

Florida Medicaid

Comment Summary for Rule 59G-1.050, F.A.C. and Responses
Regarding the Generally Accepted Professional Medical Standards
Determination on Treatment for Gender Dysphoria

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List of Attachments

Attachment A: Transcript of the Public Hearing for Rule 59G-1.050, F.A.C. Held on July 8, 2022

Attachment B: A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria

Attachment C: The Endocrine Society's Comments on Rule 59G-1.050, Florida Administrative Code

Attachment D: The American Academy of Pediatrics Comments on Rule 59G-1.050, Florida Administrative Code

Attachment E: Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims

Introduction and General Comment Summary

Comments Submitted In-Person by Hearing Attendees

On July 8, 2022, the Florida Agency for Health Care Administration (Agency) held a hearing to receive public comments on the proposed changes to Rule 59G-1.050, Florida Administrative Code (F.A.C.).¹ Attendees included physicians, attorneys, individuals who had detransitioned, and other interested parties. Of those physically present, an overwhelming majority spoke in favor of the changes that will prohibit Medicaid coverage of puberty blockers, cross-sex hormones, and sex reassignment surgery when used to treat gender dysphoria.

Among the first speakers were two former trans-males who had transitioned while teenagers. The first was Chloe Cole, a 17-year-old from California, who explained how she had taken puberty blockers and cross-sex hormones before undergoing a double mastectomy. Cole asserted that she was not capable of making those decisions when she decided to take treatments that permanently altered her body and expressed regret at having done so. She further explained how she will be unable to breastfeed a child in the future, or even be able to carry one to full term, and that she continued to experience side effects from the drugs. Her statements about how she and her parents were misled by medical professionals are quoted below:

"My parents took me to a therapist to affirm my male identity. The therapist did not care about causality or encourage me to learn to be comfortable in my body because of -- partially due to California's conversion therapy bans. He brushed off my parents' concerns about that because he had hormones, puberty blockers, and surgeries. My parents were given a suicide threat as a reason to move me forward in my transition.

I was unknowingly physically cutting off my true self from my body, irreversibly and painfully. Our transidentities were not questioned. I went through with the surgery. Despite having therapists and attending the top surgery class, I really didn't understand all of the ramifications of any of the medical decisions I was making. I wasn't capable of understanding it, and it was downplayed consistently. My parents, on the other hand, were pressured to continue my so-called gender journey with the suicide threat."

The second detransitioner, Sophia Galvin, explained how she had decided to become a trans-male at the age of 17 and began taking cross-sex hormones at 18. Her comments included how she had had a history of trauma and mental illness and that her gender dysphoria originated more out of fear of becoming a woman. Galvin further discussed how she received no support from both her physician and therapist when she decided to detransition. She concluded how she had been "harmed by this" and that medical treatment for gender dysphoria "is not good for children" and "should not be covered under Medicaid." Examples of her specific statements are quoted below:

"I had a history of mental illness. I had suicidal ideation and I would self-harm. And my wanting to transition was all in an effort to escape the fear of being a woman in this society and because of traumas that I had been through in my life. So I continued down the process, and then I ended

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¹ See Attachment A for the complete transcript of the July 8, 2022 hearing.

up removing my breasts at 19 years old because I was trapped, afraid to go back to my original ideo- -- to my original sex, and basically look crazy to the people around me."

Another speaker, Katie Caterbury, explained how her 14-year-old daughter had decided to become a trans-male and began receiving testosterone injections without parental consent prior to undergoing a double mastectomy, hysterectomy, and phalloplasty while still a minor. The speaker also stated that her state's Medicaid program reimbursed for these services despite private insurance being available. She further discussed how changing biological sex is impossible and what kind of rational physician could administer such treatments. To close, Caterbury stated that "amputating the healthy body parts of a child whose brain has not reached full decision-making maturity is simply criminal."

Jeanetter Cooper, one of the founders of Parents for Ethical Care, spoke about how many mental health therapists have become "cheerleader(s) for gender identity affirmation" and that children and their families dealing with gender dysphoria "are being met with a medical treatment for a psychological condition." Cooper further asserted that "the state has no business using taxpayer funding to turn children into permanent medical patients."

In addition to parents, detransitioners, and stakeholders, a Florida pediatric endocrinologist, Dr. Matthew Benson, spoke in support of the proposed rule changes. He explained how studies completed in Sweden and Denmark indicated that treatment for gender dysphoria increased the risk of suicide and that long-term data is insufficient to support their use. His exact statements are quoted below:

"The National Board of Health and Welfare of Sweden has recently enacted in that country pretty significant restrictions. And if we're going to do this type of care, it needs to be under an IRB-approved protocol and it needs to be based on the best data. I'm used to prescribing these medications in the sense of puberty blockers.

And one of the largest studies that came from Sweden was published around 2016, and basically what they showed is that in those individuals who are transgender and receive these types of procedures, the rates of overall mortality compared to the general population was three times that of the general population; completed suicide, 19 times that of the general population; five times suicide attempts of the general population. Similarly, in Denmark, out of a 20-year period, by the time a similar study was done, 10 percent of the population had died. We need better data. We need long-term perspective trials where we can look at adverse effects. We need much more robust data to justify these kinds of very aggressive therapies."

Other speakers in support of the proposed changes to Rule 59G-1.050, F.A.C. repeatedly commented on how the Agency's actions will "protect Florida residents, especially minors" and how "children are being pressured and socialized at a very young age to identify as transgender."

Attendees commenting in opposition to the proposed rule changes included Dr. Michael Haller, a pediatric endocrinologist at the University of Florida, who asserted that the Florida Medicaid Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria (GAPMS report) made "numerous false claims, use(d) a biased review of the literature, and relies on more so-called experts who actually lack actual expertise in the care of children with dysphoria." He further went on to explain that "nearly every major medical organization that provides care for children, as you heard

previously, have provided well-evidenced guidelines supporting gender-affirming care as the standard of care." His comments elicited a response from panelist Dr. Quentin Van Meter who responded by saying:

"These are not standards of care. Standards of care by definition are an arduous process of listening to all input from every side, every aspect, of a medical condition, and these individuals get together and they agree on someplace in the middle that they can all live with as a then standard of care. These are merely guidelines. The guidelines from the Endocrine Society specifically state they are not standards of care. They're just guidelines. They are the opinions of the individuals who wrote the guidelines. The Endocrine Society guidelines were written by nine people in the first go-round and ten in the second go-round, all of which were ideologues from the World Professional Association of Transgender Health."

Another attendee whose comments opposed the proposed rule changes was Nathan Bruemmer, who was appointed by Nikki Fried as Florida's LGBTQ consumer advocate. He argued that "documented, well-researched standards of care have been established, are based on a wide range of evidence, and conclude gender-affirming medical care is medically necessary and safe and effective. In other words, gender-affirming care is the standard of care." In addition, Bruemmer asserted how "the proposed rule as it stands would deny health care consumers in the state of Florida access to the standard of care."

Speakers who also commented against the rule's proposed changes included representatives from Equality Florida and Lambda Legal. Both of whom referred to the Agency's actions respectively as "discriminatory" and how they "will cause serious, immediate and irreparable harm to transgender Medicaid participants in Florida." In response to some of the comments advocating opposition, panelist Dr. Andre Van Mol responded with the following:

"The histories in the United Kingdom, Sweden, Finland, France, four nations that were leading this from quite some time, they did national-level reviews involving scientific organizations, divisions of governments, medical professionals. And mind you, these are nations that were leading it. And after review, they all came to the same conclusion, this should not be going on in minors at all under 16, and only between 16 and 18 under tightly-regulated studies, the kind of which we really don't see happening."

In summary, comments presented in-person at the hearing overwhelmingly supported the proposed changes to Rule 59G-1.050, F.A.C. The majority of individuals who submitted comments in opposition primarily did so via email, which are addressed in the following.

Written Comments Submitted during the Comment Period

During the comment period for the proposed changes to Rule 59G-1.050, F.A.C., the Agency received multiple submissions from the below stakeholder and advocacy groups:

American Academy of Pediatrics
Endocrine Society
Planned Parenthood
The Trevor Project
Southern Legal Counsel
University of California at Los Angeles
Equality Florida

Yale University
American Civil Liberties Union
National Health Law Program
Legal Services of Great Miami
Lambda Legal
Fenway Health
Human Rights Campaign

Transgender Legal Defense and Education Fund American Atheists Parris Law

The majority of the comments object to the proposed rule changes and provide similar arguments regarding why the Agency should not move forward with adoption. These range from stating that treatment for gender dysphoria is medically necessary and lifesaving to arguing that Florida Medicaid denying coverage of these services is discriminatory and illegal under the equal protection clause of the 14th Amendment and Section 1557 of the Affordable Care Act. In addition, some submissions listed clinical organizations that endorsed the use of puberty blockers, cross-sex hormones, and sex reassignment surgery to treat gender dysphoria. Such organizations consist of the American Medical Association, American Psychiatric Association, and the American College of Obstetricians and Gynecologists. Furthermore, comments submitted by Yale University, the American Academy of Pediatrics (AAP), and the Endocrine Society include critiques of Florida Medicaid's Generally Accepted Professional Medical Standards Determination on the Treatment for Gender Dysphoria (GAPMS report).

To support their arguments, these stakeholder and advocacy groups referenced studies and statistics. Most of which the GAPMS report deemed as low or very low quality and insufficient to meet medical necessity criteria. In addition, multiple comments listed recent court cases such as *Bostock v. Clayton County* (2020) and *Eknes-Tucker et al v. Marshall* (2022) where judges struck down prohibitions on treatment for gender dysphoria.

From the groups listed above, one (Parris Law) offered comments supporting the proposed changes, arguing evidence supporting the treatment is insufficient, an absence of a standard of care prevents malpractice lawsuits, and informed consent cannot be given by minors for these services.

Because Yale University, the AAP, and the Endocrine Society provided detailed critiques of the GAPMS report, the following sections analyze their statements and provide responses.

Agency Response to Yale University's Rule Comments and GAPMS Rebuttal

Introduction and Overview

On July 8, 2022, faculty from Yale University² submitted comments regarding the proposed changes to Rule 59G-1.050, F.A.C. and a rebuttal (referred to as the Yale rebuttal and titled as "A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria) to the GAPMS report. These comments protest the proposed rule changes and charge the Agency with justifying them based on a "shoddy quality" report. In addition, Yale's faculty provide a detailed critique of the GAPMS report in an effort to discredit the final determination. Despite composing 47 pages of content, the Yale professors do not provide sufficient evidence to support overturning Florida Medicaid's final determination and halting changes to Rule 59G-1.050, F.A.C.

Instead of providing a well-researched document that demonstrates how evidence supporting treatment of gender dysphoria is based on robust methodologies and lacks bias, Yale's faculty submitted content that is rife with ad hominem attacks, exaggerations, misrepresentations, and patently false statements. Rather than attempt to counter the GAPMS report's primary argument that the treatments lack sufficient proof to meet medical necessity criteria, the Yale rebuttal does little more than launch insults against Florida Medicaid's experts, engage in logical fallacies, and make no effort to argue that "supporting" research adequately answers any outstanding questions. Because of these flaws, the Yale professors' comments and rebuttal are biased, misleading, and even unbecoming. Based on their statements, these academics appear to be relying not on the strength of their analyses but on the eminence of Yale University as the foundation for their credibility.

Comprehensive Problems in the Yale Rebuttal

The comments and rebuttal address multiple aspects of the GAPMS report, including the report itself and the experts' contributions, particularly the literature assessment by Romina Brignardello-Petersen and Wojtek Wiercioch. When evaluating Florida Medicaid's expert content, the Yale professors engage very little with the research and analyses, choosing instead to attack credentials and professional affiliations. The only exception is Brignardello-Petersen and Wiercioch's assessment, which the Yale rebuttal offers a detailed critique. The fact that these faculty members refuse to engage with the experts' content and conclusions indicates a likely inability to do so. If Florida Medicaid's experts were truly mistaken, would not Yale's professors point to such errors rather than attempt to dismiss entire documents based on qualifications? Additionally, the Yale rebuttal errs in assuming that only those with narrow credentials are suited for critical analysis. This is illogical and overlooks the notion that the ability to critically read, analyze, and evaluate can transcend throughout similar academic disciplines.

Attempting to dismiss Florida Medicaid's expert reports by denigrating credentials is a thinly veiled method to avoid engaging with the actual content.

² Eight authors contributed to the Yale rebuttal. Six of whom are faculty at Yale University. The two remaining authors are professors at the University of Alabama at Birmingham and University of Texas Southwestern. Because the lead author, Meredithe McNamara, is faculty at the Yale School of Medicine and the report being released by the Yale Law School, this response collectively refers to the authors as the Yale faculty or Yale professors.

Another aspect of the Yale rebuttal is its over-reliance on adjectives and other descriptors. Throughout the content, its authors depend heavily on hyperbole and terms such as "shoddy," "unscientific," and "pseudo-science." Using this language is sensationalist and also a cover for weak analyses. The GAPMS report does not utilize such rhetoric because it demonstrates that treatment for gender dysphoria is experimental and investigational through careful evaluation and critical thought. In addition, adjectives and hyperbole serve only to mislead and confuse an audience while using affiliation with Yale University as cover for a paucity of reason and evidence.

A core component the Yale rebuttal lacks is making a case arguing that existing studies supporting treatment for gender dysphoria are sufficient. By not doing so, its authors fail to engage with the GAPMS report's main argument, resulting in the rebuttal's inability to demonstrate any significant flaws. What the Yale faculty needed to do was demonstrate that the methods used to prove the treatment's effectiveness were sufficient to meet medical necessity criteria. They could have accomplished this by explaining how bias was not an issue, that sample selection was robust, that participants' longitudinal histories were detailed, and that follow-up periods were lengthy. The Yale professors do none of this and repeatedly note that their evidence is "solid" and "authoritative" without providing a basis for why it is. In addition, the Yale rebuttal offers detailed critiques of Lisa Littman's work and devotes substantial content to criticizing her methods, sampling, and conclusions. This indicates a strong bias against any opposing evidence and unwillingness to consider any hypothesis going against their opinions. The authors' use of such rigorous critiques begs the question whether their "solid" studies, which they treat as irrefutable fact, would still be solid after going through the same review process.

In addition to not engaging with the GAPMS report's main argument, the Yale rebuttal uses a multitude of analogies that have no relevance to the subject at hand. In particular, the authors elaborate substantially on the Agency misusing the term "low quality" regarding evidence and go so far as to state that Florida Medicaid should not cover statins because low quality evidence also supports their use. Such language is misleading and false. For starters, multiple moderate and high-quality studies demonstrate the effectiveness of statins. Second, the benefits from this class of drugs far outweigh any potential risks. The GAPMS report sufficiently argues the risks posed by gender dysphoria treatment are too dangerous to long-term physical and mental health and that inadequate evidence is available to prove the benefits. Using such analogies deflects from the GAPMS report's main points and serves to confuse readers about the consequences of basing the use of medications and surgical procedures that pose irreversible effects on low and very low-quality evidence.

Another problem with the Yale rebuttal is its misrepresentation of evidence supporting the use of puberty blockers. In the text, the authors state that 16 studies demonstrate that cross-sex hormones and puberty blockers are effective. However, they do not list these in the citations and reference their response to Alabama and Texas' actions³, stating the bibliographic information can be found there. What those cited pages list is low quality studies that suffer from poor sampling methods, high risks of bias, and subjective self-reports. In addition, the Alabama and Texas response, written by the exact same Yale faculty, also misrepresents evidence asserting that puberty blockers are safe. All studies cited focus on children diagnosed with central precocious puberty. Children with this condition take the

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³ For the complete response to Alabama and Texas, refer to "Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims." Yale University. 28 April 2022. Access at the following link.

medication at much younger ages (e.g., 8-9 years) as opposed to those with gender dysphoria (e.g., 12-13 years). This difference in ages does not account for the rapid changes in child development that could affect the physiological effects of puberty blockers.

Agency Responses to the Yale Rebuttal's Individual Comments

Because the Yale rebuttal provides a list of criticisms regarding the GAPMS report, the following will address each individually to demonstrate that not only do the Yale professors engage in poor reasoning but how they make false claims indicating that they failed to read the entire document.

Yale Rebuttal Point 1: The GAPMS report⁴ repeatedly and erroneously dismisses solid studies as "low quality." If Florida's Medicaid program applied the GAPMS report's approach to all medical procedures equally, it would have to deny coverage for widely-used medications like statins and common medical procedures like mammograms and routine surgeries.

Agency Response: The above statement as previously discussed is based on analogies that do not relate to the subject. Not only does the Yale rebuttal provide false information regarding statins (e.g., referencing one study) but it fails to account for weighing the benefits of a medication against the risks. The GAPMS report conclusively finds that treatment for gender dysphoria poses high risks to physical and mental health while offering questionable benefits.

In addition, the GAPMS report and its attachments, Attachment C in particular, identify numerous issues with studies supporting gender "affirming" care. These problems include small sample sizes, absence of participants' longitudinal histories, and inadequate follow-up periods. Such problems leave unanswered questions such as whether mental health co-morbidities were caused by trauma rather than gender dysphoria and whether the participants still felt relief five or even ten years after transitioning. Because the available literature does not sufficiently answer those, it cannot prove if treatment for gender dysphoria is medically necessary.

Yale Rebuttal Point 2: The GAPMS report disregards robust clinical research studies and instead relies on letters to the editor and opinion pieces. The GAPMS report's analysis fails to satisfy Florida's own regulatory standards for Medicaid coverage decisions and does not undermine the scientific research that supports medical treatment for gender dysphoria.

Agency Response: This statement is patently false. The GAPMS report relies solely on peer-reviewed studies to support its determination and provides critiques to demonstrate how the evidence is insufficient to support treatment of gender dysphoria. In addition, the Agency followed the process as specified in Florida Rule (Rule 59G-1.035, F.A.C.) to evaluate puberty blockers, cross-sex hormones, and sex reassignment surgery.

One such example of how the Yale rebuttal's authors attempt to mislead readers is their critique of how the GAPMS report treated Chen et al's 2020 study, "Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Pubertal Suppression in Transgender Youth." By stating that the article is a "consensus parameter" and accusing the Agency of "cherry-picking" quotes, the Yale faculty attempt to misrepresent how the GAPMS report

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⁴ The Yale rebuttal refers to the GAPMS report as the "June 2 Report." For the purposes of clarity, this analysis replaces the term "June 2 Report" with "GAPMS report" when reproducing the Yale rebuttal's comments.

contextualizes the study. When citing Chen et al, the Agency did so to highlight how questions concerning the effect of puberty blockers on neurodevelopment remain unanswered. This is a critical point regarding whether off-label use of those drugs is safe for adolescents because if puberty blockers halt neurodevelopmental milestones they could pose significant physical costs to achieve a mental health benefit.

Furthermore, the Yale rebuttal dismisses the GAPMS report's explanations regarding how several Western European countries, including Sweden, are updating their guidelines on treatment for gender dysphoria because the evidence does not support its use in children and adolescents. These international determinations are based on robust research and careful consideration of the risks and benefits, which the Yale faculty ignore completely.

Also, the authors of the Yale rebuttal insinuate that the Agency determined that treatment for gender dysphoria is experimental and investigational based on a "student blog." This is also extremely misleading. The GAPMS report contained one citation to reference the difference between eminence-based versus evidence-based medicine. The source in no way contributed to the research used to demonstrate how the evidence supporting treatment for gender dysphoria is insufficient.

Yale Rebuttal Point 3: The GAPMS report mistakenly claims that puberty blockers and hormones are experimental because they are used "off-label" and not approved by the FDA. In fact, off-label use, when supported by scientific evidence, as is the case here, is extremely common in medical practice and especially in pediatrics.

Agency Response: This criticism is misleading. The GAPMS report does not assert puberty blockers and cross-sex hormones are experimental solely because the FDA has not approved them to treat gender dysphoria. Highlighting the drugs' off-label use serves as one example among myriad examples to explain that the evidence fails to prove these medications are safe for that clinical indication. If they were, the FDA would likely have approved them for treating gender dysphoria.

Another problem with the Yale rebuttal's criticism is that using drugs off-label is normally done to achieve a physiological effect that is documented in the research. In addition, the risks of using a drug off-label when medically necessary do not outweigh the benefits. The low-quality evidence supporting gender dysphoria treatment does not demonstrate that causing infertility, disfigurement, and mutilation is worth the supposed mental health benefits. To compare such use with drugs like statins and Gabapentin misses the point while confusing the reader. Also, the Yale faculty fail to mention any drugs created specifically for physical conditions being used off-label to address mental illness.

Yale Rebuttal Point 4: The GAPMS report falsely claims that medical care for gender dysphoria is provided to a large percentage of children who will come to regret their treatment. In fact, patients with gender dysphoria have vanishingly low rates of regret regarding their medical treatment.

The GAPMS report attempts to cast doubt on medical treatment for gender dysphoria by repeating the debunked claim that most transgender teens ultimately reject their transgender identity.

Agency Response: This is another false statement. Research does reveal that a high percentage of transgender youth will desist following puberty. Furthermore, the studies that the Yale professors rely on to make this claim are low quality and lack long-term follow-up. Additionally, the Yale rebuttal makes an erroneous statement by claiming that the GAPMS report "ignores a recent study, Olson et al. (2022), who find that after an average of 5 years of social transition, only 2.5% of youth identified as cisgender."

The above quote is highly concerning. Not only is it false because the GAPMS report actually provides a detailed analysis of Olson et al's article, but it also indicates that the Yale professors did not even read the entire GAPMS report, opting instead to read only the sections on cross-sex hormones and puberty blockers. If they had read the document in its entirety, they would have discovered the Agency addressed that research and provided an analysis.

Yale Rebuttal Point 5: The GAPMS report repeats discredited claims that "social contagion" is leading teens to become transgender. The issue, although sensationalized in the GAPMS report, is ultimately irrelevant to medical treatment, which is provided only after a multidisciplinary assessment and after a finding that gender dysphoria is persistent and medical treatment is warranted.

Agency Response: When referring to discredited claims, the Yale rebuttal is referencing a study by Lisa Littman that introduces the concept of rapid-onset gender dysphoria (ROGD). In their criticism, the authors quote their prior response to Alabama and Texas' actions, stating that Littman's study required "extensive correction" due to its "misstatements." This is also misleading. Following what was most likely significant political backlash, the journal (*PLOS One*) republished the article to clarify that the results were based on parental observations. These clarifications had no impact on the results.⁵

Additionally, the GAPMS report refers to the Littman study in its discussion of the etiology of gender dysphoria to emphasize that the causes of the condition are unknown. Furthermore, insinuating that the GAPMS report uses ROGD as a rationale for determining that treatment for gender dysphoria is experimental and investigational is unfounded. The Agency based its conclusion primarily on the paucity of quality evidence demonstrating that the treatment can alleviate the condition.

Yale Rebuttal Point 6: The GAPMS report claims that inappropriate medical care is provided to adolescents with gender dysphoria who also have anxiety, depression, and other mental health conditions. These assertions are unsupported by scientific evidence and disregard evidence-based clinical practice guidelines that provide sound guidance for treating complex cases.

Agency Response: This is also a false statement. The research explicitly states that high percentages of youths diagnosed with gender dysphoria have other mental health comorbidities (e.g., anxiety and depression). In addition, the GAPMS report highlights research revealing that these youths also have experienced elevated rates of trauma, abandonment, and other circumstances that contribute to mental illness.

⁵ For additional information on the revisions to Lisa Littman's 2018 article, "Rapid-Onset Gender Dysphoria in Adolescents and Young Adults: A Study of Parental Reports," refer to the following link.

Furthermore, the Yale rebuttal fails to mention that the "evidence-based clinical practice guidelines" originate from the World Professional Association for Transgender Health (WPATH) and the Endocrine Society. The former does not qualify as a clinical organization and serves as an advocacy group, which is highly biased; and the latter notes that its guidance is based on low and very low-quality evidence. In addition, the Endocrine Society clearly states that its guidance does not constitute a standard of care.

Yale Rebuttal Point 7: The GAPMS report speculates, without evidence, that psychotherapy alone is as effective as medical treatment for gender dysphoria. This claim contradicts the findings of solid scientific studies, which show that medical care is more effective than psychotherapy alone.

Agency Response: This criticism is extremely misleading. The GAPMS report is not about psychotherapy's effectiveness when used to treat gender dysphoria, nor does it speculate that idea. The GAPMS report is strictly about evaluating whether puberty blockers, cross-sex hormones, and sex reassignment surgery have sufficient evidence to meet medical necessity criteria. In addition, the "solid scientific studies" that the authors refer to are low quality and based on flawed methods.

Conclusion

The Yale rebuttal to Florida Medicaid's GAPMS report makes an insufficient and problematic case for overturning the determination and halting the proposed rule changes. Due to myriad flaws including ad hominem attacks, hyperbolic language, and illogical statements, the Yale rebuttal fails to demonstrate that the conclusions drawn by the GAPMS report are incorrect. Instead of presenting a logical and well-reasoned case, as the authors' years of professional experience and training suggest they are capable of, they provide 47 pages of content that ignore the GAPMS report's main argument, disseminate misinformation, and make false claims, all while doing so under the eminence of Yale University. Creating such a document demonstrates that the Yale professors are intellectually dishonest and biased to the point where they will consider no evidence that challenges their beliefs. Because of the aforementioned issues, the Yale rebuttal is not a persuasive counterargument to the GAPMS report.

Agency Response to the Endocrine Society's Comments on the GAPMS Report

On July 7, 2022, the Endocrine Society submitted comments opposing the Agency's proposed changes to Rule 59G-1.050, F.A.C. These consisted of a narrative description of how the organization develops clinical guidelines and evaluates studies in addition to multiple criticisms of the GAPMS report. After careful consideration, the Agency does not find the Endocrine Society's comments sufficiently persuasive to warrant overturning the determination and proposed rule changes based on the following reasons:

- The Endocrine Society asserts that the Agency "did not include endocrinologists with expertise in transgender medicine."
 - In response, the Agency consulted a pediatric endocrinologist when making its
 determination in addition to experts across other fields and specialties to provide a
 comprehensive analysis of the problems concerning evidence supporting treatment for
 gender dysphoria. Also, the Endocrine Society's comment insinuates that the Agency's
 expert, Quentin Van Meter, lacks the appropriate credentials to comment on areas for
 which he is fully qualified.
- Another criticism claims that the Agency "does not acknowledge the data showing harm reduction and improvements in behavioral health issues, such as depression and anxiety, with gender affirming care."
 - This statement is not true. The Agency reviewed numerous studies supporting the use of gender "affirming" care and found that the methods used to obtain those results were poor and biased, consisting of self-report surveys, lack of participant histories, small sample sizes, and insufficient follow-up periods. This led to the conclusion that the available evidence was insufficient to meet medical necessity criteria.
- The Endocrine Society further argues that the GAPMS report is flawed because it "suggests that because puberty blockers are used off-label they are experimental and investigational."
 - This criticism is misleading. The GAPMS report does not assert that puberty blockers and cross-sex hormones are experimental solely because the FDA has not approved them to treat gender dysphoria. Highlighting the drugs' off-label use serves as one example among myriad examples to explain that the evidence fails to prove these medications are safe for that clinical indication. If they were, the FDA would likely have approved them for treating gender dysphoria.

Another problem with the Endocrine Society's criticism is that using drugs off-label is normally done to achieve a physiological effect that is documented in the research. In addition, the risks of using a drug off-label when medically necessary do not outweigh the benefits. The low-quality evidence supporting gender dysphoria treatment does not demonstrate that causing infertility, disfigurement, and mutilation is worth the supposed mental health benefits.

Following its criticisms, the Endocrine Society points to multiple studies, including ones by Green et al and Turban et al, claiming that puberty blockers and cross-sex hormones can alleviate gender dysphoria. However, Attachment C of the GAPMS report composed by Romina Brignadello-Petersen determined

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these two studies present confounding evidence and suffer from critical risks of bias. These findings reinforce the notion that evidence supporting treatment for gender dysphoria is insufficient to demonstrate mental health benefits.

Based on the above evaluation of the Endocrine Society's comments, the Agency stands by the determination of the GAPMS report and the proposed changes to Rule 59G-1.050, F.A.C.

Agency Response to the AAP's Comments on the GAPMS Report

On July 7, 2022, the American Academy of Pediatrics (AAP) submitted comments to the Agency's opposing proposed changes to Rule 59G-1.050, F.A.C. The organization argues that Florida Medicaid should not deny coverage of gender "affirming" treatments because they are the "standard of care." In addition, the AAP promotes erroneous and flawed arguments while asserting that the GAPMS report misrepresents the science. Due to these deficiencies, the Agency does not find the AAP's comments compelling enough to consider overturning the determination and proposed rule changes.

Among the numerous issues, the most glaring problem with the AAP's comments is its consistent reference to puberty blockers and cross-sex hormones acting as the "standard of care" for gender dysphoria. This representation is patently false. Currently, no standard of care exists for the condition that endorses such treatments, just clinical guidelines. By deliberately confusing the two categories, the AAP is misleading its audience to believe that no debate surrounds using puberty blockers and cross-sex hormones to address gender dysphoria. The term "standard of care" has specific legal ramifications. For example, physicians who practice outside of a given standard can be found liable for medical malpractice. What this means is that a "standard of care" is the minimum level of competency a practitioner must exercise when treating a patient.⁶ Treatment for gender dysphoria has yet to reach this level. However, the AAP appears to want to obfuscate that fact.

Instead of a "standard of care," what is available supporting the use of puberty blockers and cross-sex hormones for this condition is clinical guidelines based on low-quality evidence. In its guidance, the Endocrine Society acknowledges that its recommendations are not a "standard of care" and that they are based on weak evidence. The other set of widely cited clinical guidelines is from the World Professional Association for Transgender Health (WPATH). While WPATH has clinicians serving as members, it is an advocacy group and not a professional organization. Furthermore, WPATH also bases its guidance on the same low-quality evidence as the Endocrine Society.⁷

Aside from misrepresenting the meaning of "standard of care," the AAP's comments have numerous other issues and errors, consisting of logical fallacies, false statements, and reliance on biased research. These consist of the following:

AAP Comments Problem 1: The AAP attempts to argue that because puberty blockers and cross-sex hormones are medically necessary for conditions such as endometriosis, polycystic ovarian syndrome, and acne that they are also appropriate for gender dysphoria.

Agency Response: This is a logical fallacy and blatant misrepresentation. Taking drugs to correct hormonal imbalances is medically necessary and supported by quality science. However, just because certain medications are beneficial for some conditions does not mean that using them to obtain the secondary sexual characteristics of the opposite sex is justifiable to treat a mental health issue.

⁶ Moffett P and Moore G. The Standard of Care: Legal History and Definitions: The Bad and Good News. *West J Emerg Med*. 2011. 12:1. 109-112.

⁷ For additional information regarding clinical guidelines offered by WPATH and the Endocrine Society, please refer to the Florida Medicaid Generally Accepted Professional Medical Standards Determination on the Treatment for Gender Dysphoria.

AAP Comments Problem 2: Throughout the document, the AAP attributes almost 20% of its citations to its own statement promoting gender "affirmative" care and a flawed report from Yale University composed in response to Texas and Alabama's actions regarding treating minors for gender dysphoria.⁸

Agency Response: The over-reliance on flawed statements and research compromises the credibility of not only the AAP's comments but any document that utilizes such a practice. The strength of any scientific analysis is based only on the quality of evidence used to support the findings. By using discredited and biased work, the AAP further undermines its own credibility.

AAP Comments Problem 3: The AAP asserts that "gender-affirming medical care is a highly individualized model of care."

Agency Response: This is a false statement. The AAP's method of gender "affirming" care is not individualized but a one-sized-fits-all model. According to the AAP, WPATH, and similar organizations, children and adolescents diagnosed with gender dysphoria first receive counseling followed by puberty blockers and then cross-sex hormones before undergoing sex reassignment surgery.

AAP Comments Issue 4: When addressing the GAPMS report's analyses on puberty blockers, cross-sex hormones, and desistance, the AAP attempts to argue that puberty blockers provide additional time for adolescents to "explore their gender identity" and are safe when used to treat gender dysphoria. In addition, the AAP assertions that the GAPMS report's highlighting that puberty blockers and cross-sex hormones are not FDA-approved for gender dysphoria "lack any basis."

Agency Response: The AAP misses the point when it asserts that puberty blockers allow additional time for an adolescent to explore his or her gender identity. By halting pubertal development, these physicians are prohibiting children from fully realizing their natal sex before beginning cross-sex hormones. How can the AAP argue that children and adolescents should be able to "explore" while simultaneously denying them the experience of being a physically mature male or female?

Additionally, the AAP does not acknowledge that puberty blockers do not allow for natural desistance to occur. At least five studies assert that approximately 96% of adolescents who start the drugs go on to take cross-sex hormones. Research cited in the GAPMS report, however, indicates that these youths would desist during or following puberty without medical intervention. This reinforces the notion that puberty blockers do act as a "gateway" drug for cross-sex hormones.

Regarding the AAP's comments about the drugs' lacking FDA approval for gender dysphoria and being used off-label, this criticism is misleading. The GAPMS report does not assert puberty blockers and cross-sex hormones are experimental solely because the FDA has not approved them to treat gender dysphoria. Highlighting the drugs' off-label use serves as one example among myriad examples to explain that the evidence fails to prove these medications are safe

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⁸ Please refer to "Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims." Yale University. 28 April 2022. Access at the following link. For the Agency's critique of this report, please see Attachment A.

for that clinical indication. If they were, the FDA would likely have approved them for treating gender dysphoria.

Another problem with the AAP's comments is that using drugs off-label is normally done to achieve a physiological effect that is documented in the research. In addition, the risks of using a drug off-label when medically necessary do not outweigh the benefits. The low-quality evidence supporting gender dysphoria treatment does not demonstrate that causing infertility, disfigurement, and mutilation is worth the supposed mental health benefits.

AAP Comments Issue 5: The AAP refers to multiple studies in an attempt to bolster its argument that Florida Medicaid's GAPMS report is flawed and draws the wrong conclusions. The organization states that "research shows that hormone therapy, as a component of gender-affirming care, is beneficial to caring for adolescents with gender dysphoria" and then cites two studies, one by Green et al and another by Tordoff et al.

Agency Response: The Agency worked with Romina Brignardello-Petersen and Wojtek Wiercioch to evaluate and grade available research on treatment for gender dysphoria during the GAPMS review process. Their analysis reviewed both studies cited by the AAP and concluded that they each suffered from moderate and critical risks of bias. Furthermore, the AAP refers to an additional study by Turban et al, which Brignardello-Petersen and Wiercioch also appraised as having a critical risk of bias.

Considering the myriad issues with the AAP's comments, the Agency has determined they lack any sufficient standing to overturn the GAPMS report's determination or proposed changes to Rule 59G-1.050, F.A.C. Instead of composing a well-reasoned counterargument that demonstrates the evidence supporting treatment for gender dysphoria is robust and high quality, the AAP created a document rife with errors, misrepresentations, and non-applicable analogies. Attempting to veil such comments under the eminence of the AAP serves only to mislead its audience into accepting mistruths as fact. The GAPMS report thoroughly demonstrated that the evidence supporting treatment for gender dysphoria is insufficient to meet medical necessity criteria.

Analysis of Yale University's April 2022 Report

Overview of the Yale's April 2022 Report Responding to Alabama and Texas

On April 28, 2022, six faculty members of Yale University and one from the University of Texas Southwestern released a report (Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims) in response to the Texas Attorney General's (AG) opinion and Alabama law that restricts youth access to treatments for gender dysphoria. The report addresses multiple themes including sex-reassignment surgery for minors, effectiveness of puberty blockers and cross-sex hormones, and using drugs for off-label purposes. Currently, advocacy organizations such as Lambda Legal are citing this report as one that sufficiently debunks the research used in Florida's June 2022 GAPMS report. However, the report has significant flaws related to bias, omissions, and misrepresentations of evidence as presented in the following:

Critique of the Report's Content at Large

- This report provides a highly biased critique of the Texas AG's opinion and the Alabama law. This bias is evident in the heavy criticism leveled at studies that do not support the effectiveness of treatments for gender dysphoria and the omission of highly significant facts (e.g., permanent effects of cross-sex hormones). Further proof of bias is present in the failure to subject supporting studies to the same level of academic rigor applied to the opposing research.
- Due to the bias and omissions, the conclusions of this report are misleading and provide insufficient information to its audience. Individuals that reference this report prior to receiving treatments for gender dysphoria are only getting a fraction of the information and thus cannot provide fully informed consent.
- The authors also fail to provide an understanding that demonstrating the safety and effectiveness of any given treatment requires robust, high-quality evidence. When making that case, researchers need to put forward such evidence. The report's authors do not do that. Instead, they wrongfully assume that criticizing opposing evidence while ignoring the flaws in their own sufficiently proves their case. It does not. The authors appear oblivious that the burden of proof is on them, and they provide little evidence, which is low quality, to overcome that burden.

Content on WPATH, SEGM, and the Endocrine Society

- The report misrepresents WPATH and cites it as a clinical organization, when in reality it is an advocacy group that anyone can join.
- The authors attempt to discredit the Society for Evidence-Based Gender Medicine (SEGM) by arguing that it is biased against gender "affirming" care. However, the authors do not level such criticisms toward WPATH.
- The report fails to mention that the Endocrine Society gives low grades to treatments for gender dysphoria and that the organization's guidance does not constitute a standard of care.

Content on Puberty Blockers

- The report asserts that puberty blockers are safe and do not pose any irreversible effects when
 research has not fully answered the questions about prohibiting neurodevelopmental
 milestones, reducing bone mineral density accumulation, and potentially causing long-term
 problems with fertility and sexual functions.
- All research used to substantiate the authors' claims consists of studies regarding puberty blockers when used to treat central precocious puberty, which is a separate condition requiring the drugs to be used at younger ages (e.g., 8-10 years) as opposed to when puberty begins. This is a direct misrepresentation of scientific evidence.
- The report also attempts to downplay the off-label use of puberty blockers, which the FDA has
 not approved to treat gender dysphoria. It does this by arguing that drugs approved for adults
 are used off-label for children on a frequent basis. However, these analogies are flawed for the
 following reasons:
 - The report provides no examples of drugs only approved for adults that are used offlabel for children, which makes it impossible to determine whether the medications apply to the same conditions as clinically indicated by their FDA-approved labels.
 - Examples cited of drugs being prescribed for off-label purposes are for the treatment of physical conditions such as acne. Even propranolol (beta blocker), which is used off-label to treat performance anxiety, is administered to address the accompanying physical effect of elevated blood pressure.

Content on Cross-Sex Hormones

- The report understates how cross-sex hormones can reduce fertility in trans-females (men who
 transition into women) by stating that fertility quickly returns after the estrogen and antiandrogen treatments stop. This conflicts directly with the University of California at San
 Francisco's guidance to patients that advises them to have sperm frozen prior to treatment
 because fertility will not likely return.
- The authors emphasize that estrogen treatments improve long-term cardiovascular health in trans-females. However, they make no mention of how testosterone negatively affects transmales (women who transition into men). Effects such as hypertension and cardiovascular damage receive no mention whatsoever.
- The report also fails to mention other permanent effects caused by cross-sex hormones such as enlarged breasts in trans-females and facial hair in trans-males, while downplaying the effects on fertility.

Content on Quality of the Evidence Supporting the Effectiveness of Treatment for Gender Dysphoria

- The authors fail to elaborate on the evidence supporting treatment for gender dysphoria, citing
 only a handful of studies and not providing any critique or analysis of the research methods
 used.
 - Attachment C in the AHCA reported assessed that the study by Tordoff et al published in
 2022 (cited in the Yale report) had a moderate risk of bias and small sample size.

• The authors falsely refer to research supporting treatment for gender dysphoria as the "best scientific evidence." When in reality, all published studies with supporting conclusions are low or very low quality.

Criticism of Studies That Do Not Support Treatments for Gender Dysphoria

- The report devotes significant content to critiquing Littman's study on rapid-onset gender dysphoria (ROGD) and Dhejne et al's study on transexuals in Sweden.
 - The authors state that the Dhejne study is "badly out of date," which is a very hypocritical criticism. They provide no explanation for why the study's publication date (2011) makes it invalid while citing evidence going back to 1988 on the effectiveness of puberty blockers.
 - For Littman's study, the authors criticize the survey methodology used to obtain the findings and assert repeatedly that the findings were discredited. Although the authors are correct that the research methods were not robust enough to provide moderate or high-quality results, they ignore the fact that the studies supporting the treatments also use the same methods (e.g., surveys and biased sampling selection). In addition, their analysis provides no information that debunks the ROGD phenomenon. The authors just say that the study's results have been "debunked" without substantiating their argument.



Florida Medicaid

Comment Summary for Rule 59G-1.050, F.A.C. and Responses
Regarding the Generally Accepted Professional Medical Standards
Determination on Treatment for Gender Dysphoria

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List of Attachments

Attachment A: A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria

Attachment B: The Endocrine Society's Comments on Rule 59G-1.050, Florida Administrative Code

Attachment C: The American Academy of Pediatrics Comments on Rule 59G-1.050, Florida Administrative Code

Attachment D: Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims

Introduction and General Comment Summary

During the comment period for the proposed changes to Rule 59G-1.050, Florida Administrative Code (F.A.C.), the Florida Agency for Health Care Administration (Agency) received multiple submissions from the below stakeholder and advocacy groups:

American Academy of Pediatrics
Endocrine Society
Planned Parenthood
The Trevor Project
Southern Legal Counsel
University of California at Los Angeles
Equality Florida
Transgender Legal Defense and Education Fund
American Atheists

Yale University
American Civil Liberties Union
National Health Law Program
Legal Services of Great Miami
Lambda Legal
Fenway Health
Human Rights Campaign
Parris Law

The majority of the comments object to the proposed rule changes and provide similar arguments regarding why the Agency should not move forward with adoption. These range from stating that treatment for gender dysphoria is medically necessary and lifesaving to arguing that Florida Medicaid denying coverage of these services is discriminatory and illegal under the equal protection clause of the 14th Amendment and Section 1557 of the Affordable Care Act. In addition, some submissions listed clinical organizations that endorsed the use of puberty blockers, cross-sex hormones, and sex reassignment surgery to treat gender dysphoria. Such organizations consist of the American Medical Association, American Psychiatric Association, and the American College of Obstetricians and Gynecologists. Furthermore, comments submitted by Yale University, the American Academy of Pediatrics (AAP), and the Endocrine Society include critiques of Florida Medicaid's Generally Accepted Professional Medical Standards Determination on the Treatment for Gender Dysphoria (GAPMS report).

To support their arguments, these stakeholder and advocacy groups referenced studies and statistics. Most of which the GAPMS report deemed as low or very low quality and insufficient to meet medical necessity criteria. In addition, multiple comments listed recent court cases such as *Bostock v. Clayton County* (2020) and *Eknes-Tucker et al v. Marshall* (2022) where judges struck down prohibitions on treatment for gender dysphoria.

From the groups listed above, one (Parris Law) offered comments supporting the proposed changes, arguing evidence supporting the treatment is insufficient, an absence of a standard of care prevents malpractice lawsuits, and informed consent cannot be given by minors for these services.

Because Yale University, the AAP, and the Endocrine Society provided detailed critiques of the GAPMS report, the following sections analyze their statements and provide responses.

Agency Response to Yale University's Rule Comments and GAPMS Rebuttal

Introduction and Overview

On July 8, 2022, faculty from Yale University¹ submitted comments regarding the proposed changes to Rule 59G-1.050, F.A.C. and a rebuttal (referred to as the Yale rebuttal and titled as "A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria) to the GAPMS report. These comments protest the proposed rule changes and charge the Agency with justifying them based on a "shoddy quality" report. In addition, Yale's faculty provide a detailed critique of the GAPMS report in an effort to discredit the final determination. Despite composing 47 pages of content, the Yale professors do not provide sufficient evidence to support overturning Florida Medicaid's final determination and halting changes to Rule 59G-1.050, F.A.C.

Instead of providing a well-researched document that demonstrates how evidence supporting treatment of gender dysphoria is based on robust methodologies and lacks bias, Yale's faculty submitted content that is rife with ad hominem attacks, exaggerations, misrepresentations, and patently false statements. Rather than attempt to counter the GAPMS report's primary argument that the treatments lack sufficient proof to meet medically necessity criteria, the Yale rebuttal does little more than launch insults against Florida Medicaid's experts, engage in logical fallacies, and make no effort to argue that "supporting" research adequately answers any outstanding questions. Because of these flaws, the Yale professors' comments and rebuttal are biased, misleading, and even unbecoming. Based on their statements, these academics appear to be relying not on the strength of their analyses but on the eminence of Yale University as the foundation for their credibility.

Comprehensive Problems in the Yale Rebuttal

The comments and rebuttal address multiple aspects of the GAPMS report, including the report itself and the experts' contributions, particularly the literature assessment by Romina Brignardello-Petersen and Wojtek Wiercioch. When evaluating Florida Medicaid's expert content, the Yale professors engage very little with the research and analyses, choosing instead to attack credentials and professional affiliations. The only exception is Brignardello-Petersen and Wiercioch's assessment, which the Yale rebuttal offers a detailed critique. The fact that these faculty members refuse to engage with the experts' content and conclusions indicates a likely inability to do so. If Florida Medicaid's experts were truly mistaken, would not Yale's professors point to such errors rather than attempt to dismiss entire documents based on qualifications? Additionally, the Yale rebuttal errs in assuming that only those with narrow credentials are suited for critical analysis. This is illogical and overlooks the notion that the ability to critically read, analyze, and evaluate can transcend throughout similar academic disciplines.

Attempting to dismiss Florida Medicaid's expert reports by denigrating credentials is a thinly veiled method to avoid engaging with the actual content.

¹ Eight authors contributed to the Yale rebuttal. Six of whom are faculty at Yale University. The two remaining authors are professors at the University of Alabama at Birmingham and University of Texas Southwestern. Because the lead author, Meredithe McNamara, is faculty at the Yale School of Medicine the report being released by the Yale Law School, this response collectively refers to the authors as the Yale faculty or Yale professors.

Another aspect of the Yale rebuttal is its over-reliance on adjectives and other descriptors. Throughout the content, its authors depend heavily on hyperbole and terms such as "shoddy," "unscientific," and "pseudo-science." Using this language is sensationalist and also a cover for weak analyses. The GAPMS report does not utilize such rhetoric because it demonstrates that treatment for gender dysphoria is experimental and investigational through careful evaluation and critical thought. In addition, adjectives and hyperbole serve only to mislead and confuse an audience while using affiliation with Yale University as cover for a paucity of reason and evidence.

A core component the Yale rebuttal lacks is making a case arguing that existing studies supporting treatment for gender dysphoria are sufficient. By not doing so, its authors fail to engage with the GAPMS report's main argument, resulting in the rebuttal's inability to demonstrate any significant flaws. What the Yale faculty needed to do was demonstrate that the methods used to prove the treatment's effectiveness were sufficient to meet medical necessity criteria. They could have accomplished this by explaining how bias was not an issue, that sample selection was robust, that participants' longitudinal histories were detailed, and that follow-up periods were lengthy. The Yale professors do none of this and repeatedly note that their evidence is "solid" and "authoritative" without providing a basis for why it is. In addition, the Yale rebuttal offers detailed critiques of Lisa Littman's work and devotes substantial content to criticizing her methods, sampling, and conclusions. This indicates a strong bias against any opposing evidence and unwillingness to consider any hypothesis going against their opinions. The authors' use of such rigorous critiques begs the question whether their "solid" studies, which they treat as irrefutable fact, would still be solid after going through the same review process.

In addition to not engaging with the GAPMS report's main argument, the Yale rebuttal uses a multitude of analogies that have no relevance to the subject at hand. In particular, the authors elaborate substantially on the Agency misusing the term "low quality" regarding evidence and go so far as to state that Florida Medicaid should not cover statins because low quality evidence also supports their use. Such language is misleading and false. For starters, multiple moderate and high-quality studies demonstrate the effectiveness of statins. Second, the benefits from this class of drugs far outweigh any potential risks. The GAPMS report sufficiently argues the risks posed by gender dysphoria treatment are too dangerous to long-term physical and mental health and that inadequate evidence is available to prove the benefits. Using such analogies deflects from the GAPMS report's main points and serves to confuse readers about the consequences of basing the use of medications and surgical procedures that pose irreversible effects on low and very low-quality evidence.

Another problem with the Yale rebuttal is its misrepresentation of evidence supporting the use of puberty blockers. In the text, the authors state that 16 studies demonstrate that cross-sex hormones and puberty blockers are effective. However, they do not list these in the citations and reference their response to Alabama and Texas' actions², stating the bibliographic information can be found there. What those cited pages list is low quality studies that suffer from poor sampling methods, high risks of bias, and subjective self-reports. In addition, the Alabama and Texas response, written by the exact same Yale faculty, also misrepresents evidence asserting that puberty blockers are safe. All studies cited focus on children diagnosed with central precocious puberty. Children with this condition take the

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² Please refer to "Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims." Yale University. 28 April 2022. Access at the following link.

medication at much younger ages (e.g., 8-9 years) as opposed to those with gender dysphoria (e.g., 12-13 years). This difference in ages does not account for the rapid changes in child development that could affect the physiological effects of puberty blockers.

Agency Responses to the Yale Rebuttal's Individual Comments

Because the Yale rebuttal provides a list of criticisms regarding the GAPMS report, the following will address each individually to demonstrate that not only do the Yale professors engage in poor reasoning but how they make false claims indicating that they failed to read the entire document.

Yale Rebuttal Point 1: The GAPMS report³ repeatedly and erroneously dismisses solid studies as "low quality." If Florida's Medicaid program applied the GAPMS report's approach to all medical procedures equally, it would have to deny coverage for widely-used medications like statins and common medical procedures like mammograms and routine surgeries.

Agency Response: The above statement as previously discussed is based on analogies that do not relate to the subject. Not only does the Yale rebuttal provide false information regarding statins (e.g., referencing one study) but it fails to account for weighing the benefits of a medication against the risks. The GAPMS report conclusively finds that treatment for gender dysphoria poses high risks to physical and mental health while offering questionable benefits.

In addition, the GAPMS report and its attachments, Attachment C in particular, identify numerous issues with studies supporting gender "affirming" care. These problems include small sample sizes, absence of participants' longitudinal histories, and inadequate follow-up periods. Such problems leave unanswered questions such as whether mental health co-morbidities were caused by trauma rather than gender dysphoria and whether the participants still felt relief five or even ten years after transitioning. Because the available literature does not sufficiently answer those, it cannot prove if treatment for gender dysphoria is medically necessary.

Yale Rebuttal Point 2: The GAPMS report disregards robust clinical research studies and instead relies on letters to the editor and opinion pieces. The GAPMS report's analysis fails to satisfy Florida's own regulatory standards for Medicaid coverage decisions and does not undermine the scientific research that supports medical treatment for gender dysphoria.

Agency Response: This statement is patently false. The GAPMS report relies solely on peer-reviewed studies to support its determination and provides critiques to demonstrate how the evidence is insufficient to support treatment of gender dysphoria. In addition, the Agency followed the process as specified in Florida Rule (Rule 59G-1.035, F.A.C.) to evaluate puberty blockers, cross-sex hormones, and sex reassignment surgery.

One such example of how the Yale rebuttal's authors attempt to mislead readers is their critique of how the GAPMS report treated Chen et al's 2020 study, "Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Pubertal Suppression in Transgender Youth." By stating that the article is a "consensus parameter" and accusing the Agency of "cherry-picking" quotes, the Yale faculty attempt to misrepresent how the GAPMS report

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³ The Yale rebuttal refers to the GAPMS report as the "June 2 Report." For the purposes of clarity, this analysis replaces the term "June 2 Report" with "GAPMS report" when reproducing the Yale rebuttal's comments.

contextualizes the study. When citing Chen et al, the Agency did so to highlight how questions concerning the effect of puberty blockers on neurodevelopment remain unanswered. This is a critical point regarding whether off-label use of those drugs is safe for adolescents because if puberty blockers halt neurodevelopmental milestones they could pose significant physical costs to achieve a mental health benefit.

Furthermore, the Yale rebuttal insinuates that the Agency determined that treatment for gender dysphoria is experimental and investigational based on a "student blog." This is also extremely misleading. The GAPMS report contained one citation to reference the difference between eminence-based versus evidence-based medicine. The source in no way contributed to the research used to demonstrate how the evidence supporting treatment for gender dysphoria is insufficient.

Yale Rebuttal Point 3: The GAPMS report mistakenly claims that puberty blockers and hormones are experimental because they are used "off-label" and not approved by the FDA. In fact, off-label use, when supported by scientific evidence, as is the case here, is extremely common in medical practice and especially in pediatrics.

Agency Response: This criticism is misleading. The GAPMS report does not assert puberty blockers and cross-sex hormones are experimental solely because the FDA has not approved them to treat gender dysphoria. Highlighting the drugs' off-label use serves as one example among myriad examples to explain that the evidence fails to prove these medications are safe for that clinical indication. If they were, the FDA would likely have approved them for treating gender dysphoria.

Another problem with the Yale rebuttal's criticism is that using drugs off-label is normally done to achieve a physiological effect that is documented in the research. In addition, the risks of using a drug off-label when medically necessary do not outweigh the benefits. The low-quality evidence supporting gender dysphoria treatment does not demonstrate that causing infertility, disfigurement, and mutilation is worth the supposed mental health benefits. To compare such use with drugs like statins and Gabapentin misses the point while confusing the reader. Also, the Yale faculty fail to mention any drugs created specifically for physical conditions being used off-label to address mental illness.

Yale Rebuttal Point 4: The GAPMS report falsely claims that medical care for gender dysphoria is provided to a large percentage of children who will come to regret their treatment. In fact, patients with gender dysphoria have vanishingly low rates of regret regarding their medical treatment.

The GAPMS report attempts to cast doubt on medical treatment for gender dysphoria by repeating the debunked claim that most transgender teens ultimately reject their transgender identity.

Agency Response: This is another false statement. Research does reveal that a high percentage of transgender youth will detransition following puberty. Furthermore, the studies that the Yale professors rely on to make this claim are low quality and lack long-term follow-up. Additionally, the Yale rebuttal makes an erroneous statement by claiming that the GAPMS report "ignores a recent study, Olson et al. (2022), who find that after an average of 5 years of social transition, only 2.5% of youth identified as cisgender."

The above quote is highly concerning. Not only is it false because the GAPMS report actually provides a detailed analysis of Olson et al's article, but it also indicates that the Yale professors did not even read the entire GAPMS report, opting instead to read only the sections on cross-sex hormones and puberty blockers. If they had read the document in its entirety, they would have discovered the Agency addressed that research and provided an analysis.

Yale Rebuttal Point 5: The GAPMS report repeats discredited claims that "social contagion" is leading teens to become transgender. The issue, although sensationalized in the GAPMS report, is ultimately irrelevant to medical treatment, which is provided only after a multidisciplinary assessment and after a finding that gender dysphoria is persistent and medical treatment is warranted.

Agency Response: When referring to discredited claims, the Yale rebuttal is referencing a study by Lisa Littman that introduces the concept of rapid-onset gender dysphoria (ROGD). In their criticism, the authors quote their prior response to Alabama and Texas' actions, stating that Littman's study required "extensive correction" due to its "misstatements." This is also misleading. Following what was most likely significant political backlash, the journal (*PLOS One*) republished the article to clarify that the results were based on parental observations. These clarifications had no impact on the results.⁴

Additionally, the GAPMS report refers to the Littman study in its discussion of the etiology of gender dysphoria to emphasize that the causes of the condition are unknown. Furthermore, insinuating that the GAPMS report uses ROGD as a rationale for determining that treatment for gender dysphoria is experimental and investigational is unfounded. The Agency based its conclusion primarily on the paucity of quality evidence demonstrating that the treatment can alleviate the condition.

Yale Rebuttal Point 6: The GAPMS report claims that inappropriate medical care is provided to adolescents with gender dysphoria who also have anxiety, depression, and other mental health conditions. These assertions are unsupported by scientific evidence and disregard evidence-based clinical practice guidelines that provide sound guidance for treating complex cases.

Agency Response: This is also a false statement. The research explicitly states that high percentages of youths diagnosed with gender dysphoria have other mental health comorbidities (e.g., anxiety and depression). In addition, the GAPMS report highlights research revealing that these youths also have experienced higher rates of trauma, abandonment, and other circumstances that contribute to mental illness.

Furthermore, the Yale rebuttal fails to mention that the "evidence-based clinical practice guidelines" originate from the World Professional Association for Transgender Health (WPATH) and the Endocrine Society. The former does not qualify as a clinical organization and serves as and advocacy group, which is highly biased; and the latter notes that its guidance is based on low and very low-quality evidence. In addition, the Endocrine Society clearly states that its guidance does not constitute a standard of care.

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⁴ For additional information on the revisions to Lisa Littman's 2018 article, "Rapid-Onset Gender Dysphoria in Adolescents and Young Adults: A Study of Parental Reports," refer to the following link.

Yale Rebuttal Point 7: The GAPMS report speculates, without evidence, that psychotherapy alone is as effective as medical treatment for gender dysphoria. This claim contradicts the findings of solid scientific studies, which show that medical care is more effective than psychotherapy alone.

Agency Response: This criticism is extremely misleading. The GAPMS report is not about psychotherapy's effectiveness when used to treat gender dysphoria, nor does it speculate that idea. The GAPMS report is strictly about evaluating whether puberty blockers, cross-sex hormones, and sex reassignment surgery have sufficient evidence to meet medical necessity criteria. In addition, the "solid scientific studies" that the authors refer to are low quality and based on flawed methods.

Conclusion

The Yale rebuttal to Florida Medicaid's GAPMS report makes an insufficient and problematic case for overturning the determination and halting the proposed rule changes. Due to myriad flaws including ad hominem attacks, hyperbolic language, and illogical statements, the Yale rebuttal fails to demonstrate that the conclusions drawn by the GAPMS report are incorrect. Instead of presenting a logical and well-reasoned case, as the authors' years of professional experience and training suggest they are capable of, they provide 47 pages of content that ignore the GAPMS report's main argument, disseminate misinformation, and make false claims, all while doing so under the eminence of Yale University. Creating such a document demonstrates that the Yale professors are intellectually dishonest and biased to the point where they will consider no evidence that challenges their beliefs. Because of the aforementioned issues, the Yale rebuttal is not a persuasive counterargument to the GAPMS report.

Agency Response to the Endocrine Society's Comments on the GAPMS Report

On July 7, 2022, the Endocrine Society submitted comments opposing the Agency's proposed changes to Rule 59G-1.050, F.A.C. These consisted of a narrative description of how the organization develops clinical guidelines and evaluates studies in addition to multiple criticisms of the GAPMS report. After careful consideration, the Agency does not find the Endocrine Society's comments sufficiently persuasive to warrant overturning the determination and proposed rule changes based on the following reasons:

- The Endocrine Society asserts that the Agency "did not include endocrinologists with expertise in transgender medicine."
 - In response, the Agency consulted a pediatric endocrinologist when making its
 determination in addition to experts across other fields and specialties to provide a
 comprehensive analysis of the problems concerning evidence supporting treatment for
 gender dysphoria. Also, the Endocrine Society's comment insinuates that the Agency's
 expert, Quentin Van Meter, lacks the appropriate credentials to comment on areas for
 which he is fully qualified.
- Another criticism claims that the Agency "does not acknowledge the data showing harm reduction and improvements in behavioral health issues, such as depression and anxiety, with gender affirming care."
 - This statement is not true. The Agency reviewed numerous studies supporting the use of gender "affirming" care and found that the methods used to obtain those results were poor and biased, consisting of self-report surveys, lack of participant histories, small sample sizes, and insufficient follow-up periods. This led to the conclusion that the available evidence was insufficient to meet medical necessity criteria.
- The Endocrine Society further argues that the GAPMS report is flawed because it "suggests that because puberty blockers are used off-label they are experimental and investigational."
 - This criticism is misleading. The GAPMS report does not assert that puberty blockers and cross-sex hormones are experimental solely because the FDA has not approved them to treat gender dysphoria. Highlighting the drugs' off-label use serves as one example among myriad examples to explain that the evidence fails to prove these medications are safe for that clinical indication. If they were, the FDA would likely have approved them for treating gender dysphoria.

Another problem with the Endocrine Society's criticism is that using drugs off-label is normally done to achieve a physiological effect that is documented in the research. In addition, the risks of using a drug off-label when medically necessary do not outweigh the benefits. The low-quality evidence supporting gender dysphoria treatment does not demonstrate that causing infertility, disfigurement, and mutilation is worth the supposed mental health benefits.

Following its criticisms, the Endocrine Society points to multiple studies, including ones by Green et al and Turban et al, claiming that puberty blockers and cross-sex hormones can alleviate gender dysphoria. However, Attachment C of the GAPMS report composed by Romina Brignadello-Petersen determined

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these two studies present confounding evidence and suffer from critical risks of bias. These findings reinforce the notion that evidence supporting treatment for gender dysphoria is insufficient to demonstrate mental health benefits.

Based on the above evaluation of the Endocrine Society's comments, the Agency stands by the determination of the GAPMS report and the proposed changes to Rule 59G-1.050, F.A.C.

Agency Response to the AAP's Comments on the GAPMS Report

On July 7, 2022, the American Academy of Pediatrics (AAP) submitted comments to the Agency's opposing proposed changes to Rule 59G-1.050, F.A.C. The organization argues that Florida Medicaid should not deny coverage of gender "affirming" treatments because they are the "standard of care." In addition, the AAP promotes erroneous and flawed arguments while asserting that the GAPMS report misrepresents the science. Due to these deficiencies, the Agency does not find the AAP's comments compelling enough to consider overturning the determination and proposed rule changes.

Among the numerous issues, the most glaring problem with the AAP's comments is its consistent reference to puberty blockers and cross-sex hormones acting as the "standard of care" for gender dysphoria. This representation is patently false. Currently, no standard of care exists for the condition that endorses such treatments, just clinical guidelines. By deliberately confusing the two categories, the AAP is misleading its audience to believe that no debate surrounds using puberty blockers and cross-sex hormones to address gender dysphoria. The term "standard of care" has specific legal ramifications. For example, physicians who practice outside of a given standard can be found liable for medical malpractice. What this means is that a "standard of care" is the minimum level of competency a practitioner must exercise when treating a patient.⁵ Treatment for gender dysphoria has yet to reach this level. However, the AAP appears to want to obfuscate that fact.

Instead of a "standard of care," what is available supporting the use of puberty blockers and cross-sex hormones for this condition is clinical guidelines based on low-quality evidence. In its guidance, the Endocrine Society acknowledges that its recommendations are not a "standard of care" and that they are based on weak evidence. The other set of widely cited clinical guidelines is from the World Professional Association for Transgender Health (WPATH). While WPATH has clinicians serving as members, it is an advocacy group and not a professional organization. Furthermore, WPATH also bases its guidance on the same low-quality evidence as the Endocrine Society.⁶

Aside from misrepresenting the meaning of "standard of care," the AAP's comments have numerous other issues and errors, consisting of logical fallacies, false statements, and reliance on biased research. These consist of the following:

AAP Comments Problem 1: The AAP attempts to argue that because puberty blockers and cross-sex hormones are medically necessary for conditions such as endometriosis, polycystic ovarian syndrome, and acne that they are also appropriate for gender dysphoria.

Agency Response: This is a logical fallacy and blatant misrepresentation. Taking drugs to correct hormonal imbalances is medically necessary and supported by quality science. However, just because certain medications are beneficial for some conditions does not mean that using them to obtain the secondary sexual characteristics of the opposite sex is justifiable to treat a mental health issue.

⁵ Moffett P and Moore G. The Standard of Care: Legal History and Definitions: The Bad and Good News. *West J Emerg Med*. 2011. 12:1. 109-112.

⁶ For additional information regarding clinical guidelines offered by WPATH and the Endocrine Society, please refer to the Florida Medicaid Generally Accepted Professional Medical Standards Determination on the Treatment for Gender Dysphoria.

AAP Comments Problem 2: Throughout the document, the AAP attributes almost 20% of its citations to its own statement promoting gender "affirmative" care and a flawed report from Yale University composed in response to Texas and Alabama's actions regarding treating minors for gender dysphoria.⁷

Agency Response: The over-reliance on flawed statements and research compromises the credibility of not only the AAP's comments but any document that utilizes such a practice. The strength of any scientific analysis is based only on the quality of evidence used to support the findings. By using discredited and biased work, the AAP further undermines its own credibility.

AAP Comments Problem 3: The AAP asserts that "gender-affirming medical care is a highly individualized model of care."

Agency Response: This is a false statement. The AAP's method of gender "affirming" care is not individualized but a one-sized-fits-all model. According to the AAP, WPATH, and similar organizations, children and adolescents diagnosed with gender dysphoria first receive counseling followed by puberty blockers and then cross-sex hormones before undergoing sex reassignment surgery.

AAP Comments Issue 4: When addressing the GAPMS report's analyses on puberty blockers, cross-sex hormones, and desistance, the AAP attempts to argue that puberty blockers provide additional time for adolescents to "explore their gender identity" and are safe when used to treat gender dysphoria. In addition, the AAP claims that the GAPMS report's highlighting that puberty blockers and cross-sex hormones are not FDA-approved for gender dysphoria "lack any basis."

Agency Response: The AAP misses the point when it asserts that puberty blockers allow additional time for an adolescent to explore his or her gender identity. By halting pubertal development, these physicians are prohibiting children from fully realizing their natal sex before beginning cross-sex hormones. How can the AAP argue that children and adolescents should be able to "explore" while simultaneously denying them the experience of being a physically mature male or female?

Regarding the AAP's comments about the drugs' lacking FDA approval for gender dysphoria and being used off-label, this criticism is misleading. The GAPMS report does not assert puberty blockers and cross-sex hormones are experimental solely because the FDA has not approved them to treat gender dysphoria. Highlighting the drugs' off-label use serves as one example among myriad examples to explain that the evidence fails to prove these medications are safe for that clinical indication. If they were, the FDA would likely have approved them for treating gender dysphoria.

Another problem with the AAP's comments is that using drugs off-label is normally done to achieve a physiological effect that is documented in the research. In addition, the risks of using a drug off-label when medically necessary do not outweigh the benefits. The low-quality evidence

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⁷ Please refer to "Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims." Yale University. 28 April 2022. Access at the following link. For the Agency's critique of this report, please see Attachment A.

supporting gender dysphoria treatment does not demonstrate that causing infertility, disfigurement, and mutilation is worth the supposed mental health benefits.

AAP Comments Issue 5: The AAP refers to multiple studies in an attempt to bolster its argument that Florida Medicaid's GAPMS report is flawed and draws the wrong conclusions. The organization states that "research shows that hormone therapy, as a component of gender-affirming care, is beneficial to caring for adolescents with gender dysphoria" and then cites two studies, one by Green et al and another by Tordoff et al.

Agency Response: The Agency worked with Romina Brignardello-Petersen and Wojtek Wiercioch to evaluate and grade available research on treatment for gender dysphoria during the GAPMS review process. Their analysis reviewed both studies cited by the AAP and concluded that they each suffered from moderate and critical risks of bias. Furthermore, the AAP refers to an additional study by Turban et al, which Brignardello-Petersen and Wiercioch also appraised as having a critical risk of bias.

Considering the myriad issues with the AAP's comments, the Agency has determined they lack any sufficient standing to overturn the GAPMS report's determination or proposed changes to Rule 59G-1.050, F.A.C. Instead of composing a well-reasoned counterargument that demonstrates the evidence supporting treatment for gender dysphoria is robust and high quality, the AAP created a document rife with errors, misrepresentations, and non-applicable analogies. Attempting to veil such comments under the eminence of the AAP serves only to mislead its audience into accepting mistruths as fact. The GAPMS report thoroughly demonstrated that the evidence supporting treatment for gender dysphoria is insufficient to meet medical necessity criteria.

Analysis of Yale University's April 2022 Report

Overview of the Yale's April 2022 Report Responding to Alabama and Texas

On April 28, 2022, six faculty members of Yale University and one from the University of Texas Southwestern released a report (Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims) in response to the Texas Attorney General's (AG) opinion and Alabama law that restricts youth access to treatments for gender dysphoria. The report addresses multiple themes including sex-reassignment surgery for minors, effectiveness of puberty blockers and cross-sex hormones, and using drugs for off-label purposes. Currently, advocacy organizations such as Lambda Legal are citing this report as one that sufficiently debunks the research used in Florida's June 2022 GAPMS report. However, the report has significant flaws related to bias, omissions, and misrepresentations of evidence as presented in the following:

Critique of the Report's Content at Large

- This report provides a highly biased critique of the Texas AG's opinion and the Alabama law. This bias is evident in the heavy criticism leveled at studies that do not support the effectiveness of treatments for gender dysphoria and the omission of highly significant facts (e.g., permanent effects of cross-sex hormones). Further proof of bias is present in the failure to subject supporting studies to the same level of academic rigor applied to the opposing research.
- Due to the bias and omissions, the conclusions of this report are misleading and provide insufficient information to its audience. Individuals that reference this report prior to receiving treatments for gender dysphoria are only getting a fraction of the information and thus cannot provide fully informed consent.
- The authors also fail to provide an understanding that demonstrating the safety and effectiveness of any given treatment requires robust, high-quality evidence. When making that case, researchers need to put forward such evidence. The report's authors do not do that. Instead, they wrongfully assume that criticizing opposing evidence while ignoring the flaws in their own sufficiently proves their case. It does not. The authors appear oblivious that the burden of proof is on them, and they provide little evidence, which is low quality, to overcome that burden.

Content on WPATH, SEGM, and the Endocrine Society

- The report misrepresents WPATH and cites it as a clinical organization, when in reality it is an advocacy group that anyone can join.
- The authors attempt to discredit the Society for Evidence-Based Gender Medicine (SEGM) by arguing that it is biased against gender "affirming" care. However, the authors do not level such criticisms toward WPATH.
- The report fails to mention that the Endocrine Society gives low grades to treatments for gender dysphoria and that the organization's guidance does not constitute a standard of care.

Content on Puberty Blockers

- Asserts that puberty blockers are safe and do not pose any irreversible effects when research
 has not fully answered the questions about prohibiting neurodevelopmental milestones and
 bone mineral density accumulation.
- All research used to substantiate the authors' claims consists of studies regarding puberty blockers when used to treat central precocious puberty, which is a separate condition requiring the drugs to be used at younger ages (e.g., 8-10 years) as opposed to when puberty begins. This is a direct misrepresentation of scientific evidence.
- The report also attempts to downplay the off-label use of puberty blockers, which the FDA has not approved to treat gender dysphoria. It does this by arguing that drugs approved for adults are used off-label for children on a frequent basis. However, these analogies are flawed for the following reasons:
 - The report provides no examples of drugs only approved for adults that are used offlabel for children, which makes it impossible to determine whether the medications apply to the same conditions as clinically indicated by their FDA-approved labels.
 - Examples cited of drugs being prescribed for off-label purposes are for the treatment of physical conditions such as acne. Even propranolol (beta blocker), which is used off-label to treat performance anxiety, is used to treat the accompanying physical effect of elevated blood pressure.

Content on Cross-Sex Hormones

- The report understates how cross-sex hormones can reduce fertility in trans-females (men who transition into women) by stating that fertility quickly returns after the estrogen and anti-androgen treatments stop. This conflicts directly with the University of California at San Francisco's guidance to patients that advises them to have sperm frozen prior to treatment because fertility will not likely return.
- The authors emphasize that estrogen treatments improve long-term cardiovascular health in trans-females. However, they make no mention of how testosterone negatively affects transmales (women who transition into men). Effects such as hypertension and cardiovascular damage receive no mention whatsoever.
- The report also fails to mention other permanent effects caused by cross-sex hormones such as enlarged breasts in trans-females and facial hair in trans-males, while downplaying the effects on fertility.

Content on Quality of the Evidence Supporting the Effectiveness of Treatment for Gender Dysphoria

- The authors fail to elaborate on the evidence supporting treatment for gender dysphoria, citing
 only a handful of studies and not providing any critique or analysis of the research methods
 used.
 - Attachment C in the AHCA reported assessed that the study by Tordoff et al published in 2022 (cited in the Yale report) had a moderate risk of bias and small sample size.

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• The authors falsely refer to research supporting treatment for gender dysphoria as the "best scientific evidence." When in reality, all published studies with supporting conclusions are low or very low quality.

Criticism of Studies That Do Not Support Treatments for Gender Dysphoria

- The report devotes significant content to critiquing Littman's study on rapid-onset gender dysphoria (ROGD) and Dhejne et al's study on transexuals in Sweden.
 - The authors state that the Dhejne study is "badly out of date," which is a very hypocritical criticism. They provide no explanation for why the study's publication date (2011) makes it invalid while citing evidence going back to 1988 on the effectiveness of puberty blockers.
 - For Littman's study, the authors criticize the survey methodology used to obtain the findings and assert repeatedly that the findings were discredited. Although the authors are correct that the research methods were not robust enough to provide moderate or high-quality results, they ignore the fact that the studies supporting the treatments also use the same methods (e.g., surveys and biased sampling selection). In addition, their analysis provides no information that debunks the ROGD phenomenon. The authors just say that the study's results have been "debunked" without substantiating their argument.

From: Andre Van Mol <95andrev@gmail.com>
Subject: Re: Florida Consulting [Priv/Confi/Atty WP]

Sent: 2022-05-01T18:50:48Z

Cc: "Sheeran, Andrew" <Andrew.Sheeran@ahca.myflorida.com>, "Pickle, Devona"

<Devona.Pickle@ahca.myflorida.com>

To: Weida Jason <Jason.Weida@ahca.myflorida.com>

FLORIDA MEDICAID & G:TAT.docx

Hi, Jason and team.

Please find attached my initial document for you all regarding the requested information on GAT/TAT for minors. Please note the page 1 table of contents for ease of use. One might consider starting with the center "MAJOR BULLET POINTS" section to get a feel of things. Most of what was requested follows the bullet section. However, the background information preceding this is vital to understand, and our presuming either prior knowledge or ability to skip steps could lead to trouble -- trouble easily averted by overdelivering rather than under, so I did. I left out a section demonstrating that the very high probability of mental health problems and adverse childhood experiences in transgender identified minors precedes the finding of gender dysphoria (not the other way around), as you already have an expert in child psychiatry working on that, but I can provide it if desired. The final section on the poor but oft quoted studies should be useful as well.

There is more in the document, at 55 pages and over 200 citations (partly due to repetition), than you might need, but my attorney friends revel in detail prior to distillation.

I look forward to our talking together this Friday. I can provide further information according to your requests.

Thank you, Andre

PS Jason, you mentioned DD, and I didn't catch who that was. May I ask you for forward this document to whomever requires it? Thanks again.

FLORIDA MEDICAID & G/TAT

Andre Van Mol, MD May 2022

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Sex

Is objective, identifiable, immutable, determined at conception (not "assigned at birth"), stamped on every nucleated cell, and highly consequential. $^{1\ 2\ 3\ 4}$

- 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."
- 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."6

What about intersex (disorders of sex development)?

- They are also established at conception for the 0.02% of people who have them. ⁷ 8
- 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."9
 - o DSDs usually impair fertility.¹⁰

¹ 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/ ² "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-differentlymen-and-women.

³ 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.

⁴ 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.

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

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

 $^{^{7}}$ "Intersex. What It Is And Is Not," CMDA The Point Blog, May 2, 2019.

⁸ 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/

 ⁹ 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
 ¹⁰ Słowikowska-Hilczer J, Hirschberg AL, Claahsen-van der Grinten H, et al. Fertility outcome and information on fertility issues in individuals with different forms of disorders

- **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.¹¹
 - 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)."12
 - UK GIDS Tavistock study 2020: "All had normal karyotype and endocrinology" function in 44 GD youth.¹³
- 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. 14

- o 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." 15
- **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.

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

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.

doi:10.1016/j.fertnstert.2017.08.013

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

¹² 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

¹³ 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

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

¹⁵ 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.

- o 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?**
 - o **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."¹⁶

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

- DSM 5 of the APA:¹⁷
 "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 ..." 18
- 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."
- 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."

¹⁶ 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 ¹⁷ American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders (5th ed.). Arlington, VA: American Psychiatric Publishing. P.451. ¹⁸ 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"

studies and 'desistance' theories about transgender and gender nonconforming children" by Temple Newhook et al., 19(2) INT 'L. J. TRANSGENDERISM 231–45 (2018).

¹⁹ 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**, <u>prevalence ranges</u> 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." 20
- 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%. ²¹
- American Psychological Assoc. *Handbook on Sexuality and Psychology, V1,744*:²²
 - "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."²³
- Cohen-Kettenis, 2008, J SexMed: 80-95% of gender dysphoric pre-pubertal children desist by the end of adolescence.²⁴
- Ristori, et al Int Rev Psychiatry 2016: Finding a desistance rate of 61-98% of GD cases by adulthood.²⁵
- 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." ²⁶

5

²⁰ 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

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

²² 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.)

 ²³ Singh D, Bradley SJ and Zucker KJ (2021) A Follow-Up Study of Boys With Gender Identity Disorder. *Front. Psychiatry* 12:632784. doi: 10.3389/fpsyt.2021.632784
 ²⁴ 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.

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

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

 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."²⁷

Brain development in minors ²⁸ ²⁹ ³⁰ ³¹

- Children have developing brain, their minds change often, and they don't grasp long-term consequences.³²
- 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. ³³
 - 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.³⁴

Cited therein:

National Institute of Mental Health (2001). Teenage Brain: A work in progress. http://www2.isu.edu/irh/projects/better-todays/B2T2VirtualPacket/BrainFunction/NIM-teenage%20Brain%20-%20A%20Work%20in%20Progress.pdf.

²⁷ 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
²⁸ 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-
²⁹ 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).

³⁰ 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

³¹ 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.

³² "Transing California Foster Children & Why Doctors Like Us Opposed It," PublicDiscourse.com, October 28, 2018.

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

³⁴ Andre Van Mol, "Transing California Foster Children & Why Doctors Like Us Opposed It," PublicDiscourse.com, October 28, 2018.

- 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."35
- 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.³⁶ ³⁷
- 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."38
- **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." ³⁹

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).

 $^{^{35}}$ Stephen B. Levine (2018): Informed Consent for Transgendered Patients, Journal of Sex & Marital Therapy, DOI: 10.1080/0092623X.2018.1518885.

³⁶ 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.

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

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

³⁹ 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." And it is based on only a self-diagnosis.

Do Not Prematurely Affirm:

- APA Handbook on Sexuality and Psychology (APA, 2014)
 - o "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."
 - 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 crossgender feelings do not persist..."
- 2020 Nordic J of Psychiatry:⁴³
 - "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

⁴⁰ 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.

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

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

⁴³ Riittakerttu Kaltiala, Elias Heino, Marja Työläjärvi & Laura Suomalainen (2020) Adolescent development and psychosocial functioning after starting cross-sex hormones for gender dysphoria, Nordic Journal of Psychiatry, 74:3, 213-219, DOI: <u>10.1080/08039488.2019.1691260</u>

medical treatment they may later seek to reverse or come to regret, while their underlying psychological issues remain unaddressed."44

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." ⁴⁵ 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.⁴⁶
- 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."⁴⁷
- 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." 48
- JAMA 2017: "Potential longer-term medical and surgical **risks are currently not** well defined..." 49

⁴⁸ 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

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⁴⁴ 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.

⁴⁵ 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

 $^{^{46}}$ Zucker, K. J. (2019), Debate: Different strokes for different folks. Child Adolesc Ment Health. doi: $\underline{10.1111/camh.12330}$

⁴⁷ 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

⁴⁹ 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).⁵⁰⁵¹

- 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..." 52
- 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)."53 54
- 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]."55
- 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.⁵⁶
- The Swedish National Council for Medical Ethics, 2019. 57
- Swedish Agency for Health Technology Assessment and Assessment of Social Services' 2019 literature review.⁵⁸ Found no scientific evidence to explain increase

⁵⁰ 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.

⁵¹ 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

⁵² James M. Cantor (2019): Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy, Journal of Sex & Marital Therapy, DOI:10.1080/0092623X.2019.1698481

⁵³ 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: <u>10.1080/15265161.2018.1557288</u>

⁵⁴ 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.

⁵⁵ 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.

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

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

 $^{^{58}}$ 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, 2021:⁵⁹ 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). 60
- 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."⁶¹
- UK Tavistock Gender Identity Development Service (GIDS) Controversy.
 - o 35 psychologists resigned over 3 years. 62
 - They cited the over-prescribing medicalization of kids with GD "with psychologists unable to properly assess patients over fears they will be branded 'transphobic..."
 - o "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).63
 - o 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

⁵⁹ Karolinska Policyförändring K2021-3343 March 2021 (Swedish).pdf;
Karolinska Policy Change K2021-3343 March 2021 (English, unofficial translation).pdf

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

⁶¹ Michael Biggs, The Tavistock's Experiment with Puberty Blockers, 29 July 2019,
http://users.ox.ac.uk/~sfos0060/Biggs ExperimentPubertyBlockers.pdf

⁶² "NHS 'over-diagnosing' children having transgender treatment, former staff warn,"
news.sky.com, 12 Dec. 2019. https://news.sky.com/story/nhs-over-diagnosing-childrenhaving-transgender-treatment-former-staff-warn-11875624

⁶³ 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, 2020.⁶⁴
 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."
 - o The ruling has been appealed.
- NHS Dec 2020 amendments to service specifications for Gender Identity

 Development Service (GIDS) for children and adolescents:⁶⁵ 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)* 2020.⁶⁶

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

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

https://palveluvalikoima.fi/documents/1237350/22895008/Summary minors en.pdf/aaf 9a6e7-b970-9de9-165c-abedfae46f2e/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.^{67 68 69 70}
 - o Someone can come to their senses later, but what's gone is gone.
- Do Not Prematurely Affirm:

Clin Endocrinol Metab. 102:1-35.

- 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..."⁷¹
- 2020 Nordic J of Psychiatry:⁷² ... "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."

 ⁶⁷ American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders (5th ed.). Arlington, VA: American Psychiatric Publishing. P.455.
 ⁶⁸ Singh D, Bradley SJ and Zucker KJ (2021) A Follow-Up Study of Boys With Gender Identity Disorder. *Front. Psychiatry* 12:632784. doi: 10.3389/fpsyt.2021.632784
 ⁶⁹ Hembree, W., Cohen-Kettenis, et al., (2017) Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guildeline. J

⁷⁰ 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 ⁷¹ W. Bockting, *Ch. 24: Transgender Identity Development*, in 1 American Psychological Association Handbook on Sexuality and Psychology, 750 (D. Tolman & L. Diamond eds., 2014).

⁷² Riittakerttu Kaltiala, Elias Heino, Marja Työläjärvi & 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."
- 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." 74 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.⁷⁵
- 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. ⁷⁶ ⁷⁷ ⁷⁸
 - Why? The probability of desistance.

for gender dysphoria, Nordic Journal of Psychiatry, 74:3, 213-

219, DOI: 10.1080/08039488.2019.1691260

⁷³ 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.

⁷⁴ 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

⁷⁵ 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

⁷⁶ 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.

⁷⁷ 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

⁷⁸ 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

- \circ The overwhelming likelihood of mental health and other issues preceding the diagnosis of GD. $^{79\,80\,81\,82\,83}$
- UK High Court Bell v Tavistock⁸⁴ 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.
 - o "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 2020.⁸⁵
- Transgenderism as the catch-all explanation for distress, & transition is promoted as a cure-all solution (Littman study). 86
- Skilled psychological investigation for underlying causes is shamed as "transphobic". 87
 - 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, ⁸⁸ Bell v

⁷⁹ 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.

⁸⁰ 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.

⁸¹ Kozlowska K, McClure G, Chudleigh C, et al. Australian children and adolescents with gender dysphoria: Clinical presentations and challenges experienced by a multidisciplinary team and gender service. *Human Systems*. 2021;1(1):70-95.

doi:10.1177/26344041211010777

⁸² 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

⁸³ 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.

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

 $^{^{85}\ \}underline{https://www.england.nhs.uk/wp-content/uploads/2020/12/Amendment-to-Gender-Identity-Development-Service-Specification-for-Children-and-Adolescents.pdf}$

⁸⁶ 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.

⁸⁷ "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

⁸⁸ 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, ⁸⁹ Swedish Agency for Health Technology Assessment and Assessment of Social Services' 2019 literature review. ⁹⁰), Finland COHERE, ⁹¹ Australia, ⁹² Brazil, etc. And now Florida Dept. of Health Guidelines (4/20/2022)⁹³

- 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. 9495
- 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. 96
 - Not FDA approved for this.
 - o 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.

https://palveluvalikoima.fi/documents/1237350/22895008/Summary minors en.pdf/aaf 9a6e7-b970-9de9-165c-abedfae46f2e/Summary minors en.pdf

⁸⁹ Karolinska Policyförändring K2021-3343 March 2021 (Swedish).pdf; Karolinska Policy Change K2021-3343 March 2021 (English, unofficial translation).pdf ⁹⁰ https://www.sbu.se/en/publications/sbu-bereder/gender-dysphoria-in-children-and-adolescents-an-inventory-of-the-literature/

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

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

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

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

⁹⁶ 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.

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

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.

⁹⁸ 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

⁹⁹ Brik T, Vrouenraets LJJJ, 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

¹⁰⁰ 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

¹⁰¹ 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 ¹⁰² 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)

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.

¹⁰⁴ 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.

¹⁰⁵ 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-0W7hL25idXT ilTflZUUm1w/view

106 https://transcare.ucsf.edu/guidelines/youth

⁹⁷ 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

- Males: erectile, orgasmic and ejaculatory impairment
- Females: menopausal state inducing¹⁰⁷
- Mental health issues: mood swings, depression, suicidal ideation and attempts (Lupron package insert) 108 109
- Bone mineral density compromise at its period of greatest growth. ¹¹⁰
 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. ¹¹¹ No one can have that window back.
- Cross-sex hormone risks. 112 113 114
 - o 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. 115

¹⁰⁷ 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.

¹⁰⁸ 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 ¹⁰⁹ Michael Biggs, The Tavistock's Experiment with Puberty Blockers, 29 July 2019, http://users.ox.ac.uk/~sfos0060/Biggs ExperimentPubertyBlockers.pdf

¹¹⁰ 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 ¹¹¹ 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

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

¹¹³ 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.

¹¹⁴ 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.

¹¹⁵ 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 cancer¹¹⁶
- 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? 117
- o International panel of endocrinology organizations concluded about testosterone use in women(10/2019)¹¹⁸ "...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.):
 - o 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. ¹¹⁹ 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. 120

¹¹⁶ 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

¹¹⁷ 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.)

¹¹⁸ 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.

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

¹²⁰ 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. ¹²¹ Ultimately showed neither "gender-affirming hormone treatment" nor "gender-affirming surgery" provided reductions of the mental health treatment benchmarks examined. ¹²² ¹²³
- G[T]AT's suicide reduction claim is a myth used as emotional blackmail.
 - o 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)..."124
- The chemical sterilization/castration and surgical mutilation of normal sex organs in children is not healthcare.
- NC (2012)¹²⁵ and CA (2021)¹²⁶ passed laws to compensate surviving victims of the 20th 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:

¹²¹ 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
¹²² 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
¹²³ 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.]

¹²⁴ 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://abcnews.go.com/Health/WomensHealth/north-carolina-compensate-victims-eugenics-program-sterilized/story?id=15328707

¹²⁶ https://sacramento.cbslocal.com/2021/12/31/california-program-state-sponsored-sterilization-survivors/ More indepth prior report:

 $\frac{https://ktla.com/news/california/california-to-pay-victims-forced-coerced-into-sterilization-because-state-deemed-them-unfit-to-have-children/$

- From the <u>Endocrine Society guidelines</u> themselves, even "Social transition is associated with the persistence of GD as a child progresses into adolescence."¹²⁷
- 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." 128

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 - 4.¹²⁹
 - o If puberty blocking begins at Tanner stage II as Endocrine Society guidelines suggest, menarche and spermarche won't happen. Infertility.¹³⁰
 - Administering cross-sex hormones with or right after puberty blockers means sperm and eggs won't mature. Infertility.¹³¹
 - UCSF Transgender Care, Health considerations for gender nonconforming children and transgender adolescents, subsection "Preparing for genderaffirming 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,

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

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

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

¹³⁰ 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.

¹³¹ 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": 132

"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.**¹³³ ¹³⁴
- 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

¹³² 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 ilTf[ZUUm1w/view

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

¹³⁴ 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).¹³⁵

- UK GIDS Tavistock study 2020. 136
 - o 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/2011/020263s036lbl.pdf.
 - Myungsun Shim, et al., "Effectiveness of three different luteinizing hormonereleasing 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),

¹³⁵ Michael Biggs, The Tavistock's Experiment with Puberty Blockers, 29 July 2019, http://users.ox.ac.uk/~sfos0060/Biggs_ExperimentPubertyBlockers.pdf

¹³⁶ 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." 137
- **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.¹³⁸ 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." ¹³⁹
- 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.¹⁴⁰

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

¹³⁷ 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.

¹³⁸ 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: <u>10.1530/endoabs.58.OC8.2</u>

¹³⁹ 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)

¹⁴⁰ 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..

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

- COMPLICATIONS OF CSH THERAPY: 142 143 144
 - Cross Sex Hormones (CSH)
 - Testosterone
 - Cardiovascular and cerebrovascular disease (heart attacks and strokes)
 - Breast/uterine cancer
 - Liver dysfunction
 - HTN
 - Severe acne
 - Liver cancer?¹⁴⁵
 - Estrogen
 - Dyslipidemias
 - Thromboembolic disease (blood clots)
 - Cardiovascular and cerebrovascular disease (heart attacks and strokes)
 - Breast cancer¹⁴⁶
 - Weight gain
 - Insulin resistance
 - Cholelithiasis
 - o Testosterone increases the risk of heart disease in women 4 fold,

¹⁴¹ 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, ICEM, Online, November 23, 2018..

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

Does Not Include the Right to Medical Transition, American Journal of Bioethics, 19 (2) 77 (2019). https://doi.org/10.1080/15265161.2018.1557288.

¹⁴⁴ 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.

¹⁴⁵ 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.)

¹⁴⁶ 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. 147 148 149 150
- 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.¹⁵¹
- 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".¹⁵²
- Estrogen (in MtF) can cause increased weight gain¹⁵³ and insulin resistance.¹⁵⁴
- "A pathological analysis of the genital tract of 112 FTM subjects who were given androgen for at least 6 months before hystero-salpingo-oophorectomy 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." 155
- o Testosterone in FtM can cause severe acne. 156

¹⁴⁷ 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.

¹⁴⁸ 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. ¹⁴⁹ Irwig MS. Cardiovascular Health in Transgender People. Rev Endocr Metab Disord. 2018 Aug 3 epub.

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

¹⁵¹ 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.

¹⁵² 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

¹⁵³ Journal of Clinical & Translational Endocrinology 21 (2020) 100230

¹⁵⁴ Diabetes Care 2020 Feb; 43(2): 411-417; World J Diabetes. 2020 Mar 15; 11(3): 66-77

¹⁵⁵ 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.

¹⁵⁶ British Journal of Dermatology (2019) 180, pp26–30

- International panel of endocrinology organizations said about testosterone use in women(10/2019)¹⁵⁷
 - "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." ¹⁵⁸
- Children's Hospital Los Angeles "Informed Consent Form for Feminizing Medications (transfeminine individuals on GnRH analogs)" 159 (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."

¹⁵⁷ 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.

¹⁵⁸ 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.

¹⁵⁹ 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 jlTfjZUUm1w/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.¹⁶⁰
- 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.¹⁶¹
- 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." ¹⁶² 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,¹⁶³ a major "correction" paragraph from the editors retracting the studies main finding,¹⁶⁴ and a letter from the study authors conceding their "conclusion" "was too strong."¹⁶⁵

 $^{^{160}}$ Meyer J.K. and Reter D. Sex Reassignment Follow up Arch. Gen Psychiatry 36; 1010-1015; 1979

¹⁶¹ 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.

¹⁶² 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

¹⁶³ 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.]

 ¹⁶⁴ 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
 ¹⁶⁵ 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." 166
 - "This suggests that generally SRS may reduce psychological morbidity for some individuals while increasing it for others."
 - o SRS was not an agent of statistically significant net benefit.
- Mastectomies on minors, JAMA Pediatrics, 2018.¹⁶⁷
 Questionable claim: "Chest dysphoria was high among presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults."
 Problems:
 - o "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.¹⁶⁸
- 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." ¹⁶⁹

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

¹⁶⁶ 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).

¹⁶⁷ 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

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

¹⁶⁹ Rossi Neto, R., Hintz, F., Krege, S., Rübben, 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..."
- "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.¹⁷¹
- 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." 172

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.¹⁷³ ¹⁷⁴ ¹⁷⁵ ¹⁷⁶
- 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

¹⁷⁰ 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 https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282

¹⁷² 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

¹⁷³ 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 ¹⁷⁴ https://4thwavenow.com/2018/12/19/the-theatre-of-the-body-a-detransitioned-epidemiologist-examines-suicidality-affirmation-and-transgender-identity/

¹⁷⁵ 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/

¹⁷⁶ 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)..."¹⁷⁷
- 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
- Entwistle K. Debate: Reality check Detransitioner's testimonies require us to rethink gender dysphoria. *Child Adolesc Ment Health*. 2021;26(1):15-16. doi: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 vo 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." 178
- **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."
- About 96% of US adolescents attempting suicide demonstrate at least one mental illness (Nock 2013).¹⁸⁰

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

¹⁷⁷ 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).

 $^{^{178}}$ Stephen B. Levine (2019) Informed Consent for Transgendered Patients, Journal of Sex & Marital Therapy, 45:3, 218-229, DOI: $\underline{10.1080/0092623X.2018.1518885}$

¹⁷⁹ 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

¹⁸⁰ 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).¹⁸¹
- About 5% of all youth suicide can be partly attributed to media coverage and discussion of other suicides (Kennebeck 2018)."182
- 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.¹⁸³

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 Blanchard¹⁸⁴: "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 2022.¹⁸⁵
- 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.

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

¹⁸¹ 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.

¹⁸² 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

¹⁸³ Aaron Kheriaty, "The dangerously contagious effect of assisted-suicide laws," washingtonpost.com, Nov. 20, 2015.

¹⁸⁴ 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/

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. 186
- Professor Michael Biggs of Oxford. 2019.¹⁸⁷ 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)."

¹⁸⁶ 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.

¹⁸⁷ Michael Biggs, "The Tavistock's Experiment with Puberty Blockers," 29 July 2019, http://users.ox.ac.uk/~sfos0060/Biggs ExperimentPubertyBlockers.pdf

- Amsterdam Cohort Study 2020 update. 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.
 - o 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). 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" 190

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." 191

¹⁸⁸ 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. ¹⁸⁹ https://4thwavenow.com/2018/12/19/the-theatre-of-the-body-a-detransitioned-epidemiologist-examines-suicidality-affirmation-and-transgender-identity/ ¹⁹⁰ https://a20ceadd-0fb7-4982-bbe2-

⁰⁹⁹c8bc1e2ae.filesusr.com/ugd/ec16e9 8dec43abbe5d4eaaa2dd6b561a66f95c.pdf

191 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.¹⁹² 193 194
- 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." 195
- 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.¹⁹⁶
- Michael Bailey (2020):¹⁹⁷ "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."
 - o "The minority stress model should predict that nonheterosexual persons who grow up in especially intolerant or stigmatizing cultures would be at

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

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

¹⁹⁴ 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.

¹⁹⁵ Mayer LS and McHugh P, "Sexuality and Gender: Findings from the Biological, Psychological, and Social Sciences," The New Atlantis, Fall 2016. PP 79-81.

¹⁹⁶ 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. ¹⁹⁷ 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.
- o "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 dsyphoria."
- It is the former Harry Benjamin International Gender Dysphoria Association. 198
- The World Professional Association for Transgender Health (WPATH, a membership organization for health care professionals that advocates for transgender health care)...Hruz, Mayer, McHugh¹⁹⁹
- 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, MD²⁰⁰
- "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, MD²⁰¹
- The World Professional Association for Transgender Health (WPATH) deems gender identity incongruity not "inherently pathological" and asserts that efforts to

¹⁹⁸ 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) ¹⁹⁹ 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.

²⁰⁰ 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.

²⁰¹ 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-7²⁰² (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, PhD²⁰³
- 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 is 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, PhD²⁰⁴

2. Endocrine Society Guidelines Plus

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

²⁰² 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.

²⁰³ 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

²⁰⁴ 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." 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."²⁰⁶

²⁰⁵ 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

²⁰⁶ 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."²⁰⁷
 "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.²⁰⁸
 - So how can kids be competent to choose GAT?
- Leonard Sax, MD²⁰⁹ -- "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:²¹⁰
 - o Policy Statements are produced by 10-12 member Committees or Councils, or Section (e.g., School Health, Adolescence, or Bioethics) or more commonly

²⁰⁷ 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

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

²⁰⁹ Leonard Sax, "Politicizing Pediatrics: How the AAP's Transgender Guidelines Undermine Trust in Medical Authority,"thepublic discourse.com March 13, 2019.

https://www.thepublicdiscourse.com/2019/03/50118/ ²¹⁰ Laurie Higgins, Do 66.000 Pediatricians Really Support t

²¹⁰ 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.
- o 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.**²¹¹

- "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."

²¹¹ 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 Selfidentify 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.equal.ity.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

- 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).
- o 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
 - o AJP editors expressed the need "to **seek statistical consultations."**
 - o 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 GI patients receiving and GI patients not receiving genderaffirmative 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:
 - o **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
 - o lack of control population
 - o 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.
 - o 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 genderaffirming 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, SarahDavidson, 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/10.1101/2020.12.01.2024165

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.

3 https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1

- 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.
 - o More proof that DSDs/Intersex are not GD issues.
- 98% went on from puberty blocking to CSH.
 - o 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.
 - o "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, Hacsi. (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 welladvertised 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, 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.jado health.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 themself) 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., 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).

- 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."
 - o 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.58.0C8.2.

- 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."
 - o "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]."
- o "...survey asked no questions about gender dysphoria [12]."
- o "Finally, the data are retrospective...."
- o "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."
 - O 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 surveywhich 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.").
 - o 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 Survery, 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.3
 - 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/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 ≥ 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 ≥ 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 ≥ 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."