

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT



Florida Medicaid Generally Accepted Professional Medical Standards Determination on Sex Reassignment Treatment

May 2022

ATTORNEY-CLIENT PRIVELEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

Contents

Contents	2
Introduction and Abstract	3
Health Service Summary	5
Literature Review: Introduction	11
Literature Review: Etiology of Gender Dysphoria	12
Literature Review: Desistance of Gender Dysphoria and Puberty Suppression	16
Literature Review: Hormone Therapy as a Treatment for Gender Dysphoria	19
Literature Review: Sex Reassignment Surgery	25
Literature Review: Quality of Available Evidence and Bioethical Questions	29
Coverage Policies of the U.S. and Western Europe	32
Generally Accepted Professional Medical Standards Recommendation	37
Works Cited	39

Introduction and Abstract

Introduction

The Secretary of the Florida Agency for Health Care Administration requested the Division of Florida Medicaid to review sex reassignment treatment for potential coverage under the Florida Medicaid program pursuant to Rule 59G-1.035, Florida Administrative Code (F.A.C.). In accordance with the criteria established in Rule 59G-1.035, F.A.C., sex reassignment treatment must be “consistent with generally accepted professional medical standards (GAPMS) and not experimental or investigational” (Rule 59G-1.035, F.A.C.). For the purposes of this report, the term “sex reassignment treatment” refers to medical services used to obtain the primary and/or secondary physical sexual characteristics of a male or female.

In accordance with the determination process established in rule 59G-1.035, F.A.C., “the Deputy Secretary for Medicaid will make the final determination as to whether the health service is consistent with GAPMS and not experimental or investigational” (Rule 59G-1.035, F.A.C.). In addition, this report is supplemented with appendices which provide additional analyses to determine whether this health service meets compliance with Rule 59G-1.035, F.A.C.

Abstract

As of 2022, a community of practitioners and advocates of lesbian, gay, bisexual, and transgender (LGBT) rights have promoted the use of medical interventions such as prescription drugs and surgeries to address gender dysphoria by allowing individuals who identify differently from their natal sex to receive “affirming” treatments. This approach has received much support from the mainstream media and experts who advocate that it not only benefits mental health but saves lives through suicide prevention. While all of the positive promotion can create an impression that these interventions are safe and effective, does the available evidence validate the proponents’ positions on the benefits of sex reassignment. What does the literature report on these treatments and is the research high quality. These questions require answers to determine whether Florida Medicaid should cover medications and surgical procedures to treat gender dysphoria.

To meet coverage requirements, all health services must meet Florida Medicaid’s specifications for medical necessity, which includes compliance with generally accepted professional medical standards (GAPMS) as stated in Rule 59G-1.035, F.A.C. To demonstrate whether sex reassignment treatment conforms to GAPMS, the following types of research and documentation must prove that it improves health and quality of life:

- Evidence-based clinical practice guidelines
- Published reports and articles in the authoritative medical and scientific literature related to the health service
- Effectiveness of the health service in improving the individual’s prognosis or health outcomes
- Coverage policies by other creditable insurance payor sources
- Recommendations or assessments by clinical or technical experts on the subject or field

**ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT**

Based on the above criteria, available literature and information provides insufficient evidence that sex reassignment through medical intervention is a safe and effective treatment for gender dysphoria. Studies presenting the benefits to mental health, including those claiming that the services prevent suicide, are either low or low quality and rely on unreliable methods such as surveys and retrospective analyses. Both of which are cross-sectional and highly biased. However, evidence demonstrating that these treatments cause irreversible physical changes and side effects that can affect long-term health is robust. In addition, clinical and technical expert recommendations further argue against the use of such interventions to treat what is categorized as a mental health disorder (See attachments). Considering the weak evidence supporting the use of puberty suppression, hormone therapy, and surgical procedures when compared to the stronger research demonstrating the permanent effects they cause, these treatments do not conform to the GAPMS requirements listed in Rule 59G-1.035, F.A.C. and cannot meet Florida Medicaid's criteria for medical necessity.

Health Service Summary

Gender Dysphoria

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

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

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

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

**ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT**

In 2021, the Merck Manual released a slightly different definition for gender dysphoria, citing that the condition “is characterized by a strong, persistent cross-gender identification associated with anxiety, depression, irritability, and often a wish to live as a gender different from the one associated with the sex assigned at birth.” Additionally, the Merck Manual further states that “gender dysphoria is a diagnosis requiring specific criteria but is sometimes used more loosely for people in whom symptoms do not reach a clinical threshold” (Merck Manual, 2021). This definition is largely consistent with the DSM-V but does not emphasize the distress component to the same extent.

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

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

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

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

The current usage of gender dysphoria is the result of discussions spanning across decades as demonstrated in the past editions of the DSM. Until 2013, the APA considered having gender identity issues a mental disorder by itself regardless of the presence of psychological distress. That perspective

has since shifted to only consider the adverse psychological effects of questioning one's gender as a disorder. In addition, the APA considers gender as part of one's identity, which is not subject to a diagnosis. Whether the APA has shifted its terminology and criteria for gender identity issues due to emerging clinical data or cultural changes is another question. In 1994, the APA replaced transsexualism with gender identity disorder as part of the "effort to reduce stigma" (APA, 2017). This raises questions concerning what influences decisions to revise definitions and criteria, social trends or medical evidence.

Behavioral Health Issues Co-Occurring with Gender Dysphoria

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

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

Current Available Treatments for Gender Dysphoria

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

- Behavioral Health Services: Psychologists and other mental health professionals are likely the first practitioners individuals with gender dysphoria will encounter. In accordance with clinical

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

guidelines established by the World Professional Association for Transgender Health (WPATH)², behavioral health professionals are supposed to “find ways to maximize a person’s overall psychological well-being, quality of life, and self-fulfillment.” WPATH further discourages services for attempting to change someone’s gender identity. Instead, it instructs practitioners to assess for the condition and readiness for puberty blockers or hormone therapy while offering guidance to function in a chosen gender. WPATH does assert that the clinicians do need to treat any other underlying mental health issues secondary to gender dysphoria (WPATH, 2012). However, the organization provides conflicting guidance because it also advises practitioners to prescribe hormones on demand (Levine, 2018).

- Puberty Suppression: Used only on individuals in the earliest stages of puberty (Tanner stage 2), preventing pubertal onset provides additional time to explore gender identities before the physical characteristics of biological sex develop. Proponents of this treatment assert that it reduces distress and anxiety related to the appearance of adult sexual physical features. To suppress puberty, pediatric endocrinologists inject gonadotropin releasing hormone (Gn-RH) at specific intervals (e.g., 4 weeks or 12 weeks). The Gn-RH suppresses gonadotropin receptors that allow for the development of primary and secondary adult sexual characteristics. Prior to receiving puberty suppression therapy, individuals must have received a diagnosis of gender dysphoria and have undergone a mental health evaluation (Kyriakou et al, 2020).
- Hormone Therapy: For adults and late adolescents (16 years or older), the next recommended treatment phase is taking hormones (e.g., testosterone or estrogen) to create secondary sex characteristics. In men transitioning into women, these include breast development and widening around the pelvis. Women who transition into men experience deeper voices, redistribution of fat deposits, and growing facial hair. According to the Endocrine Society, late adolescents who qualify for hormone therapy must have a confirmed diagnosis of gender dysphoria from a mental health practitioner with experience treating that population. Some physical changes induced by hormone therapy are irreversible (Endocrine Society, 2017).
- Sex Reassignment Surgery: Sometimes referred to as “gender affirming” surgery, this treatment does not consist of just one procedure but several, depending on the desires of the transitioning individual. Primarily, sex reassignment procedures alter the primary and secondary sexual characteristics. Men transitioning into women (trans-females) undergo a penectomy (removal of the penis), orchiectomy (removal of the testes), and vulvoplasty (creation of female genitals). Other procedures trans-females may undergo include breast augmentation and facial feminization. For women that transition into men (trans-males), procedures include mastectomy, hysterectomy, and phalloplasty (creation of male genitals). Because of the complexities involved in phalloplasty, many trans-males do not opt for this procedure and limit themselves to mastectomies. Additionally, the effects of sex reassignment surgery, such as infertility, are permanent (WPATH, 2012).

While proponents of these treatments argue that they are the standard of care for gender dysphoria, the U.S. Food and Drug Administration (FDA) currently has not approved any medication that is clinically

² The World Professional Association for Transgender Health asserts that it is a professional organization. However, it functions like an advocacy group by allowing open membership to non-clinicians (WPATH, 2022).

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

indicated for this condition (Unger, 2018). Although the drugs used to suppress puberty and in hormone therapy are FDA approved, the FDA did not approve them for treating gender dysphoria, meaning that their use for anything other than the clinical indications listed is off-label (American Academy of Pediatrics, 2014). As for surgical procedures, the FDA does not evaluate or approve, but it does review all surgical devices (FDA, 2021). In addition, the Endocrine Society specifically states that its practice guidelines for sex reassignment treatment does not constitute a “standard of care” and that its grades for available services are low or very low (Endocrine Society, 2017).³

Diagnosing Gender Dysphoria

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

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

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

Discussion

The diagnosis of gender dysphoria is a relatively recent concept in mental health, being the product of decades of discussion and building upon previous definitions. Instead of treating gender non-conformity as a disorder, behavioral health professionals acknowledge it as part of one’s identity and focus on

³ Disagreement over how to treat gender dysphoria, gender identity disorder, and transsexualism has persisted since sex reassignment surgery first became available in the 1970s. In a 2006 counterargument, Paul McHugh highlights how individuals seeking surgery had other reasons that extended beyond gender identity, including sexual arousal and guilt over homosexuality. In addition, he asserts that undergoing sex reassignment procedures did not improve a patient’s overall behavioral health and that providing a “surgical alteration to the body of these unfortunate people was to collaborate with a mental disorder rather than to treat it” (McHugh, 2006).

also 1979 paper ✓

**ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT**

addressing the associated distress. Considering the new criteria, this changes the dynamics of the population who would have qualified for a diagnosis before 2013 and those who would today. Given that experiencing gender non-conformity alone no longer qualifies as a disorder, behavioral health professionals are treating distress and referring adolescents and adults to therapies that are used off-label and pose irreversible effects.

**ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT**

Literature Review: Introduction

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

The following literature review addresses the multiple facets of this condition and presents areas of ongoing debate and persisting questions. Beginning with the condition's etiology and continuing with evaluations of puberty blockers, hormone therapy, and surgery, the review explains each area separately and in context of gender dysphoria at large. Additionally, the review provides an analysis on available research on mental health outcomes as well as the condition's persistence into adulthood. When taken as a whole, the available studies demonstrate that existing gender dysphoria research is inconclusive and that current treatments pose risky side effects as well as irreversible changes.

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

Literature Review: Etiology of Gender Dysphoria

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

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

- **Neuroanatomical Etiology:** During fetal development, the genitals and brain develop during different periods of a pregnancy, the first and second trimesters respectively. Because the processes are separate, misaligned development is possible where the brain may have features belonging to the opposite sex. The authors identify one study where trans-females presented with a "female-like putamen" (structure at the base of the brain) when undergoing magnetic resonance imaging (MRI) scans.⁴
- **Psychiatric Associations:** Saleem and Rizvi identify multiple studies reporting that individuals with gender dysphoria have high rates of anxiety and depressive disorders with results ranging as high as 70% having a mental health diagnosis. In addition, the pair note that schizophrenia may also influence desires to transition. However, the review does not assess whether the mental health conditions are secondary to gender dysphoria.
- **Autism Spectrum Disorder:** Evidence suggests a significant percentage of individuals diagnosed with gender dysphoria who also have ASD. The authors note that the available studies only establish a correlation and do not identify mechanisms for causation.
- **Childhood Abuse:** Like the above causes, Saleem and Rizvi note that those with gender dysphoria tended to experience higher rates of child abuse, consisting of neglect, emotional, physical, and sexual.
- **Endocrine Disruptors:** Although this cause still requires substantial research, it is a valid hypothesis regarding how phthalates found in plastics can create an imbalance of

⁴ Research on neuroanatomical etiology for gender dysphoria remains highly speculative due to limitations of brain imaging (Mayer and McHugh, 2016). In addition, neuroscience demonstrates that exposures to certain environments and stimuli as well as behaviors can affect brain changes (Gu, 2014). Furthermore, available research indicates that male and female brain have different physical characteristics but cannot be placed in separate categories due to extensive overlap of white/grey matter and neural connections (Joel et al, 2015).

not in citation
index

testosterone in fetuses during gestation, which can lead to gender dysphoria. The authors point to one study that makes this suggestion.

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

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

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

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

In addition to biological factors and correlations with ASD, researchers are exploring psychological and social factors to assess their role in gender dysphoria etiology. This literature examines a range of potential causative agents, including child abuse, trauma, and peer group influences. One such study by

Kozłowska et al from 2021 explores patterns in children with high-risk attachment issues who also had gender dysphoria. The authors wanted to assess whether past incidents of abuse, loss, or trauma showed higher rates of desiring to transition. As a basis, Kozłowska et al cite John Bowlby's research on childhood brain development, noting that the process is not linear and depends heavily on lived experiences. The study further acknowledges that biological factors combined with life events serve as the foundation for the next developmental phase and that early poor-quality attachment issues increase the risk for psychological disorders in adolescence and adulthood. Such disorders include mood and affective, suicidal ideations, and self-harm. Kozłowska et al also cite other studies that indicate a high correlation between gender dysphoria and "adverse childhood events" and further assert that the condition "needs to be conceptualized in the context of the child's lived experience, and the many different ways in which lived experience is biologically embedded to shape the developing brain and to steer each child along their developmental pathway" (Kozłowska et al, 2021).

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

This recent study raises questions regarding the medical necessity of gender dysphoria treatments such as puberty blockers and hormone therapy in adolescents. If high percentages of children diagnosed also have histories of trauma and attachment issues, should conventional behavioral health services be utilized until they reach adulthood. Would that approach not provide additional time to address underlying issues before introducing therapies that pose permanent effects. Aside from the notion that childhood abuse and adversity can potentially cause gender dysphoria, other possible explanations such as social factors (e.g., peer influences and media) may be contributing factors.

Research on rapid onset gender dysphoria (ROGD) links this phenomenon to peer and social elements. In an analysis utilizing parent surveys, Lisa Littman asserts that the rapid rise of ROGD is not associated with the traditional patterns of gender dysphoria onset (i.e., evidence of an individual's gravitation to the opposite sex documented over multiple years) but rather exposure to "social and peer contagion." Littman uses this term in the context of definitions cited in academic literature, stating that "social contagion is the spread of affect or behaviors through a population" and that "peer contagion is the

ATTORNEY-CLIENT PRIVILEGED
 ATTORNEY WORK PRODUCT PROTECTED
 DO NOT DISTRIBUTE
 DRAFT

process where an individual and peer mutually influence each other in a way that promotes emotions and behaviors that can potentially undermine their own development or harm others.” Examples of the latter’s negative effects include depression, eating disorders, and substance abuse. What prompted this study is a sudden increase of parents reporting their daughters declaring themselves to be transgender without any previous signs of gender dysphoria. Littman also indicates that these parents cite that their daughters became immersed in peer groups and social media that emphasized transgender lifestyles (Littman, 2018).

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

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

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

Littman’s study along with the others reveal that the causes of gender dysphoria are still a mystery and could have multiple biological and social elements. Because of this ongoing discussion, treatments that pose irreversible effects should not be utilized until an individual reaches adulthood. That allows adequate opportunity for individuals to receive treatment for co-existing mental disorders, affirm their gender dysphoria diagnoses, and understand how hormone therapy and surgery will affect their bodies as well as long-term health. *establish*

Literature Review: Desistance of Gender Dysphoria and Puberty Suppression

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

5 studies = gateway drug

What the two organizations do not explain is that the majority of young adolescents who exhibit signs of gender dysphoria eventually desist and conform to their natal sex and that the puberty suppression can have side effects. Both WPATH and the Endocrine Society neglect to mention that using Gn-RH for gender dysphoria is not an FDA-approved clinical indication. Furthermore, the research used to justify puberty suppression is low or very-low quality and little information is available on long-term effects (Hruz, 2019). Currently, available studies provide some support for this treatment but leave too many questions as to its effectiveness and medical necessity, especially considering how many children decide against transitioning. In addition, proponents of prescribing puberty blockers advocate that the medications provide a “wait and see” period, although halting development of primary and secondary sexual characteristics does not provide opportunities for adolescents to adapt and become comfortable with their natal sex. Instead, puberty blockers can serve as a potential “gateway drug” for hormone therapy by denying them the experience of physically maturing (Laidlaw et al, 2018).

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

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

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

Presently, no RCTs that evaluate puberty suppression as a method to treat gender dysphoria are available. Instead, the limited number of published studies on the topic utilize small sample sizes and subjective methods (Hruz, 2019). A 2015 article by Costa et al is one such example. The study asserts that “psychological support and puberty suppression were both associated with an improved global psychological functioning in gender dysphoric adolescents.” To reach this conclusion, the authors selected 201 children diagnosed with the condition and divided them into two groups, one to receive psychological support only and the other to get puberty blockers in addition to psychological support. Costa et al did not create a third group that lacked a gender dysphoria diagnosis to serve as a control. To assess whether puberty suppression is an effective treatment, the authors administered two self-assessments (Utrecht Gender Dysphoria Scale and Children’s Global Assessment Scale)⁵ to the groups at 6-month intervals during a 12-month period. Because the study relies heavily on self-assessments, the conclusions are likely biased and invalid. Another problem, that is also present and common throughout articles supporting puberty suppression, is the short-term period. Costa et al’s conclusions may not be the same if additional follow-ups occurred three or five years later (Costa et al, 2015). This further raises the question as to whether low-quality studies like Costa et al’s should serve as the basis for clinical guidelines advising clinicians to prescribe drugs for off-label purposes.

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

⁵ Behavioral health practitioners use the Children’s Global Assessment Scale (CGAS) to measure child functioning during the evaluation process to determine diagnoses. Available evidence indicates that the CGAS is not effective for evaluating children who experienced trauma and presented with mental health symptoms (Blake et al, 2006).

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

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

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

What the current literature on puberty suppression indicates is that using it to treat gender dysphoria is off-label, poses potentially permanent side effects, and has questionable mental health benefits. This small amount of evidence is the basis for WPATH and the Endocrine Society to issue guidance as a treatment for gender dysphoria but should this be the case. The limited research and lack of FDA approval for that clinical indication prompt questions about whether physically altering medication should be used to treat a problem that most adolescents who experience it later conform to their natal sex. Additional evidence is required to establish puberty suppression as a standard treatment for gender dysphoria. (good)

Literature Review: Hormone Therapy as a Treatment for Gender Dysphoria

Currently, the debate surrounding the use of hormone therapy to treat gender dysphoria revolves around its ability to improve mental health at the expense of irreversible effects. It is not about whether taking hormones can initiate physical changes. The evidence demonstrating the effectiveness of hormone therapy in achieving physical transition to the opposite sex is abundant. Also, the overall scientific consensus concludes that individuals who take hormones will most certainly develop secondary sexual characteristics while reducing the primary sexual function of their natal sex organs. What researchers continue evaluating are the short and long-term effects on mental health, impacts on overall physical health, and how the changes affect detransitioning. Of these, benefits to mental health overshadow the other discussions. Proponents of hormone therapy focus so heavily on behavioral health outcomes that they de-emphasize that these drugs cause permanent physical changes and side effects that can lead to premature death (Hruz, 2020). In actuality, some clinical guidelines do not even indicate that some of the changes are irreversible such as WPATH's.

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

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

WPATH's guidance also does not stress the irreversible nature of hormone therapy, citing the treatment as "partially reversible" and not indicating which changes are permanent. Furthermore, parts of WPATH's information are outright false and directly conflict with guidance issued by clinics and other sources. One such example consists of WPATH stating that "hormone therapy *may* (emphasis added)

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

lead to irreversible changes.” This statement is misleading when existing research states that multiple physical changes are in fact permanent. Other examples include WPATH identifying durations of specific effects of hormonal therapy such as clitoral enlargement lasting one to two years when it is actually irreversible (UCSF, 2020). WPATH also does not explain the risks to male fertility, noting that lowered sperm count or sterility is “variable.” The University of California at San Francisco (UCSF) provides starkly different information by stating that trans-females should expect to become sterile within a few months of starting hormone therapy. UCSF also advises trans-females to consult a sperm bank if they may want to father children after transitioning (WPATH, 2012; UCSF, 2020). Below is a chart that outlines the effects of hormone therapy and identifies which ones are reversible or permanent.

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

Sources: UCSF, 2020; WPATH, 2012; Endocrine Society, 2017⁶

What the above chart demonstrates is that trans-males and trans-females experience different effects from hormone therapy that can cause myriad issues in later life. For example, trans-males who opt to detransition may face different psychological challenges than trans-females related to permanent disfigurement (e.g., facial hair and deepened voices). Trans-females, on the other hand, may not endure

⁶ This chart consists of conclusions regarding physical changes made by three different clinical organizations. If one organization determined that a physical change was irreversible, that was sufficient to meet the criteria to be listed as “irreversible” in the chart.

the same issues pertaining to visible physical changes but might become despondent over being unable to reproduce. This can occur regardless of whether the transitioning individual is satisfied with sex reassignment. Given that the clinical guidelines do not provide uniform information on the permanent effects of hormone therapy, how can clinicians make sound recommendations to patients. Proponents of this treatment argue that it can alleviate symptoms of distress. However, hormone therapy's permanent effects also have the potential to cause psychological issues.

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

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

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

substantially improves the mental health of individuals with gender dysphoria, the review cannot make definitive conclusions on the treatment's benefits.

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

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

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

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

females) reported much lower numbers of behavioral health issues and trauma. Additionally, 77% of men surveyed identified as the opposite gender prior to transition, whereas just 58% of women had (Littman, 2020).

Of the reasons cited for detransitioning, the majority (60%) noted that they became more comfortable with being their natal sex. The next two reasons were concerns over complications from the treatments, primarily hormone therapy, and that transitioning did not improve mental health. Other less-cited explanations include concerns about workplace discrimination and worsening physical health. The study also notes that approximately 36% of participants experienced worse mental health symptoms. Based on the findings, Littman concludes that more research is needed in tracking the transsexual population to obtain accurate percentages of those who decide to detransition and that men and women reported varying reasons for deciding to transition and later return to their natal sex. The author notes that higher rates of trauma and peer group influences might have contributed to women's decisions, which Littman attributes partially to rapid onset gender dysphoria (Littman, 2020). What the study also indicates is that hormone therapy is not a validated treatment for gender dysphoria. Nearly all of the participants had taken them and decided against maintaining the physical changes. Given that the majority of surveyed detransitioners cited that they were comfortable with their biological sex, the study indicates that gender dysphoria is not necessarily a lifelong issue. Considering that hormone therapy causes permanent physical changes, should clinicians prescribe it when no definite cause for gender dysphoria has been identified and that it could be temporary.

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

**ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT**

Regarding hormone therapy, the literature reveals that the evidence supporting it as a treatment for gender dysphoria is weak and insufficient. Between the permanent effects, off-label use, and consequences to long-term health, hormone therapy is a risky option that does not promise a cure but does guarantee irreversible changes to both male and female bodies. Additionally, the inadequate studies serving as the basis for recommendations by clinical associations can lead to providers making poorly informed decisions for their patients. Research asserting that taking hormones improves mental health is subjective and short-term, which should disqualify it as a foundation for clinical guidelines. More studies that utilize large sample sizes and appropriate methods is required before the medical profession should consider hormone therapy one of gender dysphoria's standard treatments.

Literature Review: Sex Reassignment Surgery

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

Procedures for Trans-Females

- **Genital Surgeries:** These consist of penectomy (removal of the penis), orchiectomy (removal of the testicles), vaginoplasty (construction of a neo-vagina), clitoroplasty (construction of a clitoris), and vulvoplasty (construction of a vulva and labia). To perform, a surgeon begins by deconstructing the penis and removing the testicles. The penile shaft and glans are repurposed to serve as a neo-vagina and clitoris. If the shaft tissue is insufficient, the surgeon may opt to use a portion of intestine to build a neo-vagina. The ~~scrotum~~^{pseudop} serves as material for fashioning a vulva and labia. In addition to constructing female genitalia, the surgeon reroutes the urethra to align with the neo-vagina. Genital surgeries for trans-females result in permanent sterility (Bizic et al, 2014).
- **Chest Surgery:** To attain full breasts, trans-females can undergo enlargement. The procedure is similar to breast augmentation for women where a surgeon places implants underneath breast tissue. Prior to surgery, trans-females need to take hormones for roughly 24 months to increase breast size to get maximum benefit from the procedure (Endocrine Society, 2017).
- **Cosmetic and Voice Surgeries:** Designed to create feminine facial features, fat deposits, and vocal sounds, these procedures are secondary to those for the genitals regarding sex reassignment and intended to alter trans-females' appearances to better integrate into society as a member of the desired gender (WPATH, 2012).

Procedures for Trans-Males

- **Mastectomy:** This is the most performed sex reassignment surgery on trans-males because hormone therapy and chest-binding garments are often insufficient at diminishing breasts. To remove this secondary sexual characteristic, trans-males can undergo a mastectomy where a surgeon removes breast tissue subcutaneously (i.e., under the skin) and reconstructs the nipples to appear masculine. The procedure can result in significant scarring (Monstrey et al, 2011).

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

- Genital Surgeries: Unlike the procedures for trans-females, genital surgeries for trans-males are more complex and have lower success rates. Consisting of hysterectomy, oophorectomy (removal of the ovaries), vaginectomy (removal of the vagina), phalloplasty (construction of a penis), and scrotoplasty (construction of prosthetic testicles), a team of surgeons must manufacture a penis using skin from the patient (taken from an appendage) while removing the vagina and creating an extended urethra. The functionality of the artificial penis can vary based on how extensive the construction was. Attaining erections requires additional surgery to implant a prosthesis, and the ability to urinate while standing is often not achieved. Genital procedures for trans-males result in irreversible sterility (Monstrey et al, 2011).
- Cosmetic Surgeries: Similar to trans-females, these procedures create masculine facial features, fat deposits, and artificial pectoral muscles. They also serve to aid trans-males socially integrate as their desired gender. Surgery to deepen voices is also available but rarely performed (WPATH, 2012).

Due to sex reassignment surgery being irreversible, the criteria for receiving these procedures is the strictest of all gender dysphoria treatments. Both WPATH and the Endocrine Society suggest rigorous reviews of patient history and prior use of other therapies before approving. Furthermore, the two organizations recommend that only adults (18 years old) undergo sex reassignment surgery.⁷ Other prerequisites where WPATH and the Endocrine Society agree include ensuring a strongly documented diagnosis of gender dysphoria, addressing all medical and mental health issues, and at least 12 months of hormone therapy for genital surgeries. Although the organizations agree on most criteria, they differ regarding taking hormones prior to mastectomies. WPATH asserts that the drugs should not be a requirement, whereas the Endocrine Society advises up to 2 years of hormone therapy before undergoing the procedure (WPATH, 2012; Endocrine Society, 2017). What this indicates is that trans-males might undergo breast removal without having first pursued all options if their clinician adheres to WPATH's guidelines, which can lead to possible regret over irreversible effects.

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

Two studies conducted in Sweden provide insight on the effectiveness of sex reassignment surgery in improving transsexuals' behavioral health. Because Sweden has a nationalized health system that

⁷ Although practice guidelines indicate the minimum age to undergo sex reassignment surgery is 18, available evidence demonstrates proponents advocating mastectomies on adolescent girls as young as 13 who experience "chest dysphoria" (Olson-Kennedy et al, 2018).

yes!

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

collects data on all residents, this country can serve as a resource to assess service utilization and inpatient admissions. Both studies, one by Dhejne et al from 2011 and another by Bränström et al published in 2020, assessed individuals who had received sex reassignment surgery and examined outcomes over several decades. Dhejne et al's findings contradict the proponents' stance that the procedures reduce suicidality. Instead of acting as a prevention measure, the authors noted that individuals who underwent sex reassignment surgery were still more likely to attempt or commit suicide than those in the cisgender population. What makes this finding noteworthy and not otherwise indicated in other research is the follow-up period. Dhejne et al note that the transsexuals tracked for the study did not show an elevated suicide risk until ten years after surgery (Dhejne et al, 2011). Considering that most research cited by proponents follows sex reassignment patients for much shorter timeframes, this evidence indicates that surgery might have little to no effect in preventing suicides in gender dysphoric individuals.

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

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

The study's publication prompted numerous responses to the *American Journal of Psychiatry* (AJP), questioning its methodology. Such challenges included lacking a prospective cohort or RCT design. In addition, letters submitted to the AJP highlighted how the study did not track all participants for a full

ATTORNEY-CLIENT PRIVILEGED
 ATTORNEY WORK PRODUCT PROTECTED
 DO NOT DISTRIBUTE
 DRAFT

ten-year period (Van Mol et al, 2020). These factors caused the journal to issue a subsequent retraction, asserting that Bränström et al's conclusions were "too strong" (Kalin, 2020). Other reasons for how this study reached varying results with Dhejne et al can have multiple explanations. For starters, Bränström et al tracked a larger sample group over a later period (2005 to 2015 as opposed to 1973 to 2003) during which gender dysphoria underwent a dramatic shift in definition. Also, Dhejne et al did not see elevated suicides until after ten years, raising the question as to whether sex reassignment surgery has temporary benefits on mental health rather than permanent. Like the other Swedish study, Bränström et al's findings are a correlation and do not specifically state that the procedures cause reduced psychiatric service utilization (Bränström et al, 2020).

*actually
said
no improvement
= GAS*

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

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

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

Literature Review: Quality of Available Evidence and Bioethical Questions

Quality of Available Evidence

Proponents of puberty suppression, hormone therapy, and sex reassignment surgery frequently cite how these treatments have the potential to save lives by preventing suicide and suicidal ideation. A May 2022 story by NBC announced survey results under the headline “Almost half of LGBTQ youths “seriously considered suicide in the past year” (NBC, 2022). This is a significant claim that can have a sensational effect on patients and providers alike, but how strong is the evidence supporting it. Almost all of the data backing this assertion are based on surveys and cross-studies, which tend to yield low-quality results (Hruz, 2018). In addition, how many gender dysphoric individuals are seeing stories in the media and not questioning the narrative. Because research on the effectiveness of treatments is ongoing, a debate persists regarding their use in the adolescent and young-adult populations, and much of it is due to the low-quality studies serving as evidence.

Despite the need for stronger studies that provide definitive conclusions, many practitioners stand by the recommendations of the AAP, Endocrine Society, and WPATH. This is evident in a letter submitted to the *Tampa Bay Times* and signed by 300 clinicians, which was a rebuttal to the Florida Department of Health’s (DOH) guidance on treatment for gender dysphoria (Note: The guidance recommends against using puberty blockers, hormones, or surgery for minors) (DOH, 2022). The authors, led by six professors at the University of Florida’s College of Medicine, argue that recommendations by clinical organizations are based on “careful deliberation and examination of the evidence by experts.” However, evaluations of these studies show otherwise. Not only does the available research use cross-sectional methods such as surveys, but it provides insufficient evidence based on momentary snapshots regarding mental health benefits. These weak studies are the foundation of for the clinical organizations’ guidelines that the University of Florida professors tout as a gold standard. In addition, the letter’s authors assert that DOH’s guidance is based on a “non-representative sample of small studies and reviews, editorials, opinion pieces, and commentary” (Tampa Bay Times, 2022). This argument misses the point when it comes to evidence demonstrating whether treatments with irreversible effects are beneficial because the burden of proof is on those advocating for them, not on the professionals citing the need for further research. This raises the question concerning how much academic rigor these faculty members are applying to practice guidelines released by clinical organizations. Do they also apply the same rigor to novel treatments for other conditions (e.g., drugs, medical devices). The letter with its 300 signatories is just one example of how clinicians are using problematic guidelines to convince patients and the public at large that sex reassignment is an effective treatment for gender dysphoria.

As part of the process to evaluate health services for Medicaid coverage in accordance with Rule 59G-1.035, F.A.C., the Florida Agency for Health Care Administration consulted Romina Brignardello-Petersen and Wojtek Wiercioch who assessed the quality of 61 articles published between 2020 and 2022 (Note: See Attachment A for the full study). In their review, the pair identified research on the effectiveness of puberty blockers, hormone therapy, and sex reassignment surgery and assigned a grade (high, moderate, low, or very low) in accordance with the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach. Out of the articles reviewed, all with a few exceptions

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

received grades of low or very low quality when demonstrating outcomes regarding improvements in mental health and overall satisfaction with transitioning. For puberty blockers, Brignardello-Petersen and Wiercioch identified low quality evidence for alleviating gender dysphoria and very low quality for reducing suicidal ideation. The authors also had nearly identical findings for hormones. However, they noted moderate quality evidence for the likelihood of cardiovascular side effects. Regarding surgery, Brignardello-Petersen and Wiercioch graded articles that examined overall satisfaction and complication rates. None of the studies received grades higher than low quality. These findings led the authors to conclude that “there is great uncertainty about the effects” and that the “evidence alone is not sufficient to support” using such treatments (Brignardello-Petersen and Wiercioch, 2022).

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

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

yes!

study's publication under the headline "Few Transgender Children Change Their Minds After 5 Years" (New York Times, 2022). Such a title can add to the public's perception that gender dysphoria requires early medical intervention to address.

Bioethical Questions

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

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

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

Coverage Policies of the U.S. and Western Europe

U.S. Federal Level Coverage Policies

Medicare: In 2016 the Centers for Medicare and Medicaid Services (CMS) published a decision memo announcing that Medicare Administrative Contractors (MACs) can evaluate sex reassignment surgery coverage on a “case-by-case” basis. CMS specifically noted that the decision memo is not a National Coverage Determination and that “no national policy will be put in place for the Medicare program” (CMS, 2016). In 2017, CMS reinforced this position with a policy transmittal that repeated the 2016 memo’s criteria (CMS, 2017).⁸

The basis for Medicare’s decision is that the “clinical evidence is inconclusive” and that “robust” studies are “needed to ensure that patients achieve improved health outcomes.” In its review of available literature, CMS sought to answer whether there is “sufficient evidence to conclude that gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria.” After evaluating 33 studies that met inclusion criteria, CMS’s review concludes that “not enough high-quality evidence” is available that demonstrates sex reassignment surgery benefits mental or physical health (CMS, 2016).

U.S. Department of Veterans Affairs: The U.S. Department of Veterans Affairs (VA) does not cover sex reassignment surgery, although it will reimburse for hormone therapy and pre- and post-operative care related to transitioning. Because the VA only provides services to veterans of the U.S. armed forces, it cannot offer sex reassignment treatment to children. Additionally, the VA states that it will only provide care that meets “generally accepted standards of medical practice and determined by appropriate health care professionals to promote, preserve, or restore the health of the individual” (VA, 2020).⁹

State-Level Coverage Policies

Florida: In April 2022, DOH issued guidance for the treatment of gender dysphoria, recommending that minors not receive puberty blockers, hormone therapy, or sex reassignment surgery. The justification for recommending against these treatments is that available evidence is low-quality and that European countries also have similar guidelines. Additionally, DOH states the following bullets to support its stance:

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

⁸ The Centers for Medicare and Medicaid Services is part of the U.S. Department of Health and Human Services. Its primary functions are to administer the entire Medicare system and oversee federal compliance for state Medicaid programs. In addition, CMS sets reimbursement rates and coverage criteria for the Medicare program.

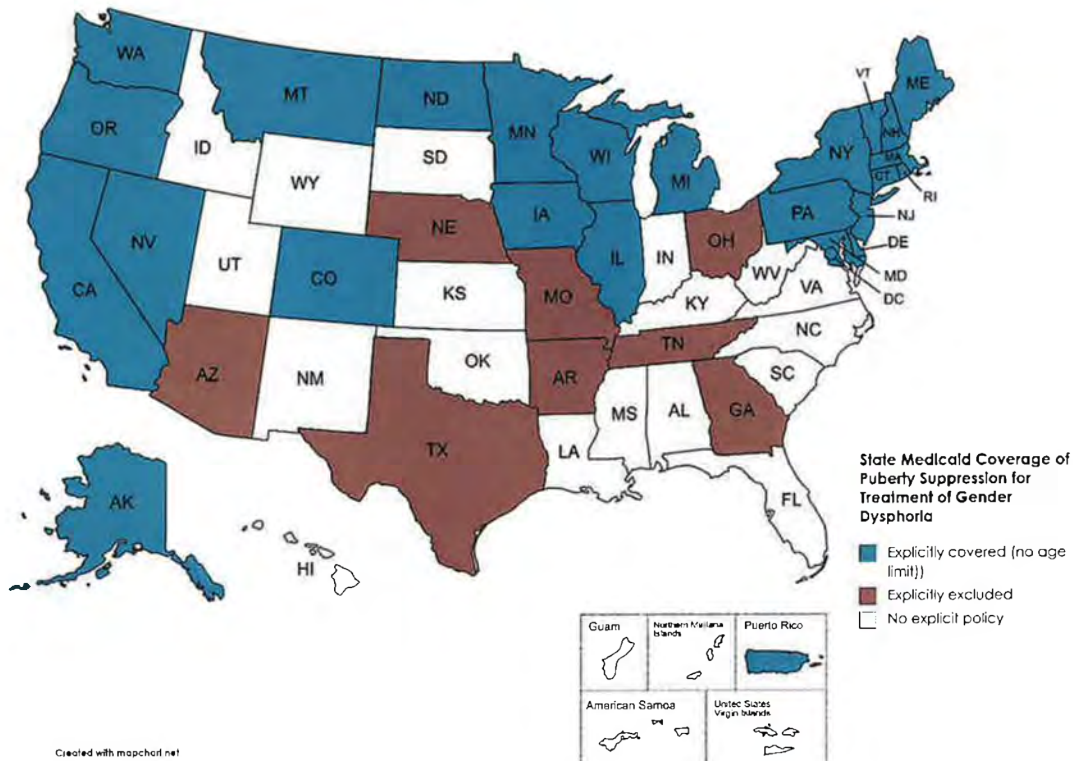
⁹ The U.S. Department of Veterans Affairs oversees the Veterans Health Administration (VHA), which consists of over 1,000 hospitals, clinics, and long-term care facilities. As the largest health care network in the U.S., the VHA provides services to veterans of the U.S. armed forces.

**ATTORNEY-CLIENT PRIVELEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT**

In a separate fact sheet released simultaneously with the guidance, DOH further asserts that “the research used to support cannot infer causation” to refute HHS’s claims (DOH, 2022).¹⁰

State Medicaid Programs: Because individual states can vary in health services offered, Medicaid programs differ in their coverage of sex reassignment treatments. The following maps identifies states that have a coverage policy stating it does reimburse for these services, states that have no policy, and states that have announced no coverage.

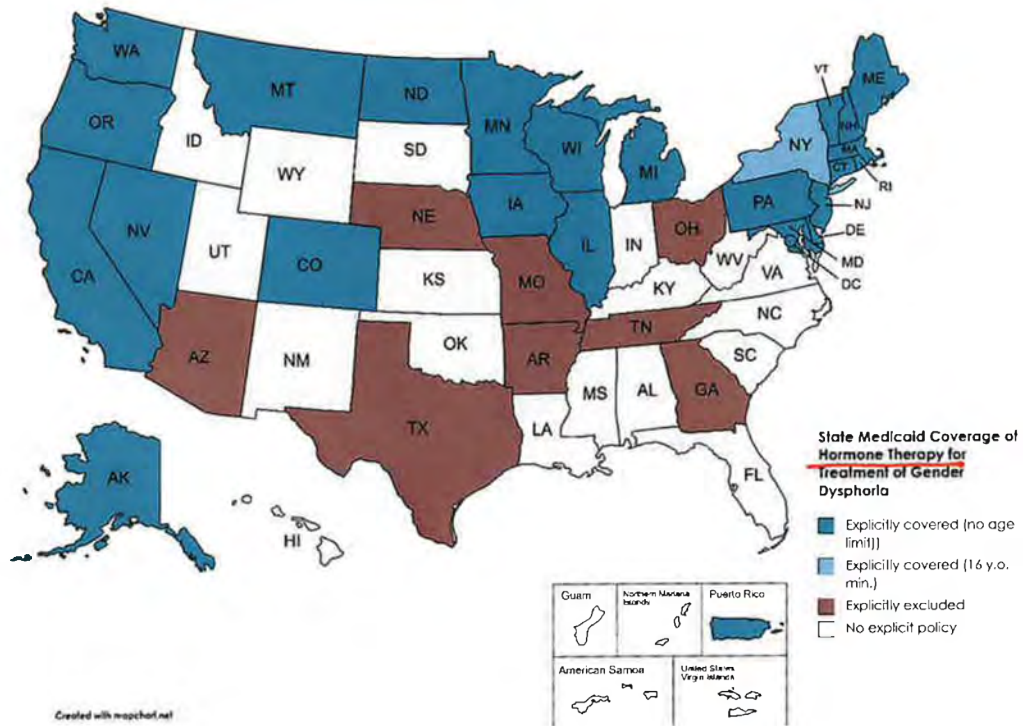
State Medicaid programs that cover puberty blockers:



State Medicaid programs that cover hormone therapy:

¹⁰ Unlike the federal government, the State of Florida delegates responsibilities for Medicaid and health care services to five separate agencies (Agency for Health Care Administration, Department of Health, Department of Children and Families, Department of Elder Affairs, and Agency for Persons with Disabilities). Each agency has its own separate head (secretary or surgeon general), which reports directly to the Executive Office of the Governor. As Florida’s public health agency, DOH oversees all county health departments, medical professional boards, and numerous health and welfare programs (e.g., Early Steps and Women, Infants, and Children). Because it oversees the boards, DOH has authority to release practice guidelines.

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT



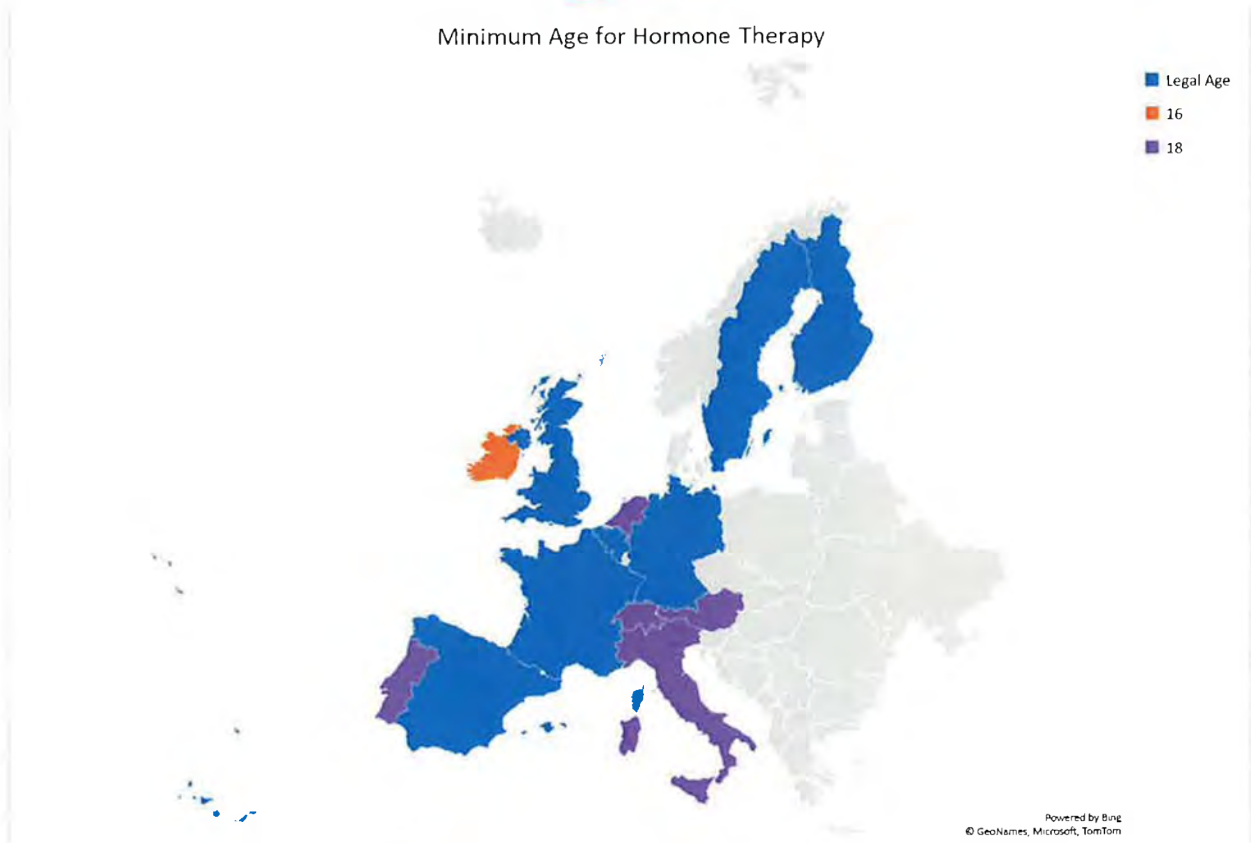
State Medicaid programs that cover sex reassignment surgery:

ATTORNEY-CLIENT PRIVELEDGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

blockers. The interim report is serving as a benchmark until the research is completed for final guidelines (The Cass Report, 2022).

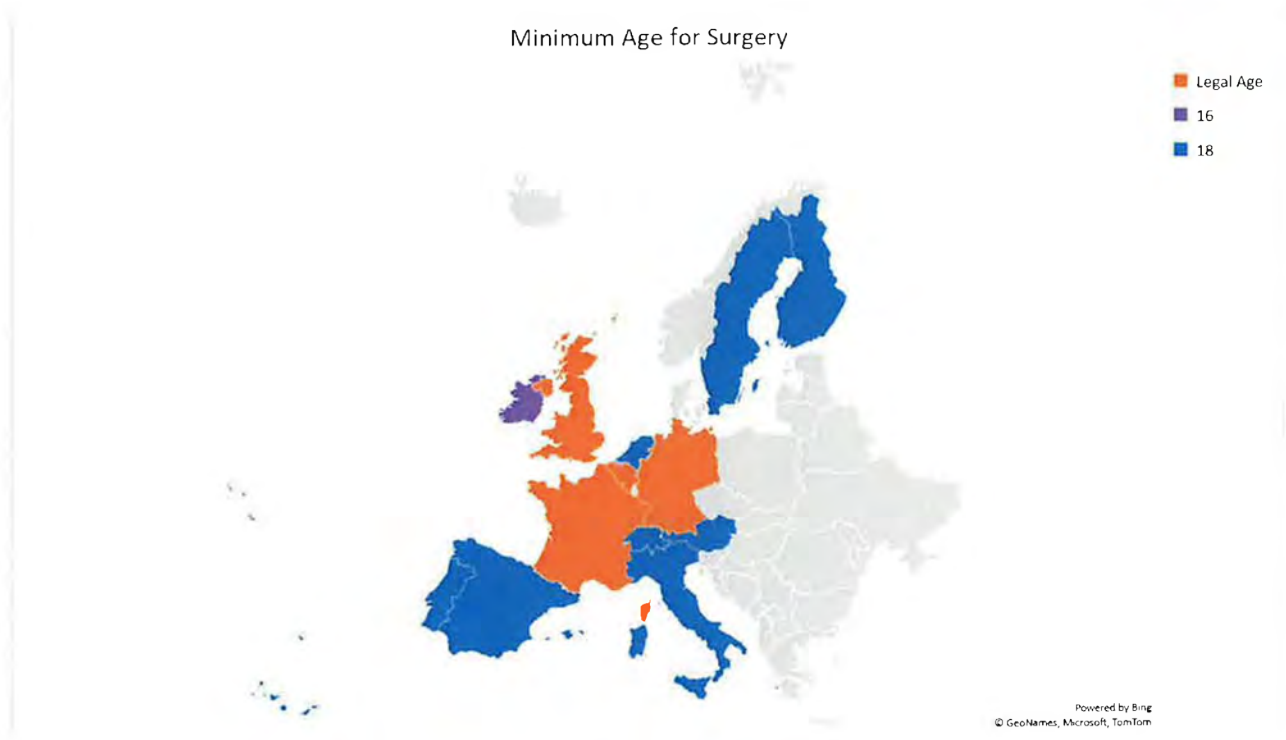
Like state Medicaid programs, health systems across Western Europe also vary in their coverage of sex reassignment treatment. The following map indicates the ages where a citizen or resident become eligible for these services.

Western European nations' requirements for hormone therapy:



Western European nations' requirements for sex reassignment surgery:

ATTORNEY-CLIENT PRIVELEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT



Generally Accepted Professional Medical Standards Recommendation

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

yes!

Rationale

Considering the available evidence is low to very low quality and that identifying as a different gender alone is not a disorder, treatments that pose irreversible effects such as hormones and surgical procedures require more research to validate whether the benefits outweigh the physical and mental costs. Questions such as what causes gender dysphoria, how many adolescents eventually detransition, and whether transsexuals regret the permanent changes to their bodies require sufficient answers before these services can become the standard of care. Additionally, the FDA needs to approve gender dysphoria as a clinical indication for hormones (e.g., testosterone and estrogen) and drugs used to suppress puberty (e.g., Gn-RH). Until these occur, medical treatments for this condition are experimental and investigational.

Concur

Do not Concur

Comments:

**ATTORNEY-CLIENT PRIVELEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT**

Deputy Secretary for Medicaid (or designee)

Date

Works Cited

- Almost Half of LGBTQ Youths ‘Seriously Considered’ Suicide in Past Year, Survey Says. *NBC News*. 4 May 2022.
- American Academy of Pediatrics. Policy Statement: Off-Label Use of Drugs in Children. *Pediatrics*. 2014. 133(3).
- American Psychiatric Association. *Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders*. 2013.
- American Psychiatric Association. *Gender Dysphoria Diagnosis*. 2017.
- American Psychiatric Association. *What Is Depression*. 2020.
- American Psychological Association. *APA Resolution on Gender Identity Change Efforts*. 2021.
- Baker GM, Guzman-Arocho YD, Bret-Mounet VC, Torous VF, Schnitt SJ, Tobias AM, Bartlett RA, Fein-Zachary VJ, Collins LC, Wulf GM, Heng YJ. Testosterone Therapy and Breast Histopathological Features in Transgender Individuals. *Mod Pathol*. 2021. 34(1).
- Blake K, Cangelosi S, Johnson-Brooks S, Belcher HME. Reliability of the GAF and CGAS with Children Exposed to Trauma. *Child Abuse and Neglect*. 2007. 31: 909-915.
- Bizic MR, Jeftovic M, Pusica S, Stojanovic B, Duisin D, Vujovic S, Rakic V, Djordjevic ML. Gender Dysphoria: Bioethical Aspects of Medical Treatment. *BioMed Research International*. 2018: 9652305.
- Bizic M, Kojovic V, Duisin D, Stanojevic D, Vujovic S, Milosevic A, Korac G, Djordjevic ML. An Overview of Neovaginal Reconstruction Options in Male to Female Transsexuals. *The Scientific World Journal*. 2014. 638919.
- Bränström R, Pachankis JE. Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study. *American Journal of Psychiatry*. 2020. 177(8).
- Brignardello-Petersen R, Wiercioch W. Effects of Gender Affirming Therapies in People with Gender Dysphoria: Evaluation of the Best Available Evidence. Unpublished: Commissioned by the Florida Agency for Health Care Administration. 2022.
- Bruggeman BS, Dayton K, Diaz A, Evans J, Haller MJ, Hudak ML, Mathews CA, Shapiro M. We 300 Florida Health Care Professionals Say the State Gets Transgender Guidance Wrong. *Tampa Bay Times*. 27 April 2022.
- Cantor J. Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy. *Journal of Sex and Marital Therapy*. 46(4).
- Cass H. *The Cass Review: Independent Review of Gender Identity Services for Children and Young People, Interim Report*. 2022.

The Centers for Medicare and Medicaid Services. Decision Memo: Gender Dysphoria and Gender Reassignment Surgery. 30 August 2016.

The Centers for Medicare and Medicaid Services. Pub 100-03 Medicare National Coverage Determinations. 3 March 2017.

Chen D, Strang JF, Kolbuck VD, Rosenthal SM, Wallen K, Waber DP, Steinberg L, Sisk CL, Roth J, Paus T, Mueller SC, McCarthy MM, Micevych PE, Martin CL, Kreukels BPC, Kenworthy L, Herting MM, Herlitz A, Haraldsen RJH, Dahl R, Crone EA, Chelune GJ, Burke SM, Berenbaum SA, Beltz AM, Bakker J, Eliot L, Vilain E, Wallace GL, Nelson EE, Garofalo R. Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Pubertal Suppression in Transgender Youth. *Transgender Health*. 2020. 5(4).

Claahsen-van der Grinten H, Verhaak C, Steensma T, Middelberg T, Roeffen J, Klink D. Gender Incongruence and Gender Dysphoria in Childhood and Adolescence – Current Insights in Diagnostics, Management, and Follow-Up. *European Journal of Pediatrics*. 2020. 180: 1349-1357.

Costa R, Colizzi M. The Effect of Cross-Sex Hormonal Treatment on Gender Dysphoria Individuals' Mental Health: A Systematic Review. *Neuropsychiatric Disease and Treatment*. 2016. 12: 1953-1966.

Costa R, Dunsford M, Skagerberg E, Holt V, Carmichael P, Colizzi M. Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria. *Journal of Sexual Medicine*. 2015. 12(11).

Davy Z, Toze M. What Is Gender Dysphoria? A Critical Systematic Narrative Review. *Transgender Health*. 2018. 3(1).

De Sanctis V, Soliman AT, Di Maio S, Soliman N, Elsedfy H. Long-Term Effects and Significant Adverse Drug Reactions (ADRs) Associated with the Use of Gonadotropin-Releasing Hormone Analogs (GnRH α) for Central Precocious Puberty: A Brief Review of Literature. *Acta Biomed*. 2019. 90(3).

De Vries ALC, McGuire JK, Steensma TD, Wagenaar ECF, Doreleijers TAH, Cohen-Kettenis PT. Young Adult Psychological Outcome after Puberty Suppression and Gender Reassignment. *Pediatrics*. 2014. 134(4).

Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Langstrom N, Landen M. Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden. *PLoS One*. 6(2).

Dutra E, Lee J, Torbati T, Garcia M, Merz CNB, Shufelt C. Cardiovascular Implications of Gender-Affirming Hormone Treatment in the Transgender Population. *Maturitas*. 2019. 129: 45-49.

Few Transgender Children Change Their Minds After 5 Years, Study Finds. *New York Times*. 4 May 2022.

Gaetano P. David Reimer and John Money Gender Reassignment Controversy: The John/Joan Case. *The Embryo Project Encyclopedia*. 2017.

Geffen S, Horn T, Smith KJ, Cahill S. Advocacy for Gender Affirming Care: Learning from the Injectable Estrogen Shortage. *Transgender Health*. 2018. 3(1).

Go JJ. Should Gender Reassignment Surgery Be Publicly Funded? *Bioethical Inquiry*. 2018. 15: 527-534.

Gu J, Kanai, R. What contributes to individual differences in brain structure. *Front Hum Neurosci*. 2014. 8:262.

Hariton E, Locascio JJ. Randomised Controlled Trials – The Gold Standard for Effectiveness Research. *BJOG: An International Journal of Obstetrics and Gynecology*. 2018. 125(13).

Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, Rosenthal SM, Safer JD, Tangpricha V, T'Sjoen GG. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinological Metabolism*. 2017. 102(11).

Herman JL, Brown TNT, Haas AP. *Suicide Thoughts and Attempts Among Transgender Adults: Findings from the 2015 U.S. Transgender Survey*. University of California at Los Angeles School of Law Williams Institute. 2019.

Hess J, Neto RR, Panic L, Rubben H, Senf W. Satisfaction with Male-to-Female Gender Reassignment Surgery. *Deutsches Arzteblatt International*. 2014. 111: 795-801.

Hruz PW. Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. *Catholic Medical Association*. 2020. 87(1).

James HA, Chang AY, Imhof RL, Sahoo A, Montenegro MM, Imhof NR, Gonzalez CA, Lteif AN, Nippoldt TB, Davidge-Pitts CJ. A Community-Bases Study of Demographics, Medical and Psychiatric Conditions, and Gender Dysphoria/Incongruence Treatment in Transgender/Gender Diverse Individuals. *Biology of Sex Differences*. 2020. 11(55).

Jensen RK, Jensen JK, Simons LK, Chen D, Rosoklija I, Finlayson C. Effect of Concurrent Gonadotropin-Releasing Hormone Against Treatment on Dose and Side Effects of Gender-Affirming Hormone Therapy in Adolescent Transgender Patients. *Transgender Health*. 2019. 4(1).

Kalin NH. Reassessing mental health treatment utilization reduction in transgender individuals after gender-affirming surgeries: a comment by the editor on the process (letter). *American Journal of Psychiatry*. 2020. 177:765.

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).

Kozłowska K, Chudleigh C, McClure G, Maguire AM, Ambler GR. Attachment Patterns in Children and Adolescents with Gender Dysphoria. *Frontiers in Psychology*. 2021. 11: 582688.

Kuper LE, Mathews S, Lau M. Baseline Mental Health and Psychosocial Functioning of Transgender Adolescents Seeking Gender-Affirming Hormone Therapy. *Journal of Developmental Behavior Pediatrics*. 2019. 40(8).

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

- Kyriakou A, Nicolaides NC, Skordis N. Current Approach to the Clinical Care of Adolescents with Gender Dysphoria. *Acta Biomed*. 2020. 91(1).
- Laidlaw M, Cretella M, Donovan K. The Right to Best Care for Children Does Not Include the Right to Medical Transition. *The American Journal of Bioethics*. 2019. 19(2).
- Laidlaw M, Van Meter QL, Hruz PW, Van Mol A, Malone WJ. Letter to the Editor: Endocrine Treatment of Gender-Dysphoria/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *Journal of Clinical Endocrinological Metabolism*. 2018.
- Lee JY, Finlayson C, Olson-Kennedy J, Garofalo R, Chan YM, Glidden DV, Rosenthal SM. Low Bone Mineral Density in Early Pubertal Transgender/Gender Diverse Youth: Findings from the Trans Youth Care Study. *Journal of the Endocrine Society*. 2020. 4(9).
- Levine SB. Informed Consent for Transgendered Patients. *Journal of Sex & Marital Therapy*. 2018. 10:1080.
- Littman L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Archives of Sexual Behavior*. 2021. 50: 3353-3369.
- Littman L. Rapid-Onset Gender Dysphoria in Adolescents and Young Adults: A Study of Parental Reports. *PLOS One*. 2018. 13(8).
- Mayer L, McHugh PR. Sexuality and Gender: Findings from the Biological, Psychological, and Social Sciences. *The New Atlantis*. 2016. Fall Edition. 103.
- McHugh PR. *The Mind Has Mountains: Reflections on Society and Psychiatry*. The Johns Hopkins University Press. 2006.
- Merck Pharmaceuticals. *Merck Manual: Professional Version*. 2021.
- Monstrey SJ, Ceulemans P, Hoebek P. Sex Reassignment Surgery in the Female-to-Male Transsexual. *Seminars in Plastic Surgery*. 2011. 25(3).
- Nguyen HB, Chavez AM, Lipner E, Hantsoo L, Kornfield SL, Davies RD, Epperson CN. Gender-Affirming Hormone Use in Transgender Individuals: Impact on Behavioral Health and Cognition. *Curr Psychiatry Rep*. 2019. 20(12).
- Olson KR, Durwood L, DeMeules M, McLaughlin KL. Mental Health of Transgender Children Who Are Supported in Their Identities. *Pediatrics*. 2015. 137(3).
- Olson KR, Durwood L, Horton R, Gallagher NM, Devor A. Gender Identity 5 Years After Social Transition. *Pediatrics*. 2022; doi: 10.1542/peds.2021-056082.
- 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 Pediatrics*. 2018. 172(5).

Palveluvalikoima of Finland. Recommendation of the Council for Choices in Health Care in Finland (Palko/Cohere Finland): Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors. 2020.

Rafferty J, AAP Committee on Psychosocial Aspects of Child and Family Health, AAP Committee on Adolescence, AAP Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness. Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents. *Pediatrics*. 2018. 142(4).

Sadr M, Korashad BS, Talaei A, Fazeli N, Honekopp J. 2D:4D Suggests a Role of Prenatal Testosterone in Gender Dysphoria. *Archives of Sexual Behavior*. 2020. 49: 421-432.

Saleem F, Rizvi SW. Transgender Associations and Possible Etiology: A Literature Review. *Cureus*. 9(12).

Shumer DE, Reisner SL, Edwards-Leeper L, Tishelman A. Evaluation of Asperger Syndrome in Youth Presenting to a Gender Dysphoria Clinic. *LGBT Health*. 2016. 3(5).

Society for Evidence Based Gender Medicine. Summary of Key Recommendations from the Swedish National Board of Health and Welfare (Socialstyrelsen/NBHW). 2022.

Steensma TD, McGuire JK, Kreukels BPC, Beekman AJ, Cohen-Kettenis PT. Factors Associated with Desistence and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study. *Journal of the American Academy of Child and Adolescent Psychiatry*. 2013. 52(6).

Tordoff DM, Wanta JW, Collin A, Stepney C, Inwards-Breland DJ, Ahrens K. Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care. *JAMA Open Network*. 2022; 59(2).

Trum H, Hoebeke P, Gooren L. Sex Reassignment of Transsexual People from a Gynecologist's and Urologist's Perspective. *Acta Obstetrica et Gynecologica*. 2016. 94: 563-567.

Turban JL, Loo SS, Almazan AN, Keuroghlian AS. Factors Leading to "Detransition" Among Transgender and Gender Diverse People in the United States: A Mixed-Method Analysis *LGBT Health*. 2021. 8(4).

UF Doctor Says Gender-Affirming Care Works for Kids Who Need It, and Can Even Save Lives. *Health News Florida*. 26 April 2022.

Unger CA. Hormone Therapy for Transgender Patients. *Translational Andrology and Urology*. 2016. 5(6).

University of California at San Francisco Health System. *Overview of Feminizing Hormone Therapy*. 2020.

University of California at San Francisco Health System. *Overview of Masculinizing Hormone Therapy*. 2020.

U.S. Department of Health and Human Services: Office for Civil Rights. HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy. 2 March 2022.

U.S. Drug Enforcement Administration. *Drug Fact Sheet: Steroids*. 2020.

ATTORNEY-CLIENT PRIVILEGED
ATTORNEY WORK PRODUCT PROTECTED
DO NOT DISTRIBUTE
DRAFT

Van der Miesen AIR, Hurley H, Bal AM, de Vries ALC. Prevalence of the Wish to Be of the Opposite Gender in Adolescents and Adults with Autism Spectrum Disorder. *Archives of Sexual Behavior*. 2018. 47: 2307-2317.

Van Mol A, Laidlaw MK, Grossman M, McHugh PR. Gender-Affirmation Surgery Conclusion Lacks Evidence. *American Journal of Psychiatry*. 2020. 177:765.

Varkey B. Principles of Clinical Ethics and Their Application to Practice. *Medical Principles and Practice*. 2021. 30: 17-28.

World Professional Association for Transgender Health. *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*. 2012.

Zhao JJ, Marchaim D, Palla MB, Bogan CW, Hayakawa K, Tansek R, Moshos J, Muthusamy A, Kotra H, Lephart PR, Wilson AN, Kaye KS. Surgical Site Infections in Genital Reconstruction Surgery for Gender Reassignment, Detroit: 1984-2008. *Surgical Infections*. 2014. 15(2).

Zucker K. Debate: Different strokes for different folks. *Child and Adolescent Mental Health*. 2019. doi.org/10.1111/camh.12330.