January 27, 2021

Submitted electronically
Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-9911-P
P.O. Box 8016
Baltimore, MD 21244

Re: Public comment regarding the proposed rule "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023"
RIN: 0938-AU65

Dear Administrator Brooks-LaSure:

Family Research Council (FRC) respectfully submits the following comments regarding the proposed rule issued by the U.S. Department of Health and Human Services (HHS) entitled, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023." This proposed rule would force insurers to cover "gender transition" procedures such as cross-sex hormones, puberty blockers, and sex reassignment surgery. Such procedures are not supported by evidence-based medicine, and if this rule were to go into effect, it would harm the very patients it purports to help.

The following remarks will address the problematic research used to promote physiological procedures (*i.e.*, puberty blockers, cross-sex hormones, and surgery), referred to as gender affirmation, to treat psychological distress as it has been defined by the Diagnostic and Statistical Manual of Mental Disorders Edition Five, (DSM-5) as Gender Dysphoria (GD). This comment speaks to the current state of the scientific literature and raises significant concerns about the quality of the evidence used to support gender affirmative care, which is the most invasive practice(s) for treating any psychological condition conceptualized in the DSM-5. Further, the studies referenced in this comment raise concern that no clear and long-term path has been established to demonstrate that gender affirmative practices (*i.e.*, puberty blockers, cross-sex hormones, and surgical procedures) successfully reduce the psychological distress characteristic of GD.

Comments from Transgender Advocates

Before looking at the studies, it's important to note what the primary transgender advocacy group has said about the current practices for treating Gender Dysphoria. The World Professional Association for Transgender Health (WPATH), formerly the Harry Benjamin International Gender Dysphoria Association, is a key promoter of using surgical procedures and off-label drugs to treat the psychological distress associated with GD. WPATH "publishes the leading clinical guidance on gender

dysphoria treatment," guidance that some medical groups claim is a "robust body of scientific evidence" and use to administer puberty blockers, cross-sex hormones, and surgical procedures.[1] But as both the First and Fifth Circuits have explained, WPATH's guidelines "reflect not consensus, but merely one side in a sharply contested medical debate."[2]

A few of the WPATH's own leaders have publicly agreed with the First and Fifth Circuits' explanation of the group's own practice guidelines:

> Dr. Stephen Levine, who helped author an early version of WPATH's guidelines, said "that later versions of WPATH were driven by political considerations rather than medical judgment."[3] Dr. Levine said that the guidelines are not "politically neutral" because WPATH is "an advocacy group for the transgendered"—which means that its positions "sometimes conflict" with "scientific" evidence and that the group does not "tolerate" "[s]kepticism and strong alternate views."[4] Dr. Levine added that the field generally is characterized by a "lack of rigorous research" about "the long-term effects of sex reassignment surgery and other gender dysphoria treatments."[5]
>
> Dr. Marci Bowers, who has conducted more than 2,000 gender transition surgeries, known as vaginoplasties, noted that in formulating the guidelines, WPATH "tr[ied] to keep out anyone who doesn't absolutely buy the party line that everything should be affirming," leaving "no room for dissent."[6] And Bowers lamented that many clinics like Planned Parenthood would start giving adolescents cross-sex hormones after just "one visit."[7]

Dr. Levine and Bowers are not the only medical and mental health professionals commenting on the credibility of the scientific evidence used to undergird gender affirmative practices.

The State of the Scientific Literature: Consensus Is Not Evidence

In 2012, the American Psychiatric Association Task Force reported on the treatment of Gender Identity Disorder (now Gender Dysphoria). The report concluded that the "quality of evidence pertaining to most aspects of treatment in all subgroups was determined to be low; however, areas of broad clinical consensus were identified and were deemed sufficient to support recommendations for treatment in all subgroups."[8] Note the use of the phrase "clinical consensus" rather than the term "evidence-based." Although this statement is from 2012, there has been very little change in the literature since the APA made this statement.

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[1] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875, at 12, 28 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[2] *Gibson v. Collier*, 920 F.3d 212, 221 (5th Cir. 2019); *Kosilek v. Spencer*, 774 F.3d 63, 78–79 (1st Cir. 2014).
[3] Ibid., 222.
[4] Ibid.
[5] Ibid.
[6] Ibid.
[7] Ibid.
[8] William Byne, et al., "Report of the American Psychiatric Association Task Force on Treatment of Gender Identity Disorder," *Archives of Sexual Behavior* 41 (2012): 759–796, https://pubmed.ncbi.nlm.nih.gov/22736225/.

A study conducted in 2021 assessed the relationship between gender-affirming practices and mental-health outcomes. This study referred back to the APA's earlier conclusion, that "the quality of evidence for treatment of gender dysphoria is low, and consequently, recommendations regarding gender-affirming care have been driven by clinical consensus where empirical evidence is lacking. This [their] study offers new data that substantiate the current clinical consensus by expanding the evidence base in support of gender-affirming surgical care." That is, the researchers who published this comment in 2021 recognized more studies are needed to claim robust empirical support for gender-affirming care that goes beyond clinical consensus.

These concerns certainly apply to the WPATH's guidelines, too, which are not true standards of care. In fact, they cannot be true standards of care because the evidence to support these practices does not exist. In short, these guidelines are "suggestions or recommendations," not "authoritative, unbiased consensus positions designed to produce optimal outcomes."[9] Worse, they are suggestions based on an ideological construct and not solid empirical data.

Given the use of highly physiologically-invasive practices associated with "gender-affirmative care," the nature of these practices should necessitate the highest standard of evidence from studies with a wide range of research methods (*e.g.*, sampling, design). Instead, many of the studies used to support these practices are from cross-sectional studies and are therefore limited in their ability to evaluate the impact of major life-altering pharmaceuticals and surgeries, particularly on minors.

Reports on Puberty Blockers

Start with puberty blockers. These drugs have been portrayed as well-known and whose "effects are reversible."[10] The effects cannot be accurately depicted as reversible because a child blocked from development can never get those years back. There is also evidence that these drugs could have long-term negative effects. At a minimum, as the U.K. High Court explained, "there is real uncertainty over the short and long-term consequences of the treatment with very limited evidence as to its efficacy, or indeed quite what it is seeking to achieve."[11]

Likewise, Britain's recent National Institute for Health and Care Excellence review concluded that no "reliable comparative studies" exist about "the effectiveness and safety of [puberty blockers] for children and adolescents."[12] Advocacy groups like the AAP also say that puberty blockers may have

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[9] William J. Malone, et al., "Letter to the Editor, Proper Care of Transgender and Gender-diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective," *The Journal of Clinical Endocrinology & Metabolism* 106, no. 8 (2021): e3287–e3288, https://academic.oup.com/jcem/article/106/8/e3287/6190133.

[10] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875, at 11 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.

[11] *Tavistock* ¶ 134; *see id.* ¶ 73 (noting "no overall improvement in mood or psychological wellbeing"); *see* Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf. https://downloads.frc.org/EF/EF21K36.pdf

[12] "Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria," National Institute for Health and Care Excellence, March 11, 2021, 40, https://bit.ly/3kJF3tc.

"long-term risks, particularly in terms of bone metabolism and fertility" that cannot currently be assessed by the "limited" research available.[13]

In terms of mental health, puberty blockers in adolescents can lead to depression and other emotional disturbances. Some evidence shows "that after a year on [puberty blockers] children reported greater self-harm, and that girls experienced more behavioral and emotional problems and expressed greater dissatisfaction with their body."[14]

Lupron, the most widely-prescribed puberty blocker for females in America, may block hormones that contribute to neurological development, "suppressing peak IQ" levels.[15] As endocrinologist Dr. William Malone has explained, puberty cannot necessarily be "restart[ed]" later: once "the system 'goes to sleep,'" "it may not wake up."[16] Finally, the use of puberty blockers may worsen gender dysphoria by "solidif[ying] the feeling of cross-gender identification."[17]

For these reasons, including the known physiological harms that come through these medical interventions (see attached paper), the U.K High Court found that "the consequences of the treatment are highly complex and potentially lifelong and life changing in the most fundamental way imaginable."[18] "The treatment goes to the heart of an individual's identity, and is thus, quite possibly, unique as a medical treatment."[19] Additionally, Britain's NICE review concluded the "limited evidence for the effectiveness and safety of gender-affirming hormones in children and adolescents with gender dysphoria" consists entirely of studies that are "uncontrolled," "observational," or have "outcomes of very low certainty."[20]

The Scientific Evidence Used to Support Transgender Medical Procedures Is Weak

Despite the learning from other countries, medical interest groups in the United States continue to claim that "research has linked gender-affirming care to a significantly lowered risk of depression, anxiety, and other negative mental health outcomes."[21] For support, medical groups have cited "a study of 50 transgender youth undergoing puberty suppression treatment [that] found that the treatment was associated with decreased depression and improved quality of life over time."[22]

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[13] Jason Rafferty, et al., "Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents," *Pediatrics* 142 (2018): 5, https://pubmed.ncbi.nlm.nih.gov/30224363/.
[14] Michael Briggs, "Tavistock's Experimentation with Puberty Blockers: Scrutinizing the Evidence," *Transgender Trend*, March 5, 2019, accessed January 27, 2022, https://www.transgendertrend.com/tavistock-experiment-puberty-blockers/.
[15] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[16] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[17] *Tavistock* ¶ 76; *see* Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[18] *Tavistock* ¶ 134; *see* Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[19] *Id.*
[20] "Evidence Review: Gender-Affirming Hormones for Children and Adolescents with Gender Dysphoria," National Institute for Health and Care Excellence, March 11, 2021 50, https://bit.ly/3chUxA3.
[21] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875, at 12 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[22] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875, at 12, 13 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.

That study—contrary to the medical group's claims of "robust" evidence—acknowledged that "there are few data concerning the impact of endocrine intervention on psychological function in transgender youth."[23] And the study's results are weak at best. Of 116 participants who entered the study, less than 50 percent completed it. Forty-seven participants were given drugs, and three participants were not. Many participants were older than age 18—as old as 25.[24] A non-randomized control group (participants given no drugs) of *three* participants is deficient, and the study makes no attempt to compare outcomes between the groups. Because the study makes little effort to control for other relevant variables, the study could not show any causal relationship between gender transition treatments and outcomes. Finally, according to the study itself, "most predictors did not reach statistical significance."[25] No entity concerned with evidence-based medicine would place so much reliance on this study.

Medical groups in support of transgender procedures have also referenced "[a] systemic analysis of 25 years of peer-reviewed articles found a robust consensus that gender-affirming treatments, including treatments such as hormone therapy, improve the overall wellbeing of transgender individuals."[26] This analysis only confirms the lack of any "robust" evidence here. The analysis says *nothing* about this issue—gender transition drugs and surgeries *for children*—and it concedes that even as to adults, available evidence is "limited" and seldom involves "prospective studies or randomized control trials."[27]

Likewise, groups advocating gender affirmative practices cite "multiple studies have revealed long-term positive outcomes for transgender people who have undergone puberty suppression."[28] But the study by Anna Van der Miesen et al., explicitly rejected these groups' proposition, stating that it does "not provide evidence about the direct benefits of puberty suppression over time and long-term mental health outcomes."[29] According to the study, "Conclusions about long-term benefits of puberty suppression should thus be made with extreme caution needing prospective long-term follow-up studies with a repeated measure design with individuals being followed over time."[30] Yet, scientific groups

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[23] Christal Achille, et al., "Longitudinal impact of gender-affirming endocrine intervention on the mental health and well-being of transgender youths: preliminary results," *International Journal of Pediatric Endocrinology* 8 (2020), https://ijpeonline.biomedcentral.com/articles/10.1186/s13633-020-00078-2.
[24] Ibid., Tbl. 1; *see also* Ibid., Tbl. 2 (apparently noting that 24 participants were only given cross-sex hormones).
[25] Ibid.
[26] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875, at 13 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[27] "What does the scholarly research say about the effect of gender transition on transgender well-being?," Cornell University, accessed January 27, 2022, https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people/.
[28] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875, at 14 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[29] Anna I. R. van der Miesen, et al., "Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared With Cisgender General Population Peers," *Journal of Adolescent Health* 66 (2020): 669, 703, https://www.sciencedirect.com/science/article/abs/pii/S1054139X20300276.
[30] Ibid.

acting in good faith would not say that a study "reveal[s] long-term positive outcomes"[31] when it expressly repudiates that reading.[32]

Regarding the claim of "long-term positive outcomes," medical groups cite a 2014 study by de Vries et al.[33] The study looked at a mere 55 people, drawn with self-selection problems from an initial group of nearly 200.[34] The study acknowledged that the self-selected group was "different from the transgender youth in community samples."[35] ("[A] selection bias could exist"). No control group existed. And the study found that gender dysphoria and "body image difficulties persisted through puberty suppression"; in fact, these problems were *worse* after puberty suppression drugs were used than before.[36] This study also found only a "small amount of scientific evidence of the medical safety and efficacy and the psychological efficacy" of treatments that have been featured as "robust" evidence.[37]

As for the commonly-cited high risk for suicide, particularly among minors who identify as transgender, groups have repeatedly cited a study by Turban et al., which used responses from an online survey drawn from trans-affirming websites as "data." The problem with this study is that it "excluded those who underwent medical intervention and then subsequently stopped identifying as transgender," and, of course, "those who actually committed suicide."[38] "73% of respondents who reported having taken puberty blockers" "said they started on them *after* the age of 18 years"—which is even not when puberty blockers are prescribed.[39] The study itself concedes that it "does not allow for determination of causation."[40]

Admission of Harm Is Rising

On the other hand, a growing body of evidence shows gender transition drugs and surgeries harm children (see the attached paper). Specifically, these interventions are risky and unnecessary as there is also evidence that up to 94 percent of children experiencing gender dysphoria no longer suffer from it by adulthood. This finding has been supported by WPATH's guidelines which report that 73 to 94 percent of children referred for gender dysphoria have conditions that do not "continue into

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[31] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875, at 14 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[32] Ibid. It is also worth noting that the study controls for few variables and relies on self-reported data rather than "a diagnosis of any mental health condition made by clinical assessment."
[33] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875, Br. 14 n.54, (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[34] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[35] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[36] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[37] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[38] Michael Biggs, "Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria," *Archives of Sexual Behavior* 49 (2020): 2227-29, https://link.springer.com/article/10.1007/s10508-020-01743-6.
[39] Ibid.
[40] Jack K. Turban, et al., "Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation," *Pediatrics* 145, no. 2 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7073269/.

adulthood."[41] And the medical groups' own study says that "predicting individual persistence at a young age will always remain difficult."[42] Other studies confirm that most children desist.[43]

However, if a child is introduced to puberty blockers to prevent normal development, once they are used, they almost always lead to the use of cross-sex hormones that permanently alter the child's body. For this reason, many countries—the United Kingdom, Sweden, and Finland included—are moving away from these experimental interventions.

A New Cohort, but an Old and Untested Method

The protocols for gender affirmation procedures were designed 15 years ago and have no application to the patient population now presenting with gender dysphoria—overwhelmingly, adolescent females.

Since 2008, the share of biological female college students identifying as transgender has increased 100-fold.[44] Twice as many girls as boys struggle with gender dysphoria, when just a few years ago, it was the opposite.[45] At the same time, "the number of gender clinics in the U.S. has grown from one in 2007 to hundreds today."[46] Medical professionals have called this rise in female gender dysphoria a "clinical phenomenon" with "uncertain diagnostic significance making up a substantial proportion."[47] Many attribute this change to the rise of "rapid onset gender dysphoria."[48] (The professor who coined the phrase was promptly relieved of her position.[49])

The lead author of the Dutch study recently cautioned practitioners about using the Dutch Protocol to treat the more recent wave of girls who present as adolescents with gender dysphoria, calling this a "new developmental pathway … involving youth with postpuberty adolescent-onset transgender

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[41] "Standards of Care for the Health of Transexual, Transgender, and Gender-Nonconforming People," World Professional Association for Transgender Health, 11, https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English2012.pdf?_t=1613669341.
[42] Annelou L.C. de Vries, et al., "Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment," Pediatrics 134, no. 4 (2014), https://pubmed.ncbi.nlm.nih.gov/25201798/.
[43] *E.g.*, Madeleine S.C. Wallien and Peggy T. Cohen-Kettenis, "Psychosexual outcome of gender-dysphoric children," Journal of the American Academy of Child and Adolescent Psychiatry 47, no. 12 (2008): 1413–1423, https://pubmed.ncbi.nlm.nih.gov/18981931/; "A follow-up study of boys with gender identity disorder," Devita Singh Ph.D. Dissertation, University of Toronto, 2012, http://images.nymag.com/images/2/daily/2016/01/SINGH-DISSERTATION.pdf.
[44] "Undergraduate Student Reference Group," American College Health Association – National College Health Assessment, Spring 2021, https://www.acha.org/documents/ncha/NCHA-III_SPRING-2021_UNDERGRADUATE_REFERENCE_GROUP_DATA_REPORT.pdf.
[45] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[46] *Id.*
[47] *Id.*
[48] Abigail Shrier, "When Your Daughter Defies Biology," *The Wall Street Journal*, January 6, 2019, accessed January 27, 2022, https://on.wsj.com/3nlHUKD.
[49] Abigail Shrier, "Top Trans Doctors Blow the Whistle on 'Sloppy' Care," *Common Sense*, October 4, 2021, accessed January 27, 2022, https://bariweiss.substack.com/p/top-trans-doctors-blow-the-whistle.

histories."[50] "According to the original Dutch protocol," she noted, "one of the criteria to start puberty suppression was a presence of gender dysphoria from early childhood," while now "the older presenting youth simply experienced gender history events at older ages."[51]

Another of the original Dutch protocol researchers agrees. Thomas Steensma, a researcher at the Center of Expertise on Gender Dysphoria, explained that it is unknown "whether studies we have done in the past can still be applied to this time. Many more children are registering, and [are] also a different type."[52] Youth "with post puberty adolescent-onset transgender histories" were not studied in the earlier evaluations.[53] Steensma criticized American physicians for "blindly adopting [the Dutch] research" without accounting for the change in population of gender dysphoria patients.[54]

Particularly given this new population, it is reasonable and responsible to put a hold on experimental treatments on unstudied patient groups. As one leading gender transition doctor—a WPATH board member—cautioned, "we're going to have more young adults who will regret having gone through this process" thanks to doctors "[r]ushing people through the medicalization'" and failing "to evaluate the mental health of someone historically in current time, and to prepare them for making such a life-changing decision."[55]

Regret: An Understudied Reality

There are also growing reports from those referred to as detransitioners. Many who *are* coerced into experimental medical interventions later regret that irreversible decision. One recent study, although limited in design, found that 60 percent of those who detransitioned "bec[ame] more comfortable identifying as their natal sex" and most "felt that they did not receive an adequate evaluation from a doctor" "before starting transition."[56]

In this study, participants recognized that there were other root causes for Gender Dysphoria that were not addressed, and the transitioning process prevented them from addressing the true source of distress:

a. **58 percent** said the GD was caused by trauma or a mental health condition

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[50] Annelou L.C. de Vries, "Challenges in Timing Puberty Suppression for Gender-Nonconforming Adolescents," *Pediatrics* 146, no. 4 (2020), https://publications.aap.org/pediatrics/article/146/4/e2020010611/79688/Challenges-in-Timing-Puberty-Suppression-for.
[51] Ibid.
[52] Grace Williams, "Dutch puberty-blocker pioneer: Stop 'blindly adopting our research'," 4th Wave Now, March 16, 2021, accessed January 27, 2022, https://bit.ly/3nj6onT.
[53] Ibid.
[54] Ibid.
[55] Amicus Brief, *Brandt v. Rutledge*¸ No. 21-2875 (8th Cir. 2021), https://downloads.frc.org/EF/EF21K36.pdf.
[56] Lisa Littman, "Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners," *Archives of Sexual Behavior* 50 (2021), https://link.springer.com/article/10.1007/s10508-021-02163-w.

b. **51 percent** reported the process of transitioning delayed or prevented them from dealing with or being treated for trauma or a mental health condition
c. **41 percent** said what they thought were feelings of being transgender were the result of a mental health condition.

In sum, there is a lack of scientific evidence to support the claim that gender affirmation practices account for any sustained reduction in Gender Dysphoria. There is evidence that puberty blockers, cross-sex hormones, and surgical procedures can cause permanent physiological damage and cause psychological harm. There is also a growing awareness of those who are unhappy with their gender affirmative care and have decided to detransition. Further investigation is needed to understand this population's experiences and those who did not fare well following these medically-based practices. Given the aforementioned reasons, at minimum, these practices should be put on hold until better evidence exists, but they should certainly not be encouraged through the current proposed rule.

Respectfully submitted,

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