *Hormone Therapy for the Treatment of Gender Dysphoria*, Hayes Medical Technology Directory (2014).

<sup>169</sup> Rossi Neto, R., Hintz, F., Krege, S., Rübhen, H., & vom Dorp, F.. (2012). Gender reassignment surgery - a 13 year review of surgical outcomes. *International braz j urol*, 38(1), 97-107. <https://dx.doi.org/10.1590/S1677-55382012000100014>

- Horbach, 2015, J of Sex Med: “Meta-analysis of the transgender surgery literature shows the **very low quality of data** used to support the efficacy of the interventions...”<sup>170</sup>
- “The **Centers for Medicare & Medicaid Services (CMS)** is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population.” – June 19, 2019, Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N), Centers for Medicare & Medicaid Services.<sup>171</sup>
- Combaz, 2017, Am J Urol Res: “With a mean interval of **72 months after surgery 51%** out of 44 patients considered themselves **very bothered by their urogynaecological problems.** . . . . “**Patients should be counselled** on the risks preoperatively, and **lifelong specialized follow-up is necessary** for the early detection and treatment of arising problems.”<sup>172</sup>

### Rising Tide of Regretters & Detransitioners

- Regretters commonly speak of initially carrying distrust of the medical and mental health professions, so particular patience and compassion are in order.<sup>173 174 175 176</sup>
- D’Angelo, et al: “However, these studies **may understate true regret rates** due to overly **stringent definitions of regret** (i.e., requiring an official application for

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<sup>170</sup> Horbach SER, Bouman M-B, Smit JM, Özer M, Buncamper ME, and Mullender MG. Outcome of vaginoplasty in male-to-female transgenders: A systematic review of surgical techniques. J Sex Med 2015;12:1499–1512. [http://ts.katja.cz/2015\\_horbach\\_et\\_al.pdf](http://ts.katja.cz/2015_horbach_et_al.pdf)

<sup>171</sup> <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAid=282>

<sup>172</sup> Combaz N, Kuhn A. Long-Term Urogynecological Complications after Sex Reassignment Surgery in Transsexual Patients: a Retrospective Study of 44 Patients and Diagnostic Algorithm Proposal, Am J Urol Res. 2017;2(2): 038-043.

<https://www.scireslit.com/Urology/AJUR-ID21.pdf>

<sup>173</sup> Sydney Wright. I Spent a Year as a Trans Man. Doctors Failed Me at Every Turn. dailysignal.com, Oct. 7, 2019. [https://www.dailysignal.com//print?post\\_id=567253](https://www.dailysignal.com//print?post_id=567253)

<sup>174</sup> <https://4thwavenow.com/2018/12/19/the-theatre-of-the-body-a-detransitioned-epidemiologist-examines-suicidality-affirmation-and-transgender-identity/>

<sup>175</sup> Stella Morabito. 30 Transgender Regretters Come Out Of The Closet. thefederalist.com, Jan. 3, 2019. <https://thefederalist.com/2019/01/03/30-transgender-regretters-come-closet-new-book/>

<sup>176</sup> Walt Heyer. Hormones, surgery, regret: I was a transgender woman for 8 years — time I can't get back. USAToday.com, Feb. 11, 2019.

<https://www.usatoday.com/story/opinion/voices/2019/02/11/transgender-debate-transitioning-sex-gender-column/1894076002/>

reversal of the legal gender status), **very high rates of participant loss to follow-up** (22%-63%) (D'Angelo, 2018 )..."<sup>177</sup>

- 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](https://doi.org/10.1007/s10508-021-02163-w)
- Entwistle K. Debate: Reality check - Detransitioners' testimonies require us to rethink gender dysphoria. *Child Adolesc Ment Health*. 2021;26(1):15-16. doi:[10.1111/camh.12380](https://doi.org/10.1111/camh.12380)
- UK Story: 'Hundreds' of young trans people seeking help to return to original sex," News.sky.com, 05 Oct 2019.  
A 28 yo detransitioning woman is setting up a charity, The Detransition Advocacy Network. Hundreds have contacted her: "they tend to be around their mid-20s, they're mostly female and mostly same-sex attracted, and often autistic as well." Some "felt shunned by the LGBT community for being a **traitor**."
- Prof. Levine: "There is much to suggest that the patient does not always know best—for example, post-transition depression, **detransition**, pre- and postsurgical suicide rates, and that researchers have concluded that postoperative patients need psychiatric care."<sup>178</sup>
- **r/detrans** | Detransition Subreddit. Reddit.com. (2020). Retrieved 22 September 2020, from <https://www.reddit.com/r/detrans/>. Over **28,000 members**.

**Causes for Suicidal Behavior: there is no one cause, but mental health issues stand out.**

- 1994. 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."<sup>179</sup>
- About 96% of US adolescents attempting suicide demonstrate at least one mental illness (Nock 2013).<sup>180</sup>

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<sup>177</sup> 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](https://doi.org/10.1177/1039856218775216)

<sup>178</sup> Stephen B. Levine (2019) Informed Consent for Transgendered Patients, *Journal of Sex & Marital Therapy*, 45:3, 218-229, DOI: [10.1080/0092623X.2018.1518885](https://doi.org/10.1080/0092623X.2018.1518885)

<sup>179</sup> 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>

<sup>180</sup> Nock MK, Green JG, Hwang I, McLaughlin KA, Sampson NA, Zaslavsky AM, Kessler RC. Prevalence, correlates, and treatment of lifetime suicidal behavior among adolescents:

- 90% of adults and adolescents who completed suicide had unresolved mental disorders (Cavanagh 2003).<sup>181</sup>
- About 5% of all youth suicide can be partly attributed to media coverage and discussion of other suicides (Kennebeck 2018).<sup>182</sup>
- The contagious nature of publicized suicide and the copycat phenomena it generates is called the Werther effect. The Papageno effect is the reduction of suicide rates prompted by the public example of pushing on.<sup>183</sup>

### **Myth of Suicide Reduction with G/TAT**

- **Emotional blackmail of bullying parents into affirming transition.**
  - You want a **dead son or a live daughter?**
  - Do you want a **transition or a funeral?**
- Bailey and Blanchard<sup>184</sup>: “There is **no persuasive evidence that gender transition reduces gender dysphoric children’s likelihood of killing themselves.**” ... “**The idea that mental health problems—including suicidality—are caused by gender dysphoria rather than the other way around ... is currently popular and politically correct. It is, however, unproven and as likely to be false as true.**”
- Oxford Sociologist Michael Biggs, “Estrogen is associated with greater suicidality among transgender males, and puberty suppression is not associated with better mental health outcomes for either sex” [comment], 19 Jan 2022.<sup>185</sup>
- **Lupron package insert:**  
Under “ADVERSE REACTIONS”  
“In postmarketing experience, **mood swings, depression, rare reports of suicidal ideation and attempt, ...**”  
Under “6.5 Postmarketing”  
“Like other drugs in this class, mood swings, including depression, have been reported. There have been very rare reports of suicidal ideation and attempt. Many, but not all, of these patients had a history of depression or other psychiatric illness.

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results from the National Comorbidity Survey Replication Adolescent Supplement. JAMA Psychiatry. 2013 Mar;70(3):300-10.

<sup>181</sup> 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.

<sup>182</sup> Kennebeck S, Bonin L. Suicidal behavior in children and adolescents: Epidemiology and risk factors. “UptoDate” [online database]. Last updated 21 November 2017. Accessed 5 November 2018

<sup>183</sup> Aaron Kheriaty, “The dangerously contagious effect of assisted-suicide laws,” washingtonpost.com, Nov. 20, 2015.

<sup>184</sup> 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/>

<sup>185</sup> <https://journals.plos.org/plosone/article/comment?id=10.1371/annotation/dcc6a58e-592a-49d4-9b65-ff65df2aa8f6>



**Patients should be counseled on the possibility of development or worsening of depression during treatment with LUPRON.”**

- **A 2011 Swedish study of all post-SRS/gender-reassignment adults showed a completed suicide rate 19 times that of the general population 10 year out.** Also nearly 3 times the rate of overall mortality and psychiatric inpatient care. This was a 30-year population-based matched cohort study of all 324 sex-reassigned persons in Sweden.<sup>186</sup>
- **Professor Michael Biggs of Oxford. 2019.<sup>187</sup>** **Criticized the UK’s NHS’s Gender Identity Development Service’s single study produced from their trial of puberty blockers, saying It showed no statistically significant difference in psychosocial functioning between the group given blockers and the group given only psychological support.** Furthermore, **unpublished evidence showed puberty blockers worsened gender dysphoria.** “In fact, the initial results **showed predominantly negative outcomes.** The only tabulated data available, for 30 of the subjects after a year on triptorelin, showed that **children reported greater self-harm;** girls experienced **more behavioural and emotional problems** and expressed **greater dissatisfaction with their body—so drugs exacerbated gender dysphoria (GIDS 2015).”**
- **Biggs, 2022.** Biggs, M. **Suicide by Clinic-Referred Transgender Adolescents** in the United Kingdom. *Arch Sex Behav* (2022). <https://doi.org/10.1007/s10508-022-02287-7> **Conclusion: "Data from the world’s largest clinic for transgender youth over 11 years** yield an estimated annual suicide rate of 13 per 100,000. **This rate was 5.5 times greater** than the overall suicide rate of adolescents of similar age, adjusting for sex composition. The estimate demonstrates the elevated risk of suicide among adolescents who identify as transgender, albeit without adjusting for accompanying psychological conditions such as autism. The proportion of individual patients who died by **suicide was 0.03%, which is orders of magnitude smaller than the proportion of transgender adolescents who report attempting suicide** when surveyed. The fact that deaths were so rare should provide some reassurance to transgender youth and their families, though of course this does not detract from the distress caused by self-harming behaviors that are non-fatal. It is **irresponsible to exaggerate the prevalence of suicide.** Aside from anything else, this trope might exacerbate the vulnerability of transgender adolescents. As the former lead psychologist at the Tavistock has warned, **“when inaccurate data and alarmist opinion are conveyed very authoritatively to families** we have to wonder what the impact would be on children’s understanding of the kind of person they are...and their likely fate” (Wren, 2015).”

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<sup>186</sup> 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.

<sup>187</sup> Michael Biggs, “The Tavistock’s Experiment with Puberty Blockers,” 29 July 2019, [http://users.ox.ac.uk/~sfos0060/Biggs\\_ExperimentPubertyBlockers.pdf](http://users.ox.ac.uk/~sfos0060/Biggs_ExperimentPubertyBlockers.pdf)

- **Amsterdam Cohort Study 2020 update.**<sup>188</sup> Among people undergoing gender affirming (transition affirming) treatment, suicide didn't really improve overall. Using further details given in the study, MtF transitioners had 2.8 times the completed suicide rate of general Dutch males, and FtM transitioners has 4.8 times the completed suicide rate of general Dutch females.
  - 35 year chart review of 8,263 Dutch patients who attended the nation's primary gender identity clinic. "Overall suicide deaths did not increase over the years: HR per year 0.97 (95% CI 0.94–1.00). In trans women, suicide death rates decreased slightly over time (per year: HR 0.96, 95% CI 0.93–0.99), while it did not change in trans men (per year: HR 1.10, 95% CI 0.97–1.25)."
- **"Paradox. The suicide rate for AYA in the non-affirming 1950s USA was much lower than it is now.** For both sexes, it was only 4.5 suicides per 100,000 AYA." Peaked in 1994 with a combined rate of 13.6; ...declined slightly and then was more or less flat until 2011, when it began again to climb." (Hacsi Horvath).<sup>189</sup> Williams Inst. Oft-cited claim of 40% suicidal ideation amongst adults with GD/TG? False claim. See Hacsi Horvath cited above.
- See also, Christopher Rosik, Ph.D., "The Creation and Inflation of Prevalence Statistics: The Case of "Conversion Therapy"<sup>190</sup>

#### **Stigma/Minority Stress does not explain for poor LGBT behavior statistics.**

- A 2016 study **examined 40 years of data in children** referred for gender dysphoria and found **"once we controlled for general behavior problems**, poor peer relations [ostracism/stigma] was no longer a significant predictor of suicidal ideation and behavior."<sup>191</sup>

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<sup>188</sup> Wiepjes CM, den Heijer M, Bremmer MA, Nota NM, de Blok CJM, Coumou BJG, Steensma TD. Trends in suicide death risk in transgender people: results from the Amsterdam Cohort of Gender Dysphoria study (1972-2017). *Acta Psychiatr Scand.* 2020 Jun;141(6):486-491. doi: 10.1111/acps.13164. Epub 2020 Mar 12. PMID: 32072611; PMCID: PMC7317390.

<sup>189</sup> <https://4thwavenow.com/2018/12/19/the-theatre-of-the-body-a-detransitioned-epidemiologist-examines-suicidality-affirmation-and-transgender-identity/>

<sup>190</sup> [https://a20ceadd-0fb7-4982-bbe2-099c8bc1e2ae.filesusr.com/ugd/ec16e9\\_8dec43abbe5d4eaaa2dd6b561a66f95c.pdf](https://a20ceadd-0fb7-4982-bbe2-099c8bc1e2ae.filesusr.com/ugd/ec16e9_8dec43abbe5d4eaaa2dd6b561a66f95c.pdf)

<sup>191</sup> Aitken, Madison & P. VanderLaan, Doug & Wasserman, Lori & Stojanovski, Sonja & Zucker, Kenneth. Self-Harm and Suicidality in Children Referred for Gender Dysphoria. *Journal of the American Academy of Child and Adolescent Psychiatry*, 55(6) · April 2016, pp. 513-520.)

- **Three Meta-analytic studies** indicate the strength of the **relationship of stigma to mental health** is significant but small, with **minority stresses** directly **explaining less than 9%** of the relationship.<sup>192 193 194</sup>
- **Mayer and McHugh’s 2016** comprehensive review of the scientific literature on sexuality and gender concluded, “...it is impossible to prove through these studies that stigma leads to poor mental health, as opposed to, for example, poor mental health leading people to report higher levels of stigma, or a third factor being responsible for both poor mental health and higher levels of stigma.”<sup>195</sup>
- During nearly a **half century period** from 1972 to 2017 in the Netherlands, increasing **cultural acceptance** (noted by the study authors) **has made little difference in suicide rates** among **gender dysphoric** patients seen by the nation’s primary gender identity clinic, **suggesting stigma is not a sufficient explanation for suicides**.<sup>196</sup>
- **Michael Bailey (2020)**:<sup>197</sup> “The [**minority stress**] **model** has not yet advanced from the “accumulating empirical associations” stage of empirical inquiry to the “eliminating rival hypotheses” stage. And at least **one obvious rival hypothesis exists: That the increased prevalence of mental health problems in non[heterosexual] persons is, at least in part, the cause, rather than the effect,** of increased self-reported experiences of stigmatization, prejudice, and discrimination.”
  - **“The minority stress model has been prematurely accepted as the default explanation for sexual orientation-associated differences in mental health.** Yet minority stress research has not generated findings uniquely explicable by the model, and it has ignored the model’s serious limitations.”
  - **“The minority stress model should predict** that nonheterosexual persons who grow up in especially intolerant or stigmatizing cultures would be at

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<sup>192</sup> Jones KP, Peddie CI, Gilrane VL, King EB, Gray AL. Not so subtle: A meta-analytic investigation of the correlates of subtle and overt discrimination. *Journal of Management*. 2016 June; 42(6): 1588-1613.

<sup>193</sup> Pascoe EA, Richman LS. Perceived discrimination and health: A meta-analytic review. *Psychological Bulletin*. 2009. 135(4): 531–554.

<sup>194</sup> Schmitt MT, Branscombe NR, Postmes T, Garcia A. The consequences of perceived discrimination for psychological well-being: A meta-analytic review. *Psychological Bulletin*. 2014. 140(4); 921-948.

<sup>195</sup> Mayer LS and McHugh P, “Sexuality and Gender: Findings from the Biological, Psychological, and Social Sciences,” *The New Atlantis*, Fall 2016. PP 79-81.

<sup>196</sup> Wiepjes CM, den Heijer M, Bremmer MA, Nota NM, de Blok CJM, Coumou BJG, Steensma TD. Trends in suicide death risk in transgender people: results from the Amsterdam Cohort of Gender Dysphoria study (1972-2017). *Acta Psychiatr Scand*. 2020 Jun;141(6):486-491. doi: 10.1111/acps.13164. Epub 2020 Mar 12. PMID: 32072611; PMCID: PMC7317390.

<sup>197</sup> Michael Bailey, J. The Minority Stress Model Deserves Reconsideration, Not Just Extension. *Arch Sex Behav* 49, 2265–2268 (2020). <https://doi.org/10.1007/s10508-019-01606-9>.

particularly high risk of mental health problems. **However, I know of no evidence for this prediction**, and there is some evidence against it.” He lists **Netherlands** as a case in point.

- “Moreover, the minority stress model has **relied exclusively on self-report data** to quantitate stigmatization, as Feinstein (2019 ) acknowledges.”

## Facade of Authority

### 1. WPATH (World Professional Association for Transgender Health)

- WPATH is not (contra the AMA Amicus in the Harris Funeral Home SCOTUS case) “the consensus of the medical and mental health community regarding the appropriate treatment for gender dysphoria.”
- It is the former Harry Benjamin International Gender Dysphoria Association.<sup>198</sup>
- The World Professional Association for Transgender Health (WPATH, a membership organization for health care professionals that advocates for transgender health care)...Hruz, Mayer, McHugh<sup>199</sup>
- WPATH is a advocacy group and not a scientific organization. “Instead of being a scientifically-based organization, WPATH acts as a politically active entity pushing aggressively for worldwide acceptance of gender incongruence as a biologically-based variation of normal behavior. WPATH pushed the American Psychiatric Association to eliminate GID as a disorder. Dr. Zucker, who chaired the committee to create the DSM-5, fought to retain an entity, which he termed Gender Dysphoria, to describe the emotional suffering of those persons with gender incongruence. This would allow patients to receive insurance coverage for treatments related to resolving the dysphoria. He succeeded in his efforts and the term GID was thus replaced.” – Quentin Van Meter, MD<sup>200</sup>
- “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.” – Steven B. Levine, MD<sup>201</sup>
- The World Professional Association for Transgender Health (WPATH) deems gender identity incongruity not “inherently pathological” and asserts that efforts to

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<sup>198</sup> 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>

<sup>199</sup> Paul W. Hruz, Lawrence S. Mayer, and Paul R. McHugh, "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," *The New Atlantis*, Number 52, Spring 2017, pp. 3-36.

<sup>200</sup> Quentin L. Van Meter. Bringing Transparency to the Treatment of Transgender Persons. *Issues in Law & Medicine*, Vol. 34, Iss. 2, Fall 2019, pp. 147-152.

<sup>201</sup> Stephen B. Levine (2018): Informed Consent for Transgendered Patients, *Journal of Sex & Marital Therapy*, DOI: 10.1080/0092623X.2018.1518885

“change gender identity and expression to become more congruent” with biological sex ineffective [ignores evidence, see below] and “unethical.” –WPATH SOC-7<sup>202</sup> (WPATH’s citation for the alleged lack of success of psychotherapy fails to support their claim. At least 15 studies or case reports exist. Michelle Cretella, Transgender Belief: A Call to Heal Minds, Preserve Bodies, and Save Lives, Joint AAPLOG/ACPeds Matthew Bulfin Medical Education Conference (online: 2020).)

- “This makes AAP’s logic entirely backwards: That WPATH’s request to depathologize gender dysphoria was rejected suggests that it is WPATH’s view—and therefore the AAP policy—which fall “outside the mainstream of traditional medical practice.” (!)” - James Cantor, PhD<sup>203</sup>
- What of WPATH’s SOC argument that it is unethical to do a controlled study of anything except gender affirmation treatments because failure to affirm is inherently harmful?  
Pediatric endocrinologist & academic Paul Hruz, MD (e-mail, 3/29/21)  
“The problem with the argument that it is unethical to do a controlled study is the erroneous assumption that the control group will not receive care. A properly controlled trial provides the same interventions in all aspects of care except for the independent variable. To be effective while ensuring subject safety, it is necessary to have a clearly developed hypothesis, a single study objective, defined endpoint, a feasible intervention regimen and anticipation of potential problems during the conduct of the experiment. With clear a priori delineation of potential adverse events and use of an “intention to treat” analysis, one can maintain safety without artificially biasing results.”
- Adults: “GD can remit in some [adult]cases (Marks et al. 2000); perhaps psychotherapy could facilitate such remission – or a reduction in GD symptoms... in some subset of the diverse group of adults [who meet the diagnosis of] GD.” ...“Unfortunately, these possibilities have not yet been investigated, and such investigations are strongly discouraged in the SOC – 7.” – Ken Zucker, PhD<sup>204</sup>

## 2. Endocrine Society Guidelines Plus

- **2017 Endocrine Society Guidelines** for treatment of gender dysphoric/gender-incongruent persons **recommended puberty blocking and cross-sex hormone**

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<sup>202</sup> Coleman E, Bockting W, Botzer M, et al. Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. *International Journal of Transgenderism* 2012; **13**(4): 165-232.

<sup>203</sup> 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

<sup>204</sup> Zucker KJ, Lawrence AA, Kreukels BP, Gender Dysphoria in Adults, *Annual Rev of Clinical Psych*, 2016. 12:20.1-20.31, p. 21.

**administration to selected minors citing “low evidence” and genital surgery for selected adults citing “very low evidence.”**

- The Guidelines rest largely on a single, uncontrolled, weakly designed study.
  - 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.
- The Endocrine Society Guidelines specifically stated, “The guidelines cannot guarantee any specific outcome, **nor do they establish a standard of care**”: “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.”<sup>205</sup> P. 3895.

In 2019 the Endocrine Society, along with an **international panel** of endocrinology societies, concluded regarding testosterone therapy in females: “the only evidence-based indication for testosterone therapy for women is for the treatment of HSDD [Hypoactive sexual desire disorder],” and that “There are insufficient data to support the use of testosterone for the treatment of any other symptom or clinical condition, or for disease prevention.” Also, “The safety of long-term testosterone therapy has not been established.”

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>.

- One and only one evidence-based recommendation for testosterone use in women, and only for short term at that, namely HSDD.
- This is bizarre, in that they made no mention of G/TAT, which would obviously be a far more aggressive and long term employment of testosterone in females. They simply dodged the subject.

## 2. American Academy of Pediatric policy

- “In 2016, **the Human Rights Campaign**, an LGBT advocacy group, partnered with the **American Academy of Pediatrics** — the nation’s most prominent professional organization for pediatricians — and the American College of Osteopathic Pediatricians to publish **a guide for families of transgender children**.”<sup>206</sup>

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<sup>205</sup> 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>

<sup>206</sup> Paul W. Hruz, Lawrence S. Mayer, and Paul R. McHugh, "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," *The New Atlantis*, Number 52, Spring 2017, pp. 3-36.

- U of Toronto psychologist James Cantor discredited the statement, “In fact, **the references that AAP cited as the basis of their policy instead outright contradicted that policy, repeatedly endorsing *watchful waiting*.**”<sup>207</sup>  
 “The AAP statement was also **remarkable in what it left out**—namely, the outcomes research on GD children.” “...**every follow-up study of GD children, without exception, found the same thing: Over puberty, the majority of GD children ceased to want to transition.**”  
 “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*.**”
- Cantor continued contra WPATH and AAP: “This makes AAP’s logic entirely backwards: That WPATH’s request to depathologize gender dysphoria was rejected suggests that it is WPATH’s view—and therefore the AAP policy—which fall “outside the mainstream of traditional medical practice.” (!)”
- AAP’s HealthDay reported (April 2017) on a U of Iowa study that kids younger than 14yo could not reliably cross a busy street safely.<sup>208</sup>
  - So how can kids be competent to choose GAT?
- Leonard Sax, MD<sup>209</sup> -- “But the American Academy of Pediatrics is now on record prioritizing the opinion of a five-year-old over the considered judgment of the child’s parents.”  
 “The AAP would not allow a five-year-old to veto the parent’s decision regarding whether to be vaccinated against diphtheria, which is today a very rare disease. Why is the AAP giving five-year-olds supreme authority for this much more profound decision?”  
 “These new guidelines are not based in evidence. On the contrary, they contradict the available research.”
- “Dr. Joseph Zanga, who serves as Clinical Professor of Pediatrics at the Medical College of Georgia and Emeritus Professor of Pediatrics at Mercer University School of Medicine, and is a past president of the American Academy of Pediatrics further clarified the policy-making process of the AAP:<sup>210</sup>
  - Policy Statements are produced by 10-12 member Committees or Councils, or Section (e.g., School Health, Adolescence, or Bioethics) or more commonly

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<sup>207</sup> 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

<sup>208</sup> <https://consumer.healthday.com/kids-health-information-23/child-safety-news-587/at-what-age-can-kids-safely-cross-the-street-721785.html>.

<sup>209</sup> Leonard Sax, “Politicizing Pediatrics: How the AAP’s Transgender Guidelines Undermine Trust in Medical Authority,” thepublicdiscourse.com March 13, 2019. <https://www.thepublicdiscourse.com/2019/03/50118/>

<sup>210</sup> Laurie Higgins, Do 66,000 Pediatricians Really Support the AAP’s “Trans”-Affirmative Policy? illinoisfamily.org, April 5, 2017. <https://illinoisfamily.org/homosexuality/66000-pediatricians-really-support-aaps-trans-affirmative-policy/>

by Section Executive Committees, whose members are nominated by their AAP State Chapter Committees (or members of the Section) and selected by Committees of the AAP Board. Confirmation is by the Board of Directors. Section Executive Committees are elected by the Section members.

- The 10 members of the AAP Board of Directors are elected by the AAP members of their district (elections never garner votes from even 40% of members) and the Executive Committee consisting of the president, president-elect, immediate past-president (elected by the AAP members nationally with equally small numbers voting), and the paid executive director (hired by the Board).
- Statements are sent to the board for review and vote. Often there is discussion at a board meeting. Rarely is there outside opinion sought, and there is never a minority report.
- Consequently, AAP members often don't even see the report until after it appears in the media. They have no direct input.

### Consensus or Else

**Consensus is not a proxy for truth.** The pro-GAT/TAT party line is in part a **Castro consensus.**<sup>211</sup>

- “A Castro Consensus is a near-unanimous show of agreement brought about by means other than the honest and uncoerced judgements of individuals.”
- “...once dependence, polarization, and external pressure are introduced...the probability of a false consensus increases dramatically.”

There is no witness protection program for medical and mental health professionals who contest the party line. They risk their jobs, careers, and safety for critiquing G/TAT in minors or adults.

### **STUDIES, POORLY DONE**

Background on common flaws of studies in this field:

- “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.
- “The fact that modern patterns of the treatment of trans individuals **are not based on controlled or long-term comprehensive follow-up studies** has allowed many ethical tensions to persist.”

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<sup>211</sup> Understanding the Role of Dependence in Consensus Formation. *Proceedings of the 2020 Truth and Trust Online (TTO 2020)*, pages 12–20, Virtual, October 16-17, 2020. <https://www.cs.hmc.edu/~montanez/pdfs/allen-2020-castro-consensus.pdf>



- 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>
- Studies that are retrospective/cross-sectional, by definition, cannot be used to make statistical generalizations. Neither the presence nor direction of causation can be determined from this study design.
  - However, the authors will then acknowledge this in the “limitations” section of such studies, followed immediately by making the disallowed conclusive assertions about causation, right after admitting “causation cannot be inferred due to the study’s cross-sectional design.”
  - Then the disallowed conclusions gets published in peer-review and quoted throughout general media.

### **2015 US Transgender Survey.**

James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). The report of the **2015 U.S. Transgender Survey**. Retrieved January 27, 2020 from National Center for Transgender Equality website, <https://www.trans equality.org/sites/default/files/docs/USTS-Full-Report-FINAL.PDF>.

- It was an online survey of transgender-identified and genderqueer adults from trans-affirming websites.
- Recruitment bias is obvious, large and multi-faceted, e.g. only trans-identified adults who are still alive responded. Not representative of the TG population. Excludes desisters, the dead, etc.
- The USTS does not ask about gender dysphoria itself, just identification.
- Studies based on it are by design retrospective, dependent upon people’s unreliable memories through ill-fitting questions.
- Not controlled for underlying mental health.
- Gideon’s 2012 textbook on survey methodology spells out a very clear warning: “An important note about convenience sampling is that you cannot make statistical generalizations from research that relies on convenience sampling.” He adds, “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.
- Statistical generalizations derived from convenience samples are precisely what these types of studies produce, so they lack validity from the start.
- Andre’s opinion: With enough of these weak studies with pre-ordained conclusions in publication, confirmation bias by citation bias is highly likely. The same erroneous studies get cited in other publications and the general media, and false conclusions become the established norm.
  - Walter R Schumm, *Assessing Citation Bias in Scientific Literature*. 2020 - 10(3). AJBSR.MS.ID.001514. Walter Schumm, Catherine R. Pakaluk, Duane W. Crawford. *Forty Years of Confirmation Bias in Social Science: Two Case Studies of Selective Citations*. *Internal Medicine Review*, Vol. 6, Iss. 4 (2020)  
[doi.org/10.18103/imr.v6i4.875](https://doi.org/10.18103/imr.v6i4.875)

- D'Angelo -- Regarding 2015 USTS: "This survey used convenience sampling, a methodology which generates low-quality data (Bornstein, Jager, & Putnick, 2013). Specifically, the participants were recruited through transgender advocacy organizations and subjects were asked to "pledge" to promote the survey among friends and family. This recruiting method yielded a large but highly skewed sample."
  - 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: Bornstein, M. H., Jager, J., & Putnick, D. L. (2013). Sampling in developmental science: Situations, shortcomings, solutions, and standards. *Developmental Review*, 33(4), 357–370. <https://doi.org/10.1016/j.dr.2013.08.003>.
- Michael Biggs, Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. *Archives of Sexual Behavior*, accepted 14 May 2020, DOI: 10.1007/s10508-020-01743-6
  - Outstanding refutation of both the general use of US Transgender Survey and J. Turban study on PBAs.

### **Amsterdam Cohort Study #1 (2018)**

Concluded: "The percentage of people who regretted gonadectomy remained small and did not show a tendency to increase."

Wiepjes CM, Nota NM, de Blok CJ, et al. **The Amsterdam Cohort of Gender Dysphoria Study (1972–2015): Trends in Prevalence, Treatment, and Regrets.** *The Journal of Sexual Medicine* 2018; 15(4): 582-90.

#### **Problems:**

- "Not all data were available from the hospital registries, particularly older data or surgeries performed in other centers" (p.590)
- A **36% loss to follow up**. "A large number of transgender people...were lost to follow-up. Although transgender people receive lifelong care, a large group (36%) did not return to our clinic after several years of treatment" (page 589).
- "Regret" only tabulated for those who had gonadectomies and then requested hormone therapy consist with biological sex "and expressed regret" (p.584); excluded all who died (p.584).
- No uniform stats on average follow-up time and variance.
- Admitted average regret time was 130 months. Page 589 admission: ""...it might be too early to examine regret rates in people who started with HT in the past 10 years." Many more patients came later in the study and counted as non-regret without allowing the expected time for such. Shifts results.

### **Amsterdam Cohort Study 2020 update.**

Wiepjes CM, den Heijer M, Bremmer MA, Nota NM, de Blok CJM, Coumou BJG, Steensma TD. **Trends in suicide death risk in transgender people: results from**

**the Amsterdam Cohort of Gender Dysphoria study (1972-2017).** Acta Psychiatr Scand. 2020 Jun;141(6):486-491. doi: 10.1111/acps.13164. Epub 2020 Mar 12. PMID: 32072611; PMCID: PMC7317390.

Among people undergoing gender affirming (transition affirming) treatment, **suicide didn't really improve overall.** Using further details given in the study, MtF transitioners had 2.8 times the completed suicide rate of general Dutch males, and FtM transitioners has 4.8 times the completed suicide rate of general Dutch females.

- **35-year chart review of 8,263 Dutch patients who attended the nation's primary gender identity clinic.** "Overall suicide deaths did not increase over the years: HR per year 0.97 (95% CI 0.94–1.00). In trans women, suicide death rates decreased slightly over time (per year: HR 0.96, 95% CI 0.93–0.99), while it did not change in trans men (per year: HR 1.10, 95% CI 0.97–1.25)."

**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>

**Quick summary version:**

In 2019 (online) **Bränström and Pachankis** published the first total population study of 9.7 million Swedish residents titled, "Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study." Looking at three limited measures of mental health service usage, they claimed that although "gender-affirming hormone treatment" provided no improvement, "gender-affirming surgeries" did.

- The online August 1, 2020 American J of Psychiatry edition contained seven critical letters, including ours; a major "correction" paragraph from the editors retracting the studies main finding, and a letter from the study authors conceding their "conclusion" "was too strong."
- In effect, the Bränström and Pachankis study demonstrated that neither "gender-affirming hormone treatment" nor "surgery" provided reductions of the mental health treatment benchmarks examined in transgender-identified people.
  - 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>
  - Andre Van Mol, Michael K. Laidlaw, Miriam Grossman, Paul R. McHugh. Gender-Affirmation Surgery Conclusion Lacks Evidence. Am J Psychiatry 2020; 177:765–766; doi: 10.1176/appi.ajp.2020.19111130. [Other six are found in the endnotes of Branstrom Response to Letters below. doi: 10.1176/appi.ajp.2020.20050599.]
  - 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>

- Richard Bränström and John E. Pachankis. Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals' Mental Health: Response to Letters. American Journal of Psychiatry 2020 177:8, 769-772 doi: 10.1176/appi.ajp.2020.20050599.

**Detailed version:**

- Total population study of Sweden 9.7M:
- Claimed that **gender-affirming surgeries (SRS) reduced mental health treatment use in transgender-identified individuals.**
  - While admitting “**gender-affirming hormone treatment**” provided **no improvement.**
- Our Team found many problems with the study (endo Michael Laidlaw, child and adolescent psychiatrist Miriam Grossman, and Prof Paul McHugh of Johns Hopkins)
- We authored a LTE of AJP critical of Branstrom.
  - Andre Van Mol, Michael K. Laidlaw, Miriam Grossman, Paul R. McHugh. Gender-Affirmation Surgery Conclusion Lacks Evidence. Am J Psychiatry 2020; 177:765–766; doi: 10.1176/appi.ajp.2020.19111130
- **August 1, 10 months later, 7 critical letters were published, including ours.** Why the wait?
  - AJP issued a **major “correction” retracting** the study’s main finding. 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>
  - AJP editors expressed the need “**to seek statistical consultations.**”
  - Consultants mostly agreed with us, authors reanalyzing their data.
  - Branstrom & Pachankis LTE admitted their “**conclusion**” “**was too strong.**” Richard Bränström and John E. Pachankis. Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals' Mental Health: Response to Letters. American Journal of Psychiatry 2020 177:8, 769-772 doi: 10.1176/appi.ajp.2020.20050599.
    - **Table 1** of their letter **compared their 3 end-points for GD patients receiving and GD patients not receiving gender-affirmative surgery.** Psychiatric outpatient visits for any mood or anxiety disorder, prescribed medications for the same, and hospitalization after suicide attempts were **all worse for the GI group receiving gender-affirmative surgery** (not all statistically significant) than for those that did not.
  - AJP correction found “**no advantage to surgery**” for GD regarding their **3 endpoints:**
    - prescriptions or health-care visits for mood or anxiety disorders
    - post-suicide attempt hospitalizations

- With neither “gender-affirming hormone treatment” nor “surgery” providing improvement : The study now seems invalidated.
- **Study Shortcomings were many:**  
The **lack of control subjects, the limited 1-year time frame, retrospective design, major loss to follow up, and the avoidance of examining completed suicides and psychiatric hospitalizations**
  - **Shortcomings:**
    - **Retrospective, not longitudinal** – looking back, not following during.
      - Figure 1, “time since last gender affirming surgery” is easily misinterpreted as a prospective 10-year follow-up that did not occur
    - lack of control population
    - the limited 1-year time frame
      - Though for all living individuals in Sweden, only for calendar year 2015 for those alive on one day, Dec 31, 2014.
    - **Loss to follow up strongly implied:**
      - **Low numbers:** The **2,679 individuals diagnosed with gender incongruence in a total population study of Sweden is a full order of magnitude below prevalence expectations from DSM-5.**
        - Where did they go?
      - **Only 3 measured outcomes:** prescriptions or health-care visits for mood or anxiety disorders, and hospitalizations post-suicide attempt
        - **That avoids looking at completed suicides, health care visits and hospitalizations for all other medical or psychological issues still related to GAS/SRS.** Ignored them!
      - **So few having had surgery of reproductive organs when such is free in Sweden.**
        - Table 3: 38% of these individuals had any kind of gender-affirming surgery, but only 53% [20%] of those had surgery of reproductive organs.
        - [For those whose last surgery was 10 or more years earlier, how many completed suicide, died of other causes, or left Sweden prior to study initiation? ]
      - **Findings are accessible in the Swedish national registers.** these omissions are glaring.

**Carmichael, UK Tavistock/GIDS study 2020:**

“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.”

**"Results** 44 patients had data at 12 months follow-up, 24 at 24 months and 14 at 36 months. All had normal karyotype and endocrinology consistent with birth-registered sex.

All achieved suppression of gonadotropins by 6 months. At the end of the study one ceased GnRHa and 43 (98%) elected to start cross-sex hormones.

There was no change from baseline in spine BMD at 12 months nor in hip BMD at 24 and 36 months, but at 24 months lumbar spine BMC and BMD were higher than at baseline (BMC +6.0 (95% CI: 4.0, 7.9); BMD +0.05 (0.03, 0.07)). There were no changes from baseline to 12 or 24 months in CBCL or YSR total t-scores or for CBCL or YSR self-harm indices, nor for CBCL total t-score or self-harm index at 36 months. Most participants reported positive or a mixture of positive and negative life changes on GnRHa. Anticipated adverse events were common.

**Conclusions** Overall patient experience of changes on GnRHa treatment was positive. We identified no changes in psychological function. Changes in BMD were consistent with suppression of growth. Larger and longer-term prospective studies using a range of designs are needed to more fully quantify the benefits and harms of pubertal suppression in GD."

Polly Carmichael, Gary Butler, Una Masic, Tim J Cole, Bianca L De Stavola, Sarah Davidson, Elin M. Skageberg, Sophie Khadr, Russell Viner. 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> <https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1>

BBC summary on the study: <https://www.bbc.com/news/uk-55282113>

My Points:

- Took 9 years to produce yet had only 44 participants, suggesting ample loss to follow up or removal from study.
- No control group of GD youth not given PBs.
- **Self-harm did not improve and “no changes in psychological function,”** meaning no improvement. (Also, “YSR [Youth Self Report] data at 36 months (n = 6) were not analysed.”)
  - **“We found no differences between baseline and later outcomes for overall psychological distress** as rated by parents and young people, nor for self-harm.”
  - **“We found no evidence of change in psychological function with GnRHa treatment** as indicated by parent report (CBCL) or self-report (YSR) of overall problems, internalising or externalising problems or self-harm. This is in contrast to the Dutch study which reported improved psychological function across total problems, externalising and internalising scores for both CBCL and YSR and small improvements in CGAS.”
- “All had normal karyotype and endocrinology” function in GD youth.
  - More proof that DSDs/Intersex are not GD issues.
- 98% went on from puberty blocking to CSH.
  - GnRHAs are gateway drugs, steppingstones to GAT/TAT.
- BMD and growth/height both showed “suppression of growth” precisely when they should be having the surge of the lifetime.
  - “As anticipated, pubertal suppression reduced growth that was dependent on puberty hormones, i.e. height and BMD. Height growth continued for those

not yet at final height, but more slowly than for their peers so height z-score fell. Similarly for bone strength, BMD and BMC increased in the lumbar spine indicating greater bone strength, but more slowly than in peers so BMD z-score fell.”

### **Professor Michael Biggs of Oxford, 2019 Critique of Carmichael/Tavistock Study**

Regarding the UK’s Tavistock and Portman NHS Trust’s Gender Identity Development Service’s experimental trial of puberty blockers for early teenagers with gender dysphoria. Oxford’s Professor Michael Biggs wrote, “To summarize, GIDS launched a study to **administer experimental drugs to children suffering from gender dysphoria.**”

“after a year on GnRHa [puberty blockers] children **reported greater self-harm**, and that girls experienced more behavioral and emotional problems and expressed greater dissatisfaction with their body—**so puberty blockers exacerbated gender dysphoria.**”

(Michael Biggs, “Tavistock’s Experimentation with Puberty Blockers: Scrutinizing the Evidence,” TransgenderTrend.com, March 5, 2019.

<https://www.transgendertrend.com/tavistock-experiment-puberty-blockers/>)

### **Cornell University “systematic literature review”**

Anonymous. Cornell University, Public Policy Research Portal. “What does the scholarly research say about the effect of gender transition on transgender well-being?” Available: <https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people/> [accessed 20 November 2019]

Horvath, Hacs. (2020). Activist-driven transgender research methods are reckless and will lead to harms. 10.13140/RG.2.2.22455.55206.

- “In 2017, anonymous authors at Cornell University produced a document titled “What does the scholarly research say about the effect of gender transition on transgender well-being?”[3]. This document purports to be a “systematic literature review.” In reality, it is a piece of propaganda, created by activists.”
- “Conclusions: The so-called “systematic literature review” produced at Cornell was nothing of the kind. “Findings” of this document should be ignored.”

### **Green, et al (2020). Trevor Project.**

Green, A.E., Price-Feeney, M., Dorison, S.H., Pick, C.J. (2020). **Self-reported conversion efforts and suicidality among US LGBTQ youths and young adults, 2018.** American Journal of Public Health, Open-Themes Research, 110(8), 1221-1227. <https://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2020.305701>

**The Trevor Project** conducted an on-line survey recruiting adolescents and young adults (AYA) who experienced “sexual orientation or gender identity conversion efforts (SOGICE)” and “who interacted with materials deemed relevant to the LGBTQ community.”

- Cross sectional, retrospective. By definition, neither the presence nor direction of causation can be determined, but they do it anyway.

- “Although noteworthy, our findings involve limitations that should be considered. For example, our data were cross sectional; thus, temporality cannot be determined.”
- **Exclusion.** This design excludes AYAs who do not or no longer identify as LGBTQ nor interact with the LGBTQ community or its materials, such as those who found therapy helpful. By excluding them it can make no conclusions about them.
- **Bias.** Prior to survey “questions specific to youth mental health and suicidality,” the LGBTQ-identified AYAs were instructed to contact the Trevor Project crisis intervention hot line if needed, thus revealing the study sponsors and their well-advertised biases.
- **Bias.** Green’s study defined SOGICE as coercive, “someone attempted to convince them to change,” which ethical change-allowing therapists don’t do.
- **Excluded** 105 participants who said they experienced SOGICE but without someone trying to “convince them change,” so it can claim nothing about non-coercive SOGICE.
- **Association as causation fallacy.** The study asserted that LGBTQ-identified youth who were over 2 times more suicidal were more likely to have experienced SOGICE therapy. The researchers then fully commit to the association as causation fallacy by concluding, “The elevated odds of suicidality observed among young LGBTQ individuals exposed to SOGICE underscore the detrimental effects of this unethical practice...”
  - No, they don’t. A more suicidal youth is more likely to seek therapy than one who is not. It does not follow that the therapy was causative of suicidality.

**Green 2021. Green 2021. Green, A.E., et al., (2021).** Association of gender-affirming hormone therapy with depression, thoughts of suicide, and attempted suicide among transgender and nonbinary youth. Society for Adolescent Health and Medicine, <https://doi.org/10.1016/j.jadohealth.2021.10.036>.

- Presupposes gender dysphoria and minority stress model as the cause of mental health problems in transgender-identified youth.

Design Failures:

- Study is retrospective/cross-sectional. So by definition, it cannot be used to make statistical generalizations. Neither the presence nor direction of causation can be determined from this study design.
  - There is a steady pattern in such literature of authors acknowledging this in the “limitations” section of such studies, as Green does here in this study: “First, causation cannot be inferred due to the study’s cross-sectional design. It is possible that those who historically have higher rates of depression and suicidal thoughts and behaviors are also less able to seek or obtain GAHT.”
  - But Green goes right ahead and conclusively asserts causation – here of receiving GAHT and improving mental health -- right after admitting “causation cannot be inferred due to the study’s cross-sectional



design.” Then it gets published in peer-review without batting an eye and quoted all around the hemisphere in general media.

- The study questions address “access” and “desire for access” to gender-affirming hormone treatment, while ignoring the actual results of such treatment.
- Ignoring Key Variables:
  - No attempt to account for other variables which are known to be high in transgender-identified youth: adverse childhood experiences (e.g. abuse), substance abuse, etc.
  - Study done during the COVID pandemic, but didn’t account for known negative effects on mental health effects during the pandemic.
  - Someone who is genuinely suicidal ( let alone actually killed themselves) are less likely to engage in surveys.
- Furthermore, Excluding from GAHT consideration all those with poor mental health is or was common gender clinic practice, even WPATH approved. Here the authors note the same in the passage quoted above (“It is possible that those who historically have higher rates of depression and suicidal thoughts and behaviors are also less able to seek or obtain GAHT.”), so to then make an issue out of the better mental health of those receiving GAHT is disingenuous — they started out with better mental health.

#### Results:

- About 44% of those receiving hormones and 57% of those who “Wanted but did not receive” hormones reported seriously considering suicide. Thus, nearly half the treatment group remains suicidal, indicating the proposed treatment is a failure.
- 60% of those receiving hormones and 75% who “Wanted but did not receive” hormones reported recent depression. Again, a treatment failure.
- “94% of those 13-17 who received GAHT had parental support compared to 80% among the full sample.” Translation, parental support made this ineffective treatment more likely to occur.

#### **Olson-Kennedy, 2018, JAMA Peds about Mastectomies on minors:**

**Questionable claim:** “Chest dysphoria was high among presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults.”

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

#### **Problems:**

- “Chest dysphoria” is a neologism of convenience, not a DSM-5 diagnosis.
- The “chest dysphoria scale” measuring tool of the authors and “is not yet validated.” (p. 435)
- Mastectomies were done on girls as young as 13 or 14 yo lacking the capacity for mature decision making or informed consent.
- Study seems flawed and unethical.

Simonsen, R. K., Giralaldi, A., Kristensen, E. & Hald, G. M. **Long-term follow-up of individuals undergoing sex reassignment surgery: Psychiatric morbidity and mortality.** *Nord J Psychiatry* 70, 241-247, doi:10.3109/08039488.2015.1081405 (2016).

- A 2016 study of nearly all (98%; n=104) of **Dutch** patients who underwent **sex reassignment surgery** from 1978-2010 found no significant difference in **psychiatric morbidity or mortality** between male to female and female to male (FtM) “save for the total number of psychiatric diagnoses where FtM held a significantly higher number of psychiatric diagnoses overall.”
  - “This suggests that generally SRS may reduce psychological morbidity for some individuals while increasing it for others.”
  - **SRS was not an agent of statistically significant net benefit.**

**2018. Tobin J et al, The effect of GnRHa treatment on bone density in young adolescents with gender dysphoria: findings from a large national cohort, *Endocrine Abstracts* (2018) 58 OC8.2 | DOI: [10.1530/endoabs.58.OC8.2](https://doi.org/10.1530/endoabs.58.OC8.2).**

- In the study’s conclusion:

“We have shown that there is no actual change in BMAD or tBMD in young transgender adolescents on long term GnRHa therapy, and certainly no true fall as initially suspected. We suggest that yearly DEXA scans may not be necessary. We also suggest that reference ranges may need to be re-defined for this patient cohort.”
- **Per Mike Laidlaw:** For the 39 adolescent girls, “Initially, they were in the 40th percentile for bone density. By the end of two years, however, they were in the lower 3rd percentile for bone density.”
- This is a disaster being papered over by deflection. Bone mineral density undergoes its greatest increase during puberty, PBAs hinder this, and the study proves it. Tobin, rather than admit that this BMD surge is greatly blocked by PBAs (“no actual change in BMAD or tBMD”), spins it to a straw argument of “no true fall as initially suspected.”

Turban JL, King D, Kobe J, Reisner SL, Keuroghlian AS (2022) **Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults.** *PLoS ONE* 17(1): e0261039. <https://doi.org/10.1371/journal.pone.0261039>

**Rebuttal of Turban 2022 “Access to gender-affirming hormones” by Prof. Michael Biggs of Oxford.**

Michael Biggs, “Estrogen is associated with greater suicidality among transgender males, and puberty suppression is not associated with better mental health outcomes for either sex” [comment], 19 Jan 2022.

<https://journals.plos.org/plosone/article/comment?id=10.1371/annotation/dcc6a58e-592a-49d4-9b65-ff65df2aa8f6>

- Turban again used the US Transgender Survey (USTS). “This data source has serious deficiencies.”
  - “The survey was not representative of the transgender population.”

- "...excluded individuals who no longer identified as transgender, the group most likely to be harmed by cross-sex hormones [10,11]."
- "...survey asked no questions about gender dysphoria [12]."
- "Finally, the data are retrospective..."
- "After all, the World Professional Association for Transgender Health's Standards of Care states that a prerequisite for prescribing cross-sex hormones is that 'significant medical or mental health concerns ... must be reasonably well-controlled' [12]."
- Translation, those with poor mental health are less likely to be given hormones and those with better mental health are selected in. Thus it is questionable to attribute better mental health to being given gender affirming hormones when better mental health was a requirement for GAH.
- The Turban 2022 GAH study excluded USTS data on surgical interventions.
- "The current article includes pubertal suppression as a confounding variable, but omits to report the result. I will report that it has no statistically significant effect on mental health, which refutes their earlier finding."
- ... "having taken puberty blockers has no statistically significant association with any outcome. This reveals that Turban et al.'s earlier finding from the USTS--which did not control for cross-sex hormones--is not robust [5]."
- Turban JL, King D, Carswell JM, Keuroghlian AS. Pubertal suppression for transgender youth and risk of suicidal ideation. *Pediatrics*. 2020;145:e20191725. doi:10.1542/peds.2019-1725
- "Table 2 tests the authors' assumption that testosterone for females is the same as estrogen for males." However, "The assumption is falsified." "After controlling for other variables, every outcome's association with testosterone differs significantly from its association with estrogen..."
- "Males who took estrogen are more likely to plan suicide, to attempt suicide, and to require hospitalization for a suicide attempt."
- And "not wanting cross-sex hormones is associated with better outcomes for males than taking estrogen." "Table 3 adds respondents who did not want (and had not taken) cross-sex hormones..." "...these respondents are less likely to suffer severe distress, less likely to have suicidal thoughts, and less likely to plan suicide."
- "Estrogen is associated with a lower probability of severe distress, but also with a higher probability of planning, attempting, and being hospitalized for suicide. The latter outcome is particularly disturbing: males who took estrogen have almost double the adjusted odds of a suicide attempt requiring hospitalization."
- "Testosterone is consistently associated with better outcomes."
- "females who took testosterone reported better outcomes than females who had not taken it, including those who did not even want it. Perhaps this is unsurprising given that several randomized control trials find testosterone acting as an antidepressant [13]."

- “Turban et al. analyze several binary outcomes. One is extreme psychological distress in the past month.... Another is suicidality in the past 12 months...”
- “Turban et al.'s analysis is impossible to replicate exactly because they do not provide sufficient details of their coding and analysis.”
- “odd discrepancies”: “According to the authors, 119 respondents reported beginning cross-sex hormones at age 14 or 15. But for the question 'At what age did you begin hormone treatment' (Q12.10), 27 respondents answered at age 14, and 61 answered at age 15, summing to 88. How did the authors obtain an additional 31 observations?”
- The real question is why the authors return again and again to this online survey-- which did not even measure the condition supposed to be treated, namely gender dysphoria--rather than conducting randomized control trials or collecting longitudinal patient data.”

**Turban JL, King D, Carswell JM, et al. Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation.**

Pediatrics Feb 2020, 145 (2) e20191725; DOI: 10.1542/peds.2019-1725

- “Using a cross-sectional survey of 20 619 transgender adults aged 18 to 36 years...” [2015 U.S Transgender Survey. Online survey of transgender and “genderqueer” adults recruited from trans-friendly websites.]
  - Retrospective, cross-sectional (“...cross-sectional design, which does not allow for determination of causation.”).
  - Self-reporting of history of adolescent puberty suppression.
  - Not controlled for other mental health factors. “...it is plausible that those without suicidal ideation had better mental health when seeking care and thus were more likely to be considered eligible for pubertal suppression.” Those with worse mental health would often be denied puberty blockage
  - Desisters and regretters would not likely be in this study group, which also only included adults, so “it does not include outcomes for people who may have initiated pubertal suppression and subsequently no longer identify as transgender.” A very limited group of respondents.
- “those who received treatment with pubertal suppression, when compared with those who wanted pubertal suppression but did not receive it, had **lower odds of lifetime suicidal ideation** (adjusted odds ratio = 0.3; 95% confidence interval = 0.2– 0.6).”
  - This was one measure of 9 that were evaluated, the only positive result reaching statistical significance.
  - But again, “...cross-sectional design, which does not allow for determination of causation.”
- However, Table 3. Under “Suicidality (past 12 mo)” reductions for suppressed group v non were seen for ideation (50.6% v 64.8%) and “ideation with plan” (55.6% v 58.2%). But “ideation with plan and attempt” for the suppressed group went up to 24.4% v 21.5% for non. “Attempt resulting in inpatient care” was 45.5% for suppression groups vs 22.8% for non.

- This study, and most any based on the US Transgender Survey, really tells us little about the effects of puberty suppression on children with gender dysphoria.

**Also contra Turban 2020:**

- Letters to editor against Turban in *Pediatrics*: (All LTEs come under a single URL) <https://pediatrics.aappublications.org/content/145/2/e20191725/tab-e-letters#re-pubertal-suppression-for-transgender-youth-and-risk-of-suicidal-ideation>
  - Scott S. Field, Den A. Trumbull, RE: Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation.
  - Patrick H Clarke, RE: Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation.
    - “The following is a brief summary of the flaws in the Turban et al.’s study, which render their conclusions misleading:
      1. The source study, the United States Transgender Survey 2015 (USTS), employed a non representative, biased convenience sample. The results from this survey are unreliable.<sup>3</sup>
      2. Over 70% of the USTS respondents demonstrably did not know what puberty blockers were, claiming to have commenced treatment after age 18. Although Turban et al. attempted to control for this, a proper adjustment was not possible.
      3. There was no control for underlying mental health. Since more stable individuals are more likely to be eligible for puberty suppression, one cannot discern mental health benefits or harms of puberty suppression without controlling for pre-treatment mental health.
      4. Turban et al. ignored their own finding that a history of puberty suppression was associated with an increase in recent serious suicide attempts.”
- M Biggs, Oxford: “The current article includes pubertal suppression as a confounding variable, but omits to report the result. I will report that it has no statistically significant effect on mental health, which refutes their earlier finding.” ... “having taken puberty blockers has no statistically significant association with any outcome. This reveals that Turban et al.’s earlier finding from the USTS--which did not control for cross-sex hormones--is not robust [5].”
  - Michael Biggs, Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. Archives of Sexual Behavior, accepted 14 May 2020, DOI: 10.1007/s10508-020-01743-6
  - Outstanding refutation of both Turban study and general use of US Transgender Survey.

Turban, J. L., Beckwith, N., Reisner, S. L., & Keuroghlian, A. S. (2020). **Association between recalled exposure to gender identity conversion efforts and psychological distress and suicide attempts among transgender adults.** *JAMA Psychiatry*, 77(1), 68–76. <https://doi.org/10.1001/jama.2020.10000>

org/10.1001/jamap sychi atry.2019.2285.

- Yet again, retrospective/cross-sectional design does not allow for establishing causality, admitted by the authors: “Limitations include its cross-sectional study design, which precludes determination of causation. It is possible that those with worse mental health or internalized transphobia may have been more likely to seek out conversion therapy rather than non-GICE therapy, suggesting that conversion efforts themselves were not causative of these poor mental health outcomes.”
- They then proceed to try to establish causality.

**Summary of Critique by 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>

- Turban et al, claimed that those responding yes to 2015 U.S. Transgender Survey (USTS) question 13.2 -- “Did any professional (such as a psychologist, counselor, religious advisor) try to make you identify only with your sex assigned at birth (in other words, try to stop you being trans)?” – has worse mental health than those answering no, and concluded that gender identity conversion efforts (GICE) should be avoided in all ages.
- Regarding 2015 USTS: “This survey used convenience sampling, a methodology which generates low-quality data (Bornstein, Jager, & Putnick, 2013). Specifically, the participants were recruited through transgender advocacy organizations and subjects were asked to “pledge” to promote the survey among friends and family. This recruiting method yielded a large but highly skewed sample.”
- Section “Invalid Measure of Gender Conversion Therapy” re USTS question 13.2: “Firstly, the question conflates mental health encounters with interactions with other types of professionals. Secondly, there is no information about whether the recalled encounter was self-initiated or coerced. Thirdly, it does not differentiate between diagnostic evaluations or a specific therapeutic intervention. There is also no information about whether the focus of the encounter was gender dysphoria or another condition. And finally, it does not determine whether shaming, threats, or other unethical tactics were utilized during the encounter.”
- “Their analysis is compromised by serious methodological flaws, including the use of a biased data sample, reliance on survey questions with poor validity, and the omission of a key control variable, namely subjects’ baseline mental health status.”
- Misinterpretation of K-6 scale. “The K-6 scale, and its cutoff score of  $\geq 13$ , was specifically developed by Kessler et al. (2003 ) in order to discriminate between cases of non-specific psychological distress and cases of serious mental illness (SMI). Scoring  $\geq 13$  is predictive of having a DSM diagnosis of schizophrenia, bipolar disorder, and a range of other major mental health conditions that cause serious functional impairment (Substance Abuse and Mental Health Services Administration, 2020 ). Thus, Turban et al.’s (2020 ) finding of an association between the recall of GICE and scoring  $\geq 13$  actually suggests that the USTS participants recalling GICE were more likely to have a severe mental illnesses diagnosis than those not recalling GICE.”

- Section “Omission of a Key Control Variable”: “In fact, failure to control for the subjects’ baseline mental health makes it impossible to determine whether the mental health or the suicidality of subjects worsened, stayed the same, or potentially even improved after the non-affirming encounter.”
- Section “Internal Inconsistencies in Mental Health”: “Another measure of psychological distress chosen by Turban et al.—substance misuse—was not significantly different between GICE and the non-GICE group. More importantly, there is a lack of consistency in the suicide measures. While lifetime suicide attempts were elevated among the GICE group, total suicide attempts in the prior 12 months, as well as suicide attempts requiring hospitalization, which generally indicate more serious attempts rather than non-suicidal self-injury, were not significantly different between the two groups.”
- “Further, Turban et al.’s choice to interpret the said association as evidence of harms of GICE disregards the fact that neither the presence nor the direction of causation can be discerned from this study due to its cross-sectional design.”
- “Arguably, even more problematic than the flawed analysis itself is the simplistic “affirmation” versus “conversion” binary, which permeates Turban et al.’s (2020 ) narrative and establishes the foundation for their analysis and conclusions.” ... “at worst, it effectively mis-categorizes ethical psychotherapies that do not fit the “affirmation” descriptor as conversion therapies. Stigmatizing non-“affirmative” psychotherapy for GD as “conversion” will reduce access to treatment alternatives for patients seeking non-biomedical solutions to their distress.”
- “Turban et al.’s (2020 ) unproven assertion that non-affirming therapies are dangerous stands in contrast to the documented risks and uncertainties associated with hormonal and surgical interventions that are a core part of the “affirmation” treatment path.”
- “We call on the scientific community to resist the stigmatization of psychotherapy for GD and to support rigorous outcome research investigating the effectiveness of various psychological treatments aimed at ameliorating or resolving GD.”

**CORRECTIONS TO FL DRAFT**

Andre Van Mol, MD

May 13, 2022

P.3 item under “Behavioral Health Issues...”, 2<sup>nd</sup> to last sentence.

Issue of behavioral health preceding gender dysphoria diagnosis.

- 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. 87% female.<sup>1</sup>
- 2014. Four nation European study found almost **70%** of people with gender identity disorder had “**a current and lifetime diagnosis**.”<sup>2</sup>
- **2018. Lisa Littman’s** parental survey of Rapid Onset Gender Dysphoria:<sup>3</sup>
  - 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
  - 83% female.
- **Kaiser-Permanente study** 2018 (Becerra-Culqui): Mental Health of Transgender and Gender Nonconforming Youth Compared With Their Peers.<sup>4</sup>
  - Gleaned from **electronic medical records of 8.8M members** in GA and CA.
  - **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: **psych disorders 7 times higher overall**, vast PR for certain ones, **psych hospitalizations 22-44 times higher, self harm 70-144 times higher, suicidal ideation 25-54 times higher** (Tables 3 & 4 of study).
  - Suicidal ideation during said 6 months before GNC findings: 7% in biological males and 5% in biological females. Far below rates claimed by activists, but still high.

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<sup>1</sup> Kaltiala-Heino R, Sumia M, Työläjäarvi 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.

<sup>2</sup> 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.

<sup>3</sup> 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>

<sup>4</sup> 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.



P.4 item under “Behavioral Health Services:” final sentence.

- “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.” – Steven B. Levine, MD<sup>5</sup>

P.5 first paragraph, first sentence regarding “standard of care for gender dysphoria”

- The Endocrine Society Guidelines specifically stated, “The guidelines cannot guarantee any specific outcome, **nor do they establish a standard of care**”:  
“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.”<sup>6</sup> P. 3895.
- 2017 Endocrine Society Guidelines for treatment of gender dysphoric/gender-incongruent persons recommended puberty blocking and cross-sex hormone administration to selected minors **citing “low evidence” and genital surgery for selected adults citing “very low evidence.”**

P.7 “Neuroanatomical Etiology” and brain studies with MRIs.

#### **Neuroimaging and Neuroplasticity.**

- Neuroimaging:  
Prof. Lawrence Mayer, 2016: “...it is now widely recognized among psychiatrists and neuroscientists who engage in brain imaging research that there are inherent and ineradicable methodological limitations of any neuroimaging study that simply associates a particular trait, such as a certain behavior, with a particular brain morphology.”<sup>7</sup>
- Neuroplasticity is a well-established principle. The brain changes with exposures and behaviors.<sup>8</sup> The “brain as muscle” analogy.
- 1997, Dr. Mark Breedlove (then at UC Berkeley), “. . . sexual experience can alter the structure of the brain, just as genes can alter it. [I]t is possible that differences in sexual behavior cause (rather than are caused by) differences in the brain.”<sup>9</sup>

#### **Brain Sex?**

- Neurons have nuclei on which sex is stamped.

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<sup>5</sup> Stephen B. Levine (2018): Informed Consent for Transgendered Patients, *Journal of Sex & Marital Therapy*, DOI: 10.1080/0092623X.2018.1518885

<sup>6</sup> 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>

<sup>7</sup> Mayer L and McHugh P, “Sexuality and Gender: Findings from the Biological, Psychological, and Social Sciences,” [TheNewAtlantis.com](http://TheNewAtlantis.com), Fall 2016, p. 103.

<sup>8</sup> Gu J, Kanai, R. “What contributes to individual differences in brain structure?” *Front Hum Neurosci.* 2014 Apr 28;8:262. doi: 10.3389/fnhum.2014.00262.

<sup>9</sup> Breedlove, M.S. (1997), “Sex on the brain,” *Nature*, 389, p. 801.

- Research has failed to establish that there is such a thing as a female brain or a male brain.<sup>10</sup>
- Researchers analyzed MRIs of more than 1,400 human brains from four datasets. They found extensive overlap between ‘females and males for all gray matter, white matter, and connections assessed.’ “These findings are corroborated by a similar analysis of personality traits, attitudes, interests, and behaviors of more than 5,500 individuals which reveals that internal consistency is extremely rare....**although there are sex/gender differences in the brain, human brains do not belong to one of two distinct categories: male brain/female brain.**”<sup>11</sup>

P.10 “Desistance of Gender Dysphoria and Puberty Suppression” sentence 2 about “can provide extra time for adolescents to explore...”

**MYTH of Buying TIME**<sup>12 13 14</sup>

- Puberty blocking is sold as “wait and see,” “buying time,” or “pause button”.<sup>15</sup>
  - It selects persistence rather than likely natural desistance.
  - Gateway drug committing a child to cross sex hormones and SRS.
- Laidlaw, et al: “In a study of 70 adolescents who were followed **after receiving PBA, 100% desired to continue on to cross-sex hormones** (de Vries et al. 2011). The natural patten of desistance has been broken...”<sup>16</sup>

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<sup>10</sup> Jordan-Young, R.M. Hormones, context, and “brain gender”: A review of evidence from congenital adrenal hyperplasia. (2012). *Social Science & Medicine*, 74, 1738-1744. <https://doi.org/10.1016/j.socscimed.2011.08.026>

<sup>11</sup> Joel, D., Berman, Z., Tavor, L., et al. Sex beyond the genitalia: The human brain mosaic. (2015). *PNAS*, 112(50), 15468-15473. [www.pnas.org/cgi/doi/10.1073/pnas.1509654112](http://www.pnas.org/cgi/doi/10.1073/pnas.1509654112)

<sup>12</sup> Singh, Devita. “A Follow up Study of Boys with Gender Dysphoria.” *nymag.com*, 2012, [images.nymag.com/images/2/daily/2016/01/SINGH- DISSERTATION.pdf](https://images.nymag.com/images/2/daily/2016/01/SINGH- DISSERTATION.pdf).

<sup>13</sup> Michael Laidlaw, Michelle Cretella, Kevin Donovan, *The Right to Best Care for Children Does Not Include the Right to Medical Transition*, *American Journal of Bioethics*, 19 (2):75-77 (2019). <https://doi.org/10.1080/15265161.2018.1557288>.

<sup>14</sup> de Vries, A. L. C., T. D. Steensma, T. A. H. Doreleijers, and P. T. Cohen-Kettenis. 2011. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *The Journal of Sexual Medicine* 8(8): 2276–2283. doi: 10.1111/j.1743-6109.2010.01943.x).

<sup>15</sup> 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..

<sup>16</sup> Michael Laidlaw, Michelle Cretella, Kevin Donovan, *The Right to Best Care for Children Does Not Include the Right to Medical Transition*, *American Journal of Bioethics*, 19 (2):75-77 (2019). <https://doi.org/10.1080/15265161.2018.1557288>

Cited: de Vries, A. L. C., T. D. Steensma, T. A. H. Doreleijers, and P. T. Cohen-Kettenis. 2011. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *The Journal of Sexual Medicine* 8(8): 2276–2283. doi: 10.1111/j.1743-6109.2010.01943.x.

- The **discontinuation rate** for transition **after initiating PB is low**. 1.4% per Wiepjes, et al.,<sup>17</sup> 1.9% per Brik, et al.,<sup>18</sup> and 3.5% per Kuper, et al.<sup>19</sup>, and 2% per Carmichael, et al.<sup>20</sup>

P.13 first paragraph, 2<sup>nd</sup> sentence about “standard treatment for gender dysphoria”.

- Experimental, not proven effective or safe.
- The Endocrine Society Guidelines specifically stated, “The guidelines cannot guarantee any specific outcome, **nor do they establish a standard of care**”:  
“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.”<sup>21</sup> P. 3895.

P.19 last paragraph, 4<sup>th</sup> line down, “recommend that only adults (18 years old) undergo sex reassignment surgery...”

- But mastectomies are being done to 13 year olds.
- **Olson-Kennedy, 2018, JAMA Peds about Mastectomies on minors:**
  - **Questionable claim:** “Chest dysphoria was high among presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults.”
    - 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
  - **Problems:**
    - “Chest dysphoria” is a neologism of convenience, not a DSM-5 diagnosis.

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<sup>17</sup> 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(4):582–590

<sup>18</sup> Brik T, Vrouwenraets LJ, de Vries MC, Hannema SE. Trajectories of adolescents treated with gonadotropinreleasing hormone analogues for gender dysphoria [published online ahead of print March 9, 2020]. *Arch Sex Behav.* doi:10.1007/s10508-020-01660-8

<sup>19</sup> Kuper LE, Stewart S, Preston S, Lau M, Lopez X. Body dissatisfaction and mental health outcomes of youth on gender-affirming hormone therapy. *Pediatrics.* 2020;145(4):e20193006

<sup>20</sup> 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

<sup>21</sup> 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>

- The “chest dysphoria scale” measuring tool of the authors and “is not yet validated.” (p. 435)
- **Mastectomies were done on girls as young as 13 or 14 yo** lacking the capacity for mature decision making or informed consent.
- Study seems flawed and unethical.

P.21 “Branstrom et al’s study”

- 2019 (online) Bränström and Pachankis. First total population study of 9.7 million Swedish residents.<sup>22</sup> Ultimately showed neither “gender-affirming hormone treatment” nor “gender-affirming surgery” provided reductions of the mental health treatment benchmarks examined.<sup>23 24</sup>

**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>

**Quick summary version:**

In 2019 (online) **Bränström and Pachankis** published the first total population study of 9.7 million Swedish residents titled, “Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study.” Looking at three limited measures of mental health service usage, they claimed that although “gender-affirming hormone treatment” provided no improvement, “gender-affirming surgeries” did.

- **The online August 1, 2020 American J of Psychiatry edition contained seven critical letters, including ours; a major “correction” paragraph from the editors retracting the studies main finding, and a letter from the study authors conceding their “conclusion” “was too strong.”**
- In effect, the Bränström and Pachankis study demonstrated that neither “gender-affirming hormone treatment” nor “surgery” provided reductions of the mental health treatment benchmarks examined in transgender-identified people.
  - 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>

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<sup>22</sup> 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>

<sup>23</sup> 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>

<sup>24</sup> Andre Van Mol, Michael K. Laidlaw, Miriam Grossman, Paul R. McHugh. Gender-Affirmation Surgery Conclusion Lacks Evidence. Am J Psychiatry 2020; 177:765–766; doi: 10.1176/appi.ajp.2020.19111130.

[Other six are found in the endnotes of Branstrom Response to Letters below. doi: 10.1176/appi.ajp.2020.20050599.]

- Andre Van Mol, Michael K. Laidlaw, Miriam Grossman, Paul R. McHugh. Gender-Affirmation Surgery Conclusion Lacks Evidence. *Am J Psychiatry* 2020; 177:765–766; doi: 10.1176/appi.ajp.2020.19111130. [Other six are found in the endnotes of Branstrom Response to Letters below. doi: 10.1176/appi.ajp.2020.20050599.]
- 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>
- Richard Bränström and John E. Pachankis. Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals' Mental Health: Response to Letters. *American Journal of Psychiatry* 2020 177:8, 769-772 doi: 10.1176/appi.ajp.2020.20050599.

P.23, last paragraph concerned “2022 Olson”

### **Social Transitioning**

- **Social transitioning** by itself leads to persistence of GD:
  - From **the Endocrine Society guidelines** themselves, even “**Social transition is associated with the persistence of GD** as a child progresses into adolescence.”<sup>25</sup>
  - Ken Zucker: “Gender **social transition** of prepubertal children will **increase dramatically the rate of gender dysphoria persistence** when compared to follow-up studies of children with gender dysphoria who did not receive this type of psychosocial intervention and, oddly enough, **might be characterized as iatrogenic**.”<sup>26</sup>
- Please see again the prior section on PBA use selecting persistence over natural desistance.

Additional Comments on “Regret” Rates.

- Regret rates with GAT are not low, and studies underestimate them due to “overly stringent definitions of regret” “very high rates of participant loss to follow-up (22%-63%) (D’Angelo, 2018 )...”<sup>27</sup>

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<sup>25</sup> Hembree, W., Cohen-Kettenis, et al., (2017) Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*,102:1–35.

<sup>26</sup> Zucker, K. Debate: Different strokes for different folks. *Child and Adolescent Mental Health*. Accepted for publication: 18 March 2019.

<sup>27</sup> 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](https://doi.org/10.1177/1039856218775216)

- The chemical sterilization/castration and surgical mutilation of normal sex organs in children is not healthcare.

#### Lack of Randomized Controlled Trials

- Zucker, 2019. "...the field suffers from a vexing problem: There are **no randomized controlled trials (RCT) of different treatment approaches**, so the front-line clinician has to rely on lower-order levels of evidence in deciding on what the optimal approach to treatment might be."<sup>28</sup>
- Hruz, 2020. **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."<sup>29</sup>
- Levine, 2020. "The fact that modern patterns of the **treatment of trans individuals are not based on controlled or long-term comprehensive follow-up studies** has allowed many ethical tensions to persist."<sup>30</sup>

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<sup>28</sup> Zucker, K. J. (2019), Debate: Different strokes for different folks. *Child Adolesc Ment Health*. doi:[10.1111/camh.12330](https://doi.org/10.1111/camh.12330)

<sup>29</sup> 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>

<sup>30</sup> 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>

4:22

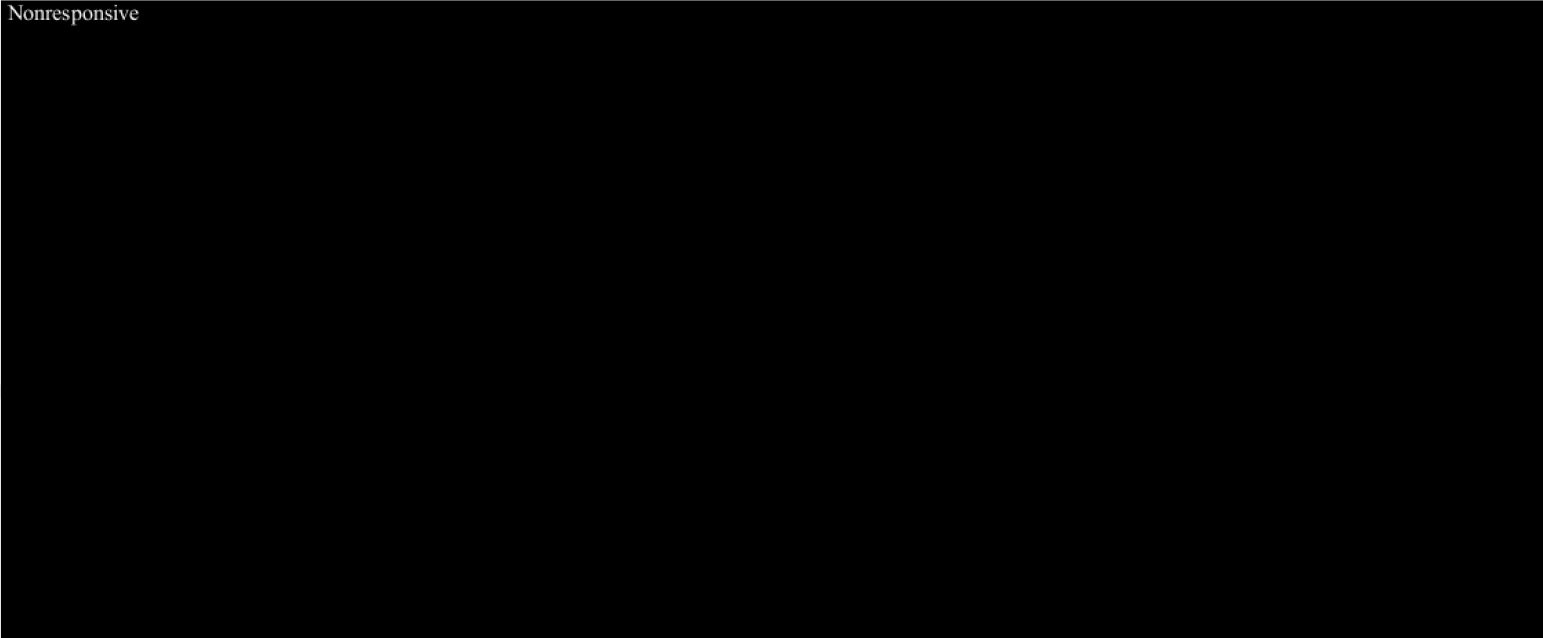
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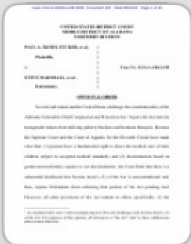
Jason >



Nonresponsive



Mon, May 16 at 3:59 PM



**eknes-tucker-ruling-on-pi-5-13-22.pdf**  
PDF Document · 208 KB

Mon, May 16 at 5:43 PM

The judge isn't very nice to our friend James Cantor

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**From:** Williams, Susan C.  
**Sent:** Monday, May 23, 2022 11:29 AM EDT  
**To:** \"Rubin\", \" Kelly; \"Forbes\", \" Jesseka; Kelly.Rubin@ahca.myflorida.com; Jesseka.Forbes@ahca.myflorida.com  
**Subject:** RE: Document  
**Attachments:** image001.png

Not at this time.

---

**From:** Rubin, Kelly <Kelly.Rubin@ahca.myflorida.com>  
**Sent:** Monday, May 23, 2022 10:23 AM  
**To:** Williams, Susan C. <Susan.Williams@ahca.myflorida.com>; Forbes, Jesseka <Jesseka.Forbes@ahca.myflorida.com>  
**Subject:** RE: Document

Nai has been in here multiple times talking about this issue and looking for federal statute to clarify if we must pay or not pay for this.

Do you think it would help to let him review this?

Cole just said he wants draft responses on the SPA letter so we can discuss tomorrow, so I'm not going to read this right now.

Kelly D. Rubin, R.Ph.  
Senior Pharmacist  
Medicaid Policy Bureau  
Agency for Health Care Administration  
Phone: 850-412-4163  
Fax: 850-410-3309



---

**From:** Williams, Susan C. <[Susan.Williams@ahca.myflorida.com](mailto:Susan.Williams@ahca.myflorida.com)>  
**Sent:** Monday, May 23, 2022 9:35 AM  
**To:** Rubin, Kelly <[Kelly.Rubin@ahca.myflorida.com](mailto:Kelly.Rubin@ahca.myflorida.com)>; Forbes, Jesseka <[Jesseka.Forbes@ahca.myflorida.com](mailto:Jesseka.Forbes@ahca.myflorida.com)>  
**Subject:** Document

Please review the updated from Shantrice.

---

**From:** Greene, Shantrice <[ShantriceR.Greene@ahca.myflorida.com](mailto:ShantriceR.Greene@ahca.myflorida.com)>  
**Sent:** Friday, May 20, 2022 3:47 PM  
**To:** Williams, Susan C. <[Susan.Williams@ahca.myflorida.com](mailto:Susan.Williams@ahca.myflorida.com)>; Forbes, Jesseka



<[Jesseka.Forbes@ahca.myflorida.com](mailto:Jesseka.Forbes@ahca.myflorida.com)>

**Subject:** Gender Dysphoria Document

Greetings,

Attached is the revised Cross-Sex Hormone Therapy Document for your review.

Thank you,

---

**Shantrice R. Greene** – Senior Pharmacist  
+1 850-412-4232 (Office)



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AHCA Bldg 3 Rm 2325A – Bureau of Medicaid Policy  
2727 Mahan Drive Tallahassee, FL 32308  
[ShantriceR.Greene@ahca.myflorida.com](mailto:ShantriceR.Greene@ahca.myflorida.com)



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RICK SCOTT  
GOVERNOR

JUSTIN M. SENIOR  
INTERIM SECRETARY

**CROSS-SEX HORMONE THERAPY  
GAPMS DETERMINATION REPORT WITH RECOMMENDATION**

**Date:** ~~{DATE}~~ May 20, 2022  
**To:** ~~Both Kidder, Interim Deputy Secretary for Medicaid~~ Ashley Peterson  
**From:** Bureau of Medicaid Policy  
**Subject:** ~~Cross-Sex Hormone Therapy~~

**PURPOSE**

~~In order for~~ For the use of cross-sex hormone therapy to be covered under the Florida Medicaid program, it must meet medical necessity criteria as defined in Rule 59G-1.010, Florida Administrative Code (F.A.C.), and be funded through the General Appropriations Act of Chapter 216, Florida Statutes (F.S.).

Pursuant to the criteria set forth in Rule 59G-1.010, F.A.C., the use of cross-sex hormone therapy must be consistent with generally accepted professional medical standards (GAPMS) as determined by the Medicaid program, and not experimental or investigational.

In accordance with the determination process established in Rule 59G-1.035, F.A.C., the Deputy Secretary for Medicaid will make the final determination as to whether the use of cross-sex hormone therapy is consistent with generally accepted professional medical standards and not experimental or investigational.

If it is determined that cross-sex hormone therapy is consistent with generally accepted professional medical standards, this report will be supplemented with an addendum which analyzes additional factors to determine whether this health service should be covered under the Florida Medicaid program.

**RECOMMENDATION**

This report recommends cross-sex hormone therapy as a health service that is consistent with generally accepted professional medical standards and is supported in compendia as off-label use. There are clinical guidelines that have been published for the use of cross-sex hormones by the Endocrine Society, September 2009 and the World Professional Association for Transgender Health (WPATH 7<sup>th</sup> version). These guidelines are considered standards of care for transgender patients and provide parameters to determine the diagnosis of gender dysphoria, at what age to start treatment of cross-sex hormone therapy, and monitoring parameters that should be in place during treatment.

Veteran's Administration, Centers for Medicaid and Medicare, many commercial and Medicaid plans have protocols in place to provide access of the use of cross-sex hormone therapy in transgender patients.

**Commented [GS1]:** Newest guidelines published April Dec 2016  
[Hormone therapy for transgender patients - PMC \(nih.gov\)](https://pubmed.ncbi.nlm.nih.gov/31822222/)

**Commented [GS2]:** Cross-Sex hormones are usually recommended at the age of sixteen.

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## REPORT WITH RECOMMENDATION

This report with recommendation is presented as the summary assessment considering the factors identified in Rule 59G-1.035, F.A.C., based on the collection of information from credible sources of reliable evidence-based information. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- A ~~high level~~ **high-level** review of relevant disease processes.
- An overview of the health service information.
- Clearance from the government regulatory body (e.g., Food and Drug Administration).
- Evidence based clinical practice guidelines.
- A review of the literature considered by the relevant medical community or practitioner specialty associations from credible scientific evidence-based literature published in peer reviewed journals and
- Consensus of coverage policy from commercial and other state Medicaid insurers.

## HEALTH SERVICE SUMMARY

### Reproductive Hormones

The hormones commonly considered as reproductive hormones in the body are testosterone, estrogen, and progesterone. Testosterone is often referred to as a male hormone, and estrogen and progesterone are often referred to as female hormones. However, there are ~~not~~ exclusively male or female hormones that have been identified. The physical manifestations of gender result from differences in the amounts of individual hormones in the body and differences in their patterns of secretion, first in utero and then again during puberty. In other words, testosterone, estrogen, and progesterone are produced by men and women, but in differing amounts and in different patterns.

### Cross-Sex Hormone Therapy

Cross-sex hormone therapy assists transgender patients to reflect the desired sex through physical changes. This is accomplished by increasing the testosterone in assigned females at birth, in conjunction with suppressing the estrogen in their bodies. Assigned males at birth will have their testosterone levels suppressed while their estrogen levels will be increased.

Currently, there are drugs approved by the FDA that increase testosterone in men with hypogonadism and increase estrogen in women for various approved indications in addition to men with advanced prostate cancer (Analytics, 2016). Estrogen and testosterone are the medications mainly used in cross-sex hormone therapy. Female to Male (FTM) patients, are prescribed testosterone, unless contraindicated. Male to Female patients, are prescribed estrogen, unless contraindicated (Levine, 2013). Anti-androgen agents may be used in conjunction with cross-sex hormone therapy, such as: progestins, gonadotropin releasing hormone agonists, spironolactone, or 5-alpha reductase inhibitors.

Testosterone has a variety of available formulations: ~~buccal~~ **oral**, intramuscular (IM), topical, transdermal, and ~~intranasal~~ **subcutaneous**. ~~The oral formulation of testosterone is not available in the United States.~~ FTM patients most commonly use transdermal/topical, or IM routes of

**Commented [GS3]:** Cross-Sex Hormone therapy remains the same. (Table 1 and 2 of article)

**Commented [GS4]:** Testosterone current formulations are include subcutaneous now. (Parental and Implant). Oral Testosterone Undecanoate is now available in the U.S. (Tiando and Jatzeno).

Table 1 of article

administration because it provides better hormone levels. Estrogen also has various formulations available: transdermal, ~~vaginal, spray~~, oral, ~~subcutaneous~~, and intramuscular. The most common route of administration for (MTF): oral, IM or transdermal (Tangpricha, 2016). For the purposes of this report, an analysis is being performed on the use of cross-sex hormone therapy concentrating on testosterone and estrogen.

**Commented [GS5]:** Estrogen current formulations include: Oral, Parental (SubQ, IM), Transdermal and SubQ implant. No mention of vaginal or spray formulations.

### Government Regulatory Body Approval

The Food and Drug Administration (FDA) has approved testosterone for hypogonadism in men and estrogen is approved in women for various indications (see below) and for men with advanced prostate cancer:

Testosterone (testosterone cypionate, testosterone enanthate, testosterone undecanoate)

- Indications for use: Primary hypogonadism or hypogonadotropic hypogonadism in men
- Off Label Use: various doses used in clinical trials, including testosterone cypionate 200mg IM every 2 weeks for gender identity disorder female- to male transsexual (Analytics, 2016)
- Possible side effects of testosterone FTM therapy: acne, polycythemia, dyslipidemia, transaminitis, weight gain, hypertension and mood lability. After 6 to 8 weeks of hormone treatment of testosterone, deepening of the voice occurs and is irreversible (Gibson et al., 2010)

### Testosterone options for transgender men

<u>Route</u>	<u>Formulation</u>	<u>Dosing</u>
<u>Oral (not available in United States)</u>	<u>Testosterone undecanoate</u>	<u>160–240 mg/day</u>
<u>Parental (subcutaneous, intramuscular)</u>	<u>Testosterone enanthate, cypionate</u>	<u>50–200 mg/week</u> <u>100–200 mg/10–14 days</u>
<u>Implant (subcutaneous)</u>	<u>Testopel®</u>	<u>75 mg/pellet</u>
<u>Transdermal</u>	<u>Testosterone gel (1%)</u> <u>Testosterone patch</u>	<u>2.5–10 g/day</u> <u>2.5–7.5 mg/day</u>

- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5182227/#:~:text=for%20some%20patients.,Table%201,2.5%E2%80%937.5%20mg/day,-Open%20in%20a>

Estrogen (conjugated estrogens, esterified estrogens, estradiol, estradiol acetate, estradiol cypionate, estradiol valerate)

- Indications for use: Advanced prostate cancer- androgen dependent men, metastatic breast cancer, lower than normal estrogen levels in women,

prevention of osteoporosis (postmenopausal), vulvovaginal, vulvovaginal atrophy (menopausal), and moderate to severe menopausal vasomotor symptoms

- Off Label use: Conjugated estrogens, 17-beta estradiol and ethinyl estradiol may be effective in changing the physical external appearance for male to female transsexuals (Analytics, 2016)

#### Estrogen and anti-androgen options for transgender women

<u>Route</u>	<u>Formulation</u>	<u>Dosing</u>
<u>Oral</u>	<u>Estradiol</u>	<u>2–4 mg daily</u>
<u>Parental (subcutaneous, intramuscular)</u>	<u>Estradiol valerate</u>	<u>5–30 mg every 2 weeks</u>
<u>Transdermal</u>	<u>Estradiol</u>	<u>0.1–0.4 mg twice weekly</u>
<u>Anti-androgens</u>	<u>Progesterone</u>	<u>20–60 mg PO daily</u>
	<u>Medroxyprogesterone acetate</u>	<u>150 mg IM every 3 months</u>
	<u>GnRH agonist (leuprolide)</u>	<u>3.75–7.5 mg IM monthly</u>
	<u>Histrelin implant</u>	<u>50 mg implanted every 12 months</u>
	<u>Spironolactone</u>	<u>100–200 mg PO daily</u>
	<u>Finasteride</u>	<u>1 mg PO daily</u>

[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5182227/#:~:text=profiles%20\(14\).-.Table%202.1%20mg%20PO%20daily,-Open%20in%20a](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5182227/#:~:text=profiles%20(14).-.Table%202.1%20mg%20PO%20daily,-Open%20in%20a)

- Side effects of estrogen in MTF therapy: decreased facial and body hair, fat redistribution, decreased spontaneous erections, softened skin, growth of breast tissue, and growth plate closure, increased risk of thromboembolic disease, liver dysfunction, cholelithiasis, hypertension, and hyperprolactinemia. Breast development will begin almost immediately upon estrogen administration, will proceed in a cyclical fashion, and will be as large as can be expected after approximately two years of treatment.

## LITERATURE REVIEW

### Gender Dysphoria

The Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria (GD) (formally referred to as gender identity disorder) as an individual's affective or cognitive discontent with their assigned gender at birth. GD refers to the **distress** that may accompany the incongruence between the individual's experienced or expressed gender and their assigned gender. Evidence of this distress is the hallmark of the disorder. The diagnostic criteria are divided into a category for children and a category for adolescents and adults. The disorder is manifested differently as the individual ages or enters different developmental stages. Both categories require marked incongruence between the individual's experienced or expressed

gender and their assigned gender of at least a six months' duration and clinically significant distress or impairment in social, school (occupation for adults), or other important areas of functioning (Association, 2014)

Diagnostic criteria in children include: a strong desire to be the other gender or an insistence that they are the other gender; a preference for wearing clothing associated with the other gender; preference for cross gender roles in simulated play; preference for toys, games, or activities usually associated with the other gender; preference for playmates of the other gender; and the dislike of their sexual anatomy. Studies have shown that ~~the majority of most~~ children (80%) diagnosed with gender dysphoria will not continue to be gender dysphoric after puberty (Moller et al., 2009; Wallien & Cohen-Kettenis, 2008; and Drummond et al., 2008).

For the 20% of children who persist in their feelings of gender dysphoria, clinicians may begin to explore alternative treatment approaches beyond psychotherapy after the onset of puberty, including medical interventions such as the use of gonadotropin releasing hormone (GnRH) analogs to suppress puberty. It is generally introduced in children who have reached a minimum of Tanner Stage 2 (a scale used to determine physical development in children, adolescents and adults based on external primary and secondary sex characteristics) which is usually at the age of 12-16 (Cohen-Kettenis et al.2011). Other drugs, such as progestins and antiandrogens (spironolactone and 5-alpha reductase inhibitors) have been used to suppress physical changes in puberty. In addition to puberty suppression therapy, a physician may also begin to prescribe cross-sex hormones, though the latter does not generally begin until the ages of 16-18 (de Vries et al. 2011).

Cross-sex hormone therapy is the primary medical intervention sought by transgender people. Exogenous hormones have a clear impact on fertility. Patients must be informed and counseled regarding options for fertility and evaluation of medical conditions that can be exacerbated by hormone depletion, prior to treatment with sex hormones of the desired sex in both adolescents and adults. The patient must be made aware of the possibility of infertility/sterilization with the use of cross-sex hormone therapy. Fertility preservation options may include sperm, oocyte, embryo, ovarian tissue or testicular tissue cryopreservation. Transgender patients who undergo fertility preservation or assisted reproduction should be informed of the lack of data on outcomes. The use of cross-sex therapy alone does not guarantee prevention of pregnancy, if sexually active contraception is required. Testosterone is a teratogen and is contraindicated in pregnancy. The effects of ~~long-term~~long-term exogenous testosterone and estrogen are unclear, but the possible side effects should be addressed (Francisco, Center, and Information, 2016)

It is important to note that most of the literature reviewed in development of this analysis concluded that more systematic research is required to determine the long-term efficacy of medical treatment for adolescents with gender dysphoria (Kaltiala-Heino et al. 2015; Jarin et al. 2016; Lee et al. 2016, March et al. 2015; Vance et al. ~~2014;~~Vrouenraets2014; Vrouenraets et al 2015)

### Clinical Outcome

No perspective, randomized, controlled trials were located that have evaluated the safety and efficacy of the use of cross-sex hormones to produce physical effects in transgender patients. The current information used has been derived primarily from observational study or has been extrapolated from the use of hormones for the approved FDA indications (Tangpricha, 2016).

**Commented [G56]:** Still valid per article "Gender Dysphoria in Children" published November 2018  
[Gender Dysphoria in Children | American College of Pediatricians \(acped.org\)](#)

This analysis summarizes information obtained from scientific literature published in credible peer-reviewed journals related to the use of cross-sex hormone therapy. This section also briefly cites the positions from the relevant medical societies, and summarizes the key articles referenced in support of their positions.

Recommendations from The Endocrine Society Guidelines are as follows:

- We recommend that the diagnosis of gender identity disorder (GID) be made by a mental health professional (MHP). For children and adolescents, the MHP should also have training in child and adolescent developmental psychopathology.
- Given the high rate of remission of GID after the onset of puberty, we recommend against a complete social role change and hormone treatment in pre-pubertal children with GID
- We recommend that physicians evaluate and ensure that applicants understand the reversible and irreversible effects of hormone suppression (~~e.g.e.g.~~, GnRH analog treatment) and cross-sex hormone treatment before they start hormone treatment.
- We recommend that all transsexual individuals be informed and counseled regarding options for fertility prior to initiation of puberty suppression in adolescents and prior to treatment with sex hormones of the desired sex in both adolescents and adults.
- We suggest that pubertal development of the desired opposite sex be initiated at about the age of 16 year, using a gradually increasing dose schedule of cross-sex steroids.
- We recommend referring hormone-treated adolescents for surgery when 1) the real-life experience (RLE) has resulted in a satisfactory social role change; 2) the individual is satisfied about the hormonal effects; and 3) the individual desires definitive surgical changes.
- We suggest that treatment with GnRH analogs be continued during treatment with cross-sex steroids to maintain full suppression of pituitary gonadotropin levels and, thereby, gonadal steroids. When puberty is initiated with a gradually increasing schedule of sex steroid doses, the initial levels will not be high enough to suppress endogenous sex steroid secretion
- Baseline labs and scheduled routine monitoring for known risks throughout adulthood
- Maintain physiologic levels of appropriate sex hormones in the range of the desired gender and monitor for known risks of gender-appropriate sex hormones
- Lifetime continuation of cross-sex hormone therapy usually required unless medically ~~contraindicated~~ contraindicated (Hembree et al., 2009)

WPATH Version 7 Standard of Care recommendations for Cross-Sex Hormone therapy:

- Persistent, well-documented gender ~~dysphoria~~ dysphoria.
- Capacity to make a fully informed decision and to consent for ~~treatment~~ treatment.
- If significant medical or mental health concerns are present, they must be reasonably well controlled.
- Mental health professional competent in diagnosing and treating ordinary problems of children and adolescents; trained in childhood and adolescent developmental psychopathology; and must meet the competency requirements for mental health professionals working with adults.

- A staged process of physical interventions of adolescents is recommended to allow the adolescents and their parents to assimilate fully the effects of earlier interventions: fully reversible interventions (~~i.e.~~, GnRH analogues, spironolactone, progestins) partially reversible interventions (~~i.e.~~, hormone therapy to masculinize or feminize the body, cross-sex hormones) and irreversible interventions (surgical procedures).
- Adolescents may be eligible to begin feminizing/masculinizing hormone therapy preferably with parental consent at 16.
- Regimens for hormone therapy in gender dysphoric adolescents differ substantially from those used in adults (Hembree et al., 2009). The hormone regimen is adjusted to account for emotional, somatic and mental development that occurs throughout adolescence.

#### Possible risk Factors associated with Cross-Sex Hormone therapy:

- Adolescents undergoing partially reversible cross-gender hormone therapy should be monitored for progress in transition and for any potential medical complications.
- MTF patients started on estrogen might develop deep venous thrombosis, prolactinomas, hypertension, hypertriglyceridemia, cardiovascular disease, type 2 diabetes, liver disease, and decreased libido and are at increased risk of breast cancer. Spironolactone can lead to hyperkalemia and decreased blood pressure.
- FTM patients receiving testosterone may develop hyperlipidemia, polycythemia, male pattern baldness, acne, cardiovascular disease, hypertension, type 2 diabetes, breast cancer, cervical cancer, ovarian cancer, uterine cancer, destabilization of certain psychiatric disorders (~~i.e.~~, bipolar, schizoaffective disorders (Hembree et al., 2009; Tangpricha, 2016)

#### Monitoring for FTM on hormone therapy:

- Monitor for virilizing and adverse effects every 3 months for first year and then every 6 – 12 months.
- Monitor serum testosterone at follow-up visits with a practical target in the male range (300 – 1000 ng/dl). Peak levels for patients taking parenteral testosterone can be measured 24 – 48 h after injection. Trough levels can be measured immediately before injection.
- Monitor hematocrit and lipid profile before starting hormones and at follow-up visits.
- Bone mineral density (BMD) screening before starting hormones for patients at risk for osteoporosis. Otherwise, screening can start at age 60 or earlier if sex hormone levels are consistently low.
- FTM patients with cervixes or breasts should be screened appropriately. (~~site~~**Site reference**)
- Monitor renal function, liver function ~~tests~~ **fasting** glucose, insulin, hemoglobin A1C, bone density and bone age.
- FTM patients should have axillary lymph nodes examined (Gooren et al., 2008; Jain & Bradbeer, 2007; Sobralske, 2005).

#### Monitoring for MTF on hormone therapy:



- Monitor for feminizing and adverse effects every 3 months for first year and then every 6– 12 months.
- Monitor serum testosterone and estradiol at follow-up visits with a practical target in the female range (testosterone 30 – 100 ng/dl; E2 <200 pg/ml).
- Monitor prolactin and triglycerides before starting hormones and at follow-up visits.
- Monitor potassium levels if the patient is taking spironolactone.
- Bone mineral density screening before starting hormones for patients at risk for osteoporosis. Otherwise, start screening at age 60 or earlier if sex hormone levels are consistently low.
- MTF patients should be ~~be~~ advised to do breast self-exams and be screened for breast and prostate cancer appropriately. Breast ~~self-exams~~~~self-exams~~ should be advised (Gooren et al., 2008; Jain & Bradbeer, 2007; Sobralnske, 2005).

## COVERAGE POLICY

### Federal Regulations

Federal regulations for Medicaid specify that a state may limit coverage of a drug with respect to the treatment of a specific disease or condition for an identified population (if any) based on the drug's labeling, if it does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary. In addition, states may exclude a drug when the prescribed use of the drug is not for a medically accepted indication, either approved by the FDA or supported by information from the appropriate compendia. These guidelines apply to a state's administration of its Medicaid prescribed drug benefit in both managed care and non-managed care delivery systems.

States are also required to implement a drug use review program for covered outpatient drugs in order to assure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical results. The program is required to assess data on drug use against predetermined standards, consistent with the following:

- Compendia, consisting of the following:
  1. American Hospital Formulary Service Drug ~~Information;~~~~Information.~~
  2. United States Pharmacopeia-Drug Information (or its successor publications); and
  3. the DRUGDEX Information System; and
- The peer-reviewed medical literature.

Federal law requires states to provide services to eligible recipients under the age of 21 years, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. This is known as the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit. Included are diagnostic services, treatment, equipment, supplies, and other measures described in section 1905(a) of the Social Security Act, codified in Title 42 of the United States Code 1396d (a). As such, services for recipients under the age of 21 years exceeding any coverage limitations specified within a state's policies maybe approved, if medically necessary.

### Florida Medicaid

In order to be reimbursed by Florida Medicaid, a drug must be medically necessary and either (a) prescribed for medically accepted indications and dosages found in the drug labeling or drug compendia in accordance with section 1927(k) (6) of the Social Security Act, or (b) prior authorized by a qualified clinical specialist approved by the Agency for Health Care Administration (Agency).

The criteria that are utilized under the Florida Medicaid program in the authorization of drugs for off-label purposes are as follows:

1. Documentation submitted with trial and failure or intolerance to all FDA- approved medications for the indication **AND**
2. Phase III clinical studies published in peer review journals to support the non-FDA approved use **AND**
3. Usage supported by publications in peer reviewed medical literature **and** one or more citations in at least one of the following compendia:
  - a. American Hospital Formulary Service Drug Information (AHFS)
  - b. United States Pharmacopeia-Drug Information (or its successor publications)
  - c. DRUGDEX Information System

Florida Medicaid covers hormone therapy for all FDA approved indications/uses or when the information in the appropriate compendium supports the use of the drug in the treatment of the specific disease state or condition. Testosterone and estrogen are not FDA approved for cross-sex hormone therapy in patients with gender dysphoria. However, DRUGDEX Information System's compendia addresses off-label use of testosterone cypionate, conjugated estrogens, 17-beta estradiol and ethinyl estradiol in the use of cross-sex hormone therapy.

Children/adolescents diagnosed with gender dysphoria are also eligible to receive an array of other medical and behavioral health interventions (e.g., individual and family therapy, psychological evaluations/assessments, other medical evaluation and management services) necessary to address their presenting signs and symptoms.

Health plans contracted to provide services under the Florida Medicaid Statewide Medicaid Managed Care program are required to cover all prescription drugs listed in the Agency's Medicaid Preferred Drug List (PDL). In addition, the health plan's prior authorization criteria and protocols may not be more restrictive than those used by the Agency as indicated in the Florida Statutes, the Florida Administrative Code, the Medicaid State Plan and those posted on the Agency website.

Florida Medicaid provides services to eligible recipients under the age of 21 years, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. Medical necessity in the State of Florida must meet the following conditions:

1. Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe ~~pain~~; pain.
2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not ~~in excess of more than~~ the patient's ~~needs~~; needs.
3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or ~~investigational~~; investigational.

4. Be reflective of the level of service that can be safely furnished, and for which ~~not~~ equally effective and more conservative or less costly treatment is available statewide; and
5. Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

If a service exceeds the coverage described within a Florida Medicaid policy or the associated fee schedule, a request (along with all supporting documentation) may be submitted to the Agency or its designee for review.

#### **Federal**

CMS implemented a new rule by the Department of Health and Human Services implements Section 1557 of the Affordable Care Act (ACA), "Nondiscrimination in Health Programs and Activities." This rule applies to all health programs that receive federal funding or assistance, including state Medicaid agencies, as well as most health insurance issuers. Effective July 18, ~~2016~~2016, are other provisions including provisions related to discrimination based on gender identity, pregnancy, or transgender status. Individuals must be provided equal access to health services without discrimination related to gender or identity. Entities can still review for medical necessity ~~as long as if~~ the review is not discriminatory towards these individuals and utilizes a neutral rule or principal. Categorical exclusion or limits on services related to gender transition are discriminatory as well.

#### **Medicare**

Transgender beneficiaries can use hormone therapy, which are coverable under the Medicare Part D prescription drug benefit program. The *Medicare Benefit Policy Manual*, Chapter 15, page 15, subsection 50.4.2, discusses the unlabeled use of a drug. The policy states that "FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice." Medicare provides a special billing code (condition code 45) when gender mis-match claims may be a problem (<http://www.transequality.org/sites/default/files/docs/kyr/MedicareAndTransPeople.pdf>)

#### **Veteran's Administration**

Veteran's Administration Pharmacy Benefits Management has criteria for adult transgender men testosterone replacement therapy in as well as adult transgender women estrogen replacement therapy. [http://www.pbm.va.gov/PBM/clinicalguidance/criteriaforuse/Transgender\\_Cross\\_Sex\\_Hormone\\_Therapy\\_in\\_FtM\\_Female\\_to\\_Male\\_CFU.pdf](http://www.pbm.va.gov/PBM/clinicalguidance/criteriaforuse/Transgender_Cross_Sex_Hormone_Therapy_in_FtM_Female_to_Male_CFU.pdf)

[http://www.pbm.va.gov/PBM/clinicalguidance/criteriaforuse/Transgender\\_Cross\\_Sex\\_Hormone\\_Therapy\\_in\\_MtF\\_Male\\_to\\_Female\\_CFU.pdf](http://www.pbm.va.gov/PBM/clinicalguidance/criteriaforuse/Transgender_Cross_Sex_Hormone_Therapy_in_MtF_Male_to_Female_CFU.pdf)

### State Medicaid Programs

All state Medicaid programs cover hormone therapy for the approved FDA indications and when the criteria for off-label use are met. Some state Medicaid programs are also adopting coverage policies that allow for reimbursements of cross-sex therapy in adolescents diagnosed with gender dysphoria. This report highlights the coverage policies for some Medicaid programs that do cover the service, as follows:

1. Colorado Medicaid covers behavioral health services, GnRH analogs/agonists, cross-sex hormone therapy, gender confirmation surgery, [physical therapy](#) and ~~pre-~~ and post-operative care.
2. Maryland Medicaid covers cross-sex hormone therapy for recipients 18 and older.
3. Rhode Island Medicaid covers behavioral health services, pharmacological and hormonal therapy to delay physical changes of puberty, and pharmacological and hormonal therapy that is non-reversible and produces masculinization or feminization. Some services require prior authorization.
4. Washington State Medicaid covers behavioral health services, puberty suppression therapy, hormonal therapy, and gender reassignment surgery. They have had policy in place since February 2014 regarding access to care.
5. California, New York and Massachusetts are obligated to pay for gender transition.
6. Oregon covers cross-sex hormone therapy for adolescents and adults who meet eligibility and readiness criteria.
7. Montana covers cross-sex hormone therapy for transgender recipients. Testosterone requires a prior authorization to ensure treatment is for appropriate diagnoses.
8. Indiana covers cross-sex hormone therapy for gender dysphoria recipients.
9. Illinois removed gender restrictions on estradiol and testosterone in 04/01/2015 based on the Endocrine Society recommendations.

**Commented [GS7]:** Colorado also covers physical therapy, hormone therapy, and surgical procedures  
[Gender-Affirming Care Billing Manual | Colorado Department of Health Care Policy & Financing](#)

### Private Insurers:

The following private insurers have criteria in place to access medications for cross-sex hormone therapy:

Moda Health ~~Plan Inc~~ [Plan Inc](https://www.modahealth.com/pdfs/med_criteria/GenderReassignment.pdf), Gender Reassignment Medical Necessity:  
[https://www.modahealth.com/pdfs/med\\_criteria/GenderReassignment.pdf](https://www.modahealth.com/pdfs/med_criteria/GenderReassignment.pdf)

Fallonhealth: Transgender Services Clinical Coverage Criteria

<http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=20&ved=0ahUKEwjeharT6ubQAhVH5iYKHZYfAlq4ChAWCF8wCQ&url=http%3A%2F%2Fwww.fchp.org%2Fproviders%2Fmedical-management%2F~%2Fmedia%2Ffiles%2FProviderPDFs%2FMedicalPolicies%2FTransgenderServices.ashx&usq=AFQjCNHGumXLS82ivBfVGHP6bXEeJObdQ>

**Blue regence Transgender Services Policy**

<http://blue.regence.com/trgmedpol/medicine/med153.pdf>

### GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

Cross-sex hormone therapy may be considered a health service that is consistent with generally accepted professional medical standards for the approved FDA indications (i.e., hypogonadism, hypoestrogenism) and for off-label use when supported by citations in at least one of the compendia. Since Florida Medicaid already provides coverage of hormone therapy in the FDA approved indications and for use in treating the conditions cited in the compendia, no further policy coverage analyses are needed to supplement this report on this point.

Based upon the available published literature, cross-sex hormone therapy should be considered a health service that is consistent with generally accepted professional medical standards in the treatment of gender dysphoria. Most of the studies published thus far on the use of cross-sex hormone therapy in gender dysphoric children/adolescents have concluded that further systematic research is required to determine the long-term safety and efficacy of this approach. The guidelines for transgender patients in the Endocrine Society and WPATH are controversial because they are based primarily on expert opinion rather than scientific data, given the paucity of the outcomes data on the effects of mental health and medical interventions (Vance, Ehrensaft, and Rosenthal, 2014; Rosenthal, 2014). However, the standards of care for cross-sex hormone therapy seem to be consistent in the approach with diagnosis, monitoring and dosing of the transgender patients. Indeed, hormone therapy and surgery have been found to be medically necessary to alleviate gender dysphoria in many people (American Medical Association, 2008; Anton, 2009; Tangpricha, 2016). Regimens for hormone therapy in gender dysphoric adolescents differ substantially from those used in adults. The hormone regimens for youth are adapted to account for the somatic, emotional, and mental development that occurs throughout adolescence (Hembree et al., 2009). As the research on this topic continues to evolve, more conclusive evidence may emerge that supports the long-term efficacy and effectiveness of this treatment approach.

### EPSDT Considerations:

Clinical guidelines from the Endocrine Society and WPATH recommend this therapy for certain adolescents, albeit based upon weak evidence. In certain circumstances, the risks of not treating an adolescent may be worse than the potential long-term consequences of treatment. Moreover, it is noted extensively in the literature that adolescents contending with gender

dysphoria often experience a myriad of emotional, physical, and societal challenges. Unresolved, the distress can manifest into a host of behavioral health problems including depression, anxiety, and suicidal ideation and self-mutilation. Florida pays for services for children when they protect life and /or prevent significant disability or harm, in accordance with the state’s medical necessity definition.

Testosterone cypionate, conjugated estrogens, 17-beta estradiol and ethinyl estradiol have documented off-label use in DRUGDEX. Because of this supporting documentation in the compendia, the off-label criteria could be used to evaluate each patient on a ~~case-by-case~~ case-by-case basis. This report recommends cross-sex hormone therapy as a health service that is consistent with generally accepted professional medical standards. Consistent with EPSDT requirements, the request can be evaluated on an individualized basis to determine if the service is medically necessary (~~e.g.e.g.~~ it is administered to protect life and/or prevent significant disability, such as to prevent suicide or self-mutilation) to ensure that all less invasive interventions have been exhausted, and to ensure that this treatment approach presents as the best alternative given the adolescent’s psychological state and presenting signs and symptoms.

**REFERENCES**

1. Unger C. A. (2016). Hormone therapy for transgender patients. *Translational andrology and urology*, 5(6), 877–884. <https://doi.org/10.21037/tau.2016.09.04>

\_\_\_\_ Concur

\_\_\_\_ Do Not Concur

Comments:

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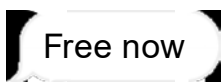
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\_\_\_\_\_  
Signature  
Deputy Secretary for Medicaid (or designee)

\_\_\_\_\_  
Date

iMessage

Tue, Apr 26, 5:16 PM



Sun, May 1, 4:31 PM

Happy weekend, Jason. I sent you the requested document earlier today. See you on Friday.  
Andre

Text Message

Fri, May 6, 9:01 AM

Financing the movement and its tactics:

- Jennifer Bilek, The Billionaires Behind the LGBT Movement, [firstthings.com](https://www.firstthings.com/web-exclusives/2020/01/the-billionaires-behind-the-lgbt-movement), Jan. 21, 2020. <https://www.firstthings.com/web-exclusives/2020/01/the-billionaires-behind-the-lgbt-movement>
- Jennifer Bilek, "Who Are the Rich, White Men Institutionalizing Transgender Ideology?" the [federalist.com](https://thefederalist.com/2018/02/20/rich-white-men-institutionalizing-transgender-ideology/), Feb. 20, 2018. <https://thefederalist.com/2018/02/20/rich-white-men-institutionalizing-transgender-ideology/>
- James Kirkup details a handbook attributed to the Dentons law firm, Thomas Reuters Foundation, and the International Lesbian, Gay, Bisexual, Transgender, Queer and Intersex Youth & Student Organisation (IGLYO), outlining the tactics by which trans lobbies influenced public bodies, politicians, officials, education and even police forces so fast and well. "The document that reveals the remarkable tactics of trans lobbyists," [blogs.spectator.co.uk](https://blogs.spectator.co.uk/2019/12/the-document-that-reveals-the-remarkable-tactics-of-trans-lobbyists/), 2 Dec 2019. <https://blogs.spectator.co.uk/2019/12/the-document-that-reveals-the-remarkable-tactics-of-trans-lobbyists/>. The Dentons.Reuters.IGLYO document: [https://www.iglyo.com/wp-content/uploads/2019/11/IGLYO\\_v3-1.pdf](https://www.iglyo.com/wp-content/uploads/2019/11/IGLYO_v3-1.pdf)



Not Delivered

iMessage

Jason, I sent that only to you to minimize scatter risk. If you prefer it be sent by e-mail, I'll do that on request. And thanks for allowing me to help Florida with this effort. Good time with you all today.



Great talk. Thanks again for your time and help.

Glad to help. Thanks.

Sat, May 21, 10:40 AM

Ohio House Families, Aging and Human Services Committee - 5-19-2022 | Ohio House of Representatives  
ohiohouse.gov



My testimony starts at 3:52:14 and goes to 4:24:07 due to all the Q&A time.

Thanks!

Really good witnesses before and after, I'm just leading you to mine. Other witnesses: a minor burned by GAT, lesbian-identified mom who lost her child for refusing GAT for her, trans-ident'd adults who concur this is not for kids, leaders of parent group of those whose kids got railroaded into GAT, retired endocrinologist who was top of the GLBT list for docs in his part of Ohio who quit doing GAT at all due to obvious harms and no helps of underlying problems, Matt Sharp of ADF, and me. I had had it with Rep. Dr. Lifton's boloney activist ad hominem, gaslighting and jamming tactics of the witnesses (along with another rep who tried it too but in a more silly manner), so when she offered the first question and with the usual crap, I let her have it, then told the committee what I really thought.

When you have time, would you help us find some folks that are Florida based? Looking for similar folks — people who regret GAT, docs who don't do it anymore, etc.... I'm just not sure how to begin finding this propel in Florida.

Those people\*

Any assistance would be appreciated. And you can bill for your time, as you have been.

I think I might know someone who can help. I'll check it out. Also, I sent a prelim on charges to you, just asking if I did it right and need to know to whom to submit them, unless you



right and need to know to whom to submit them, unless you agree with the charges and can pass them along. Thirdly, my updated Microsoft suite seems to have been corrupted by the North Koreans or something and won't let me save or alter docs, so I'm having fun with that. We'll get there.

Sat, May 21, 6:57 PM

OK, that was a fail. They sent me the names of the doctors you already know. I'll check some more.

OK, more info maybe coming Monday.

Tue, Jun 7, 10:49 AM

DD is going to email you to schedule a call for Friday.

Ok

I wanted to plant a seed in your brain. We may be having a rule hearing in Tallahassee on Tuesday, July 5. I'd ask you to think about possibly coming to that. We can talk about it on Friday, but I just wanted you to think about it. Obviously we would pay for your time and travel expenses.

Noted.

Fri, Jun 10, 7:02 AM

Paul. [\(314\) 566-3467](tel:(314)566-3467)

Thanks

Tue, Jun 14, 7:40 AM

Let's discuss your email over the phone. Please call whenever you have time. Thanks.

Thu, Jun 16, 12:48 PM

Hearing is set for Friday July 8 from 3:00 to 5:00 PM.

I will ask DD to reach out to you regarding logistics

Ok

Tue, Jun 28, 11:30 AM

Greetings, mighty Jason. Will there be somebody from the department contacting me about travel and lodging arrangements in the near future? FYI, I live in Redding California, local airport served by United and Alaska air. United gives access to San Francisco and LAX, so hopeful that makes connections easy.

Sat, Jul 9, 3:52 PM

Hi, Jason. Happy vacation. I have some thoughts in follow up and future prep regarding eventualities. Should I make this an e-mail labelled privileged and confidential for you to distribute or is phone better? If phone, it can surely wait for your return to work. Andre

Hi Andre, yes let's do over the phone. Just me and you? Or should we included anyone else from the team?

Next week would be better if that's ok

Outstanding. Enjoy your vacation and we'll talk to you the week after.  
Stay clear of the hazardous marine life. :-)

Haha. I'll try.

Thanks again for making the trek out. Appreciate all of your efforts.

Pleased to be a part.

Tue, Jul 19, 6:20 PM

Hi, Jason. Andre here. Regarding the email, do you prefer comments on a separate document, or tagged in comments on the one you sent? I imagine the separate document is messier but that a tagged PDF might be easier to use? Or not? My first comment is over a page long.

Wed, Jul 20, 5:39 AM

Sorry for delay

Whatever is easiest for you

Separate document. 11 pages. It's in your email. :-)

Awesome

Thanks so much!

Thu, Jul 28, 8:36 AM

J-man, might you send me the link the public can use to access the GAPMS report? Looking forward to the same for the rule when available. I have lectures to update and be given in the US and abroad in the coming few months and blogs to write. 😊 Many thanks. Andre

Thu, Aug 25, 3:16 PM

Jason, Andre here. Regarding the AAP's letter criticizing the GAPMS report, that is available to the public on the Florida Medicaid website, isn't it?

Yale is public

Not sure about aap

Will check with team in AM

Thanks

Need me to send it to someone? We could probably do that. But let's discuss over the phone tomorrow.

No, with the AAP busily hanging themselves in Wall Street Journal, ACPeds and some others would like to have the link to the AAP Florida Medicaid protest letter to go along with links they have to the AAP policy in press releases they are making.

Fri, Aug 26, 8:24 AM

Good morning, Jason. Would we have any word yet on whether or not the AAP letter to Florida Medicaid is fair game and available for electronic forwarding?

Thanks,  
Andre

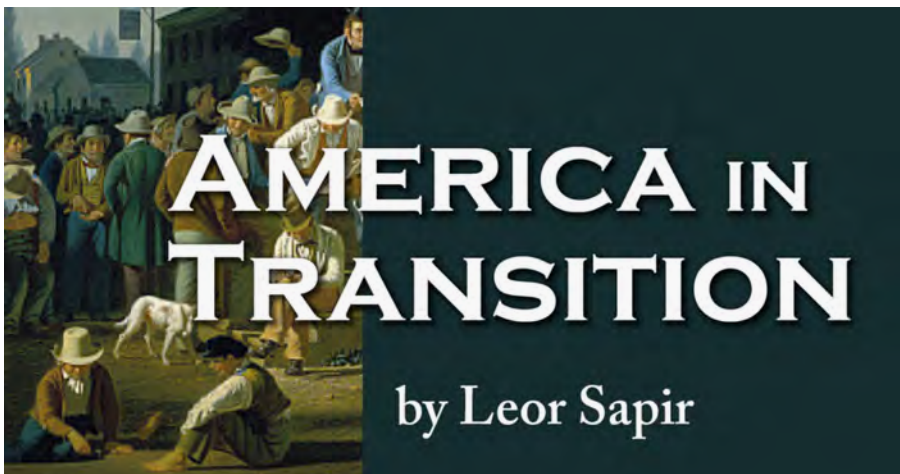
Fri, Aug 26, 12:31 PM

Jason, don't worry about the press release. It is going out now and says nothing about Florida. Do however be concerned about WSJ submissions. That is what we intend. Thanks.

Just tried you

Sat, Aug 27, 10:54 AM

And here is a piece from Dr. Sapir, the co-author of the WSJ piece slamming the Amer Acad of Peds about a week ago. It nicely explains a lot about why Northern Europe is leading the charge against gender alteration interventions ("GAT" (t for therapy), or my preference of TAT, as it affirms transition and not gender) while the USA flounders politically on it. The hole in the argument is that Canada is parliamentary too, and it looks worse than the USA on this issue, not better. Overall, great article.



Trans Extremism and the Weak American State  
genspect.org

Wed, Sep 7, 3:53 PM

Understood

Sun, Sep 11, 12:50 PM

Happy Sunday, Jason. I am preparing a set of lectures I will be giving in a European nation next month. One of the topics is international movement on the subject at hand. Is

Time for a call to discuss ?

Yes

Mon, Sep 12, 12:24 PM

Have not succeeded in carving out the time to call you today. Will try again tomorrow.

Wed, Sep 14, 8:57 AM

That much mention of my other qualifications.



Lawsuit Suggests Zealotry Disguised as Medicine Led to Denial of Medicaid Coverage for Trans Treatments  
miaminewtimes.com

Mon, Oct 31, 6:50 PM

It's yours now.

OK,. Tomorrow.

Sun, Nov 6, 2:22 PM

Happy Sunday Jason Just messaging to say I am making

Happy Sunday Jason - just messaging to say I am making word of Florida Medicaid and board of medicine victories in my lectures, a big international one recently in Budapest, and soon, if I understand this correctly, before the European Parliament in December. Again, it's a downer to not have testified for the board of medicine, but I think it was very wise of you and therefore the board to have taken my advice that you wanted to have specialists doing the testifying rather than a family physician. It worked out very well and continues to. Being part of the team pushing forward with the right cause is what counts, not polishing my ego. :). Glad to play my part.

Fri, Jan 27, 11:03 AM



Pediatric Group Ordered To Provide Florida Docs On Why It Supports Sex Changes For Kids

[dailycaller.com](https://www.dailycaller.com)

In a related story: Florida runs up tab in Medicaid transgender case - CBS Miami ([cbsnews.com](https://www.cbsnews.com/miami/news/florida-runs-up-tab-in-medicaid-transgender-case/))  
<https://www.cbsnews.com/miami/news/florida-runs-up-tab-in-medicaid-transgender-case/>

Delivered

**From:** Weida, Jason  
**Subject:** Fwd: Charges  
**To:** ""Pickle""; "" Devona; Devona.Pickle@ahca.myflorida.com  
**Cc:** Andre Van Mol  
**Sent:** May 21, 2022 8:19 PM (UTC-04:00)

Forwarding to DD.

Get [Outlook for iOS](#)

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**From:** Andre Van Mol <95andrev@gmail.com>  
**Sent:** Saturday, May 21, 2022 1:10:58 PM  
**To:** Weida, Jason <Jason.Weida@ahca.myflorida.com>  
**Subject:** Charges

Hi, Jason.

As my services in collaboration with the Florida Dept. of Medicaid have come to completion, in my understanding, I was advised it is time to submit charges.

May I ask your guidance at this point?

Here is what the itemization looks like. Do these seem to be in order and appropriate according to our agreement?

Thanks,  
 Andre Van Mol, MD

**Andre Van Mol, MD**  
 12860 Yanot Drive  
 Redding, CA 96003  
 Tel. 530-604-9370  
[95andrev@gmail.com](mailto:95andrev@gmail.com)

Jason Weida  
 Florida Dept of Medicaid  
 Bldg 3 Room 2413  
 2727 Mahan Dr.  
 Tallahassee, FL. 32308

RE: Itemized charges for consulting

May 21, 2022

Dear Mr. Weida,

Thank you and your team for the privilege of serving as a consultant on your Florida Medicaid policy project regarding payment of services related to gender dysphoria. Please find below a listing of hours spent on the project and why.

4/28/2022	3 hours	Research and drafting of master background document
4/29/2022	4 hours	Research and drafting of master background document
4/30/2022	2 hours	Completion of master background document
5/06/2022	1 hour	Teleconference with FL Medicaid Quality team
5/11/2022	2 hours	Read and critique FL Medicaid proposed policy draft
5/12/2022	3 hours	Read and critique FL Medicaid proposed policy draft
5/13/2022	1.5 hours	Teleconference with FL Medicaid Quality team followed by

research and provision of further data

5/17/2022 1 hours Read and edit final Medicaid policy draft

5/18/2022

10 min Final consultation via telephone with FL team member. No charge.

Total hours = 17.5 hours at \$350 per hour

Total charges = \$6,125.00

Andre Van Mol, MD



---

**From:** Romina Brignardello Petersen  
**Sent:** Tuesday, May 24, 2022 11:47 AM EDT  
**To:** Nai.Chen@ahca.myflorida.com; Devona.Pickle@ahca.myflorida.com  
**CC:** Pickle, Devona  
**Subject:** Invoice for evidence evaluation  
**Attachments:** Invoice FL RBP.pdf

Dear Nai,

Please see attached my invoice

Please let me know if there is anything else you need from me

Best,

Romina

# INVOICE

Romina Brignardello-Petersen  
SIN 589814391

38 Kipling Rd  
Hamilton, ON, L8S 3X3, Canada  
Phone +1 905 5317013  
rominabp@gmail.com

DATE May 24, 2022

**TO**

AHCA- Medicaid Policy  
MS20  
2727 Mahan Drive  
Tallahassee, FL, 32308  
United States

Invoice 1/1  
Requisition No. PR12152548

Description	Amount
<i>Consulting: Evidence evaluation (systematic review of the literature to identify and summarize the best available evidence regarding the effects of gender affirming therapies in people with gender dysphoria), April 20- May 17, 2022, total: 116 hours (\$300 USD per hour)</i>	
<i>Details:</i>	
- Search and selection of reviews	33 hours \$9900
- Reviews appraisal and synthesis	38 hours \$11400
- Preparation of reports	24 hours \$7200
- Meetings	5 hours \$1500
- Search and synthesis of new studies	16 hours \$4800
<b>Total</b>	<b>\$34800 USD</b>

Deposits should be made to the following bank account:

ABA number: 026009593  
Bank of America Swift code: BOFAUS3NXXX  
Canada swift code: TDOMCATTOR  
Institution number: 004  
Branch transit number: 25362  
Account number: 7127161  
Bank name: TD Canada Trust  
Bank address: 194 James St S, Hamilton, Ontario, L8P 3A7, Canada  
Account holder: Romina Brignardello Petersen  
Account holder address: 38 Kipling Rd, Hamilton, ON, L8S 3X3, Canada

Cheques can be mailed to  
Romina Brignardello Petersen  
38 Kipling Rd, Hamilton, ON, L8S 3X3, Canada

I certify that all costs and fees claimed for payment are accurate and were performed in furtherance of the Agreement between Romina Brignardello Petersen and the Agency for Health Care Administration

If you have any questions concerning this invoice, please contact Romina Brignardello-Petersen ([rominabp@gmail.com](mailto:rominabp@gmail.com))

A handwritten signature in black ink, appearing to read 'Romina Brignardello-Petersen', written in a cursive style.



RON DESANTIS  
GOVERNOR

SIMONE MARSTILLER  
SECRETARY

June [Date], 2022

[Name], [Title, if applicable]  
[Entity]  
[Mailing Address]

Dear [Mr.][Ms.][Mx.] [Surname]:

Thank you for your request for a workshop regarding Rule 59G-1.050, Florida Administrative Code (F.A.C.) General Medicaid Policy. On June 2, 2022, the Agency issued Generally Accepted Professional Medical Standards (GAPMS) report *[GAPMS report name (will be a hyperlink to the website)]*. Based on the findings and recommendations contained therein, the Agency for Health Care Administration finds it unnecessary to hold a public workshop and your request is denied in accordance with section 120.54(2)(c) Florida Statutes (F.S.).

The Agency encourages you to submit written comment electronically to [MedicaidRuleComments@ahca.myflorida.com](mailto:MedicaidRuleComments@ahca.myflorida.com).

Sincerely,

Simone Marstiller  
Secretary, Agency for Health Care Administration

2727 Mahan Drive • Mail Stop #8  
Tallahassee, FL 32308  
AHCA.MyFlorida.com



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PURSUANT TO §119.071(1)(g)1., F.S.

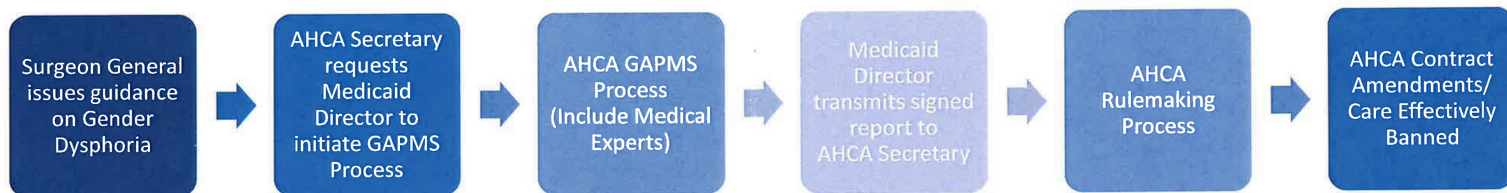
### Projected Rulemaking Timeline

June 3	June 16	June 17	July 8	July 11	July 12	July 19	August 8
NORD published in FAR	Issue Response Letter	NOPR & Hearing information publishes in the FAR	Rulemaking Hearing	Hearing Comment Period	Adoption Package submitted to JAPC	File the rule for Adoption with DoS	Rule is Effective
Received Request for Workshop	Send NOPR to OFARR & FAR	Send Notice of Proposed Rule to JAPC					

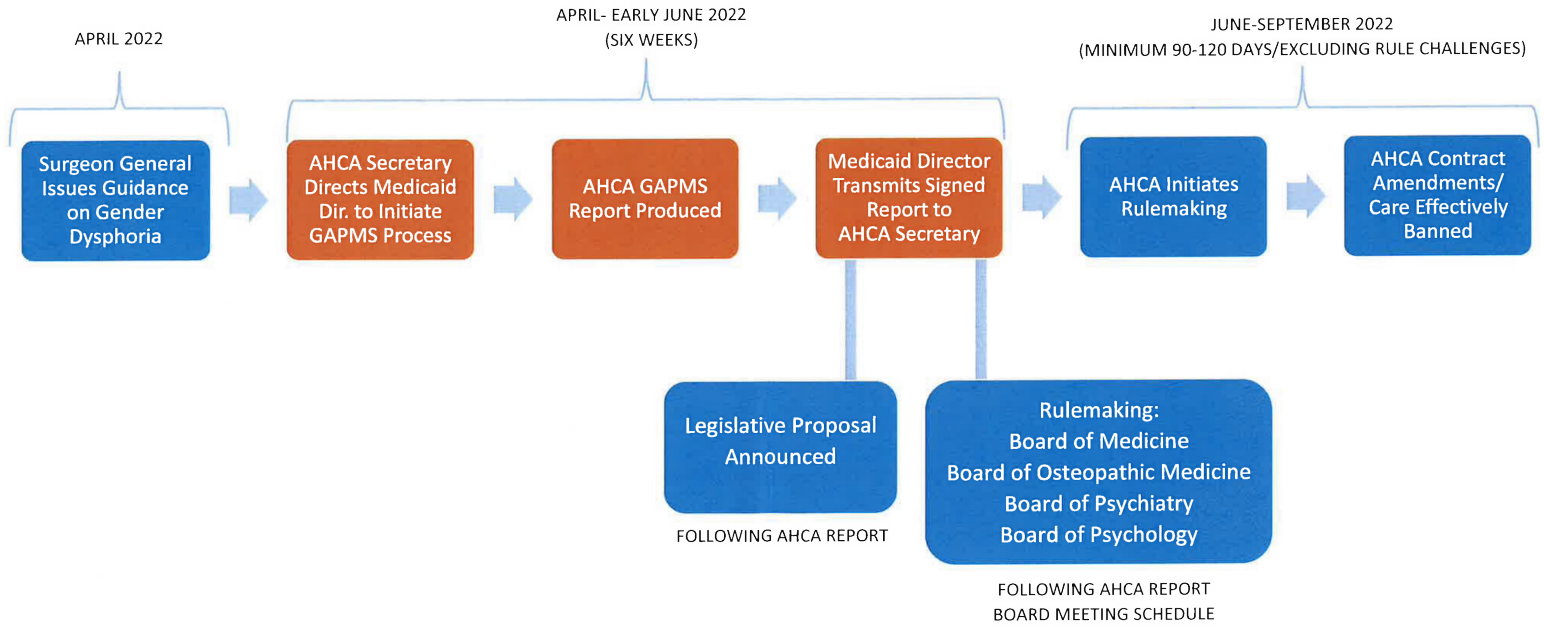
Acronym Key	
GAPMS	Generally Accepted Professional Medical Standards
FAR	Florida Administrative Register
NORD	Notice of Rule Development
NOPR	Notice of Proposed Rule
JAPC	Joint Administrative Procedures Committee
DoS	Department of State

ATTORNEY WORK PRODUCT  
CONFIDENTIAL - PURSUANT TO  
§ 119.071(n), F.S. (1993)

## Gender Dysphoria/Transgender Health Care Non-Legislative Pathway



## Gender Dysphoria/Transgender Health Care Policy Pathway



^ GAPMS: Determining Generally Accepted Professional Medical Standards

## Medicaid Policy Routing and Tracking Form

Date:	<input type="text" value="6/1/2022"/>
Assignment Title:	<input type="text" value="GAPMS Report"/>
Assignment Type:	<input type="text" value="GAPMS"/>
Final Due Date:	<input type="text" value="6/2/2022"/>
Extensions:	<input type="text" value="No"/>
Reassigned:	<input type="text" value="No"/>
Reassigned to:	<input type="text"/>
Reassigned from:	<input type="text"/>
Date of Completion:	<input type="text"/>
Assignment Summary (brief):	<input type="text" value="GAPMS review for services"/>
Attachment(s):	Attachment Document.docx Please upload your draft documents/responses
Section:	<input type="text" value="Canadian Prescription Drug Importation Program"/>
Prepared By:	Brackett, Matt
Position:	<input type="text" value="Other"/>
Preparer Phone:	<input type="text" value="850-412-4151"/>
Preparer Room Number:	<input type="text" value="2249"/>

**Reviewed by and Routing Timeline(s):**

Name	Title	Start Date	End Date	Date Received	Todays Date and Initial	Approval
Devona (D.D.) Pickle	AHC Administrator	<input type="text" value="6/1/2022"/>	<input type="text" value="6/1/2022"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Ann Dalton	Bureau Chief	<input type="text" value="6/1/2022"/>	<input type="text" value="6/1/2022"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Jason Weida	ADS Policy/Quality	<input type="text" value="6/1/2022"/>	<input type="text" value="6/1/2022"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Tom Wallace	Deputy Secretary for Medic	<input type="text" value="6/2/2022"/>	<input type="text" value="6/2/2022"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
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		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>

<b>Notes:</b> <input style="width: 100%; height: 20px;" type="text"/>	
<b>Edits</b>	<b>Edits</b>
Edit 1 <input style="width: 95%; height: 30px;" type="text"/>	Edit 2 <input style="width: 95%; height: 30px;" type="text"/>
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## Medicaid Policy Routing and Tracking Form

Date:	6/1/2022
Assignment Title:	GAPMS Report
Assignment Type:	GAPMS
Final Due Date:	6/2/2022
Extensions:	No
Reassigned:	No
Reassigned to:	
Reassigned from:	
Date of Completion:	
Assignment Summary (brief):	GAPMS review for services
Attachment(s):	Attachment Document.docx Please upload your draft documents/responses
Section:	Canadian Prescription Drug Importation Program
Prepared By:	Brackett, Matt
Position:	Other
Preparer Phone:	850-412-4151
Preparer Room Number:	2249

**Reviewed by and Routing Timeline(s):**

Name	Title	Start Date	End Date	Date Received	Today's Date and Initial	Approval
Devona (D.D.) Pickle	AHC Administrator	6/1/2022	6/1/2022	6/1/22	6/1/22 [Signature]	<input checked="" type="checkbox"/>
Ann Dalton	Bureau Chief	6/1/2022	6/1/2022	6/1/22	6/1/22 [Signature]	<input checked="" type="checkbox"/>
Jason Weida	ADS Policy/Quality	6/1/2022	6/1/2022	6/1/22	6/1/22 [Signature]	<input checked="" type="checkbox"/>
Tom Wallace	Deputy Secretary for Medic	6/2/2022	6/2/2022	6/1/22	6/2/22 TW	<input checked="" type="checkbox"/>
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# Florida Medicaid

## Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria

**June 2022**

Ron DeSantis, Governor  
Simone Marstiller, Secretary



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## Introductory Remarks and Abstract

### Generally Accepted Professional Medical Standards

The Secretary of the Florida Agency for Health Care Administration requested that the Division of Florida Medicaid review the treatment of gender dysphoria for a coverage determination pursuant to Rule 59G-1.035, Florida Administrative Code (F.A.C.) (See Attachment A for the Secretary's Letter to Deputy Secretary Tom Wallace). The treatment reviewed within this report included "sex reassignment treatment," which refers to medical services used to obtain the primary and/or secondary physical sexual characteristics of a male or female. 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., see Attachment B for the complete rule text).

The determination process requires that "the Deputy Secretary for Medicaid will make the final determination as to whether the health service is consistent with GAPMS and not experimental or investigational" (Rule 59G-1.035, F.A.C.). In making that determination, Rule 59G-1.035, F.A.C., identifies several factors for consideration. Among other things, the rule contemplates the consideration of "recommendations or assessments by clinical or technical experts on the subject or field" (Rule 59G-1.035(4)(f), F.A.C.). Accordingly, this report attaches five assessments from subject-matter experts:

- **Attachment C:** Romina Brignardello-Petersen, DDS, MSc, PhD and Wojtek Wiercioch, MSc, PhD: *Effects of Gender Affirming Therapies in People with Gender Dysphoria: Evaluation of the Best Available Evidence*. 16 May 2022.
- **Attachment D:** James Cantor, PhD: *Science of Gender Dysphoria and Transsexualism*. 17 May 2022.
- **Attachment E:** Quentin Van Meter, MD: *Concerns about Affirmation of an Incongruent Gender in a Child or Adolescent*. 17 May 2022.
- **Attachment F:** Patrick Lappert, MD: *Surgical Procedures and Gender Dysphoria*. 17 May 2022.
- **Attachment G:** G. Kevin Donovan, MD: *Medical Experimentation without Informed Consent: An Ethicist's View of Transgender Treatment for Children*. 16 May 2022.

### Abstract

Available medical literature provides insufficient evidence that sex reassignment through medical intervention is a safe and effective treatment for gender dysphoria. Studies presenting the benefits to mental health, including those claiming that the services prevent suicide, are either low or very low quality and rely on unreliable methods such as surveys and retrospective analyses, both of which are cross-sectional and highly biased. Rather, the available evidence demonstrates that these treatments cause irreversible physical changes and side effects that can affect long-term health.

Five clinical and technical expert assessments attached to this report recommend against the use of such interventions to treat what is categorized as a mental health disorder (See attachments):

- **Health Care Research:** Brignardello-Petersen and Wiercioch performed a systematic review that graded a multitude of studies. They conclude

that evidence supporting sex reassignment treatments is low or very low quality.

- **Clinical Psychology:** Cantor provided a review of literature on all aspects of the subject, covering therapies, lack of research on suicidality, practice guidelines, and Western European coverage requirements.
- **Plastic Surgery:** Lappert provided an evaluation explaining how surgical interventions are cosmetic with little to no supporting evidence to improve mental health, particularly those altering the chest.
- **Pediatric Endocrinology:** Van Meter explains how children and adolescent brains are in continuous phases of development and how puberty suppression and cross-sex hormones can potentially affect appropriate neural maturation.
- **Bioethics:** Donovan provides additional insight on the bioethics of administering these treatments, asserting that children and adolescents cannot provide truly informed consent.

Following a review of available literature, clinical guidelines, and coverage by other insurers and nations, Florida Medicaid has determined that the research supporting sex reassignment treatment is insufficient to demonstrate efficacy and safety. In addition, numerous studies, including the reports provided by the clinical and technical experts listed above, identify poor methods and the certainty of irreversible physical changes. 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.

## Health Service Summary

### Gender Dysphoria

Frequently used to describe individuals whose gender identity conflicts with their natural-born sex, the term gender dysphoria has a history of evolving definitions during the past decades (Note: This report uses the term “gender” in reference to the construct of male and female identities and the term “sex” when regarding biological characteristics). Prior to the publication of the *Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders* (DSM-V), the American Psychiatric Association (APA) used the diagnosis of gender identity disorder (GID) to describe individuals who sought to transition to the opposite gender. However, behavioral health clinicians sought a revision after determining that using GID created stigma for those who received the diagnosis. This is despite the APA having adopted GID to replace the previous diagnosis of transsexualism for the exact same reason (APA, 2017).<sup>1</sup>

When crafting its new definition and terminology, the APA sought to remove the stigma of classifying as a disorder the questioning of one’s gender identity by focusing instead on the psychological distress that such questioning can evoke. This approach argues that individuals seeking behavioral health and transition services are doing so due to experiencing distress and that gender non-conformity by itself is not a mental health issue. This led to the adoption of gender dysphoria in 2013 when the APA released the DSM-V. In addition to using a new term, the APA also differentiated the diagnosis between children and adolescents and adults, listing different characteristics for the two age groups (APA, 2017).

According to the DSM-V, gender dysphoria is defined as “the distress that may accompany the incongruence between one’s experienced or expressed gender and one’s assigned gender.” As for the criteria to receive the diagnosis, the APA issued stricter criteria for children than adolescents and adults. For the former, the APA states that a child must meet six out of eight behavioral characteristics such as having “a strong desire to be of the other gender or an insistence that one is the other gender” or “a strong preference for cross-gender roles in make-believe or fantasy play.” The criteria for adults and adolescents are less stringent with individuals only having to meet two out of six characteristics that include “a strong desire to be the other gender” or “a strong desire to be rid of one’s primary and/or secondary sexual characteristics.” The APA further notes that these criteria can also apply to young adolescents (DSM-V, 2013).

In 2021, the Merck Manual released a slightly different definition for gender dysphoria, citing that the condition “is characterized by a strong, persistent cross-gender identification associated with anxiety, depression, irritability, and often a wish to live as a gender different from the one associated with the

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<sup>1</sup> The concept of gender being part of identity and disconnected from biological sex originated during the mid-twentieth century and was publicized by psychologist John W. Money. His research asserted that gender was a complete social construct and separate from biology, meaning that parents and/or caregivers could imprint on a young child (under three years) the identity of a boy or girl. In 1967, Money’s theories led to a failed experiment on twin boys where physicians surgically transitioned one to appear as a girl. The twin that underwent sex reassignment never fully identified as a female. However, Money never publicly acknowledged this and reported the experiment as a success. Furthermore, he promoted his conclusions across the scientific community, concealing what actually unfolded. As a result, Money’s ideas on gender fluidity served as a basis for performing procedures on children with hermaphroditic features or genital abnormalities. The case reveals how the understanding of a concept (e.g., gender) at any given time can lead to incorrect medical decisions with irreversible consequences (Gaetano, 2015).

sex assigned at birth.” Additionally, the Merck Manual further states that “gender dysphoria is a diagnosis requiring specific criteria but is sometimes used more loosely for people in whom symptoms do not reach a clinical threshold” (Merck Manual, 2021). This definition is largely consistent with the DSM-V but does not emphasize the distress component to the same extent.<sup>2</sup>

Like other behavioral health diagnoses classified in the DSM-V, gender dysphoria has the following subtypes:

- **Early-Onset Gender Dysphoria:** This subtype begins during childhood and persists through adolescence into adulthood. It can be interrupted by periods where the individual does not experience gender dysphoria signs and may classify as homosexual (DSM-V, 2013).
- **Late-Onset Gender Dysphoria:** Occurring after puberty or during adulthood, this subtype does not begin until late adolescence and can emerge following no previous signs of gender dysphoria. The APA attributes this partially to individuals who did not want to verbalize their desires to transition (DSM-V, 2013).

Further studies have identified additional subtypes of gender dysphoria. In 2018, Lisa Littman introduced the concept of a rapid-onset subtype. Classified as rapid-onset gender dysphoria (ROGD), it features characteristics such as sudden beginnings during or following puberty. However, it differs from the DSM-V definitions because ROGD is associated with other causes such as social influences (e.g., peer groups, authority figures, and media). In other words, adolescents who had no history of displaying typical gender dysphoria characteristics go through a sudden change in identity following intense exposure to peers and/or media that heavily promotes transgender lifestyles (Littman, 2018). While more long-term studies are needed to confirm whether ROGD is a temporary or long-term condition, Littman’s study has initiated discussions regarding potential causes of gender dysphoria as well as introduced a potential subtype.

Additionally, the frequent use of gender dysphoria in clinical and lay discourse has led to a fracturing of the definition. Studies on the topic frequently do not apply the DSM-V’s criteria for the diagnosis and overlook certain key features such as distress. In a 2018 review by Zowie Davy and Michael Toze, the authors evaluated 387 articles that examine gender dysphoria and noted stark departures from the APA’s definition. They further asserted that the APA intended to “reduce pathologization” by establishing a new definition for gender dysphoria in the DSM-V. This in turn would reduce diagnoses, although as Davy and Toze note, the tendency for the literature to diverge from the APA’s definition may result in increased numbers of individuals classified as having gender dysphoria when they do not meet the DSM-V’s criteria (Davy and Toze, 2018). This further raises the question of whether individuals are receiving potentially irreversible treatments for the condition when they might not actually have it.

The current usage of gender dysphoria is the result of discussions spanning across decades as demonstrated in the past editions of the DSM. Until 2013, the APA considered having gender identity issues a mental disorder by itself regardless of the presence of psychological distress. That perspective has since shifted to only consider the adverse psychological effects of questioning one’s gender as a disorder. In addition, the APA considers gender as part of one’s identity, which is not subject to a diagnosis. Whether the APA has shifted its terminology and criteria for gender identity issues due to

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<sup>2</sup> Following the release of the Florida Department of Health’s guidelines for treating gender dysphoria, Merck removed its definition for “gender dysphoria” from the Merck Manual (Fox News, 2022).



emerging clinical data or cultural changes is another question. In 1994, the APA replaced transsexualism with gender identity disorder as part of the “effort to reduce stigma” (APA, 2017). This raises questions about what influences decisions to revise definitions and criteria; is it social trends or medical evidence?

### **Behavioral Health Issues Co-Occurring with Gender Dysphoria**

Because gender dysphoria pertains directly to the distress experienced by an individual who desires to change gender identities, secondary behavioral health issues can co-occur such as depression and anxiety. If left untreated, these conditions can lead to the inability to function in daily activities, social isolation, and even suicidal ideation. Studies do confirm that adolescents and adults with gender dysphoria report higher levels of anxiety, depression, and poor peer relationships than the general population (Kuper et al, 2019). Other associated conditions include substance abuse, eating disorders, and compulsivity. A significant proportion of individuals with gender dysphoria also have autism spectrum disorder (ASD) (Saleem and Rizvi, 2017). Although the number reporting secondary issues is increased, individuals diagnosed with gender dysphoria do not necessarily constitute the entire population that is gender non-conforming (i.e., does not identify with natal sex), and no information is available breaking down the percentage of those who are non-conforming with gender dysphoria and those who are non-conforming with no distress. Additionally, available research raises questions as to whether the distress is secondary to pre-existing behavioral health disorders and not gender dysphoria. This is evident in the number of adolescents who reported anxiety and depression diagnoses prior to transitioning (Saleem and Rizvi, 2017).

Furthermore, conventional treatments for secondary behavioral health issues are available. These include cognitive behavioral therapy, medication, and inpatient services. The APA reports that treatments for these are highly effective with 80% to 90% of individuals diagnosed with depression responding positively (APA, 2020). In addition, a high percentage of adolescents diagnosed with gender dysphoria had received psychiatric treatment for a prior or co-occurring mental health issue. A 2015 study from Finland by Kaltiala-Heino et al noted that 75% of children seeking sex reassignment services had been treated by a behavioral health professional (Kaltiala-Heino et al, 2015).

### **Diagnosing Gender Dysphoria**

Prior to the publication of the DSM-V, diagnosing individuals experiencing gender identity issues followed a different process. Behavioral health clinicians could assign the diagnosis based on gender non-conformance alone. That has changed since 2013. Today, non-conforming to one’s gender is part of personal identity and not a disorder requiring treatment. This change has led professional associations to shift the diagnostic criteria for gender dysphoria to focus on the distress caused by shifting identities (DSM-V, 2013).

For adolescents, the APA identifies “a marked incongruence between one’s experienced/expressed gender and natal sex, of at least 6 months’ duration” as the core component of gender dysphoria (DSM-V, 2013). What the APA does not elucidate is the threshold for “marked.” This raises questions as to whether practitioners exercise uniformity when applying the diagnostic criteria or if they do so subjectively. For example, the WPATH’s *Standards of Care for the Health of Transsexual, Transgender, and Gender Non-Conforming People* provides guidance on the processes mental health practitioners should use when assessing for gender dysphoria but offers no benchmarks for meeting diagnostic criteria (WPATH, 2012).

Such processes include evaluating for gender non-conforming behaviors and other co-existing mental disorders like anxiety or depression. This involves not only interviewing the adolescent but also the family in addition to reviewing medical histories. WPATH also asserts that gender dysphoria assessments need to account for peer relationships, academic performance, and provide information of potential treatments. This last component is necessary because it might affect an individual's choices regarding transitioning, particularly if the information does not correspond to the desired outcome (WPATH, 2012).

The diagnosis of gender dysphoria is a relatively recent concept in mental health, being the product of decades of discussion and building upon previous definitions. Instead of treating gender non-conformity as a disorder, behavioral health professionals acknowledge it as part of one's identity and focus on addressing the associated distress. Considering the new criteria, this changes the dynamics of the population who would have qualified for a diagnosis before 2013 and those who would today. Given that desiring to transition into a gender different from natal sex no longer qualifies as a disorder, behavioral health professionals are treating distress and referring adolescents and adults to therapies that are used off-label and pose irreversible effects.

#### **Current Available Treatments for Gender Dysphoria**

At present, proposed treatment for gender dysphoria occurs in four stages, beginning with psychological services and ending with sex reassignment surgery. As an individual progresses through each stage, the treatments gradually become more irreversible with surgical changes being permanent. Because of the increasing effects, individuals must have attempted treatment at the previous stage before pursuing the next one (Note: late adolescents and adults have already completed puberty and do not require puberty blockers). Listed in order, the four stages are as follows:

- **Behavioral Health Services:** Psychologists and other mental health professionals are likely the first practitioners individuals with gender dysphoria will encounter. In accordance with clinical guidelines established by the World Professional Association for Transgender Health (WPATH)<sup>3</sup>, behavioral health professionals are supposed to “find ways to maximize a person's overall psychological well-being, quality of life, and self-fulfillment.” WPATH further discourages services for attempting to change someone's gender identity. Instead, it instructs practitioners to assess for the condition and readiness for puberty blockers or cross-sex hormones while offering guidance to function in a chosen gender. WPATH does assert that the clinicians do need to treat any other underlying mental health issues secondary or co-occurring with gender dysphoria (WPATH, 2012). However, the organization provides conflicting guidance because it also advises practitioners to prescribe cross-sex hormones on demand (Levine, 2018).
- **Puberty Suppression:** Used only on individuals in the earliest stages of puberty (Tanner stage 2), preventing pubertal onset provides additional time to explore gender identities before the physical characteristics of biological sex develop. This treatment is intended to reduce distress and anxiety related to the appearance of adult sexual physical features. To suppress puberty, pediatric endocrinologists inject gonadotropin releasing hormone (Gn-RH) at specific intervals (e.g., 4 weeks or 12 weeks). The Gn-RH suppresses gonadotropin receptors that allow for the

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<sup>3</sup> The World Professional Association for Transgender Health asserts that it is a professional organization. However, it functions like an advocacy group by allowing open membership to non-clinicians (WPATH, 2022).

development of primary and secondary adult sexual characteristics. Prior to receiving puberty suppression therapy, individuals must have received a diagnosis of gender dysphoria and have undergone a mental health evaluation (Kyriakou et al, 2020).

- **Cross-Sex Hormones:** For adults and late adolescents (16 years or older), the next treatment phase recommended is taking cross-sex hormones (e.g., testosterone or estrogen) to create secondary sex characteristics. In men transitioning into women, these include breast development and widening around the pelvis. Women who transition into men experience deeper voices, redistribution of fat deposits, and growing facial hair. According to the Endocrine Society, late adolescents who qualify for cross-sex hormones must have a confirmed diagnosis of gender dysphoria from a mental health practitioner with experience treating that population. Some physical changes induced by these hormones are irreversible (Endocrine Society, 2017).
- **Sex Reassignment Surgery:** Sometimes referred to as “gender affirming” surgery, this treatment does not consist of just one procedure but several, depending on the desires of the transitioning individual. Primarily, sex reassignment procedures alter the primary and secondary sexual characteristics. Men transitioning into women (trans-females) undergo a penectomy (removal of the penis), orchiectomy (removal of the testes), and vulvoplasty (creation of female genitals). Other procedures trans-females may undergo include breast augmentation and facial feminization. For women that transition into men (trans-males), procedures include mastectomy (removal of the breasts), hysterectomy (removal of the uterus), oophorectomy (removal of the ovaries), and phalloplasty (creation of male genitals). Because of the complexities involved in phalloplasty, many trans-males do not opt for this procedure and limit themselves to mastectomies. Additionally, the effects of sex reassignment surgery, such as infertility, are permanent (WPATH, 2012).

While some clinical organizations assert that they are the standard of care for gender dysphoria, the U.S. Food and Drug Administration (FDA) currently has not approved any medication as clinically indicated for this condition (Unger, 2018). Although puberty blockers and cross-sex hormones are FDA approved, the FDA did not approve them for treating gender dysphoria, meaning that their use for anything other than the clinical indications listed is off-label (American Academy of Pediatrics, 2014). As for surgical procedures, the FDA does not evaluate or approve them, but it does review all surgical devices (FDA, 2021). In addition, the Endocrine Society concedes that its practice guidelines for sex reassignment treatment does *not* constitute a “standard of care” and that its grades for available services are low or very low (Endocrine Society, 2017).<sup>4</sup>

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<sup>4</sup> Disagreement over how to treat gender dysphoria, gender identity disorder, and transsexualism has persisted since sex reassignment surgery first became available in the 1960s. In a 2006 counterargument, Paul McHugh highlights how individuals seeking surgery had other reasons that extended beyond gender identity, including sexual arousal and guilt over homosexuality. In addition, he asserts that undergoing sex reassignment procedures did not improve a patient’s overall behavioral health and that providing a “surgical alteration to the body of these unfortunate people was to collaborate with a mental disorder rather than to treat it” (McHugh, 2006).

## Literature Review: Introduction

Currently, an abundance of literature and studies on gender dysphoria is available through academic journals, clinical guidelines, and news articles. Similar to other mental health issues, the material addresses a broad range of topics consisting of available treatments, etiology (i.e., causes), risks, benefits, and side effects. Although most stories reported by the media indicate that treatments such as cross-sex hormones and sex reassignment surgery are the most effective, research reveals that numerous questions still exist. These include what are the long-term health effects of taking cross-sex hormones, what are the real causes of gender dysphoria, and how many individuals that transition will eventually want to revert to their natal sex. Additionally, much of the available research is inconclusive regarding the effectiveness of sex reassignment treatments with multiple studies lacking adequate sample sizes and relying on subjective questionnaires. While much of the scientific literature leans in favor of cross-sex hormones and surgery as options for improving the mental health of individuals with gender dysphoria, it does not conclusively demonstrate that the benefits outweigh the risks involved, either short or long-term. What studies do reveal with certainty is that sex reassignment surgery and cross-sex hormones pose permanent effects that can result in infertility, cardiovascular disease, and disfigurement. All of this indicates that further research is necessary to validate available treatments for gender dysphoria. Thus, physicians, who recommend sex reassignment treatment, are not adhering to an evidence-based medicine approach and are following an eminence-based model.

The following literature review addresses the multiple facets of this condition and presents areas of ongoing debate and persisting questions. Beginning with the condition's etiology and continuing with evaluations of puberty blockers, cross-sex hormones, and surgery, the review explains each area separately and in context of gender dysphoria at large. Additionally, the review provides an analysis on available research on mental health outcomes as well as the condition's persistence into adulthood. Taken as a whole, the available studies demonstrate that existing gender dysphoria research is inconclusive and that current treatments are used to achieve cosmetic benefits while posing risky side effects as well as irreversible changes.

## Literature Review: Etiology of Gender Dysphoria

What causes gender dysphoria is an ongoing debate among experts in the scientific and behavioral health fields. Currently, the research indicates that diagnosed individuals have higher proportions of autism spectrum disorder (ASD), history of trauma or abuse, fetal hormone imbalances, and co-existing mental illnesses. Also, experts acknowledge that genetics may factor into gender dysphoria. Another potential cause is social factors such as peer and online media influence. At the moment, none of the studies provides a definite cause and offer only correlations and weakly supported hypotheses. In addition, evidence favoring a biological explanation is highly speculative. However, the research does raise questions about whether treatments with permanent effects are warranted in a population with disproportionately high percentages of ASD, behavioral health problems, and trauma.

In a 2017 literature review by Fatima Saleem and Syed Rizvi, the authors examine gender dysphoria's numerous potential causes and the remaining questions requiring further research. In conclusion, the pair indicate that associations exist between the condition and ASD, schizophrenia, childhood abuse, genetics, and endocrine disruption chemicals but that more research is needed to improve understanding of how these underlying issues factor into a diagnosis. Throughout the review, Saleem and Rizvi identify the following as potential contributing elements to the etiology of gender dysphoria:

- **Neuroanatomical Etiology:** During fetal development, the genitals and brain develop during different periods of a pregnancy, the first and second trimesters respectively. Because the processes are separate, misaligned development is possible where the brain may have features belonging to the opposite sex. The authors identify one study where trans-females presented with a "female-like putamen" (structure at the base of the brain) when undergoing magnetic resonance imaging (MRI) scans.<sup>5</sup>
- **Psychiatric Associations:** Saleem and Rizvi identify multiple studies reporting that individuals with gender dysphoria have high rates of anxiety and depressive disorders with results ranging as high as 70% having a mental health diagnosis. In addition, the pair note that schizophrenia may also influence desires to transition. However, the review does not assess whether the mental health conditions are secondary to gender dysphoria.
- **Autism Spectrum Disorder:** Evidence suggests a significant percentage of individuals diagnosed with gender dysphoria also have ASD. The authors note that the available studies only establish a correlation and do not identify mechanisms for causation.
- **Childhood Abuse:** Like the above causes, Saleem and Rizvi note that those with gender dysphoria tended to experience higher rates of child abuse across all categories, including neglect, emotional, physical, and sexual.
- **Endocrine Disruptors:** Although this cause still requires substantial research, it is a valid hypothesis regarding how phthalates found in plastics can create an imbalance of testosterone in fetuses during gestation, which can potentially lead to gender dysphoria. The authors point to one study that makes this suggestion.

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<sup>5</sup> Research on neuroanatomical etiology for gender dysphoria remains highly speculative due to limitations of brain imaging (Mayer and McHugh, 2016). In addition, neuroscience demonstrates that exposures to certain environments and stimuli as well as behaviors can affect brain changes (Gu, 2014). Furthermore, available research indicates that male and female brains have different physical characteristics but cannot be placed in separate categories due to extensive overlap of white/grey matter and neural connections (Joel et al, 2015).

Saleem and Rizvi's review reveal that gender dysphoria's etiology can have multiple factors, most of which require treatments and therapies not consisting of cross-sex hormones or surgery. (Saleem and Rizvi, 2017).

Out of the research on the condition's etiology, a large portion focuses on the correlation with ASD. One of the more substantial studies by Van der Miesen et al published in 2018 evaluates 573 adolescents and 807 adults diagnosed with ASD and compares them to 1016 adolescents and 846 adults from the general population. The authors' findings note that adolescents and adults with ASD were approximately 2.5 times more likely to indicate a desire of becoming the opposite sex. Although the methodology used to reach this conclusion consisted of surveys where respondents had a choice of answering "never," "sometimes," or "often," the results correspond with those of similar studies. Van der Miesen et al also indicate that most responses favoring a change in gender responded with "sometimes." Additionally, the authors do not state how many in their sample group actually had a gender dysphoria diagnosis. (Van der Miesen et al, 2018).

Another study by Shumer et al from 2016 utilizes a smaller sample size (39 adolescents) referred to an American hospital's gender clinic. Unlike Van der Miesen et al's research, Shumer et al evaluate subjects with a diagnosis of gender dysphoria for possible signs of ASD or Asperger's syndrome. Their findings revealed that 23% of patients presenting at the clinic would likely have one of the two conditions. Possible explanations for the high percentage are the methods used to gather the data. Shumer et al requested a clinical psychologist to administer the Asperger Syndrome Diagnostic Scale to the parents of the sample patients, four of whom already had an ASD diagnosis. The authors conclude that the evidence to support high incidence of gender dysphoria in individuals with ASD is growing and that further research is needed to determine the specific cause (Shumer et al, 2016).

Research indicating a strong correlation between ASD and gender dysphoria is not the only area where new studies are emerging. Discussions about the effects of prenatal testosterone levels are also becoming more prevalent. One such example is Sadr et al's 2020 study that looks at the lengths of the index and ring fingers (2D:4D) of both left and right hands of 203 individuals diagnosed with gender dysphoria. The authors used this method because prenatal testosterone levels can affect the length ratios of 2D:4D. By comparing the ratios of a group with gender dysphoria to a cohort from the general population, Sadr et al could assess for any significant difference. Their results indicated a difference in trans-females who presented with more feminized hands. For trans-males, the difference was less pronounced. The results for both groups were slight, and the meta-analysis that accompanies the study notes no statistically significant differences in multiple groups from across cultures. However, Sadr et al further assert that the evidence strongly suggests elevated prenatal testosterone levels in girls and reduced amounts in boys may contribute to gender dysphoria, requiring additional research (Sadr et al, 2020).

In addition to biological factors and correlations with ASD, researchers are exploring psychological and social factors to assess their role in gender dysphoria etiology. This literature examines a range of potential causative agents, including child abuse, trauma, and peer group influences. One such study by Kozłowska et al from 2021 explores patterns in children with high-risk attachment issues who also had gender dysphoria. The authors wanted to assess whether past incidents of abuse, loss, or trauma are associated with higher rates of persons desiring to transition. As a basis, Kozłowska et al cite John Bowlby's research on childhood brain development, noting that the process is not linear and depends

heavily on lived experiences. The study further acknowledges that biological factors combined with life events serve as the foundation for the next developmental phase and that early poor-quality attachment issues increase the risk for psychological disorders in adolescence and adulthood. Such disorders include mood and affective disorders, suicidal ideations, and self-harm. Kozłowska et al also cite other studies that indicate a high correlation between gender dysphoria and “adverse childhood events” and further assert that the condition “needs to be conceptualized in the context of the child’s lived experience, and the many different ways in which lived experience is biologically embedded to shape the developing brain and to steer each child along their developmental pathway” (Kozłowska et al, 2021).

For their study, Kozłowska et al recruited 70 children diagnosed with gender dysphoria and completed family assessments going back three generations. This in-depth level was necessary to ascertain any and all events that could affect a child’s developmental phases. Additionally, the researchers individually assessed the diagnosed children. To establish comparisons, Kozłowska et al performed assessments on a non-clinical group and a mixed-psychiatric group. Their results demonstrate that children with gender dysphoria have significantly higher rates of attachment issues as well as increased reports of “adverse childhood events” such as trauma (e.g., domestic violence and physical abuse). Furthermore, the authors indicate that a high proportion of families reported “instability, conflict, parental psychiatric disorder, financial stress, maltreatment events, and relational ruptures.” These results led Kozłowska et al to conclude that gender dysphoria can be “associated with developmental pathways – reflected in at-risk patterns of attachment and high rates of unresolved loss and trauma – that are shaped by disruptions to family stability and cohesion.” The study also cites that treatment requires “a comprehensive biopsychosocial assessment with the child and family, followed by therapeutic interventions that address, insofar as possible, the breadth of factors that are interconnected with each particular child’s presentation” (Kozłowska et al, 2021).

This recent study raises questions regarding the medical necessity of gender dysphoria treatments such as puberty blockers and cross-sex hormones for adolescents. If high percentages of children diagnosed with gender dysphoria also have histories of trauma and attachment issues, should conventional behavioral health services be utilized without proposing treatments that pose irreversible effects? Would that approach not provide additional time to address underlying issues before introducing therapies that pose permanent effects (i.e., the watchful waiting approach)?

Aside from the notion that childhood abuse and adversity can potentially cause gender dysphoria, other possible explanations such as social factors (e.g., peer influences and media) may be contributing factors. Research on rapid onset gender dysphoria (ROGD) links this phenomenon to peer and social elements. In an analysis utilizing parent surveys, Lisa Littman asserts that the rapid rise of ROGD is not associated with the traditional patterns of gender dysphoria onset (i.e., evidence of an individual’s gravitation to the opposite sex documented over multiple years) but rather exposure to “social and peer contagion.” Littman uses this term in the context of definitions cited in academic literature, stating that “social contagion is the spread of affect or behaviors through a population” and that “peer contagion is the process where an individual and peer mutually influence each other in a way that promotes emotions and behaviors that can potentially undermine their own development or harm others.” Examples of the latter’s negative effects include depression, eating disorders, and substance abuse. What prompted this study is a sudden increase of parents reporting their daughters declaring themselves to be transgender without any previous signs of gender dysphoria. Littman also indicates

that these parents cite that their daughters became immersed in peer groups and social media that emphasized transgender lifestyles (Littman, 2018).

In addition to identifying characteristics of ROGD, the study examines social media content that provides information to adolescents regarding how to obtain cross-sex hormones through deception of physicians, parents, and behavioral health professionals. Such guidance includes coaching on how to fit a description to correspond to the DSM-V and pressures to implement treatment during youth to avoid a potential lifetime of unhappiness in an undesirable body. Littman further states that “online content may encourage vulnerable individuals to believe that non-specific symptoms and vague feelings should be interpreted as gender dysphoria.” The study also notes that none of the individuals assessed using the parental surveys qualified for a formal diagnosis using the DSM-V criteria (Littman, 2018).

The survey responses revealed similar data to Kozłowska et al’s study with 62.5% of the adolescents having a mental health or neurodevelopmental disorder. Furthermore, the responses indicate a rapid desire to bypass behavioral health options and pursue cross-sex hormones. 28.1% of parents surveyed stated that their adolescents did not want psychiatric treatments. One parent even reported that their daughter stopped taking prescribed anti-depressants and sought advice only from a gender therapist. Littman’s research further reveals that 21.2% of parents responded that their adolescent received a prescription for puberty blockers or cross-sex hormones at their first visit (Littman, 2018). These responses indicate that practitioners do not uniformly follow clinical guidelines when making diagnoses or prescribing treatment.

In the discussion, Littman proposes two hypotheses for the appearance of ROGD. The first states that social and peer contagion is one of the primary causes, and the second asserts that ROGD is a “maladaptive coping mechanism” for adolescents dealing with emotional and social issues. While the surveyed parents did not report early signs of gender dysphoria, a majority noted that their daughters had difficulty in handling negative emotions. Littman concludes that ROGD is distinct from gender dysphoria as described in the DSM-V and that further research is needed to assess whether the condition is short or long-term (Littman, 2018). What the study does not explore, but raises the question, is what proportion of those being treated for gender dysphoria are adolescents with ROGD.

Littman’s study along with the others reveal that the causes of gender dysphoria are still a mystery and could have multiple biological and social elements. Because of this ongoing uncertainty, treatments that pose irreversible effects should not be utilized to address what is still categorized as a mental health issue. That allows adequate opportunity for individuals to receive treatment for co-existing mental disorders, establish their gender dysphoria diagnoses, and understand how cross-sex hormones and surgery will alter the appearance of their bodies as well as long-term health.



## Literature Review: Desistance of Gender Dysphoria and Puberty Suppression

The World Professional Association for Transgender Health (WPATH) and the Endocrine Society both endorse the use of gonadotropin releasing hormones (Gn-RH) to suppress puberty in young adolescents who have gender dysphoria. Both organizations state that the treatment is safe and fully reversible. In addition, they state that delaying pubertal onset can provide extra time for adolescents to explore the gender in which they choose to live. The associations further state that puberty suppression is necessary to prevent the development of primary and secondary sexual characteristics that can inhibit successful transitions into adulthood (WPATH, 2012; Endocrine Society, 2017). Of the two groups, WPATH offers clinical criteria an individual should meet to qualify for puberty suppression such as addressing psychological co-morbidities and assessing whether gender dysphoria has intensified (WPATH, 2012).

Neither organization explains that the majority of young adolescents who exhibit signs of gender dysphoria eventually desist and conform to their natal sex and that the puberty suppression can have side effects. Both organizations neglect to mention that using Gn-RH for gender dysphoria by altering the appearance is not an FDA-approved clinical indication. Furthermore, the research used to justify puberty suppression is low or very-low quality and little information is available on long-term effects (Hruz, 2019). Additionally, in his assessment, Quentin Van Meter explained that physical differences between central precocious puberty and natural onset puberty demonstrate that Gn-RH does not have permanent adverse effects for those treated for the former but can for the latter such as insufficient bone-mineral density and neural development (Van Meter, 2022). Also, as recently as May 17, 2022, during a U.S. Senate Committee on Appropriations hearing, Lawrence Tabak, acting director of the National Institutes of Health, responded to Senator Marco Rubio, acknowledging that no long-term studies are available evaluating the effects of puberty blockers when used for gender dysphoria (U.S. Senate Committee on Appropriations, 2022).

Currently, some studies provide weak support for this treatment but leave too many questions as to its effectiveness and medical necessity, especially considering how many children decide against transitioning. In addition, puberty blockers halt development of primary and secondary sexual characteristics and deny opportunities for adolescents to adapt and become comfortable with their natal sex. Instead, puberty blockers can serve as a potential “gateway drug” for cross-sex hormones by denying them the experience of physically maturing (Laidlaw et al, 2018).

A 2013 study by Steensma et al offers data on the percentage of children who opt not to transition after experiencing gender dysphoria. The authors follow 127 adolescents (mean age of 15 during the evaluation period) for four years who had been referred to a Dutch gender dysphoria clinic. Out of this cohort, 47 (37%; 23 boys and 24 girls) continued experiencing the condition and applied for sex reassignment treatment. The other 80 adolescents never returned to the clinic. Because this clinic was the only one that treated gender dysphoria in the Netherlands, Steensma et al assumed that those who did not return no longer desired transitioning. The study indicates one of the key predictors for persisting gender dysphoria was the age of first presentation. Older adolescents that started going to the clinic were more likely to persist, while younger adolescents tended not to follow through. Steensma et al provide further insight into other predicting factors, particularly on how each individual views his or her gender identity. The authors note that adolescents who “wished they were the other sex” were more likely to become desisters and that those who “believed that they were the other sex” persisted

and later sought sex reassignment treatment (Steensma et al, 2013). While the study focuses on factors that contribute to the condition's persistence or desistance, it raises the question as to whether puberty suppression is necessary when age plays such an important role regarding the decision to transition.

WPATH and the Endocrine Society state that the primary reason for initiating pubertal suppression is not to treat a physical condition but to improve the mental health of adolescents with gender dysphoria. However, available research does not yield definitive results that this method is effective at addressing a mental health issue. The "gold standard" for medical studies is the randomized-controlled trial (RCT). Because RCTs utilize large sample sizes, have blind testing groups (i.e, placebos), and use objective controls, they can offer concrete conclusions and shape the array of established treatments. In addition, RCTs require comparisons between cohort outcomes and ensure that participants are randomly assigned to each group. These measures further reduce the potential for bias and subjectivity (Hariton and Locascio, 2018).

Presently, no RCTs that evaluate puberty suppression as a method to treat gender dysphoria are available. Instead, the limited number of published studies on the topic utilize small sample sizes and subjective methods (Hruz, 2019). A 2015 article by Costa et al is one such example. The study asserts that "psychological support and puberty suppression were both associated with an improved global psychological functioning in gender dysphoric adolescents." To reach this conclusion, the authors selected 201 children diagnosed with the condition and divided them into two groups, one to receive psychological support only and the other to get puberty blockers in addition to psychological support. Costa et al did not create a third group that lacked a gender dysphoria diagnosis to serve as a control. To assess whether puberty suppression is an effective treatment, the authors administered two self-assessments (Utrecht Gender Dysphoria Scale and Children's Global Assessment Scale)<sup>6</sup> to the groups at 6-month intervals during a 12-month period. Because the study relies heavily on self-assessments, the conclusions are likely biased and invalid. Another problem that is also present and common throughout articles supporting puberty suppression is the short-term period of the study. Costa et al's conclusions may not be the same if additional follow-ups occurred three or five years later (Costa et al, 2015). This further raises the question whether low-quality studies like Costa et al's should serve as the basis for clinical guidelines advising clinicians to prescribe drugs for off-label purposes.

Aside from questionable research, information regarding the full physical effects of puberty suppression is incomplete. In a 2020 consensus parameter prepared by Chen et al, 44 experts in neurodevelopment, gender development, and puberty/adolescence reached a conclusion stating that "the effects of pubertal suppression warrant further study." The basis for this was that the "full consequences (both beneficial and adverse) of suppressing endogenous puberty are not yet understood." The participating experts emphasized that the treatment's impact on neurodevelopment in adolescents remains unknown. Chen et al explain that puberty-related hormones play a role in brain development as documented in animal studies and that stopping these hormones also prevents neurodevelopment in addition to sexual maturation. The authors further raise the question whether normal brain development resumes as if it had not been interrupted when puberty suppression ceases. Because this

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<sup>6</sup> Behavioral health practitioners use the Children's Global Assessment Scale (CGAS) to measure child functioning during the evaluation process to determine diagnoses. Available evidence indicates that the CGAS is not effective for evaluating children who experienced trauma and presented with mental health symptoms (Blake et al, 2006).

question remains unanswered, it casts doubt on the veracity of organizations' assertions that puberty suppression is "fully reversible" (Chen et al, 2020).

In addition to the unanswered questions and low-quality research, puberty suppression causes side effects, some of which have the potential to be permanent. According to a 2019 literature review by De Sanctis et al, most side effects associated with Gn-RH are mild, consisting mostly of irritation around injection sites. However, clinicians have linked the drug to long-term conditions such as polycystic ovarian syndrome, obesity, hypertension, and reduced bone mineral density. While reports of these events are low and the authors indicate that Gn-RH is safe for treating central precocious puberty (Note: De Sanctis et al do not consider gender dysphoria in their analysis), the review raises questions about whether off-label use to treat a psychological condition is worth the risks (De Sanctis et al, 2019).

Furthermore, De Sanctis et al cite studies noting increased obesity rates in girls who take Gn-RH but that more research is needed to gauge the consistency. Additionally, the authors note that evidence is strong regarding reduced bone mineral density during puberty suppression but indicate that the literature suggests it is reversible following treatment (De Sanctis et al, 2019). While research leans toward the reversibility of effects on bone mineral density, the quantity of studies available on this subject are limited. Also, no long-term research has been completed on how puberty suppression affects bone growth. This is significant because puberty is when bone mass accumulates the most (Kyriakou et al, 2020). One example of a complication involving bone growth and Gn-RH is slipped capital femoral epiphysis. This condition occurs when the head of the femur (i.e., thighbone) can slip out of the pelvis, which can eventually lead to osteonecrosis (i.e., bone death) of the femoral head. Although the complication is rare, its link to puberty suppression indicates that the "lack of adequate sex hormone exposure" could be a cause (De Sanctis et al, 2019).

The current literature on puberty suppression indicates that using it to treat gender dysphoria is off-label, poses potentially permanent side effects, and has questionable mental health benefits. The limited research and lack of FDA approval for that clinical indication prompt questions about whether medications with physically altering effects should be used to treat a problem that most adolescents who experience it will later overcome by conforming to their natal sex. Additional evidence is required to establish puberty suppression as a standard treatment for gender dysphoria.

## Literature Review: Cross-Sex Hormones as a Treatment for Gender Dysphoria

Currently, the debate surrounding the use of cross-sex hormones to treat gender dysphoria revolves around their ability to improve mental health without causing irreversible effects. It is not about whether taking cross-sex hormones can alter someone's appearance. The evidence demonstrating the effectiveness of cross-sex hormones in achieving the secondary sexual characteristics of the opposite sex is abundant. Also, the overall scientific consensus concludes that individuals who take cross-sex hormones will reduce the primary sexual function of his or her natal sex organs. What researchers continue evaluating are the short and long-term effects on mental health, impacts on overall physical health, and how the changes affect the ability to detransition. Of these, benefits to mental health overshadow the other discussions. Prescribers of cross-sex hormones focus so heavily on behavioral health outcomes that they de-emphasize that these drugs cause permanent physical changes and side effects that can lead to premature death (Hruz, 2020). Some clinical guidelines such as WPATH's do not even indicate that some of the changes are irreversible.

Like puberty suppression, the Endocrine Society and WPATH provide guidance on administering cross-sex hormones to individuals with gender dysphoria. Both organizations state that this treatment should not be administered without a confirmed diagnosis of gender dysphoria and only after a full psychosocial assessment. In addition, behavioral health practitioners must ensure that any mental comorbidities are not affecting the individual's desire to transition. WPATH and the Endocrine Society further state that clinicians should administer hormone replacements such as testosterone and Estradiol (estrogen) in gradual phases, where the dose increases over several months. For trans-females, the organizations state that progesterone (anti-androgen) is also necessary to block the effects of naturally produced testosterone (WPATH, 2012; Endocrine Society, 2017). When taking cross-sex hormones, trans-males need increased doses for the first six months. After that, the testosterone's effects are the same on lower doses. Once started, individuals cannot stop taking hormones unless they desire to detransition (Unger, 2016).

Although the two groups provide similar guidance, they vary on statements that can have significant impact on long-term outcomes, particularly regarding age. According to WPATH's standards, 16 years is the general age for initiating cross-sex hormones, but the organization acknowledges that the treatment can occur for younger individuals depending on circumstances (WPATH, 2012). This differs from the Endocrine Society, which states no specific age for appropriateness and explains the disagreements in assigning a number. The group highlights that most adolescents have attained sufficient competence by age 16 but may not have developed adequate abilities to assess risk (Endocrine Society, 2017). This raises the question whether adolescents can make sound decisions regarding their long-term health. Additionally, the varying guidance raises an issue with WPATH not only using age 16 as a standard but also indicating that younger adolescents are capable of making that choice.

WPATH's guidance also does not stress the irreversible nature of cross-sex hormones, citing the treatment as "partially reversible" and not indicating which changes are permanent. Furthermore, parts of WPATH's information are misleading and directly conflict with guidance issued by clinics and other sources. One such example consists of WPATH stating that "hormone therapy *may* (emphasis added) lead to irreversible changes." This statement is misleading in light of existing research, which indicates that multiple physical changes are permanent. In addition, WPATH claims that certain effects of cross-

sex hormones such as clitoral enlargement can last one to two years when it is actually irreversible (UCSF, 2020). WPATH also does not explain the risks to male fertility, noting that lowered sperm count or sterility is “variable.” The University of California at San Francisco (UCSF) provides starkly different information by stating that trans-females should expect to become sterile within a few months of starting cross-sex hormones. UCSF also advises trans-females to consult a sperm bank if they may want to father children after transitioning (WPATH, 2012; UCSF, 2020). Below is a chart that outlines the effects of cross-sex hormones and identifies which ones are reversible or permanent.

<b>Physical Changes Effectuated by Cross-Sex Hormones</b>	
<b>Physical Changes in Trans-Males (Female-to-Male Transitions)</b>	
<b>Physical Change</b>	<b>Reversible or Irreversible</b>
Oily Skin or Acne	Reversible
Facial and Body Hair Growth	Irreversible
Male-Pattern Baldness	Irreversible
Increased Muscle Mass	Reversible
Body Fat Redistribution	Reversible
Ceasing of Menstruation	Reversible
Enlarged Clitoris	Irreversible
Vaginal Atrophy	Reversible
Deepening of Voice	Irreversible
<b>Physical Changes in Trans-Females (Male-to-Female Transitions)</b>	
Body Fat Redistribution	Reversible
Decreased Muscle Mass	Reversible
Skin Softening or Decrease in Oiliness	Reversible
Lower Libido	Reversible
Fewer Spontaneous Erections	Reversible
Male Sexual Dysfunction	Possibly Irreversible
Breast Growth	Irreversible
Decrease in Testicular Size	Reversible
Decrease in Sperm Production or Infertility	Likely Irreversible
Slower Facial and Body Hair Growth	Reversible

Sources: UCSF, 2020; WPATH, 2012; Endocrine Society, 2017<sup>7</sup>

The above chart demonstrates that trans-males and trans-females experience different effects from cross-sex hormones that can cause myriad issues in later life. For example, trans-males who opt to detransition may face challenges related to permanent disfigurement (e.g., facial hair and deepened voices). Trans-females, on the other hand, may not endure the same issues pertaining to visible physical changes but might become despondent over being unable to reproduce. This can occur regardless of whether the transitioning individual is satisfied with sex reassignment. Given that the clinical guidelines do not provide uniform information on the permanent effects of cross-sex hormones, clinicians are unable to make sound recommendations to patients. This treatment can supposedly alleviate symptoms

<sup>7</sup> This chart consists of conclusions regarding physical changes made by three different clinical organizations. If one organization determined that a physical change was irreversible, that was sufficient to meet the criteria to be listed as “irreversible” in the chart.

of distress. However, cross-sex hormones' permanent effects also have the potential to cause psychological issues.

Arguments favoring cross-sex hormones assert that the desired physical changes can alleviate mental health issues in individuals with gender dysphoria but do not consider that hormones used in this manner, like puberty blockers, are off-label. While the FDA has approved estrogen and testosterone for specific clinical indications (e.g., hypogonadism), it has not cleared these drugs for treating gender dysphoria. Additionally, these arguments do not acknowledge that the U.S. Drug Enforcement Administration (DEA) lists testosterone as a Schedule III controlled substance, meaning that it has a high probability of abuse (DEA, 2022). Furthermore, evidence of psychological benefit from cross-sex hormones is low-quality and relies heavily on self-assessments taken from small sample groups (Hruz, 2020).

A 2019 study by Kuper et al seeks to demonstrate that adolescents desiring cross-sex hormones have elevated rates of depression, anxiety, and challenges with peer relationships. To make their findings, the authors provided questionnaires to 149 adolescents who presented at a gender clinic in Dallas, Texas and concluded that half of the sample group experienced increased psychological issues. One problem with the study is that it relies on parent or self-assessments such as the Youth-Self Report, Body-Image Scale, and the Child Behavior Checklist. While these assessments have strong reliability, the sample is cross-sectional, consisting of gender dysphoric individuals who presented for an initial visit at the clinic. Also, Kuper et al do not directly link these psychological symptoms to gender dysphoria but rather insinuate a strong connection. Without an analysis of the longitudinal histories of the participants, the study cannot demonstrate whether gender dysphoria was a direct cause of the psychological issues, which could possibly result from trauma, abuse, or family dysfunction. Kuper et al's study only presents weak correlation between adolescents who report symptoms of distress and gender dysphoria. While the authors do not claim that the participants' psychological problems caused the condition, they fail to explicitly state that no demonstrable relationship exists and explain that their findings are "broadly consistent with the previous literature" (Kuper et al, 2019).

Additionally, a more comprehensive literature review from 2019 by Nguyen et al evaluates the effect of cross-sex hormones on mental health outcomes. Although the authors argue that the evidence supports the treatment, they do note that available studies use "uncontrolled observational methods" and "rely on self-report." The review also asserts that "future research should focus on applying more robust study designs with large sample sizes, such as controlled prospective cohort studies using clinician-administered ratings and longitudinal designs with appropriately matched control groups." All of these are characteristics of RCTs. While Nguyen et al highlight flaws in the studies in their conclusion, they do not emphasize them in their analysis, opting to focus primarily on results. Another problem with the studies selected for the review is the short-term periods for evaluation. Out of 11 studies Nguyen et al discuss, only one tracks its participants for 24 months. The others only follow their cohorts for 6 or 12 months (Nguyen et al, 2019). Without long-term data to support assertions that cross-sex hormones substantially improve the mental health of individuals with gender dysphoria, the review cannot make definitive conclusions on the treatment's benefits.

Basing their stances on this low-quality evidence, clinical associations such as the American Academy of Pediatrics (AAP) and the American Psychology Association endorse the use of cross-sex hormones as treatments for gender dysphoria. In particular, the AAP discourages use of the term "transition" and

asserts that medical treatments used to obtain secondary characteristics of the opposite sex are “gender affirming.” This decision mirrors the DSM-V’s interpretation of gender being part of identity. The AAP further states that taking cross-sex hormones is an “affirmation and acceptance of who they (i.e., patient) have always been” (AAP, 2018). The American Psychological Association also takes a similar stance in its *Resolution on Gender Identity Change Efforts* by asserting that medical treatments such as puberty suppression, cross-sex hormones, and surgery improve mental health and quality of life and reinforce the notion that transitioning and seeking sex reassignment therapies do not constitute a psychological disorder (American Psychological Association, 2021). Stances like these can substantially influence practitioners and their treatment recommendations. Given that low-quality evidence serves as the basis for supportive positions, this raises questions about whether clinicians can make informed decisions for their patients that will promote the best outcomes.

James Cantor published a critique in 2020 of the AAP’s endorsement of “gender affirming” treatments, arguing that the organization did not base its recommendations on established medical evidence. He asserts that the AAP’s position is based on research that does not support intervention but rather supports “watchful waiting” because most transgender youths desist and identify as their natal sex during puberty. Cantor further argues that the AAP not only disregards evidence but also cites “gender affirming” interventions as the only effective method. To conclude, he states the organization is “advocating for something far in excess of mainstream practice and medical consensus” (Cantor, 2020).

Given those evidentiary problems, those who rely on the AAP’s endorsement as a basis for “gender affirming” treatments are practicing eminence-based medicine as opposed to evidence-based medicine. Eminence-based medicine refers to clinical decisions made by relying on the opinions of prominent health organizations rather than relying on critical appraisals of scientific evidence (Nhi Le, 2016). While it is true that the AAP has more knowledge than a lay person and a degree of credibility in the medical community, the opinions of such organizations are not valid unless they are based on quality evidence.

Research on sex reassignment also does not adequately address the reasons for and prevalence of detransitioning. Although no definite numbers are available regarding the percentage of transgender people who decide to detransition, research indicates that roughly 8% decide to return to their natal sex. The reasons range from treatment side effects to more self-exploration that provided insight on individuals’ gender dysphoria. In a 2020 study by Lisa Littman, 101 people who had detransitioned provided their basis for doing so. Out of the sample group, 96% had taken cross-sex hormones and 33% had sex reassignment surgery. The average age for transitioning was 22 years, and the mean duration for the transition was 4 years. This indicates that even allowing additional time beyond the recommended age of 16 years can still lead to regrets. The study also raises the question as to whether individuals who transitioned at 16 or younger wanted to detransition in greater numbers. The author further offers reasons why these individuals sought cross-sex hormones and surgery, which include having endured trauma (mental or sexual), homophobia (challenged to accept oneself as a homosexual), peer and media influences, and misogyny (applicable only to trans-males). To obtain the results, the participants responded to a survey that asked about their backgrounds (e.g., reasons for transitioning, mental health comorbidities), and motivations for detransitioning. Littman noted that half of the women (former trans-males) had a mental health disorder and/or had experienced trauma within a year of deciding to transition. Men (former trans-females) reported much lower numbers of behavioral health issues and trauma after de-transitioning. Additionally, 77% of men surveyed identified as the opposite gender prior to transition, whereas just 58% of women had (Littman, 2020).

Of the reasons cited for detransitioning, the majority (60%) noted that they became more comfortable with their natal sex. Other reasons included concerns over complications from the treatments, primarily cross-sex hormones, and lack of improved mental health. Other less-cited explanations include concerns about workplace discrimination and worsening physical health. The study also notes that approximately 36% of participants experienced worse mental health symptoms. Based on the findings, Littman concludes that more research is needed in tracking the transgender population to obtain accurate percentages of those who decide to detransition and that men and women reported varying reasons for deciding to transition and later return to their natal sex. The author notes that higher rates of trauma and peer group influences might have contributed to women's decisions, which Littman attributes partially to rapid onset gender dysphoria (Littman, 2020). What the study also indicates is that cross-sex hormones are not a validated treatment for gender dysphoria. Nearly all of the participants had taken them and decided against maintaining the physical changes. Given that the majority of surveyed detransitioners cited that they were comfortable with their biological sex, the study indicates that gender dysphoria is not necessarily a lifelong issue. This necessarily raises doubts about whether cross-hormones, which cause permanent physical damage, is justified.

In addition to the psychological factors, cross-sex hormones pose significant long-term health risks to transitioning individuals. Currently, little information is available given that researchers have not had adequate time to study the effects in this population. However, use of hormones for other conditions has yielded data on how these drugs can affect the body and the cardiovascular system in particular. Because of the high dosages required to achieve physical change and the need to continuously take the drugs, cross-sex hormones can potentially harm quality of life and reduce life expectancy for transitioning individuals. According to Dutra et al, trans-females are three times more likely to die from a cardiovascular event than the general population. In their 2019 literature review, Dutra et al examined the results of over 50 studies evaluating the effects of cross-sex hormones on not only transgender individuals but those with menopause and other endocrine disorders, all of which indicate that use of estrogen or testosterone can increase risks for cardiovascular disease. Throughout their review, Dutra et al cite examples of trans-females having higher triglyceride levels after 24 months of cross-sex hormones and how researchers halted a study on estrogen due to an increase in heart attacks among participants. Another article the authors reference indicates a higher risk for thromboembolisms (i.e., blood clots) in trans-females. For trans-males, Dutra et al explain that research shows significant increased risk for hypertension, high cholesterol, obesity, and heart attacks. One study noted that trans-males have a four times greater risk of heart attack compared to women identifying as their natal sex. Dutra et al conclude that most transgender individuals are younger than 50 and that more studies are needed as this population ages. They do note that available studies indicate that cross-sex hormones pose dangers to long-term cardiovascular health (Dutra et al, 2019).

In sum, the literature reveals that the evidence for cross-sex hormones as a treatment for gender dysphoria is weak and insufficient. Between the permanent effects, off-label use, and consequences to long-term health, cross-sex hormones are a risky option that does not promise a cure but does guarantee irreversible changes to both male and female bodies. Additionally, the inadequate studies serving as the basis for recommendations by clinical associations can lead to providers making poorly informed decisions for their patients. Research asserting that taking cross-sex hormones improves mental health is subjective and short-term. More studies that utilize large sample sizes and appropriate



methods is required before the medical profession should consider cross-sex hormones as one of gender dysphoria's standard treatments.

## Literature Review: Sex Reassignment Surgery

The final phase of treatment for gender dysphoria is sex reassignment surgery. This method consists of multiple procedures to alter the appearance of the body to resemble an individual's desired gender. Some procedures apply to the genitals (genital procedures) while others affect facial features and vocal cords (non-genital procedures). While the surgery creates aesthetical aspects, it does not fully transform someone into the opposite biological sex. Transgender persons who undergo the procedures must continue taking cross-sex hormones to maintain secondary sexual characteristics. Additionally, all physical changes are irreversible, and the success rate of a surgery varies depending on the procedure and the population. For example, surgeries for trans-females have much better results than those for trans-males. Complications such as post-operative infections can also arise with the urinary tract system. However, sex reassignment surgery supposedly can provide drastic, if not complete, relief from gender dysphoria (Endocrine Society, 2017). The following is a list of procedures (both genital and non-genital) for trans-females and trans-males that create physical features of the desired sex.

### Procedures for Trans-Females

- **Genital Surgeries:** These consist of penectomy (removal of the penis), orchiectomy (removal of the testicles), vaginoplasty (construction of a neo-vagina), clitoroplasty (construction of a clitoris), and vulvoplasty (construction of a vulva and labia). To perform, a surgeon begins by deconstructing the penis and removing the testicles. The penile shaft and glans are repurposed to serve as a neo-vagina and artificial clitoris (Note: These are not actual female genitalia but tissue constructed to resemble female anatomy). If the shaft tissue is insufficient, the surgeon may opt to use a portion of intestine to build a neo-vagina. The scrotum serves as material for fashioning a vulva and labia. In addition to constructing female genitalia, the surgeon reroutes the urethra to align with the neo-vagina. Genital surgeries for trans-females result in permanent sterility (Bizic et al, 2014).
- **Chest Surgery:** To attain full breasts, trans-females can undergo enlargement. The procedure is similar to breast augmentation for women where a surgeon places implants underneath breast tissue. Prior to surgery, trans-females need to take cross-sex hormones for roughly 24 months to increase breast size to get maximum benefit from the procedure (Endocrine Society, 2017).
- **Cosmetic and Voice Surgeries:** Designed to create feminine facial features, fat deposits, and vocal sounds, these procedures are secondary to genital procedures and intended to alter trans-females' appearances to better integrate into society as a member of the desired gender (WPATH, 2012).

### Procedures for Trans-Males

- **Mastectomy:** This is the most performed sex reassignment surgery on trans-males because cross-sex hormones and chest-binding garments are often insufficient at diminishing breasts. To remove this secondary sexual characteristic, trans-males can undergo a mastectomy where a surgeon removes breast tissue subcutaneously (i.e., under the skin) and reconstructs the nipples to appear masculine. The procedure can result in significant scarring (Monstrey et al, 2011).
- **Genital Surgeries:** Unlike the procedures for trans-females, genital surgeries for trans-males are more complex and have lower success rates. Consisting of hysterectomy, oophorectomy

(removal of the ovaries), vaginectomy (removal of the vagina), phalloplasty (construction of a penis), and scrotoplasty (construction of prosthetic testicles), a team of surgeons must manufacture a penis using skin from the patient (taken from an appendage) while removing the vagina and creating an extended urethra. The functionality of the artificial penis can vary based on how extensive the construction was. Attaining erections requires additional surgery to implant a prosthesis, and the ability to urinate while standing is often not achieved. Genital procedures for trans-males result in irreversible sterility (Monstrey et al, 2011).

- **Cosmetic Surgeries:** Similar to trans-females, these procedures create masculine facial features, fat deposits, and artificial pectoral muscles. They aid trans-males with socially integrating as their desired gender. Surgery to deepen voices is also available but rarely performed (WPATH, 2012).

Because sex reassignment surgery is irreversible, the criteria for receiving these procedures is the strictest of all gender dysphoria treatments. WPATH and the Endocrine Society suggest rigorous reviews of patient history and prior use of other therapies before approving. Furthermore, the two organizations recommend that only adults (18 years old) undergo sex reassignment surgery.<sup>8</sup> WPATH and the Endocrine Society also recommend ensuring a strongly documented diagnosis of gender dysphoria, addressing all medical and mental health issues, and at least 12 months of cross-sex hormones for genital surgeries. Although the organizations agree on most criteria, they differ on whether hormones should be taken prior to mastectomies. WPATH asserts that hormones should not be a requirement, whereas the Endocrine Society advises up to 2 years of cross-sex hormones before undergoing the procedure (WPATH, 2012; Endocrine Society, 2017). What this indicates is that trans-males might undergo breast removal without having first pursued all options if their clinician adheres to WPATH's guidelines, which can lead to possible regret over irreversible effects.

As with cross-sex hormones, sex reassignment surgery's irreversible physical changes can potentially show marked mental health improvements and prevent suicidality in people diagnosed with gender dysphoria. In April 2022, the chair of the University of Florida's pediatric endocrinology department, Dr. Michael Haller, advocated for the benefits of "gender affirming" treatments (WUSF, 2020). However, the available evidence calls such statements into question. Recent research assessing both cross-sex hormones and sex reassignment surgery indicate that the effects on "long-term mental health are largely unknown." In studies regarding the benefits of surgery, the results have the same weaknesses as the research for the effectiveness of cross-sex hormones. These include small sample sizes, self-report surveys, and short evaluation periods, all of which are insufficient to justify recommendations for irreversible treatments (Bränström et al, 2020).

Two studies conducted in Sweden provide insight on the effectiveness of sex reassignment surgery in improving the behavioral health of transgender persons. Because Sweden has a nationalized health system that collects data on all residents, this country can serve as a resource to assess service utilization and inpatient admissions. Both studies, one by Dhejne et al from 2011 and another by Bränström et al published in 2020, assessed individuals who had received sex reassignment surgery and examined outcomes over several decades. Dhejne et al's findings indicate that sex reassignment

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<sup>8</sup> Although practice guidelines indicate the minimum age to undergo sex reassignment surgery is 18, available evidence demonstrates that mastectomies have been performed on adolescent girls as young as 13 who experience "chest dysphoria" (Olson-Kennedy et al, 2018).

procedures do not reduce suicidality. The authors explained that individuals who underwent sex reassignment surgery were still more likely to attempt or commit suicide than those in the general population. This study is unique because it monitored the subjects over a long period of time. Dhejne et al note that the transgender persons tracked for the study did not show an elevated suicide risk until ten years after surgery (Dhejne et al, 2011). Given that a high proportion of research follows sex reassignment patients for much shorter timeframes, this evidence indicates that surgery might have little to no effect in preventing suicides in gender dysphoric individuals over the long run.

In addition to having an increased suicide risk, Dhejne et al discuss how individuals who underwent sex reassignment procedures also had higher mortality due to cardiovascular disease. The authors do not list the specific causes but establish the correlation. Given that cross-sex hormones can damage the heart, the increased risk could be related to the drugs and not the surgery. Furthermore, the study explains that the tracked population had higher rates of psychiatric inpatient admissions following sex reassignment. Dhejne et al established this by examining the rates of psychiatric hospitalizations in these individuals prior to surgery and noted higher utilization in the years following the procedures. These results are in comparison to the Swedish population at large. While the study contradicts other research emphasizing improvements in mental health issues, it has its limitations. For example, the sample size is small. Dhejne et al identified only 324 individuals who had undergone sex reassignment surgery between 1973 and 2003. In addition, the authors noted that while the tracked population had increased suicide risks when compared to individuals identifying as their natal sex, the rates could have been much higher if the procedures were not available (Dhejne et al 2011). What this study postulates is that sex reassignment surgery does not necessarily serve as a “cure” to the distress resulting from gender dysphoria and that ongoing behavioral health care may still be required even after a complete transition.

Bränström et al’s study evaluating the Swedish population used a larger sample (1,018 individuals who had received sex reassignment surgery) but tracked them for just a ten-year period (2005 to 2015).<sup>9</sup> Unlike Dhejne et al, the authors did not track suicides and focused primarily on mood or anxiety disorder treatment utilization. Their results indicate that transgender persons who had undergone surgery utilized psychiatric outpatient services at lower rates and were prescribed medications for behavioral health issues at an annual decrease rate of 8%. Bränström et al also did not limit comparisons to Sweden’s overall population and factored in transgender persons who take cross-sex hormones but have not elected to have surgery. Those results still presented a decrease in outpatient mental health services. However, Bränström et al note that individuals only on cross-sex hormones showed no significant reduction in that category, which calls into question claims regarding effectiveness of cross-sex hormones in ameliorating behavioral issues.

The Bränström et al study prompted numerous responses questioning its methodology. The study lacked a prospective cohort or RCT design, and it did not track all participants for a full ten-year period (Van Mol et al, 2020). These criticisms resulted in a retraction, asserting that Bränström et al’s conclusions were “too strong” and that further analysis by the authors revealed that the new “results demonstrated no advantage of surgery in relation to subsequent mood or anxiety disorder-related

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<sup>9</sup> Although Bränström et al claim to follow individuals for a ten-year period, peer reviews of the research revealed that this was not the case, noting the authors had varying periods of tracking, ranging from one to ten years (Van Mol et al, 2020).

health care visits or prescriptions or hospitalizations following suicide attempts in that comparison” (Kalin, 2020).

There are multiple explanations for why the Bränström et al study reached different results than the Dhejne et al study. For starters, Bränström et al tracked a larger sample group over a later period (2005 to 2015 as opposed to 1973 to 2003) during which gender dysphoria underwent a dramatic shift in definition. Also, Dhejne et al did not see elevated suicides until after ten years, raising the question as to whether sex reassignment surgery has temporary benefits on mental health rather than long-term or permanent benefits. Like the other Swedish study, Bränström et al’s findings are a correlation and do not specifically state that the procedures cause reduced psychiatric service utilization (Bränström et al, 2020).

A 2014 study by Hess et al in Germany evaluated satisfaction with sex reassignment procedures by attempting to survey 254 trans-females on their quality of life, appearance, and functionality as women. Out of the participants selected, only 119 (47%) returned completed questionnaires, which Hess et al indicate is problematic because dissatisfied trans-females might not have wanted to provide input. The results from the collected responses noted that 65.7% of participants reported satisfaction with their lives following surgery and that 90.2% indicated that the procedures fulfilled their expectations for life as women. While these results led Hess et al to conclude that sex reassignment surgery generally benefits individuals with gender dysphoria, the information is limited and raises questions (Hess et al, 2014). Such questions include whether the participants had mental health issues before or after surgery and did their satisfaction wane over time. Hess et al only sent out one questionnaire and not several to ascertain consistency over multiple years. Questions like these raise doubts about the validity of the study. Although Hess et al’s research is just one study, numerous others utilize the same subjective methods to reach their conclusions (Hruz, 2018).

In his assessment, Patrick Lappert contributes additional insight on the appropriate clinical indications for mastectomies, noting that removal of breast tissue is necessary following the diagnosis of breast cancer or as a prophylactic against that disease. He cites that this basis is verifiable through definitive laboratory testing and imaging, making it an objective diagnosis, whereas gender dysphoria has no such empirical methods to assess and depends heavily on the patient’s perspective. Also, Lappert notes that trans-males who make such decisions are doing so on the idea that the procedure will reduce their dysphoria and suicide risk. However, they are making an irreversible choice based on anticipated outcomes supported only by weak evidence, and thus cannot provide informed consent (Lappert, 2022).

The literature is inconclusive on whether sex reassignment surgery can improve mental health for gender dysphoric individuals. Higher quality research is needed to validate this method as an effective treatment. This includes studies that obtain detailed participant histories (e.g., behavioral diagnoses) and track participants for longer periods of time. These are necessary to evaluate the full effects of treatments that cause irreversible physical changes. In addition, sex reassignment procedures can result in severe complications such as infections in trans-females and urethral blockage in trans-males. Health issues related to natal sex can also persist. For example, trans-males who undergo mastectomy can still develop breast cancer and should receive the same recommended screenings (Trum et al, 2015). Until more definitive evidence becomes available, sex reassignment surgery should not qualify as a standard treatment for gender dysphoria.

## Literature Review: Quality of Available Evidence and Bioethical Questions

### Quality of Available Evidence

Clinical organizations that have endorsed puberty suppression, cross-sex hormones, and sex reassignment surgery frequently state that these treatments have the potential to save lives by preventing suicide and suicidal ideation. The evidence, however, does not support these conclusions. James Cantor notes that actual suicides (defined as killing oneself) are low, occur at higher rates for men, and that interpretations of available research indicate a blurring of numbers between those with gender dysphoria and homosexuals (Cantor, 2022). Although information exists that contradicts certain arguments, media outlets continue to report stories emphasizing the “lifesaving” potential of sex reassignment treatment. A May 2022 story by NBC announced survey results under the headline “Almost half of LGBTQ youths ‘seriously considered suicide in the past year’” (NBC, 2022). This is a significant claim that can have a sensational effect on patients and providers alike, but how strong is the evidence supporting it? Almost all of the data backing this assertion are based on surveys and cross-studies, which tend to yield low-quality results (Hruz, 2018). In addition, how many gender dysphoric individuals are seeing stories in the media and not questioning the narrative? Because research on the effectiveness of treatments is ongoing, a debate persists regarding their use in the adolescent and young-adult populations, and much of it is due to the low-quality studies serving as evidence.

In their assessment, Romina Brignardello-Petersen and Wojtek Wiercioch examined the quality of 61 articles published between 2020 and 2022 (Note: See Attachment A for the full study). They identified research on the effectiveness of puberty blockers, cross-sex hormones, and sex reassignment surgery and assigned a grade (high, moderate, low, or very low) in accordance with the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach. Out of the articles reviewed, all with a few exceptions received grades of low or very low quality when demonstrating outcomes regarding improvements in mental health and overall satisfaction with transitioning. For puberty blockers, Brignardello-Petersen and Wiercioch identified low quality evidence for alleviating gender dysphoria and very low quality for reducing suicidal ideation. The authors also had nearly identical findings for cross-sex hormones. However, they noted moderate quality evidence for the likelihood of cardiovascular side effects. Regarding surgery, Brignardello-Petersen and Wiercioch graded articles that examined overall satisfaction and complication rates. None of the studies received grades higher than low quality. These findings led the authors to conclude that “there is great uncertainty about the effects” of sex reassignment treatments and that the “evidence alone is not sufficient to support” using such treatments. Among the studies graded was one the U.S. Department of Health and Human Services cited in its information on “gender affirming” treatments. The authors noted this research had a “critical risk of bias” and was of low quality (Brignardello-Petersen and Wiercioch, 2022).

For his part, James Cantor provided a review of available literature, which addresses studies on etiology, desistance, effectiveness of puberty blockers and cross-sex hormones, suicidal behaviors, and clinical association and international guidelines. Throughout his analysis, Cantor cites weak evidence, poor methodologies (e.g., retrospective versus prospective studies), and lack of professional endorsements in research that indicates the benefits of sex reassignment treatment. Additionally, he notes that improvements in the behavioral health of adolescents who take cross-sex hormones can be attributed to the counseling they receive concurrently and that suicidality is not likely to result from gender

dysphoria but from co-occurring mental disorders. The reasoning behind the third point is based on the blending of suicide and suicidality, which are two distinct concepts. The former refers specifically to killing oneself, and the second regards ideation and threats in attempts to receive help. Cantor specifically notes that actual suicides are highly unlikely among gender dysphoric individuals, particularly trans-males. His other conclusions indicate that young children who experience gender identity issues will most likely desist by puberty, that multiple phenomena can cause the condition, and that Western European health services are not recommending medical intervention for minors. The basis for these statements is the paucity of high to moderate quality evidence on the effectiveness of sex reassignment treatments and numerous studies demonstrating desistance (Cantor, 2022).

Despite the need for stronger studies that provide definitive conclusions, many practitioners stand by the recommendations of the AAP, Endocrine Society, and WPATH. This is evident in a letter submitted to the *Tampa Bay Times*, which was a rebuttal to the Florida Department of Health's (DOH) guidance on treatment for gender dysphoria (Note: The guidance recommends against using puberty blockers, cross-sex hormones, or surgery for minors) (DOH, 2022). The authors, led by six professors at the University of Florida's College of Medicine, state that recommendations by clinical organizations are based on "careful deliberation and examination of the evidence by experts." However, evaluations of these studies show otherwise. Not only does the available research use cross-sectional methods such as surveys, but it provides insufficient evidence based on momentary snapshots regarding mental health benefits. These weak studies are the foundation for the clinical organizations' guidelines that the University of Florida professors tout as a gold standard. In addition, the letter's authors state that DOH's guidance is based on a "non-representative sample of small studies and reviews, editorials, opinion pieces, and commentary" (Tampa Bay Times, 2022). That statement misses the point when it comes to evidence demonstrating whether treatments with irreversible effects are beneficial because the burden of proof is on those advocating for this treatment, not on those acknowledging the need for further research. This raises the question concerning how much academic rigor these professors are applying to practice guidelines released by clinical organizations and whether they also apply the same level of rigor to novel treatments for other conditions (e.g., drugs, medical devices).

Another example of a lack of rigor is a 2019 article by Herman et al from the University of California at Los Angeles (UCLA) that evaluated responses to a 2015 national survey on transgender individuals and suicide. Unlike other studies, this one utilized a large cohort with 28,000 participants from across the U.S. responding. However, the researchers used no screening criteria and did not randomly select individuals. In addition, responses consisted entirely of self-reports with no supporting evidence to even prove a diagnosis of gender dysphoria. Although Herman et al conclude that the U.S. transgender population is at higher risk for suicidal behaviors, the authors' supporting evidence is subjective and serves as a weak basis. Additionally, the survey results do not establish gender dysphoria as a direct cause of suicide or suicidal ideation. The questions required participants to respond about their overall physical and mental health. Out of those that indicated "poor" health, 77.7% reported suicidal thoughts or attempts during the previous year, whereas just 29.1% of participants in "excellent" health had. These percentages indicate that causes beyond gender dysphoria could be affecting suicidal behaviors. Other reasons cited include rejection by family or religious organizations and discrimination. The authors also acknowledge that their findings are broad, not nationally representative, and should serve as a basis for pursuing future research (Herman et al, 2019).

Yet another example is a study published in 2022 by Olson et al tracks 300 young children that identify as transgender over a 5-year period, and asserts low probabilities for detransitioning, while supporting interventions such as puberty blockers. The authors found that children (median age of 8 years) who identified as a gender that differed from their natal sex were unlikely to desist at a rate of 94% and conclude that “transgender youth who socially transitioned at early ages” will continue “to identify that way.” While this appears to contradict earlier studies that demonstrate most young adolescents who change gender identities return to their “assigned gender at birth,” the authors note differences and limitations with the results. For example, Olson et al notes that they did not verify whether the participants met the DSM-V’s diagnostic criteria for gender dysphoria and that the children’s families supported the decisions to transition. Instead, the authors relied on a child’s chosen pronouns to classify as transgender. Also, Olson et al acknowledged that roughly 66% of the sample was biologically male. This is particularly significant considering that the majority of transitioning adolescents in recent years were natal females. Another issue with the study includes the median age at the end of follow-up (13 years), which is when boys begin puberty. Furthermore, the authors cite that the participants received strong parental support regarding the transitions, which constitutes positive reinforcement (Olson et al, 2022). Other research demonstrates that such feedback on social transitioning from parents and peers can prevent desistance following pubertal onset (Zucker, 2019). Despite these limitations, the New York Times announced the study’s publication under the headline “Few Transgender Children Change Their Minds After 5 Years” (New York Times, 2022). Such a title can add to the public’s perception that gender dysphoria requires early medical intervention to address.

### **Bioethical Questions**

The irreversible physical changes and potential side effects of sex reassignment treatment raise significant ethical questions. These questions concern multiple bioethical principles including patient autonomy, informed consent, and beneficence. In a 2019 article, Michael Laidlaw, Michelle Cretella, and Kevin Donovan argue that prescribing puberty blockers or cross-sex hormones on the basis that they will alleviate psychological symptoms should not be the standard of care for children with gender dysphoria. Additionally, the three authors assert that such treatments “constitute an unmonitored, experimental intervention in children without sufficient evidence of efficacy or safety.” The primary ethical question Laidlaw, Cretella, and Donovan pose is whether pushing physical transitioning, particularly without parental consent, violates fully informed consent (Laidlaw et al, 2019).

In accordance with principles of bioethics, several factors must be present to obtain informed consent from a patient. These consist of being able to understand and comprehend the service and potential risks, receiving complete disclosure from the physician, and voluntarily providing consent. Bioethicists generally do not afford the ability of giving informed consent to children who lack the competence to make decisions that pose permanent consequences (Varkey, 2021). Laidlaw, Cretella, and Donovan reinforce this point regarding sex reassignment treatment when they state that “children and adolescents have neither the cognitive nor the emotional maturity to comprehend the consequences of receiving a treatment for which the end result is sterility and organs devoid of sexual function” (Laidlaw et al, 2019). This further raises the question whether clinicians who make such treatment recommendations are providing full disclosure about the irreversible effects and truly obtaining informed consent.



Another issue is the conflict between consumerism and the practitioner's ability to provide appropriate care. Consumerism refers to patients learning about treatments through media/marketing and requesting their health care provider to prescribe it, regardless of medical necessity. Considering that social media is rife with individuals promoting "gender affirmative" drugs and surgeries, children are making self-assessments based on feelings they may not understand and that can lead to deep regret in the future (Littman, 2018). This can contribute to patients applying pressure on their doctors to prescribe medications not proven safe or effective for the condition. Consumerism can also affect bioethical compliance because it constrains clinicians from using their full "knowledge and skills to benefit the patient," which is "tantamount to a form of patient abandonment and therefore is ethically indefensible" (Varkey, 2021).

In his assessment, G. Kevin Donovan explains the bioethical challenges related to sex reassignment treatment, emphasizing the lack of informed consent when administering these services. He asserts that gender dysphoria is largely a self-diagnosis practitioners cannot verify with empirical tests (e.g., labs and imaging) and that providing such treatments is experimental. Because of the lack of consent and off-label use of puberty blockers and cross-sex hormones, Donovan raises the question as to how "experienced and ethical physicians so mislead others or be so misled themselves?" He further attributes this phenomenon to societal and peer pressures that influence self-diagnosis and confirm decisions to transition. As a result, these pressures lead to individuals wanting puberty blockers, cross-sex hormones, and surgery. Donovan goes on to identify several news stories where embracing sex reassignment treatment is a "cult-like" behavior. To conclude, he links these factors back to the failure to obtain informed consent from transgender patients and how that violates basic bioethical principles (Donovan, 2022).

## Coverage Policies of the U.S. and Western Europe

### U.S. Federal Level Coverage Policies

**Medicare:** In 2016, the Centers for Medicare and Medicaid Services (CMS) published a decision memo announcing that Medicare Administrative Contractors (MACs) can evaluate sex reassignment surgery coverage on a “case-by-case” basis.<sup>10</sup> CMS specifically noted that the decision memo is not a National Coverage Determination and that “no national policy will be put in place for the Medicare program” (CMS, 2016). This memo was the result of CMS reviewing over 500 studies, reports, and articles to the validity of the procedures. Following its evaluation, CMS determined that “the quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding . . . small sample sizes, lack of validated assessment tools, and considerable (number of participants in the studies) lost to follow up.” In 2017, CMS reinforced this position with a policy transmittal that repeated the 2016 memo’s criteria (CMS, 2017).

The basis for Medicare’s decision is that the “clinical evidence is inconclusive” and that “robust” studies are “needed to ensure that patients achieve improved health outcomes.” In its review of available literature, CMS sought to answer whether there is “sufficient evidence to conclude that gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria.” After evaluating 33 studies that met inclusion criteria, CMS’s review concludes that “not enough high-quality evidence” is available “to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively.” Additionally, out of the 33 studies, just 6 provided “useful information” on the procedures’ effectiveness, revealing that their authors “assessed quality of life before and after surgery using validated (albeit non-specific) psychometric studies” that “did not demonstrate clinically significant changes or differences in psychometric test results” following sex reassignment surgery (CMS, 2016).

**U.S. Department of Defense – Tricare:** Tricare does not cover sex reassignment surgery, but it will cover psychological services such as counseling for individuals diagnosed with gender dysphoria and cross-sex hormones when medically necessary (Tricare, 2022).<sup>11</sup>

**U.S. Department of Veterans Affairs:** The U.S. Department of Veterans Affairs (VA) does not cover sex reassignment surgery, although it will reimburse for cross-sex hormones and pre- and post-operative care related to transitioning. Because the VA only provides services to veterans of the U.S. armed forces, it cannot offer sex reassignment treatment to children (VA, 2020).<sup>12</sup>

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<sup>10</sup> The Centers for Medicare and Medicaid Services is part of the U.S. Department of Health and Human Services. Its primary functions are to administer the entire Medicare system and oversee federal compliance of state Medicaid programs. In addition, CMS sets reimbursement rates and coverage criteria for the Medicare program.

<sup>11</sup> Tricare is the insurance program that covers members of the U.S. armed forces and their families. This includes children of all ages.

<sup>12</sup> The U.S. Department of Veterans Affairs oversees the Veterans Health Administration (VHA), which consists of over 1,000 hospitals, clinics, and long-term care facilities. As the largest health care network in the U.S., the VHA provides services to veterans of the U.S. armed forces.

### State-Level Coverage Policies

**Florida:** In April 2022, DOH issued guidance for the treatment of gender dysphoria, recommending that minors not receive puberty blockers, cross-sex hormones, or sex reassignment surgery.<sup>13</sup> The justification offered for recommending against these treatments is that available evidence is low-quality and that European countries also have similar guidelines. Accordingly, DOH provided the following guidelines:

- “Social gender transition should not be a treatment option for children or adolescents.”
- “Anyone under 18 should not be prescribed puberty blockers or hormone therapy.”
- “Gender reassignment surgery should not be a treatment option for children or adolescents.”
- “Children and adolescents should be provided social support by peers and family and seek counseling from a licensed provider.”

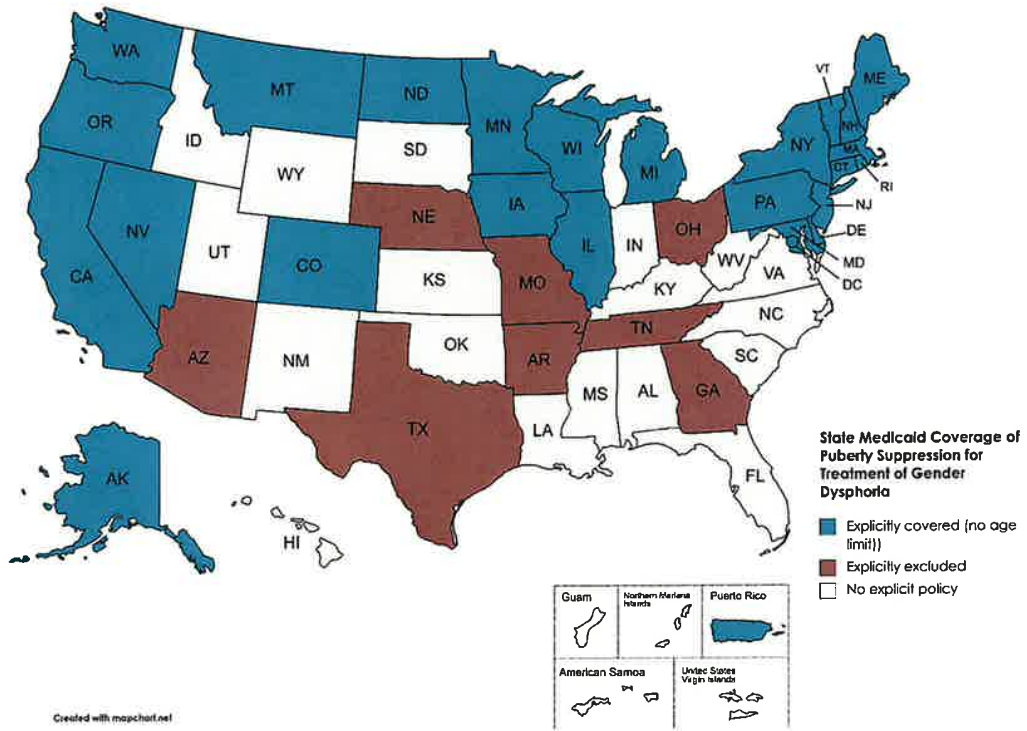
In a separate fact sheet released simultaneously with the guidance, DOH further asserts that the evidence cited by the federal government cannot establish sex reassignment treatment’s ability to improve mental health (DOH, 2022).

**State Medicaid Programs:** Because individual states differ in health services offered, Medicaid programs vary in their coverage of sex reassignment treatments. The following maps identify states that cover sex reassignment treatments, states that have no policy, and states that do not cover such treatments.

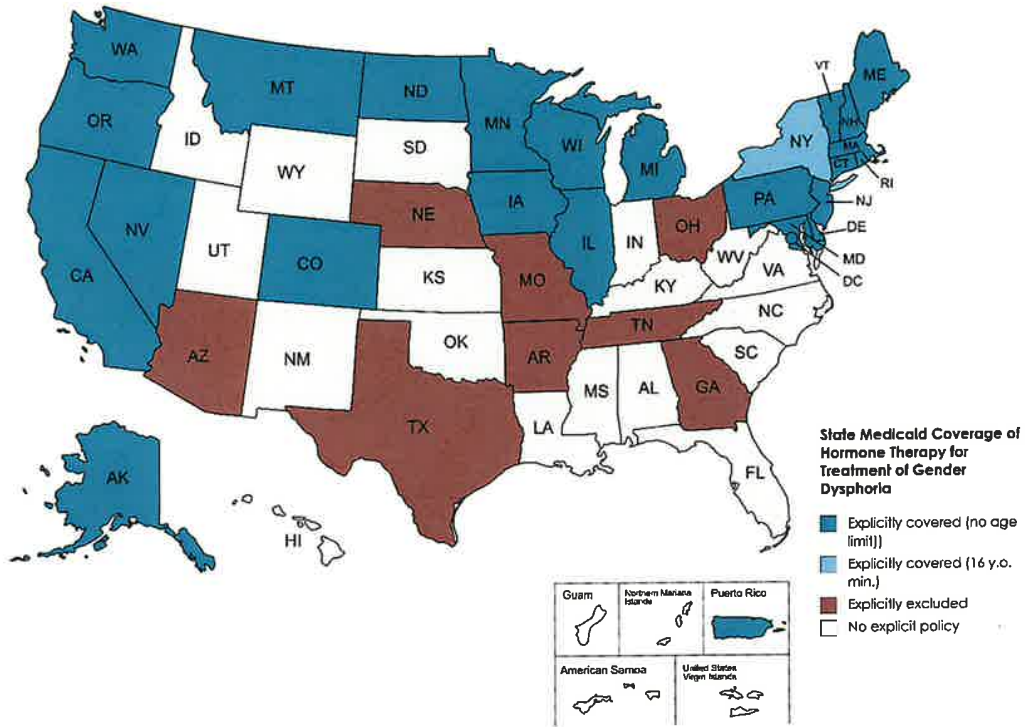
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<sup>13</sup> Unlike the federal government, the State of Florida delegates responsibilities for Medicaid and health care services to five separate agencies (Agency for Health Care Administration, Department of Health, Department of Children and Families, Department of Elder Affairs, and Agency for Persons with Disabilities). Each agency has its own separate head (secretary or surgeon general), which reports directly to the Executive Office of the Governor. As Florida’s public health agency, DOH oversees all county health departments, medical professional boards, and numerous health and welfare programs (e.g., Early Steps and Women, Infants, and Children). Because it oversees the boards, DOH has authority to release practice guidelines.

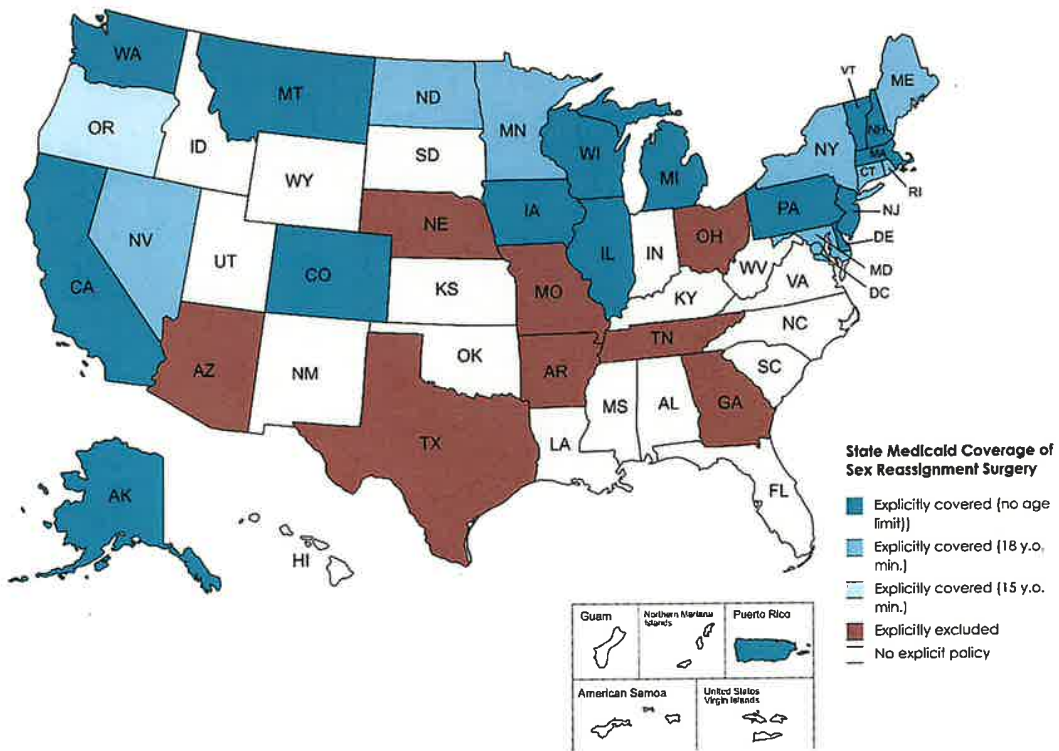
State Medicaid programs with coverage decisions regarding puberty blockers:



State Medicaid programs with coverage decisions regarding cross-sex hormones:



State Medicaid programs with coverage decisions regarding sex reassignment surgery:



## **Western Europe**

Scandinavian countries such as Sweden and Finland have released new guidelines on sex reassignment treatment for children. In 2022, the Swedish National Board of Health stated that “the risks of hormonal interventions for gender dysphoric youth outweigh the potential benefits.” With the exception of youths who exhibited “classic” signs of gender identity issues, adolescents who present with the condition will receive behavioral health services and gender-exploratory therapy (Society for Evidence Based Gender Medicine, 2022).

In Finland, the Palveluvalikoima issued guidelines in 2020 stating that sex reassignment in minors “is an experimental practice” and that “no irreversible treatment should be initiated.” The guidelines further assert that youths diagnosed with gender dysphoria often have co-occurring psychiatric disorders that must be stabilized prior to prescribing any cross-sex hormones or undergoing sex reassignment surgery (Palveluvalikoima, 2020).

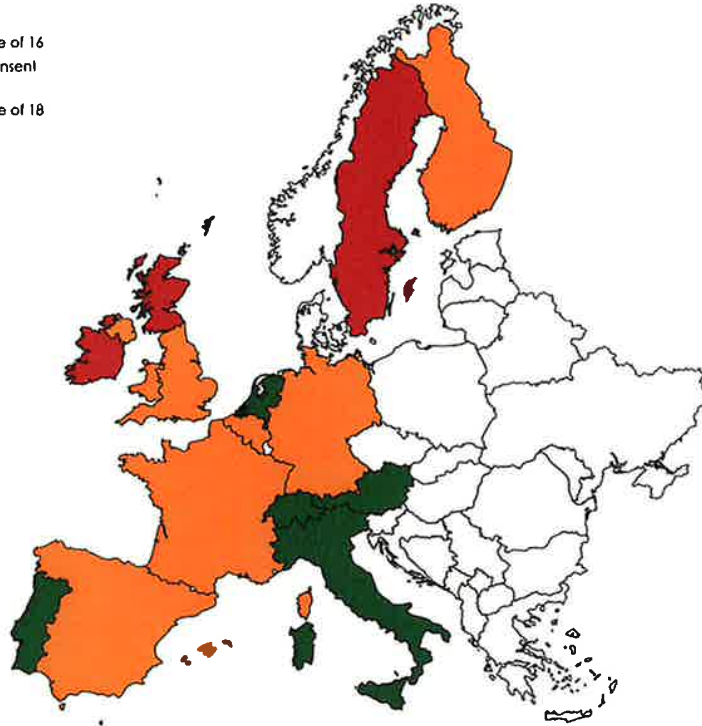
The United Kingdom (U.K.) is also reassessing the use of irreversible treatments for gender dysphoria due the long-term effects on mental and physical health. In 2022, an independent interim report commissioned by the U.K.’s National Health Service (NHS) indicates that additional research and systematic changes are necessary to ensure the safe treatment of gender dysphoric youths. These include reinforcing the diagnosis process to assess all areas of physical and behavioral health, additional training for pediatric endocrinologists, and informing parents about the uncertainties regarding puberty blockers. The interim report is serving as a benchmark until the research is completed for final guidelines (The Cass Report, 2022).

Like state Medicaid programs, health systems across Western Europe also vary in their coverage of sex reassignment treatment.

Western European nations' requirements for cross-sex hormones:

The Age of Consent for Hormonal Treatments in Western Europe

- Prohibited Under Age of 16
- General Medical Consent Rules Apply\*
- Prohibited Under Age of 18

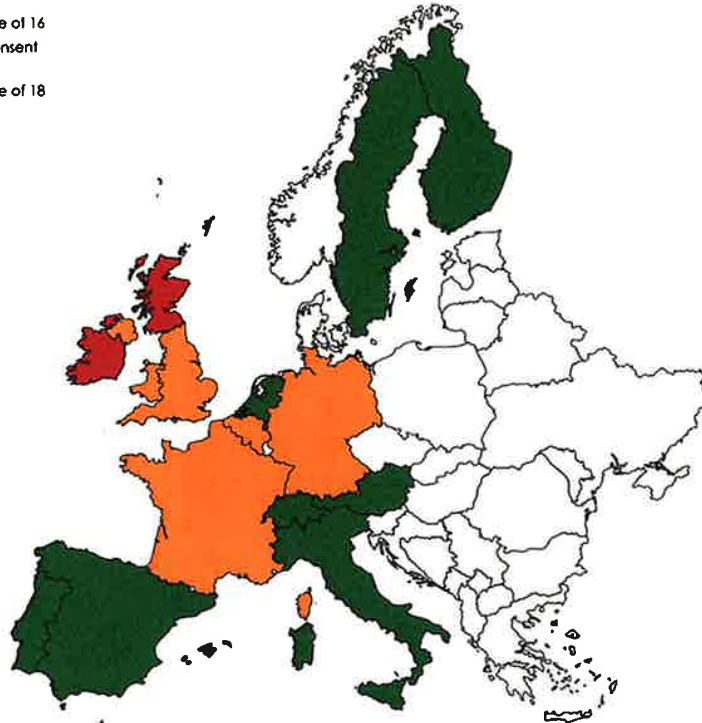


*In this context, the age requirement for access to any medical treatment without consent of parents or of a public authority. This age may range from 16 to 18 years depending on each country's laws.*

Western European nations' requirements for sex reassignment surgery:

**The Age of Consent for Surgery in Western Europe**

- Prohibited Under Age of 16
- General Medical Consent Rules Apply\*
- Prohibited Under Age of 18



*In this context, the age requirement for access to any medical treatment without consent of parents or of a public authority. This age may range from 16 to 18 years depending on each country's laws.*



### Generally Accepted Professional Medical Standards Recommendation

This report does not recommend sex reassignment treatment as a health service that is consistent with generally accepted professional medical standards. Available evidence indicates that the services are not proven safe or effective treatments for gender dysphoria.

#### Rationale

The available medical literature provides insufficient evidence that sex reassignment through medical intervention is a safe and effective treatment for gender dysphoria. As this report demonstrates, the evidence favoring “gender affirming” treatments, including evidence regarding suicidality, is either low or very low quality:

- **Puberty Blockers:** Evidence does not prove that puberty blockers are safe for treatment of gender dysphoria. Evidence that they improve mental health and reduce suicidality is low or very low quality.
- **Cross-Sex Hormones:** Evidence suggesting that cross-sex hormones provide benefits to mental health and prevents suicidality is low or very low quality. Rather, evidence shows that cross-sex hormones cause multiple irreversible physical consequences as well as infertility.
- **Sex Reassignment Surgery:** Evidence of improvement in mental health and reduction in suicidality is low or very low quality. Sex reassignment surgery results in irreversible physical changes, including sterility.

While clinical organizations like the AAP endorse the above treatments, none of those organizations relies on high quality evidence. Their eminence in the medical community alone does not validate their views in the absence of quality, supporting evidence. To the contrary, the evidence shows that the above treatments pose irreversible consequences, exacerbate or fail to alleviate existing mental health conditions, and cause infertility or sterility. Given the current state of the evidence, the above treatments do not conform to GAPMS and are experimental and investigational.

**Concur**                       **Do not Concur**

#### Comments:

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 Deputy Secretary for Medicaid (or designee)

6/2/22  
 \_\_\_\_\_  
 Date

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## Attachments

**Attachment A:** Secretary for the Florida Agency for Health Care Administration's Letter to Deputy Secretary Thomas Wallace. 20 April 2022.

**Attachment B:** Complete text of Rule 59G-1.035, F.A.C.

**Attachment C:** Romina Brignardello-Petersen, DDS, MSc, PhD and Wojtek Wiercioch, MSc, PhD: *Effects of Gender Affirming Therapies in People with Gender Dysphoria: Evaluation of the Best Available Evidence*. 16 May 2022.

**Attachment D:** James Cantor, PhD: *Science of Gender Dysphoria and Transsexualism*. 17 May 2022.

**Attachment E:** Quentin Van Meter, MD: *Concerns about Affirmation of an Incongruent Gender in a Child or Adolescent*. 17 May 2022.

**Attachment F:** Patrick Lappert, MD: *Surgical Procedures and Gender Dysphoria*. 17 May 2022.

**Attachment G:** G. Kevin Donovan, MD: *Medical Experimentation without Informed Consent: An Ethicist's View of Transgender Treatment for Children*. 16 May 2022.



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**From:** Peterson, Ashley  
**Sent:** Friday, June 3, 2022 12:50 PM EDT  
**To:** "\\Weida\\"; Jason; Jason.Weida@ahca.myflorida.com  
**CC:** Dalton, Ann  
**Subject:** Materials  
**Attachments:** Gender Dysphoria Prescribed Therapies.pdf

These are being printed for in person attendees at 1PM.

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**Ashley Peterson - AGENCY FOR HEALTH CARE ADMINISTRATOR-SES**



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GD DRUG CLASS	TRANSITION STATUS	PREFERRED DRUG STATUS	DRUG	ROUT OF ADMINISTRATION	COMMENTS	MECHANISM OF ACTION
ESTROGENS	MTF	GENERIC PREFERRED FOR BOTH SEXES	ESTRADIOL	ORAL TRANSDERMAL	MIN AGE 12	Increases estrogen and progesterone in the body, leading to feminization of the patient while also reducing some testosterone in the body.
			ESTRADIOL VALERATE	SUBCUTANEOUS INTRAMUSCULAR		
			PROGESTERONE	ORAL		
			MEDROXYPROGESTERONE	TRANSDERMAL		
GONADOTROPIN RELEASING HORMONE (GnRH) AGONIST	MTF	AUTO-PA - LOOKS FOR VARIOUS DIAGNOSIS. GENDER DYSPHORIA IS NOT A DIAGNOSIS AND CLAIM WILL DENY. DOCTOR WILL HAVE TO USE OFF-LABEL CRITERIA AND PROVIDE DOCUMENTATION.	LEUPROLIDE	INTRAMUSCULAR	MIN AGE 18	Reduces testosterone release – slows puberty and visible secondary sex characteristics such as enlarged breasts and widened hips of females, facial hair and Adam's apples on males, and pubic hair on both.
			LUPRON	INTRAMUSCULAR	MIN AGE 18	
			LUPRON DEPOT	INTRAMUSCULAR	MIN AGE 18	
			LUPANETA PACK	INTRAMUSCULAR	MIN AGE 18	
			TRIPTODUR	INJECTABLE	MIN AGE 2 YEARS MAX AGE 12 YEARS	
			ZOLADEX	IMPLANT	MIN AGE 18	
			VIADUR	IMPLANT	MIN AGE 18	
SYNAREL	NASAL SPRAY					
ANTIHYPERTENSIVE	MTF	GENERIC PREFERRED FOR BOTH SEXES	SPIRONOLACTONE	ORAL		Directly inhibits testosterone secretion and androgen binding to the androgen receptor
5-ALPHA REDUCTASE INHIBITOR	MTF	GENERIC PREFERRED FOR BOTH SEXES	FINASTERIDE	ORAL		Blocks the conversion of testosterone to its active agent which affects scalp hair loss and body hair growth.
TESTOSTERONES	FTM	THE ONLY TESTOSTERONES THAT CAN BE RECEIVED WITHOUT A PA ARE INJECTABLES. THE REMAINING PRODUCTS REQUIRE A CLINICAL PA WITH A REQUIREMENT OF MALE AND DIAGNOSIS OF PRIMARY OR SECONDARY HYPOGONADISM AND THE PATIENT DOES NOT HAVE A HISTORY OF PROSTATE CARCINOMA OR MALE BREAST CARCINOMA. IF A DOCTOR IS WANTING TO USE THE DRUG FOR GD, THE OFF-LABEL CRITERIA WOULD HAVE TO BE USED AND DOCUMENTATION PROVIDED.	TESTOSTERONE UNDECANOATE	ORAL	MIN AGE 18	Increases testosterone in the body to suppress feminine characteristics and increase male characteristics such as a deeper voice, facial hair, etc. while also decreasing some estrogen in the body.
			TESTOPEL	IMPLANT	MIN AGE 18	
			TESTOSTERONE GEL	TRANSDERMAL	MIN AGE 18	
			TESTOSTERONE PATCH	TRANSDERMAL	MIN AGE 18	

CODE	PREFERRED DRUG STATUS	HCPCS/FMMIS DESCRIPTION	*	QRG DESCRIPTION	HIC3	REVIEW CLASS NAME	MAX QTY	COMMENTS
J1071	<b>GENERIC PREFERRED</b>	TESTOSTERONE CYPIONATE 1MG		TESTOSTERONE CYPIONATE 1MG	F1A	ANDROGENIC AGENTS	400	
J3121	<b>GENERIC PREFERRED</b>	TESTOSTERONE ENANTHATE 1MG		TESTOSTERONE ENANTHATE 1MG	F1A	ANDROGENIC AGENTS	400	
J9217	<b>BRAND PREFERRED</b>	LEUPROLIDE ACETATE FOR DEPOT		LEUPROLIDE ACETATE FOR DEPOT SUSPENSION 7.5MG (LUPRON DEPOT)	V10	ANTINEOPLASTIC; PITUITARY SUPPRESSIVE AGENTS, LHRH	6	
J9218	<b>GENERIC PREFERRED</b>	LEUPROLIDE ACETATE 1MG		LEUPROLIDE ACETATE 1MG	V10	ANTINEOPLASTIC; PITUITARY SUPPRESSIVE AGENTS, LHRH	1	
J1050	<b>GENERIC PREFERRED</b>	MEDROXYPROGESTERONE ACETATE 1MG		MEDROXYPROGESTERONE ACETATE 1MG	G8C	CONTRACEPTIVES	1000	MIN AGE 12 YEARS
J1000	NON-PREFERRED	DEPO-ESTRADIOL CYPIONATE UP TO 5MG		DEPO-ESTRADIOL CYPIONATE UP TO 5MG	G1A	ESTROGEN AGENTS, INJECTABLE	1	
J1380	<b>GENERIC PREFERRED</b>	ESTRADIOL VALERATE UP TO 10MG		ESTRADIOL VALERATE UP TO 10MG	G1A	ESTROGEN AGENTS, INJECTABLE	4	
J1950	<b>BRAND PREFERRED</b>	LEUPROLIDE ACETATE PER 3.75MG DEPOT		LEUPROLIDE ACETATE PER 3.75MG DEPOT SUSPENSION (LUPANETA, LUPRON DEPOT)	P1M	PITUITARY SUPPRESSIVE AGENTS, LHRH	12	MIN AGE 18 YEARS
J3316	<b>BRAND PREFERRED</b>	TRIPTORELIN XR 3.75MG		TRIPTORELIN XR 3.75MG (TRIPTODUR)	P1P	PITUITARY SUPPRESSIVE AGENTS, LHRH	6	MIN AGE 2 YEARS
J9202	<b>BRAND PREFERRED</b>	GOSERELIN ACETATE IMPLANT PER 3.6MG		GOSERELIN ACETATE IMPLANT PER 3.6MG (ZOLADEX)	V10	PITUITARY SUPPRESSIVE AGENTS, LHRH	3	MIN AGE 18 YEARS
J9225	NON-PREFERRED	HISTRELIN IMPLANT (VANTAS) 50MG		HISTRELIN IMPLANT (VANTAS) 50MG	V10	PITUITARY SUPPRESSIVE AGENTS, LHRH	1	DX: C61-C61; MIN AGE 18
J9226	NON-PREFERRED	HISTRELIN (SUPPRELIN LA) IMPLANT 50MG		HISTRELIN (SUPPRELIN LA) IMPLANT 50MG	P1P	PITUITARY SUPPRESSIVE AGENTS, LHRH	1	MIN AGE 2 YEARS

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