The Facts About "Gender Affirming Care" (GAC)[1] for Children and Adolescents

Claim 1: GAC is proven "safe" and leads to better mental health outcomes for children and adolescents who identify as transgender or who are diagnosed with gender dysphoria.

Not true. "Gender-affirming" hormones and surgeries have NOT been proven safe or effective at improving the mental health of children and adolescents who identify as transgender or who are diagnosed with gender dysphoria.

No long-term studies demonstrate that GAC for children and adolescents leads to better mental health outcomes. A recent comprehensive independent review of clinical studies commissioned by Florida (May 2022) found that the evidence in support of GAC was of "low" and "very low" certainty because of small sample sizes, biased samples, limited follow-up, and inconsistent outcome measures. The Florida evidence review concluded that "[d]ue to the limitations in the body of evidence, there is great uncertainty about the effects of puberty blockers, cross-sex hormones and surgeries in young people with gender dysphoria." (See 2022 Florida Literature Review, AHCA, Attachment C, p.5.)

Several recent European systematic reviews of evidence on GAC came to similar conclusions. Public health authorities in the UK, Finland, and Sweden all concluded that there is insufficient evidence to support the claim that either puberty blockers or cross-sex hormones provide mental health benefits for gender dysphoric children and adolescents. The Swedish health authority, for example, came to the stark conclusion that "the risks of puberty suppressing treatment with GnRH-analogues and gender-affirming hormonal treatment currently outweigh the possible benefits, and that the treatments should be offered only in exceptional cases."

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[1] The term "gender affirming care" (GAC) is used throughout for purposes of clarity. It is the terms used by the Biden Administration and other health professional organizations to describe medical treatments and interventions including puberty blockers, cross-sex hormones and surgeries designed to affirm the individual's "gender identity" and address any "gender dysphoria" (clinical distress or discomfort) which can result therefrom.

Claim 2: GAC is "medically necessary."

False. No studies demonstrate that GAC (or the individual treatments promoted as part of GAC) is "medically necessary" for children and adolescents who identify as transgender or who have been diagnosed with gender dysphoria.

The definition of "medically necessary" varies, but generally requires proven benefit to the patient. Medicare, for example, defines services as "medically necessary" if they "are needed to diagnose or treat an illness, injury, condition, disease, or its symptoms—and that meet accepted standards of medicine.

Determining "medical necessity" requires an accurate diagnosis. There are no reliable assessment methods to determine whether a particular child or adolescent experiencing gender dysphoria or identifying as transgender is likely to resolve those feelings (i.e., desist from transgender identification) or likely to persist in transgender identification or to benefit long term from medical transition. According to multiple studies, about 85% of gender dysphoric children naturally desist by the end of puberty (see, e.g., James M. Cantor, 2019).

A determination of "medically necessary" also requires evidence that the proposed treatment will benefit the patient. No randomized control group or long-term, comparative approach studies have been conducted to assess whether minors who undergo medical transition experience better long-term outcomes or less suicidality than gender dysphoric or transgender-identifying minors who do not undergo medical transition or who are treated with psychotherapy only (see discussion of suicidality below). Further, there are no standardized, validated instruments to reliably assess patient outcomes of medical or surgical interventions, nor even agreement as to the appropriate outcomes to be measured for each GAC procedure. In the absence of standardized assessment instruments and outcome measures in the studies to date, it is difficult to reliably assess possible patient benefit from GAC.

Claim 3: GAC is consistent with established medical standards of care.

Not true. There is currently no established medical standard of care for the treatment of children and adolescents who identify as transgender or who have been diagnosed with gender dysphoria.

State laws define the duty of care required in providing medical treatments, in contrast to medical organizations which may draft non-binding guidelines or recommendations.

The field of "gender medicine" lacks sufficient high-quality evidence (e.g., there are no randomized controlled clinical trials for the use of puberty blockers or cross sex hormones in the treatment of gender dysphoria in children and adolescents). In addition to significant gaps in knowledge, there is no consensus on pharmaceutical dosing, few validated instruments to measure outcomes, and little agreement on outcome measures. Although multiple professional societies have issued various treatment guidelines, these vary in their recommendations on how best to manage gender dysphoria in in this population, and in the quality of evidence on which they are based. They do *not* establish a standard of care—and, in fact, the key guidelines often referenced in support of GAC (e.g., the WPATH guidelines, discussed below, and the Endocrine Society's guidelines) expressly state that they are not "standards of care" but "flexible clinical guidelines" that cannot guarantee any specific outcome.

Claim 4: WPATH established the standard of care for the treatment of persons identifying as transgender or diagnosed with gender dysphoria.

False. The WPATH (World Professional Association for Transgender Health) "Standards of Care Volume 7" [2] (SOC), clearly states that the "standards" are merely "flexible clinical guidelines" for "promoting optimal healthcare and guiding the treatment of people experiencing gender dysphoria."

In addition, the SOC specifically sets an expectation that "individual health professionals and programs may modify" the suggested protocols. As such, the WPATH SOC cannot be viewed or used as authoritative medical standards of care. They are merely practice suggestions. Further, many gender clinics do not regard them as binding, and freely depart of the WPATH guidelines or set their own (e.g., Mount Sinai Center for Transgender Medicine and Surgery).

Finally, the WPATH SOC document acknowledges that its evidence-base is limited and that WPATH did not utilize any systematic reviews of evidence in its formation. Furthermore, several countries have established their own Standards of Care which depart from the WPATH

[2] WPATH Standards of Care Volume 8 is scheduled for publication by mid-September 2022. At this time, based upon a review of the proposed draft, the position of WPATH with respect to role of their SOC is largely unchanged and they continue to acknowledge that their evidence base is limited.

SOC (e.g., Sweden and Finland). More recently the UK announced plans to shut down the Tavistock Gender Identity Development clinic in an effort to establish new evidence-based protocols emphasizing mental health services.

Claim 5: All major U.S. medical organizations support GAC.

Misleading. While many U.S. medical organizations support "gender affirming care," the majority of these organizations have conducted no independent reviews of their own, but instead rely upon the WPATH SOC as the sole source of their recommendations.

WPATH SOC 7, however, acknowledged the "controversial" nature of social transition and "sex reassignment surgery." Further, these medical organizations' recommendations do not represent the international consensus of those practicing in the field (or even of the organizations' membership).

In the last 30 years, evidence-based medicine has replaced the "consensus of experts" methodology to establish best practices. Medicine has increasingly relied on systematic reviews to show whether an intervention is safe, effective, and medically necessary. Even so, a recent commentary by gender clinicians admits that the WPATH "[s]tandards of care reflect expert consensus more than they reflect rigorous outcome data."

Notably, for this issue, the Endocrine Society commissioned two systematic reviews for its 2017 guidelines. It recognized that there is only "very low-quality" or, at best, "low quality" evidence supporting the use either of puberty blockers or cross-sex hormones. Under the GRADE approach to assessing the quality of evidence and the strength of recommendations, there is little confidence in the estimated effect (i.e., the true effect is likely to be substantially different from the estimated effect) or there is limited confidence in the estimated effect (i.e., the true effect might be substantially different from the estimated effect). As a result, the Endocrine Society guidelines could only "suggest"—*not recommend*—using puberty blockers, indicating skepticism about whether those who receive such treatments "derive, on average, more benefit than harm."

Likewise, in reviewing the same studies in 2016, the U.S. Centers for Medicare & Medicaid Services concluded that "[b]ased on an extensive assessment of the clinical evidence ... there is

not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively."

Claim 6: GAC is "life-saving" and prevents suicide.

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

Studies that purport to show an increased rate of suicidality among transgender-identified adolescents contain estimates often based on methodologically flawed non-random surveys that neither differentiate suicidal ideation from suicidal behaviors nor address severity. Self-report survey data must be interpreted with caution as research has shown that suicidal thoughts and non-fatal attempts may represent general distress rather than an intention to die. Surveys of suicidality of clinical trans-identifying individuals do not represent the adolescent trans-identifying population as a whole and are likely to inflate the true population estimates of suicidality.

In addition, while recognizing an association between trans-identification and suicidality, causality is unclear. Specifically, there is no evidence that suicidality is caused by gender dysphoria nor is it reduced, in the long term, by gender affirming hormones or surgeries. Further, suicidality is a well-documented symptom of depression, anxiety, personality disorders, identity issues and autism spectrum disorder, all of which are over-represented among trans-identifying adolescents. Like other children and adolescents who experience "other forms of psychological distress, children with gender dysphoria present in the context of multiple interacting risk factors that include at-risk attachment, unresolved loss/trauma, family conflict and loss of family cohesion, and exposure to multiple ACEs [adverse childhood events]." Similarly, research has shown that the majority of trans-identifying teens are also same-sex attracted or bisexual and that there is a heightened risk of suicidality in sexual minority populations, for reasons that are

unclear. Clearly, suicidality amongst trans-identified adolescents is multifactorial; it cannot be merely attributed to their gender dysphoria.

Finally, while WPATH SOC 7 treatment protocols require that the individual be mentally "stable" (i.e., mental health issues should be "well controlled") before the initiation of gender transition, the narrative of "transition or suicide" has the real potential to increase the risk of suicide—in part by sending a false message to vulnerable young people that, given their gender dysphoria, suicide is inevitable and that medical GAC alone will prevent it. However, the appropriate response to suicidality is appropriate mental health treatment, not medical or surgical transition procedures. There is no reliable evidence that gender-affirming care or gender transition eliminates the risk of suicide.

Claim 7: Puberty blockers for gender transition purposes are just a "pause" and are fully reversible.

False. While puberty blocking drugs have been used for several decades to halt early onset (precocious) puberty in children, they are not without controversy or risk. When used appropriately, they delay puberty in a child, but cause significant side effects, including compromised bone density and other long-term health consequences.

Although puberty blockers have been shown to be effective in pausing puberty, the US Food and Drug Administration in July added a warning to their use based upon reported adverse events of pseudotumor cerebri (elevated intracranial pressure that can cause vision loss). Puberty blockers used as part of GAC are used "off-label" and there are no studies as to their safety or effectiveness when administered to an otherwise healthy child to stop normally timed puberty.

Puberty blockers used to address precocious puberty merely delay puberty onset in very young children usually for a period of 2-3 years. Puberty Blockers used to treat gender dysphoria can begin at the time of normal puberty onset (as young as 10 years old) and be used for 3-4 years. The Cass Review, an independent review currently commissioned by NHS England to evaluate how to best care of gender-dysphoric youth, stated in its 2021 interim report: "it is important that it is not assumed that outcomes for, and side effects in, children treated for precocious puberty will necessarily be the same in children or young people with gender dysphoria."

Concerns have been raised that puberty blockers are psychologically irreversible (since over 95% of all treated youth proceed to cross-sex hormones), that they may harm bone development, may permanently alter the brain, and that it is not yet known how they affect other vital organs, all of which undergo significant structural changes during uninterrupted puberty.

Claim 8: GAC is no different than the many medical treatments that have not been the subject of random controlled clinical trials, are used "off label," are based on low-quality evidence, or are diagnosed solely on the subjective experience of the patient.

Misleading. There are no other treatments that so profoundly and uniquely impact the long-term mental, emotional, social, and physical lives of minors which have none of the normative safeguards to ensure a reliable diagnosis and the safety and effectiveness of the treatment to adequately and ethically prevent unnecessary medical harms.

Claim 9: Children and adolescents can give informed consent for GAC.

False. Given GAC's significant, irreversible impact on a person's entire life, the lack of high-quality evidence as to its safety and effectiveness, the unknown long-term consequences, and the inability for clinicians to reliably determine which minors, if any, might persist in transgender identification or gender dysphoria into adulthood, children and adolescents are not competent to provide informed consent to GAC.

In addition, it is questionable whether children and adolescents, even those who are very mature and intelligent, can give meaningful consent to the loss of functions they have not yet experienced or appreciate, notably the loss of sexual function or fertility in adulthood. Neither can they fully understand the long-term risks to their health posed by procedures and interventions which lead to a lifetime of dependency on medical care. Thus, even when adolescents are legally old enough, in a particular jurisdiction, to consent to medical care (which, in some jurisdictions, is as young as age 15), children and adolescents do not have the requisite capacity or competency to provide informed consent for irreversible interventions such as cross-sex hormones and surgery.

Claim 10: Not providing GAC is discriminatory.

False. It is not discriminatory for a provider, exercising his or her best medical judgment, to refuse to provide "gender affirming care," particularly in light of the following medical considerations:

A. **The physician's ethical duty to "do no harm."**

B. **GAC has not been proven to be safe and effective for its stated purpose. It is not discriminatory to withhold unproven treatments.**

C. **There is no reliable way to diagnose, with reasonable certainty, whether, when, or for whom GAC might be "medically necessary." Withholding a particular treatment, in light of a particular patient's uncertain diagnosis, is not discriminatory.**

D. **Professional judgments of the appropriateness of, or medical necessity for, the use of medications or surgical procedures are not made in the abstract, but always in consideration of a particular patient, the patient's diagnosis, the availability of alternative treatments, and the evidence supporting the use of the specific treatment in question for the patient's specific diagnosis and concrete medical circumstances.** For example, the fact that a physician surgically removes a particular patient's cancerous breasts, does not establish a treatment right for a patient with noncancerous breasts to demand that the same surgeon remove her noncancerous breasts—or to claim discrimination when the surgeon refuses. Similarly, the use of puberty blockers for the treatment of precocious puberty (treating a physiological disorder) is not the same as blocking naturally timed puberty (creating a disease state). The use of sex hormones to treat a pathological deficiency in hormones (restoring a natural balance) is not the same as introducing unnaturally high doses of hormones into the body of a person of one sex, in order to raise the person's hormone levels to unnatural, unhealthy levels which mimic the hormonal profile of the opposite sex. Sex differences are real and have concrete health consequences. These are different treatments, with different treatment objectives, risks, and outcomes.