NO. 22-1927

In The

United States Court Of Appeals

For The Fourth Circuit

CHRISTOPHER FAIN; SHAUNTAE ANDERSON, individually and on behalf of all others similarly situated,

Plaintiffs - Appellees,

v.

WILLIAM CROUCH, in his official capacity as Cabinet Secretary of the West Virginia Department of Health and Human Resources; CYNTHIA BEANE, in her official capacity as Commissioner for the West Virginia Bureau for Medical Services; WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, Bureau for Medical Services,

Defendants – Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA AT HUNTINGTON

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Gender Dysphoria

In this chapter, there is one overarching diagnosis of gender dysphoria, with separate developmentally appropriate criteria sets for children and for adolescents and adults. The area of sex and gender is highly controversial and has led to a proliferation of terms whose meanings vary over time and within and between disciplines. An additional source of confusion is that in English "sex" connotes both male/female and sexuality. This chapter employs constructs and terms as they are widely used by clinicians from various disciplines with specialization in this area. In this chapter, *sex* and *sexual* refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and nonambiguous internal and external genitalia. Disorders of sex development denote conditions of inborn somatic deviations of the reproductive tract from the norm and/or discrepancies among the biological indicators of male and female. *Cross-sex* hormone treatment denotes the use of feminizing hormones in an individual assigned male at birth based on traditional biological indicators or the use of masculinizing hormones in an individual assigned female at birth.

The need to introduce the term *gender* arose with the realization that for individuals with conflicting or ambiguous biological indicators of sex (i.e., "intersex"), the lived role in society and/or the identification as male or female could not be uniformly associated with or predicted from the biological indicators and, later, that some individuals develop an identity as female or male at variance with their uniform set of classical biological indicators. Thus, *gender* is used to denote the public (and usually legally recognized) lived role as boy or girl, man or woman, but, in contrast to certain social constructionist theories, biological factors are seen as contributing, in interaction with social and psychological factors, to gender development. *Gender assignment* refers to the initial assignment as male or female. This occurs usually at birth and, thereby, yields the "natal gender." *Gender-atypical* refers to somatic features or behaviors that are not typical (in a statistical sense) of individuals with the same assigned gender in a given society and historical era; for behavior, *gender-nonconforming* is an alternative descriptive term. *Gender reassignment* denotes an official (and usually legal) change of gender. *Gender identity* is a category of social identity and refers to an individual's identification as male, female, or, occasionally, some category other than male or female. *Gender dysphoria* as a general descriptive term refers to an individual's affective/cognitive discontent with the assigned gender but is more specifically defined when used as a diagnostic category. *Transgender* refers to the broad spectrum of individuals who transiently or persistently identify with a gender different from their natal gender. *Transsexual* denotes an individual who seeks, or has undergone, a social transition from male to female or female to male, which in many, but not all, cases also involves a somatic transition by cross-sex hormone treatment and genital surgery (*sex reassignment surgery*).

Gender dysphoria refers to the distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender. Although not all individuals will experience distress as a result of such incongruence, many are distressed if the desired physical interventions by means of hormones and/or surgery are not available. The current term is more descriptive than the previous DSM-IV term *gender identity disorder* and focuses on dysphoria as the clinical problem, not identity per se.

Gender Dysphoria

Diagnostic Criteria

Gender Dysphoria in Children 302.6 (F64.2)

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be Criterion A1):

1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).
2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
3. A strong preference for cross-gender roles in make-believe play or fantasy play.
4. A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender.
5. A strong preference for playmates of the other gender.
6. In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities.
7. A strong dislike of one's sexual anatomy.
8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.

B. The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.

Specify if:

With a disorder of sex development (e.g., a congenital adrenogenital disorder such as 255.2 [E25.0] congenital adrenal hyperplasia or 259.50 [E34.50] androgen insensitivity syndrome).

Coding note: Code the disorder of sex development as well as gender dysphoria.

Gender Dysphoria in Adolescents and Adults 302.85 (F64.1)

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:

1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).
2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).
3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Specify if:

With a disorder of sex development (e.g., a congenital adrenogenital disorder such as 255.2 [E25.0] congenital adrenal hyperplasia or 259.50 [E34.50] androgen insensitivity syndrome).

Coding note: Code the disorder of sex development as well as gender dysphoria.

Specify if:

Posttransition: The individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one cross-sex medical procedure or treatment regimen—namely, regular cross-sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in a natal male; mastectomy or phalloplasty in a natal female).

Specifiers

The posttransition specifier may be used in the context of continuing treatment procedures that serve to support the new gender assignment.

Diagnostic Features

Individuals with gender dysphoria have a marked incongruence between the gender they have been assigned to (usually at birth, referred to as *natal gender*) and their experienced/expressed gender. This discrepancy is the core component of the diagnosis. There must also be evidence of distress about this incongruence. Experienced gender may include alternative gender identities beyond binary stereotypes. Consequently, the distress is not limited to a desire to simply be of the other gender, but may include a desire to be of an alternative gender, provided that it differs from the individual's assigned gender.

Gender dysphoria manifests itself differently in different age groups. Prepubertal natal girls with gender dysphoria may express the wish to be a boy, assert they are a boy, or assert they will grow up to be a man. They prefer boys' clothing and hairstyles, are often perceived by strangers as boys, and may ask to be called by a boy's name. Usually, they display intense negative reactions to parental attempts to have them wear dresses or other feminine attire. Some may refuse to attend school or social events where such clothes are required. These girls may demonstrate marked cross-gender identification in role-playing, dreams, and fantasies. Contact sports, rough-and-tumble play, traditional boyhood games, and boys as playmates are most often preferred. They show little interest in stereotypically feminine toys (e.g., dolls) or activities (e.g., feminine dress-up or role-play). Occasionally, they refuse to urinate in a sitting position. Some natal girls may express a desire to have a penis or claim to have a penis or that they will grow one when older. They may also state that they do not want to develop breasts or menstruate.

Prepubertal natal boys with gender dysphoria may express the wish to be a girl or assert they are a girl or that they will grow up to be a woman. They have a preference for dressing in girls' or women's clothes or may improvise clothing from available materials (e.g., using towels, aprons, and scarves for long hair or skirts). These children may role-play female figures (e.g., playing "mother") and often are intensely interested in female fantasy figures. Traditional feminine activities, stereotypical games, and pastimes (e.g., "playing house"; drawing feminine pictures; watching television or videos of favorite female characters) are most often preferred. Stereotypical female-type dolls (e.g., Barbie) are often favorite toys, and girls are their preferred playmates. They avoid rough-and-tumble play and competitive sports and have little interest in stereotypically masculine toys (e.g., cars, trucks). Some may pretend not to have a penis and insist on sitting to urinate. More

rarely, they may state that they find their penis or testes disgusting, that they wish them removed, or that they have, or wish to have, a vagina.

In young adolescents with gender dysphoria, clinical features may resemble those of children or adults with the condition, depending on developmental level. As secondary sex characteristics of young adolescents are not yet fully developed, these individuals may not state dislike of them, but they are concerned about imminent physical changes.

In adults with gender dysphoria, the discrepancy between experienced gender and physical sex characteristics is often, but not always, accompanied by a desire to be rid of primary and/or secondary sex characteristics and/or a strong desire to acquire some primary and/or secondary sex characteristics of the other gender. To varying degrees, adults with gender dysphoria may adopt the behavior, clothing, and mannerisms of the experienced gender. They feel uncomfortable being regarded by others, or functioning in society, as members of their assigned gender. Some adults may have a strong desire to be of a different gender and treated as such, and they may have an inner certainty to feel and respond as the experienced gender without seeking medical treatment to alter body characteristics. They may find other ways to resolve the incongruence between experienced/expressed and assigned gender by partially living in the desired role or by adopting a gender role neither conventionally male nor conventionally female.

Associated Features Supporting Diagnosis

When visible signs of puberty develop, natal boys may shave their legs at the first signs of hair growth. They sometimes bind their genitals to make erections less visible. Girls may bind their breasts, walk with a stoop, or use loose sweaters to make breasts less visible. Increasingly, adolescents request, or may obtain without medical prescription and supervision, hormonal suppressors ("blockers") of gonadal steroids (e.g., gonadotropin-releasing hormone [GnRH] analog, spironolactone). Clinically referred adolescents often want hormone treatment and many also wish for gender reassignment surgery. Adolescents living in an accepting environment may openly express the desire to be and be treated as the experienced gender and dress partly or completely as the experienced gender, have a hairstyle typical of the experienced gender, preferentially seek friendships with peers of the other gender, and/or adopt a new first name consistent with the experienced gender. Older adolescents, when sexually active, usually do not show or allow partners to touch their sexual organs. For adults with an aversion toward their genitals, sexual activity is constrained by the preference that their genitals not be seen or touched by their partners. Some adults may seek hormone treatment (sometimes without medical prescription and supervision) and gender reassignment surgery. Others are satisfied with either hormone treatment or surgery alone.

Adolescents and adults with gender dysphoria before gender reassignment are at increased risk for suicidal ideation, suicide attempts, and suicides. After gender reassignment, adjustment may vary, and suicide risk may persist.

Prevaience

For natal adult males, prevalence ranges from 0.005% to 0.014%, and for natal females, from 0.002% to 0.003%. Since not all adults seeking hormone treatment and surgical reassignment attend specialty clinics, these rates are likely modest underestimates. Sex differences in rate of referrals to specialty clinics vary by age group. In children, sex ratios of natal boys to girls range from 2:1 to 4.5:1. In adolescents, the sex ratio is close to parity; in adults, the sex ratio favors natal males, with ratios ranging from 1:1 to 6.1:1. In two countries, the sex ratio appears to favor natal females (Japan: 2.2:1; Poland: 3.4:1).

Development and Course

Because expression of gender dysphoria varies with age, there are separate criteria sets for children versus adolescents and adults. Criteria for children are defined in a more con-

crete, behavioral manner than those for adolescents and adults. Many of the core criteria draw on well-documented behavioral gender differences between typically developing boys and girls. Young children are less likely than older children, adolescents, and adults to express extreme and persistent anatomic dysphoria. In adolescents and adults, incongruence between experienced gender and somatic sex is a central feature of the diagnosis. Factors related to distress and impairment also vary with age. A very young child may show signs of distress (e.g., intense crying) only when parents tell the child that he or she is "really" not a member of the other gender but only "desires" to be. Distress may not be manifest in social environments supportive of the child's desire to live in the role of the other gender and may emerge only if the desire is interfered with. In adolescents and adults, distress may manifest because of strong incongruence between experienced gender and somatic sex. Such distress may, however, be mitigated by supportive environments and knowledge that biomedical treatments exist to reduce incongruence. Impairment (e.g., school refusal, development of depression, anxiety, and substance abuse) may be a consequence of gender dysphoria.

Gender dysphoria without a disorder of sex development. For clinic-referred children, onset of cross-gender behaviors is usually between ages 2 and 4 years. This corresponds to the developmental time period in which most typically developing children begin expressing gendered behaviors and interests. For some preschool-age children, both pervasive cross-gender behaviors and the expressed desire to be the other gender may be present, or, more rarely, labeling oneself as a member of the other gender may occur. In some cases, the expressed desire to be the other gender appears later, usually at entry into elementary school. A small minority of children express discomfort with their sexual anatomy or will state the desire to have a sexual anatomy corresponding to the experienced gender ("anatomic dysphoria"). Expressions of anatomic dysphoria become more common as children with gender dysphoria approach and anticipate puberty.

Rates of persistence of gender dysphoria from childhood into adolescence or adulthood vary. In natal males, persistence has ranged from 2.2% to 30%. In natal females, persistence has ranged from 12% to 50%. Persistence of gender dysphoria is modestly correlated with dimensional measures of severity ascertained at the time of a childhood baseline assessment. In one sample of natal males, lower socioeconomic background was also modestly correlated with persistence. It is unclear if particular therapeutic approaches to gender dysphoria in children are related to rates of long-term persistence. Extant follow-up samples consisted of children receiving no formal therapeutic intervention or receiving therapeutic interventions of various types, ranging from active efforts to reduce gender dysphoria to a more neutral, "watchful waiting" approach. It is unclear if children "encouraged" or supported to live socially in the desired gender will show higher rates of persistence, since such children have not yet been followed longitudinally in a systematic manner. For both natal male and female children showing persistence, almost all are sexually attracted to individuals of their natal sex. For natal male children whose gender dysphoria does not persist, the majority are *androphilic* (sexually attracted to males) and often self-identify as gay or homosexual (ranging from 63% to 100%). In natal female children whose gender dysphoria does not persist, the percentage who are *gynephilic* (sexually attracted to females) and self-identify as lesbian is lower (ranging from 32% to 50%).

In both adolescent and adult natal males, there are two broad trajectories for development of gender dysphoria: early onset and late onset. *Early-onset gender dysphoria* starts in childhood and continues into adolescence and adulthood; or, there is an intermittent period in which the gender dysphoria desists and these individuals self-identify as gay or homosexual, followed by recurrence of gender dysphoria. *Late-onset gender dysphoria* occurs around puberty or much later in life. Some of these individuals report having had a desire to be of the other gender in childhood that was not expressed verbally to others. Others do not recall any signs of childhood gender dysphoria. For adolescent males with late-onset gender dysphoria, parents often report surprise because they did not see signs of gender

dysphoria during childhood. Expressions of anatomic dysphoria are more common and salient in adolescents and adults once secondary sex characteristics have developed.

Adolescent and adult natal males with early-onset gender dysphoria are almost always sexually attracted to men (androphilic). Adolescents and adults with late-onset gender dysphoria frequently engage in transvestic behavior with sexual excitement. The majority of these individuals are gynephilic or sexually attracted to other posttransition natal males with late-onset gender dysphoria. A substantial percentage of adult males with late-onset gender dysphoria cohabit with or are married to natal females. After gender transition, many self-identify as lesbian. Among adult natal males with gender dysphoria, the early-onset group seeks out clinical care for hormone treatment and reassignment surgery at an earlier age than does the late-onset group. The late-onset group may have more fluctuations in the degree of gender dysphoria and be more ambivalent about and less likely satisfied after gender reassignment surgery.

In both adolescent and adult natal females, the most common course is the early-onset form of gender dysphoria. The late-onset form is much less common in natal females compared with natal males. As in natal males with gender dysphoria, there may have been a period in which the gender dysphoria desisted and these individuals self-identified as lesbian; however, with recurrence of gender dysphoria, clinical consultation is sought, often with the desire for hormone treatment and reassignment surgery. Parents of natal adolescent females with the late-onset form also report surprise, as no signs of childhood gender dysphoria were evident. Expressions of anatomic dysphoria are much more common and salient in adolescents and adults than in children.

Adolescent and adult natal females with early-onset gender dysphoria are almost always gynephilic. Adolescents and adults with the late-onset form of gender dysphoria are usually androphilic and after gender transition self-identify as gay men. Natal females with the late-onset form do not have co-occurring transvestic behavior with sexual excitement.

Gender dysphoria in association with a disorder of sex development. Most individuals with a disorder of sex development who develop gender dysphoria have already come to medical attention at an early age. For many, starting at birth, issues of gender assignment were raised by physicians and parents. Moreover, as infertility is quite common for this group, physicians are more willing to perform cross-sex hormone treatments and genital surgery before adulthood.

Disorders of sex development in general are frequently associated with gender-atypical behavior starting in early childhood. However, in the majority of cases, this does not lead to gender dysphoria. As individuals with a disorder of sex development become aware of their medical history and condition, many experience uncertainty about their gender, as opposed to developing a firm conviction that they are another gender. However, most do not progress to gender transition. Gender dysphoria and gender transition may vary considerably as a function of a disorder of sex development, its severity, and assigned gender.

Risk and Prognostic Factors

Temperamental. For individuals with gender dysphoria without a disorder of sex development, atypical gender behavior among individuals with early-onset gender dysphoria develops in early preschool age, and it is possible that a high degree of atypicality makes the development of gender dysphoria and its persistence into adolescence and adulthood more likely.

Environmental. Among individuals with gender dysphoria without a disorder of sex development, males with gender dysphoria (in both childhood and adolescence) more commonly have older brothers than do males without the condition. Additional predisposing

factors under consideration, especially in individuals with late-onset gender dysphoria (adolescence, adulthood), include habitual fetishistic transvestism developing into autogynephilia (i.e., sexual arousal associated with the thought or image of oneself as a woman) and other forms of more general social, psychological, or developmental problems.

Genetic and physiological. For individuals with gender dysphoria without a disorder of sex development, some genetic contribution is suggested by evidence for (weak) familiality of transsexualism among nontwin siblings, increased concordance for transsexualism in monozygotic compared with dizygotic same-sex twins, and some degree of heritability of gender dysphoria. As to endocrine findings, no endogenous systemic abnormalities in sex-hormone levels have been found in 46,XY individuals, whereas there appear to be increased androgen levels (in the range found in hirsute women but far below normal male levels) in 46,XX individuals. Overall, current evidence is insufficient to label gender dysphoria without a disorder of sex development as a form of intersexuality limited to the central nervous system.

In gender dysphoria associated with a disorder of sex development, the likelihood of later gender dysphoria is increased if prenatal production and utilization (via receptor sensitivity) of androgens are grossly atypical relative to what is usually seen in individuals with the same assigned gender. Examples include 46,XY individuals with a history of normal male prenatal hormone milieu but inborn nonhormonal genital defects (as in cloacal bladder exstrophy or penile agenesis) and who have been assigned to the female gender. The likelihood of gender dysphoria is further enhanced by additional, prolonged, highly gender-atypical postnatal androgen exposure with somatic virilization as may occur in female-raised and noncastrated 46,XY individuals with 5-alpha reductase-2 deficiency or 17-beta-hydroxysteroid dehydrogenase-3 deficiency or in female-raised 46,XX individuals with classical congenital adrenal hyperplasia with prolonged periods of non-adherence to glucocorticoid replacement therapy. However, the prenatal androgen milieu is more closely related to gendered behavior than to gender identity. Many individuals with disorders of sex development and markedly gender-atypical behavior do not develop gender dysphoria. Thus, gender-atypical behavior by itself should not be interpreted as an indicator of current or future gender dysphoria. There appears to be a higher rate of gender dysphoria and patient-initiated gender change from assigned female to male than from assigned male to female in 46,XY individuals with a disorder of sex development.

Culture-Related Diagnostic Issues

Individuals with gender dysphoria have been reported across many countries and cultures. The equivalent of gender dysphoria has also been reported in individuals living in cultures with institutionalized gender categories other than male or female. It is unclear whether with these individuals the diagnostic criteria for gender dysphoria would be met.

Diagnostic Markers

Individuals with a somatic disorder of sex development show some correlation of final gender identity outcome with the degree of prenatal androgen production and utilization. However, the correlation is not robust enough for the biological factor, where ascertainable, to replace a detailed and comprehensive diagnostic interview evaluation for gender dysphoria.

Functional Consequences of Gender Dysphoria

Preoccupation with cross-gender wishes may develop at all ages after the first 2–3 years of childhood and often interfere with daily activities. In older children, failure to develop age-typical same-sex peer relationships and skills may lead to isolation from peer groups and to distress. Some children may refuse to attend school because of teasing and harass-

ment or pressure to dress in attire associated with their assigned sex. Also in adolescents and adults, preoccupation with cross-gender wishes often interferes with daily activities. Relationship difficulties, including sexual relationship problems, are common, and functioning at school or at work may be impaired. Gender dysphoria, along with atypical gender expression, is associated with high levels of stigmatization, discrimination, and victimization, leading to negative self-concept, increased rates of mental disorder comorbidity, school dropout, and economic marginalization, including unemployment, with attendant social and mental health risks, especially in individuals from resource-poor family backgrounds. In addition, these individuals' access to health services and mental health services may be impeded by structural barriers, such as institutional discomfort or inexperience in working with this patient population.

Differential Diagnosis

Nonconformity to gender roles. Gender dysphoria should be distinguished from simple nonconformity to stereotypical gender role behavior by the strong desire to be of another gender than the assigned one and by the extent and pervasiveness of gender-variant activities and interests. The diagnosis is not meant to merely describe nonconformity to stereotypical gender role behavior (e.g., "tomboyism" in girls, "girly-boy" behavior in boys, occasional cross-dressing in adult men). Given the increased openness of atypical gender expressions by individuals across the entire range of the transgender spectrum, it is important that the clinical diagnosis be limited to those individuals whose distress and impairment meet the specified criteria.

Transvestic disorder. Transvestic disorder occurs in heterosexual (or bisexual) adolescent and adult males (rarely in females) for whom cross-dressing behavior generates sexual excitement and causes distress and/or impairment without drawing their primary gender into question. It is occasionally accompanied by gender dysphoria. An individual with transvestic disorder who also has clinically significant gender dysphoria can be given both diagnoses. In many cases of late-onset gender dysphoria in gynephilic natal males, transvestic behavior with sexual excitement is a precursor.

Body dysmorphic disorder. An individual with body dysmorphic disorder focuses on the alteration or removal of a specific body part because it is perceived as abnormally formed, not because it represents a repudiated assigned gender. When an individual's presentation meets criteria for both gender dysphoria and body dysmorphic disorder, both diagnoses can be given. Individuals wishing to have a healthy limb amputated (termed by some *body integrity identity disorder*) because it makes them feel more "complete" usually do not wish to change gender, but rather desire to live as an amputee or a disabled person.

Schizophrenia and other psychotic disorders. In schizophrenia, there may rarely be delusions of belonging to some other gender. In the absence of psychotic symptoms, insistence by an individual with gender dysphoria that he or she is of some other gender is not considered a delusion. Schizophrenia (or other psychotic disorders) and gender dysphoria may co-occur.

Other clinical presentations. Some individuals with an emasculinization desire who develop an alternative, nonmale/nonfemale gender identity do have a presentation that meets criteria for gender dysphoria. However, some males seek castration and/or penectomy for aesthetic reasons or to remove psychological effects of androgens without changing male identity; in these cases, the criteria for gender dysphoria are not met.

Comorbidity

Clinically referred children with gender dysphoria show elevated levels of emotional and behavioral problems—most commonly, anxiety, disruptive and impulse-control, and de-

pressive disorders. In prepubertal children, increasing age is associated with having more behavioral or emotional problems; this is related to the increasing non-acceptance of gender-variant behavior by others. In older children, gender-variant behavior often leads to peer ostracism, which may lead to more behavioral problems. The prevalence of mental health problems differs among cultures; these differences may also be related to differences in attitudes toward gender variance in children. However, also in some non-Western cultures, anxiety has been found to be relatively common in individuals with gender dysphoria, even in cultures with accepting attitudes toward gender-variant behavior. Autism spectrum disorder is more prevalent in clinically referred children with gender dysphoria than in the general population. Clinically referred adolescents with gender dysphoria appear to have comorbid mental disorders, with anxiety and depressive disorders being the most common. As in children, autism spectrum disorder is more prevalent in clinically referred adolescents with gender dysphoria than in the general population. Clinically referred adults with gender dysphoria may have coexisting mental health problems, most commonly anxiety and depressive disorders.

Other Specified Gender Dysphoria

302.6 (F64.8)

This category applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The other specified gender dysphoria category is used in situations in which the clinician chooses to communicate the specific reason that the presentation does not meet the criteria for gender dysphoria. This is done by recording "other specified gender dysphoria" followed by the specific reason (e.g., "brief gender dysphoria").

An example of a presentation that can be specified using the "other specified" designation is the following:

The current disturbance meets symptom criteria for gender dysphoria, but the duration is iess than 6 months.

Unspecified Gender Dysphoria

302.6 (F64.9)

This category applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The unspecified gender dysphoria category is used in situations in which the clinician chooses *not* to specify the reason that the criteria are not met for gender dysphoria, and includes presentations in which there is insufficient information to make a more specific diagnosis.

In the Matter of:

CHRISTOPHER FAIN

vs

WILLIAM CROUCH, et al.

DR. DAN KARASIC

April 15, 2022

5010 Dempsey Drive
Cross Lanes WV 25313
304-415-1122

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN; ZACHARY MARTELL; BRIAN McNEMAR, SHAWN ANDERSON a/k/a SHAUNTAE ANDERSON; and LEANNE JAMES, individually and on behalf of all others similarly situated,

Plaintiffs,

vs. Civil Action No. 3:20-cv-00740

WILLIAM CROUCH, in his official capacity as Cabinet Secretary of the West Virginia Department of Health and Human Resources; CYNTHIA BEANE, in her official capacity as Commissioner for the West Virginia Bureau for Medical Services; WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES; JASON HAUGHT, in his official capacity as Director of the West Virginia Public Employees Insurance Agency; and THE HEALTH PLAN OF WEST VIRGINIA, INC.,

Defendants.

"CONFIDENTIAL"
VIDEOTAPED DEPOSITION OF DR. DAN KARASIC
BY VIDEO CONFERENCE

The videotaped deposition of Dr. Dan Karasic was taken on April 15, 2022, at 12:02 p.m., at 5010 Dempsey Drive, Cross Lanes, West Virginia.

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I N D E X

A. Yes. I'm familiar with the process to get to gender incongruence by the World Health Organization for ICD. But the United States, in terms of ICD adoption, is way behind the rest of the world. So we only -- we were using ICD-9 which was adopted by -- you know, was created around 1975, up until just a few years ago. And then we moved to ICD-10 while they were already working on its replacement.

So just our CMS - Center for Medicare and Medicaid Services - it is just very slow in new adoption of -- and so they have their own ICD CM, which is the American -- it's the ICD-10-CM, which is the American version of the ICD that's in use here. I don't know whether I'll still be in practice when ICD-11 is adopted -- or alive, when the ICD-11 is adopted in the United States.

Q. Okay. So it sounds like it might not matter for practical purposes in the United States anytime soon. But under ICD-11, for gender incongruence -- if I'm understanding that diagnostic code correctly, there is no requirement of clinically significant distress

InterQual®

2021, Apr. 2021 Release CP:Procedures

(1, 2, 3, 4, 5, 6, 7, 8)

Subset: Gender Affirmation Surgery

Requested Service: Hysterectomy for Gender Affirmation Surgery

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Primary gender affirmation surgery

(9) 1. Strong and persistent cross-gender identification ≥ 6 months

- ☐ A) Yes
- ☐ B) No

> • If option Yes selected, then go to question 2
> • No other options lead to the requested service

(9) 2. Choose all that apply:

- ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
- ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
- ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
- ☐ D) Strong desire to be the other gender or an alternative gender
- ☐ E) Strong desire to be treated as the other gender
- ☐ F) Strong confidence that typical feelings and reactions are of the other gender
- ☐ G) Other clinical information (add comment)

> • If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
> • No other options lead to the requested service

Primary gender affirmation surgery (continued...)

3. Choose all that apply:
   - ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
   - ☐ B) Clinically significant increased risk of suffering
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Gender affirmation surgery, Choose one:
   - ☐ A) Female-to-male surgery, genital
   - ☐ B) Female-to-male surgery, other
   - ☐ C) Male-to-female surgery, genital
   - ☐ D) Male-to-female surgery, other
   - ☐ E) Other clinical information (add comment)

   • If option A selected, then go to question 5
   • No other options lead to the requested service

5. Choose all that apply:
   - ☐ A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery
   - ☐ B) Persistent and well-documented gender dysphoria
   - ☐ C) Capacity to make fully informed decisions and to consent
   - ☐ D) No psychiatric disorder by history or psychiatric disorder controlled
   - ☐ E) Other clinical information (add comment)

   • If the number of options selected is 4 and option E not selected, then go to question 6
   • No other options lead to the requested service

6. Choose all that apply:
   - ☐ A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated
   - ☐ B) Lived ≥ 12 months in gender role congruent with gender identity
   - ☐ C) Other clinical information (add comment)

   • If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here
   • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

3:
Guidelines agree that gender affirmation surgical intervention is appropriate for individuals 18 years of age or older, as these procedures are irreversible; however, behavioral health counseling and hormone therapy may be used to treat individuals who have been diagnosed with gender dysphoria at an earlier age. The sooner the diagnosis is made and treatment options are discussed, the more successful the individual is when transitioning (Hembree et al., Endocr Pract 2017, 23: 1437; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

4:
According to the American Psychiatric Association, the Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria as a condition where sex assigned at birth is incongruent with experienced or desired gender, resulting in distress and suffering. Distress must persist for at least six months and result in a desire to change (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). Transgender persons are described as someone whose gender identity, behavior or expression, is not typical of that assigned at birth, including those who are gender dysphoric. In the United States, approximately 0.6%, or 1.4 million adults identify as transgender individuals. The prevalence is similar worldwide and has doubled in the last decade (Flores et al., How many adults identify as Transgender in the United States? 2016).
Therapeutic options for gender dysphoria or transgender individuals include psychotherapy, hormonal treatment, and gender affirmation surgery (GAS). Dressing, acting, or speaking consistent with the correct gender, taking hormones, changing one's name, and surgical intervention are possible activities carried out to identify with the correct gender. Some transgender individuals do not define themselves as conforming to the gender binary (male or female) and may also use terms such as gender non-conforming, pangender, agender, bigender, polygender, gender fluid, gender queer, or gender neutral. This will impact their treatment choices (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013).
GAS is a treatment option for gender dysphoria and is often the final stage of transition. GAS is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities working in conjunction with each other to assist the candidate for gender affirmation achieve successful outcomes. Before undertaking GAS, candidates need to undergo important medical and psychological evaluations to confirm that surgery is the most appropriate treatment choice. Procedures vary significantly from female-to-male and male-to-female and are generally comprised of a series of primary and secondary sex character changes, chest reconstruction, facial alterations and voice-modification. After working with a transgender care team, a surgical plan is tailored to the individual's needs to relieve gender dysphoria. Treatment standardization in this population is not possible as clinical presentations and symptoms will vary significantly with each individual. A specialized, multidisciplinary transgender care team may include, but is not limited to, practitioners in primary care, behavioral health, speech and language therapy, dermatology, endocrinology, urology, gynecology, and plastic surgery. Collaborative care, joint participation in goal setting along with regular follow-up is crucial (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional

Association for Transgender Health. 2011, 7: 1-112).

5:
Although there are many publications on gender affirmation surgery (GAS), most articles are observational case studies, have less than 30 participants, do not have strong evidence, or are focused on surgical technique. There is a paucity of published evidence that is adequately powered or designed to allow definitive conclusions on safety and efficacy of the individual surgical procedures. Surgical technique and observational case studies represent the largest body of evidence. Future research is needed to improve patient selection, surgical procedure selection and patient outcome.

Statistics around GAS are primarily estimations. Private facilities are not mandated to report this data; there are variations on how surgical procedures are staged and many of the procedures are identified as simply cosmetic, therefore making data collection difficult. In addition, the complexity and various reconstructive scenarios distinguishing procedures with multiple stages from revisional affirmation surgery is not truly accounted for. Although estimates vary, the American Society of Plastic Surgeons stated that there was a 155% increase in gender affirmation surgeries in 2017, approximating over 8,300 facial, body contouring and sex surgeries (American Society of Plastic Surgeons, 2017 Plastic Surgery Statistics Report. 2018).

6:
These criteria include the following procedures:

Bilateral Mastectomy
Breast Augmentation
Clitoroplasty
Gender Confirmation Surgery
Gender Reassignment Surgery
Hysterectomy
Intersex Surgery
Labiaplasty
Male Chest Contouring
Metoidioplasty
Orchiectomy
Ovariectomy
Penectomy
Penile Prosthesis
Permanent Hair Removal
Phalloplasty
Salpingo-oophorectomy
Scrotoplasty
Sex Reassignment Surgery
Transgender Surgery
Transsexual Surgery
Urethroplasty
Vaginoplasty
Vulvoplasty

7:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

8:

This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

9:
Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

10:
The most common female-to-male (FtM) genital procedures include hysterectomy, ovariectomy, salpingo-oophorectomy, metoidioplasty, phalloplasty, penile prosthesis, scrotoplasty, and urethroplasty. Permanent hair removal can be done prior to a number of genital surgeries.

The most common FtM chest procedures are mastectomy and male chest contouring. There are also various body contouring, facial and voice modification surgeries (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

11:
Surgical risks in female-to-male (FtM) genital and breast surgeries include, but are not limited to, infection, unsightly scarring, nipple necrosis, contour irregularities, urinary tract stenosis, fistulas, necrosis of neophallus, micropenis, and incapacity to stand while urinating. FtM genital surgery has been less successful than male-to-female genital surgery because of the difficulty creating a functional and aesthetic penis from smaller clitoral tissue (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

12:
The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

The most common MtF chest procedure is breast augmentation. Permanent hair removal can be done prior to a number of genital surgeries. There are also various body contouring, facial and voice modification surgeries that may be appropriate MtF procedures (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

13:
Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

14:
Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

15:
It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Councilor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

16:
A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

17:
Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

18:
Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

19:

Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

20:

I/O Setting:
Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
All others - Outpatient

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

ICD-10-PCS (circle all that apply): 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UT97ZL, 0UT97ZZ, 0UT98ZL, 0UT98ZZ, 0UT9FZL, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58180, 58260, 58262, 58275, 58290, 58291, 58541, 58542, 58543, 58544, 58552, 58553, 58554, 58570, 58571, 58572, 58573, Other _____

InterQual®

2021, Apr. 2021 Release CP:Procedures

(1, 2, 3, 4, 5, 6, 7, 8)

Subset: Gender Affirmation Surgery

Requested Service: Phalloplasty for Gender Affirmation Surgery

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Primary gender affirmation surgery

(9) 1. Strong and persistent cross-gender identification ≥ 6 months

- ☐ A) Yes
- ☐ B) No

> • If option Yes selected, then go to question 2
> • No other options lead to the requested service

(9) 2. Choose all that apply:

- ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
- ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
- ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
- ☐ D) Strong desire to be the other gender or an alternative gender
- ☐ E) Strong desire to be treated as the other gender
- ☐ F) Strong confidence that typical feelings and reactions are of the other gender
- ☐ G) Other clinical information (add comment)

> • If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
> • No other options lead to the requested service

Primary gender affirmation surgery (continued...)

3. Choose all that apply:
   - ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
   - ☐ B) Clinically significant increased risk of suffering
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Gender affirmation surgery, Choose one:
   - ☐ A) Female-to-male surgery, genital
   - ☐ B) Female-to-male surgery, other
   - ☐ C) Male-to-female surgery, genital
   - ☐ D) Male-to-female surgery, other
   - ☐ E) Other clinical information (add comment)

   • If option A selected, then go to question 5
   • No other options lead to the requested service

5. Choose all that apply:
   - ☐ A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery
   - ☐ B) Persistent and well-documented gender dysphoria
   - ☐ C) Capacity to make fully informed decisions and to consent
   - ☐ D) No psychiatric disorder by history or psychiatric disorder controlled
   - ☐ E) Other clinical information (add comment)

   • If the number of options selected is 4 and option E not selected, then go to question 6
   • No other options lead to the requested service

6. Choose all that apply:
   - ☐ A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated
   - ☐ B) Lived ≥ 12 months in gender role congruent with gender identity
   - ☐ C) Other clinical information (add comment)

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   • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

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2:

Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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According to the American Psychiatric Association, the Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria as a condition where sex assigned at birth is incongruent with experienced or desired gender, resulting in distress and suffering. Distress must persist for at least six months and result in a desire to change (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). Transgender persons are described as someone whose gender identity, behavior or expression, is not typical of that assigned at birth, including those who are gender dysphoric. In the United States, approximately 0.6%, or 1.4 million adults identify as transgender individuals. The prevalence is similar worldwide and has doubled in the last decade (Flores et al., How many adults identify as Transgender in the United States? 2016).

Therapeutic options for gender dysphoria or transgender individuals include psychotherapy, hormonal treatment, and gender affirmation surgery (GAS). Dressing, acting, or speaking consistent with the correct gender, taking hormones, changing one's name, and surgical intervention are possible activities carried out to identify with the correct gender. Some transgender individuals do not define themselves as conforming to the gender binary (male or female) and may also use terms such as gender non-conforming, pangender, agender, bigender, polygender, gender fluid, gender queer, or gender neutral. This will impact their treatment choices (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013).

GAS is a treatment option for gender dysphoria and is often the final stage of transition. GAS is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities working in conjunction with each other to assist the candidate for gender affirmation achieve successful outcomes. Before undertaking GAS, candidates need to undergo important medical and psychological evaluations to confirm that surgery is the most appropriate treatment choice. Procedures vary significantly from female-to-male and male-to-female and are generally comprised of a series of primary and secondary sex character changes, chest reconstruction, facial alterations and voice-modification. After working with a transgender care team, a surgical plan is tailored to the individual’s needs to relieve gender dysphoria. Treatment standardization in this population is not possible as clinical presentations and symptoms will vary significantly with each individual. A specialized, multidisciplinary transgender care team may include, but is not limited to, practitioners in primary care, behavioral health, speech and language therapy, dermatology, endocrinology, urology, gynecology, and plastic surgery. Collaborative care, joint participation in goal setting along with regular follow-up is crucial (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional

Association for Transgender Health. 2011, 7: 1-112).

5:

Although there are many publications on gender affirmation surgery (GAS), most articles are observational case studies, have less than 30 participants, do not have strong evidence, or are focused on surgical technique. There is a paucity of published evidence that is adequately powered or designed to allow definitive conclusions on safety and efficacy of the individual surgical procedures. Surgical technique and observational case studies represent the largest body of evidence. Future research is needed to improve patient selection, surgical procedure selection and patient outcome.

Statistics around GAS are primarily estimations. Private facilities are not mandated to report this data; there are variations on how surgical procedures are staged and many of the procedures are identified as simply cosmetic, therefore making data collection difficult. In addition, the complexity and various reconstructive scenarios distinguishing procedures with multiple stages from revisional affirmation surgery is not truly accounted for. Although estimates vary, the American Society of Plastic Surgeons stated that there was a 155% increase in gender affirmation surgeries in 2017, approximating over 8,300 facial, body contouring and sex surgeries (American Society of Plastic Surgeons, 2017 Plastic Surgery Statistics Report. 2018).

6:

These criteria include the following procedures:

Bilateral Mastectomy
Breast Augmentation
Clitoroplasty
Gender Confirmation Surgery
Gender Reassignment Surgery
Hysterectomy
Intersex Surgery
Labiaplasty
Male Chest Contouring
Metoidioplasty
Orchiectomy
Ovariectomy
Penectomy
Penile Prosthesis
Permanent Hair Removal
Phalloplasty
Salpingo-oophorectomy
Scrotoplasty
Sex Reassignment Surgery
Transgender Surgery
Transsexual Surgery
Urethroplasty
Vaginoplasty
Vulvoplasty

7:

InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

8:

This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

9:
Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

10:
The most common female-to-male (FtM) genital procedures include hysterectomy, ovariectomy, salpingo-oophorectomy, metoidioplasty, phalloplasty, penile prosthesis, scrotoplasty, and urethroplasty. Permanent hair removal can be done prior to a number of genital surgeries.

The most common FtM chest procedures are mastectomy and male chest contouring. There are also various body contouring, facial and voice modification surgeries (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

11:
Surgical risks in female-to-male (FtM) genital and breast surgeries include, but are not limited to, infection, unsightly scarring, nipple necrosis, contour irregularities, urinary tract stenosis, fistulas, necrosis of neophallus, micropenis, and incapacity to stand while urinating. FtM genital surgery has been less successful than male-to-female genital surgery because of the difficulty creating a functional and aesthetic penis from smaller clitoral tissue (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

12:
The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

The most common MtF chest procedure is breast augmentation. Permanent hair removal can be done prior to a number of genital surgeries. There are also various body contouring, facial and voice modification surgeries that may be appropriate MtF procedures (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

13:
Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

14:
Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

15:
It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Councilor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

16:
A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

17:
Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

18:
Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

19:

Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

20:

I/O Setting:
Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
All others - Outpatient

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

CPT® (circle all that apply): 55899, Other _____

Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria

Lisa Littman

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Notice of republication

After publication of this article [1], questions were raised that prompted the journal to conduct a post-publication reassessment of the article, involving senior members of the journal's editorial team, two Academic Editors, a statistics reviewer, and an external expert reviewer. The post-publication review identified issues that needed to be addressed to ensure the article meets *PLOS ONE*'s publication criteria. Given the nature of the issues in this case, the *PLOS ONE* Editors decided to republish the article, replacing the original version of record with a revised version in which the author has updated the Title, Abstract, Introduction, Discussion, and Conclusion sections, to address the concerns raised in the editorial reassessment. The Materials and methods section was updated to include new information and more detailed descriptions about recruitment sites and to remove two figures due to copyright restrictions. Other than the addition of a few missing values in Table 13, the Results section is unchanged in the updated version of the article. The Competing Interests statement and the Data Availability statement have also been updated in the revised version. The original version of the published article is appended to this Correction as S1 File.

This Correction Notice serves to provide additional clarifications and context for the article in response to questions raised during the post-publication review of this work.

Emphasis that this is a study of parental observations which serves to develop hypotheses

This study of parent observations and interpretations serves to develop the hypotheses that rapid-onset gender dysphoria is a phenomenon and that social influences, parent-child conflict, and maladaptive coping mechanisms may be contributing factors for some individuals. Rapid-onset gender dysphoria (ROGD) is not a formal mental health diagnosis at this time. This report did not collect data from the adolescents and young adults (AYAs) or clinicians and therefore does not validate the phenomenon. Additional research that includes AYAs, along with consensus among experts in the field, will be needed to determine if what is described here as rapid-onset gender dysphoria (ROGD) will become a formal diagnosis. Furthermore, the use of the term, rapid-onset gender dysphoria should be used cautiously by clinicians and parents to describe youth who appear to fall into this category. The term should not be used in a way to imply that it explains the experiences of all gender dysphoric youth nor should it be used to stigmatize vulnerable individuals. This article has been revised to better reflect that these parent reports provide information that can be used to develop hypotheses about factors that may contribute to the onset and/or expression of gender dysphoria among this demographic group.

Because this is a study of parent reports, there is some information about the AYAs that the parents would not have access to and the answers might reflect parent perspectives. Examples where parent answers reflect their perspective of the AYA include answers concerning the child's mental well-being, the parent-child relationship, and whether the child has high expectations about transitioning. However, it is also important to note that there are other survey items where the parent would have direct access to information about their child and that those answers reflect items that can be directly observed. Examples of this type include age, natal sex, diagnoses given by medical providers in the presence of the parent, directly observed behaviors of the child and the child's friend group, school performance, whether the child has dropped out or required a leave of absence from school, has been unable to hold a job, whether the child went to a clinic, or received treatment. Readers are reminded to keep in mind that this is a study of parent report and consideration of what information parents may or may not have access to is an important element of the findings.

Questions on whether the article describes adolescent-onset gender dysphoria or if it describes something new

There is some controversy over whether what is described as rapid onset of gender dysphoria, particularly in natal females, falls under the existing definition of late-onset or adolescent-onset gender dysphoria or whether it represents a new kind of development or presentation. This controversy might be a false dichotomy because both might be true. Although recent observations of adolescents and young adults who are predominantly natal female having a sudden onset of gender dysphoria symptoms beginning during or after puberty might technically fall under the existing definitions and criteria for adolescent and adult gender dysphoria [2], the substantial change in the demographics of patients presenting for care, the inversion of the sex ratio with disproportionate increase in adolescent natal females [3–5], and the new phenomenon of natal females exhibiting adolescent-onset and late-onset gender dysphoria [6–8] signal that something new may be happening as well. These changes may indicate that there are new etiologies leading to gender dysphoria and it is unclear, particularly without research about these new populations, whether gender dysphoria in this context has the same outcomes, desistence and persistence rates, and response to treatment as the gender dysphorias that have been previously studied.

Expanded discussion of qualitative analyses

Because this is a descriptive, exploratory study into a new topic with very little existing data, the addition of the qualitative analysis of two questions in addition to the quantitative analysis allowed for a greater depth of information to be used in the development of hypotheses. A grounded theory approach was selected as the strategy of choice for handling the qualitative data. There were two reviewers consisting of a professor with a PhD degree and expertise in qualitative methods (MM) [9] and the author (LL) who holds an MD and MPH degree, and has published both qualitative and quantitative research papers [10–11]. Each reviewer independently read and re-read the open-text responses in an iterative process to identify major themes arising from the data. Once each reviewer independently listed major themes and coded the open-text responses according to those themes, both reviewers compared notes to collaboratively revise and refine the major themes identified. Once an agreed-upon final list of themes was developed, attention was turned back to the data to code the open-text response with the final list of themes. After this task was completed, LL selected salient quotes to reflect each major theme, shared the quotes with MM, and both discussed collaboratively until agreement for the final list of major themes and associated quotes was reached. The incorporation of both the qualitative and quantitative analysis allowed for a more vivid picture of parent perspectives about the friendship group dynamics and behaviors and clinician interactions than could have been obtained from just one type of analysis.

Clarification of study design, methods, and related limitations

As mentioned in the article, the study design of this research falls under descriptive research: as such, it did not assign an exposure, there were no comparison groups, and the study's output was hypothesis-generating rather than hypothesis-testing [12]. Descriptive studies often represent a first inquiry into an area of research and the findings of descriptive studies are used to generate new hypotheses that can be tested in subsequent research [12–13]. Because of the known limitations of descriptive studies, claims about causal associations cannot be made [12], and there were none made in the article. The conclusions of the current study are that the findings raise certain hypotheses and that more research is needed. Simple descriptive metrics to describe the quantitative characteristics of a sample in a descriptive study are the appropriate measures to use in this study. Additionally, because the data were collected at one point in time, no claims of cause and effect can be made.

All research methods have advantages and limitations. Obtaining information from parents (and guardians) about the health and well-being of children and adolescents is an established method of research [14]. Parental report, used elsewhere and in this study, offers the advantages of collecting data from adults who are knowledgeable about the child, who are able and willing to complete research activities such as detailed surveys, and who can provide details that are not available by other methods. Limitations of parental report include information that parents may not be aware of and parental biases. Anonymous surveys, used elsewhere and in this study, are advantageous for topics that might be stigmatized and can allow participants to be more honest in their responses but introduce the limitation that the researcher cannot verify the identity and experiences of the participants. The use of targeted recruitment and convenience samples, used elsewhere and in this study, offers the benefit of connecting with hard-to-reach populations but introduces limitations associated with selection bias that can subsequently be addressed by further studies. For the current study, selection bias may have resulted in findings that are more positive or more negative than would be found in a larger and less self-selected population. Subsequent studies should address these issues.

Updated Information about recruitment

Concerns were raised that this study only posted links to the recruitment information on selected sites that are viewed as being unsupportive of transition. However, announcements about the study included requests to distribute the recruitment information and link, and because information about where the participants encountered the announcement was not collected, it is not known which populations were ultimately reached. It has come to light that a link to the recruitment information and research survey was posted on a private Facebook group perceived to have a pro-gender-affirming perspective during the first week of the recruitment period (via snowball sampling). This private Facebook group is called "Parents of Transgender Children" and has more than 8,000 members. This means that parents participating in this research may have viewed the recruitment information from one of at least four sites with varied perspectives. Specifically, three of the sites that posted recruitment information expressed cautious or negative views about medical and surgical interventions for gender dysphoric adolescents and young adults and cautious or negative views about categorizing gender dysphoric youth as transgender. And, one of the sites that posted recruitment information is perceived to be pro-gender-affirming. The rest of the Correction notice will refer to recruitment from the four sites that are known to have posted the survey in the first week of recruitment: 4thwavenow, transgendertrend, Youth Trans Critical Professionals, and Parents of Transgender Children.

Parental approaches to gender dysphoria and views on medical interventions

To oversimplify parental approaches as simply "accepting" or "rejecting" misrepresents the range of responses and complexity of approaches that parents take when addressing the needs of their gender dysphoric children. Parental approaches are complex and cover many variables. For example, one parental approach might be to affirm the child as a person, support gender nonconformity, support gender exploration, support mental health evaluation and treatment as needed, support the exploration of potential underlying causes for the dysphoria while expressing caution about medical interventions. Another approach might be to affirm the child's newly declared gender identity, support gender nonconformity, support a liberal approach to medical intervention while expressing caution about mental health evaluation and caution about the exploration of potential underlying causes for the dysphoria. To categorize the former as "rejecting" and the latter as "accepting" would be inaccurate.

This study recruited participants based on whether participants thought their child exhibited a sudden or rapid onset of gender dysphoria beginning during or after puberty and did not recruit based on parental beliefs about what types of approaches toward gender dysphoric AYAs are best. Although one of the sites posting recruitment information might be considered to hold a pro-gender affirming perspective and three sites might be considered to hold a cautious or even negative perspective about medical or surgical interventions, the site where a participant first heard about the study may not be an accurate reflection of their beliefs and whether they endorse or disagree with the content of the websites. Data about where participants first heard about this study were not collected. Future studies should seek a wider array of websites to post recruitment information, recruit from clinicians with varied approaches to gender dysphoria, and ask specific questions about parental beliefs regarding their approach to their child's gender dysphoria, including: whether parents support or don't support gender exploration, gender nonconformity, mental health

evaluation and treatment, exploration of potential underlying causes for dysphoria, non-heterosexual sexual identity, and whether they hold a liberal, cautious or negative view about the use of medical and surgical interventions for gender dysphoric youth. Exploration about what types of affirmation are endorsed by parents including affirmation of the child as a person and affirmation of the child's gender identity would also be valuable.

Expanded discussion about limitations and biases

Regarding the reporting of gender dysphoria, an absence of childhood gender dysphoria and whether the AYA was gender dysphoric at the time of survey completion were based on parent report of whether certain indicators of gender dysphoria were observed prior to puberty or at the time of the survey. These determinations were not diagnoses made by clinicians. Three of the indicators listed in the DSM-5 include information that a parent might not have access to (unless the child told them directly) [2], and therefore answers based on parent perceptions may not accurately reflect the experiences or traits of the AYAs themselves. However, the other five indicators include readily observable behaviors and preferences that would seem difficult for a parent not to notice such as: strong preference or strong resistance to wearing certain kinds of clothing; strong preference or strong rejection of specific toys, games and activities; and strong preference for playmates of the other gender [2]. It is possible that a parent could have ignored some of these indicators, though other people in the child's life may have observed them. To improve the reliability of this measure, future studies should include evaluation from clinicians with input from parents, AYAs and from third party informants such as teachers, pediatricians, mental health professionals, babysitters, and other family members who knew the youth during childhood to verify the whether the readily observable behaviors and preferences were present or absent during childhood.

For a clinician to make a diagnosis of gender dysphoria in childhood, a child would need to exhibit at least six of the eight indicators. Given that 97.6% of the participants reported 2 or fewer readily observable indicators, even if hypothetically all participants incorrectly under-reported all three of the subtler indicators, 97.6% would still have fewer than six indicators. So, although no clinical evaluation was performed and a clear presence or absence of a diagnosis cannot be verified, given the reports of the easily observed behaviors and preferences, it can be said that it would be very unlikely for these AYAs to have met criteria for childhood gender dysphoria if they had seen a clinician for an evaluation.

There is expected variation in how objective parents can be about their own children. Some individual biases may limit the objectivity of parents. This descriptive study was not designed to explore or measure the objectivity of participants. Participants may have first learned about this study from one of four (or more) sites described previously where recruitment information was posted. It is possible that exposure to websites that take a cautious or negative approach to transition during adolescence and young adulthood and exposure to websites that take a pro-gender-affirming approach might influence how parents report about their children's experiences. There have not been any studies to determine if parents who seek information from online sites in general, don't seek information from online sites, or seek information from specific online sites, including the four sites noted for this study, differ in their ability to provide objective assessments of their children. However, if there were an excess of participants who, compared to other parents who take surveys reporting on their children, were less able to be objective about their children, it could limit some of the findings of the study, particularly for findings that are more interpretive rather than the findings that are more concrete.

The research survey did not specifically ask whether parents supported their AYAs' exploration of gender identity, so whether and what numbers of participants supported their child's exploration of gender identity is unknown. However, if there were an excess of parents who did not support the exploration of gender identity, it could potentially result in higher reports of declining mental health. The parents' perception that their child's mental health and the parent-child relationship were worse after the child announced a transgender-identification could be due to several variables such as conflict between parent and child, maladaptive coping mechanisms, or worsening psychiatric issues unrelated to gender. The trajectories for adolescent-onset gender dysphoria are not well understood and additional research is desperately needed.

There are many ways that parents can provide support for their child which include: affirming them as a unique and valuable person and as a loved member of the family; supporting their emotional and financial needs; supporting them in pursuing their interests; supporting them to develop the skills needed for self-sufficiency; supporting their choices of gender nonconforming clothing and interests; supporting their exploration of their identity; and supporting them in their critical thinking skills. Parental support is multifaceted and should not be oversimplified into a binary of whether a parent agrees or disagrees with a specific medical course. This study was not designed to measure different types of support provided by parents or levels of support. If there were an excess of parents who were unsupportive of their children, it might affect some of these initial findings. The nature and extent of parental support—including the many different ways that parents can support their children in becoming healthy, self-sufficient adults—is well worth further study.

Clarification of Fig 1

The purpose of Fig 1 was to provide the reader with a quick sense of what kinds of advice can be found and shared on Reddit and Tumblr. One example includes an excerpt from a publicly available Tumblr blog that posted a list of purported indirect signs of gender dysphoria. This excerpt is indeed an example of advice that can be found on Tumblr. Note, however, that the excerpted Tumblr post itself does not reflect the full content of the original blog it refers to, nor does the excerpt in Fig 1. The original blog is titled, "'That was dysphoria?' 8 signs and symptoms of indirect gender dysphoria" [15].

Discussion of the ICD-11 change from "gender dysphoria" to "gender incongruence"

The ICD-11 will go into effect in January 2022, and, with this change, the new diagnosis of "gender incongruence" will replace "gender dysphoria." Because the current descriptive, exploratory study raises hypotheses about factors that may contribute to the onset and/or expression of gender dysphoria and concludes that more research is needed, it is unlikely that the change in diagnostic criteria will appreciably change the conclusion of the study, although the terminology may become outdated.

Supporting information

S1 File. PDF of the original article version that was published on August 16, 2018 (two figures removed due to copyright restrictions).
https://doi.org/10.1371/journal.pone.0214157.s001
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Do Clinical Data from Transgender Adolescents Support the Phenomenon of "Rapid Onset Gender Dysphoria"?

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Although emergence of gender dysphoria at puberty is long established, a distinct pathway of rapid onset gender dysphoria was recently hypothesized based on parental data. Using adolescent clinical data, we tested a series of associations that would be consistent with this pathway, however, our results did not support the rapid onset gender dysphoria hypothesis. *(J Pediatr 2022;243:224-7).*

Puberty has long been understood as one period when gender dysphoria often first emerges.[1] Although most transgender (trans) older adolescents and adults report needing gender-affirming medical care (hormones and/or surgeries), and also report having been aware of their gender at young ages,[2] only a small proportion receive gender-affirming care as adolescents. Use of hormonal suppression with a gonadotropic-releasing hormone agonist, and hormones such as estrogen and testosterone therapies in trans and gender-diverse adolescents is supported by the American Academy of Pediatrics, the Pediatric Endocrine Society, the Endocrine Society, and the World Professional Association for Transgender Health.[1,3-5] Referrals to adolescent gender clinics have increased internationally, particularly among those assigned female at birth.[6-9]

In 2018, a phenomenon of rapid onset gender dysphoria was hypothesized as a distinct pathway involving social contagion among youth vulnerable due to mental or neurodevelopmental disorders,[10-12] raising public concerns regarding potential for later regret following gender-affirming medical care. This discussion has occurred primarily in the context of data from a single online parental survey.[10,11] Although this parental study has generated controversy,[13] methodologic and social critique,[12,14,15] and calls for additional research,[16,17] its hypotheses have not yet been tested on data from youth themselves. Specifically, rapid onset gender dysphoria is hypothesized as a phenomenon in youth with gender dysphoria emerging at or after puberty, socially influenced through peer contagion, and with contributing factors including poor mental health, neurodevelopmental disabilities, parent-child conflict, and maladaptive coping strategies.[10,11]

If the rapid onset gender dysphoria hypothesis indeed characterizes a distinct clinical phenomenon, and these youth access referrals for hormone suppression or gender-affirming hormones, then we would expect to see differentiation within clinical samples between those with more-recent (ie, rapid-onset) vs more-remote knowledge regarding their gender. Based on the published hypothesis,[10] we would expect more recent gender knowledge to be associated with self-reported mental health measures, mental health and neurodevelopmental disability diagnoses, behaviors consistent with maladaptive coping (eg, self-harm), support from online and/or transgender friends but not parents, and lesser gender dysphoria. We aim to test these hypotheses.

Methods

Baseline data (2017-2019) from the Trans Youth CAN! Cohort included pubertal/postpubertal adolescents age <16 years attending a first referral visit for hormone suppression or gender-affirming hormones at 10 Canadian medical clinics that provide specialized gender-affirming care to adolescents through a range of different care models. Ethics approval was received from all study sites. Years gender was known was missing for 1 participant (excluded), for a final sample of n = 173. Methods and measures are described in detail elsewhere.[18]

Self-reported measures were obtained from baseline interviewer-administered adolescent surveys,[19] and diagnoses from baseline clinical records.[20] Recent gender knowledge was coded by subtracting age in years from age adolescents self-reported they "realized your gender was different from what other people called you." As ages were whole numbers, a difference of 1 could indicate <1 year to just under 2 years. Values ≤1 were coded as recent gender knowledge, with an alternate definition (values ≤2) for sensitivity analysis. Mental health symptoms were assessed with the Overall Anxiety Severity and Impairment Scale,[21] the Modified Depression Scale,[22] and the Kessler-6 scale for psychological distress.[23] Mental health diagnoses extracted from chart included anxiety, depression, personality disorder, eating disorder, and neurodevelopmental disorder diagnoses

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*List of additional members of the Trans Youth CAN! Study Group is available at www.jpeds.com (**Appendix**).

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included autism, obsessive compulsive disorder, or attention deficit hyperactivity disorder. Gender dysphoria symptoms were assessed using the Trans Youth CAN! Gender Distress Scale.[24] Self-reported mental health behaviors included self-harm, substance use, and suicidal behavior. Three measures captured social connections to online and trans communities: having gender-supportive online friends was coded if adolescents reported online friends who knew their gender and were "very supportive," and having online or trans friends as general sources of support was indicated in checklist items. Parental support was coded if youth indicated all biological/step/foster parents were "very supportive" of their gender identity or expression.

Statistical analyses were conducted using SAS v 9.4.1 (SAS Institute, Inc), weighted to account for clinics' different recruitment periods due to staggered start dates, to improve generalizability.[18] For analyses of associations between recency of gender knowledge and hypothesized correlates, a series of multiple regressions was conducted, with recency as the independent variable of interest, controlling for age and sex assigned at birth. Linear regressions were used for continuous dependent variables (eg, psychometric scales). For dichotomous dependent variables, modified Poisson regression with robust variance estimation was used.[25] As "rapid-onset" has not been precisely defined, we conducted a sensitivity analysis repeating these analyses using the alternate (value ≤2) definition of recent gender knowledge.

Results

Recency of gender knowledge is presented in the **Figure**, results of hypothesized associations (recency value ≤ 1) in **Table I**, and variable means and frequencies in **Table II** (available at www.jpeds.com). Controlling for age and sex assigned at birth, recent gender knowledge was not significantly associated with depressive symptoms, psychological distress, past diagnoses with mental health issues or neurodevelopmental disorders, gender dysphoria symptoms, self-harm, past-year suicide attempt, having gender-supportive online friends, general support from online friends or transgender friends, or gender support from parents. Recent gender knowledge was associated with lower scores on anxiety severity/impairment (b = −3.272; 95% CI −5.172, −1.373), and lower prevalence of marijuana use (prevalence ratio = 0.11; 95% CI 0.02, 0.82), counter to hypothesized directions of effect. For sensitivity analysis using the alternate (value ≤2) definition of recent gender knowledge, we found all results substantively the same in statistical significance and direction of effect, except past-year marijuana use, which now only approached statistical significance ($P = .0677$).

Discussion

We did not find support within a clinical population for a new etiologic phenomenon of rapid onset gender dysphoria during adolescence. Among adolescents under age 16 years seen in specialized gender clinics, associations between more recent gender knowledge and factors hypothesized to be involved in rapid onset gender dysphoria were either not statistically significant, or were in the opposite direction to what would be hypothesized. This putative phenomenon was posited based on survey data from a convenience sample of parents recruited from websites,[10] and may represent the perceptions or experiences of those parents, rather than of

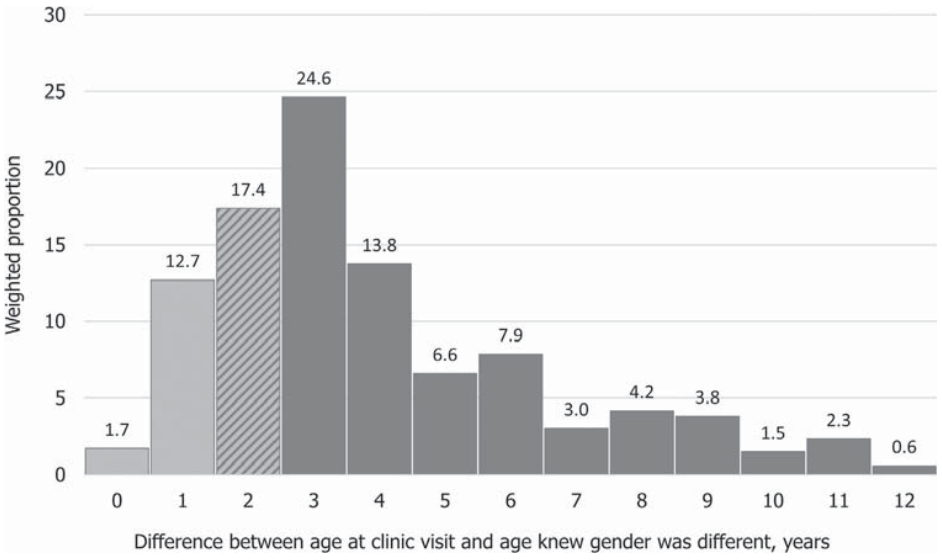

Figure. Recency of gender knowledge among adolescents age <16 years referred to Canadian clinics for hormone suppression or gender-affirming hormones (n = 173). Age at which knew gender was different was subtracted from current age in years; thus, "2 years" could range from more than 1 year to less than 3 years. Lighter gray represents recent gender knowledge in this analysis, with a sensitivity analysis also including the patterned bar.

Table I. Associations between short-term awareness of gender and variables hypothesized to be associated with rapid-onset gender dysphoria, controlling for age and sex assigned at birth

Dependent variables	B*	SE	*P*	PR*	95% CI†
Mental health scales					
Anxiety severity/impairment (OASIS)	−3.272	0.961	.0008		(−5.172, −1.373)
Depressive symptoms (MDS)	−1.276	0.845	.1328		(−2.944, 0.392)
Psychological distress (K6)	−1.156	1.060	.2771		(−3.248, 0.936)
Record of diagnosis with mental health disorder‡	−0.509	0.315	.1059	0.60	(0.32, 1.11)
Record of diagnosis with neurodevelopmental disorder§	0.066	0.362	.8563	1.07	(0.52, 2.17)
Gender dysphoria/distress (TYC-GDS)	−0.193	0.122	.1139		(−0.434, 0.047)
Mental health related behaviors					
Self-harm, past year	−0.052	0.191	.7833	0.95	(0.65, 1.38)
Marijuana use, past year	−2.178	1.010	.0310	0.11	(0.02, 0.82)
Past-year suicide attempt	−0.592	0.785	.4505	0.55	(0.12, 2.58)
Social connection indicators¶					
Reports having online friends supportive of gender	−0.050	0.157	.7505	0.95	(0.70, 1.29)
Indicates online friends as source of general support	−0.223	0.286	.4366	0.80	(0.46, 1.40)
Indicates trans friends as source of general support	−0.049	0.298	.1016	0.61	(0.34, 1.10)
All parents supportive of gender identity/expression	−0.004	0.202	.9836	1.00	(0.67, 1.48)

B, beta regression; *K6*, Kessler-6 Scale *MDS*, Modified Depression Scale; *OASIS*, Overall Anxiety Severity and Impairment Scale; *PR*, prevalence ratio; *TYC-GDS*, Trans Youth CAN! Gender Distress Scale.
*Estimates adjusted for age in years and sex assigned at birth.
†95% CIs for betas (for linear regressions) or PRs (for modified Poisson regressions).
‡Extracted from medical record: any diagnosis from clinic or referrer of anxiety, depression, personality disorder, eating disorder. Personality disorder diagnoses were uncommon (n = 2) and no youth had a record of eating disorder diagnosis.
§Extracted from medical record: any diagnosis from clinic or referrer of attention deficit hyperactivity disorder, obsessive compulsive disorder, or autism.
¶Hypothesized by other authors based on a survey of parents recruited from websites generally unsupportive of gender-affirming care.[10]

adolescents, particularly those who may enter into clinical care. Similar analyses should be replicated using additional clinical and community data sources. Our finding of lower anxiety severity/impairment scores in adolescents with more recent gender knowledge suggests the potential for longstanding experiences of gender dysphoria (or their social complications) playing a role in development of anxiety, which could also be explored in future research. ■

The Trans Youth CAN! Study Team thank the trans youth and their families who have generously shared their time and experience with us. We acknowledge the contribution of the local site teams to participant recruitment, in particular the team of research assistants involved in data collection.

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50 Years Ago in *The Journal of Pediatrics*

What Changed the Prognosis of Juvenile Dermatomyositis?

Sullivan DB, Cassidy JT, Petty RE, Burt A. Prognosis in childhood dermatomyositis. J Pediatr 1972;80:555-63.

The addition of systemic corticosteroids to the treatment of juvenile dermatomyositis played a pivotal role in changing the outcome of this disease. This commentary published 50 years ago summarized the demographic, clinical, laboratory, pathology, treatment, and outcome of 18 children with dermatomyositis seen between 1960 and 1969 in a single center. The medical treatment consisted of systemic corticosteroids with tapering over 2 years. In a previous classic report from 1964,[1] on which we wrote a commentary in 2014,[2] only 33% were treated with corticosteroids. The outcomes were grim: one-third died, another one-third remained crippled, and only one-third recovered completely. However, in this study merely 8 years later, no deaths from dermatomyositis were recorded. Seventeen of the 18 children were functionally independent after treatment, but 8 of 18 developed calcinosis. Four patients had residual skin scaring, 4 developed mild joint contractures, and 6 had muscle atrophy. It is important to note that most of the cases in this series (13/18) were mild and monophasic, and only 5 patients had dyspnea or dysphagia indicative of a more severe disease, thus contributing to the good prognosis.

Modern aggressive therapy includes corticosteroid-sparing medications. Methotrexate is given as first-line treatment together with corticosteroids. Other medications for severe or chronic disease include intravenous immunoglobulin, calcineurin inhibitors, cyclophosphamide, and biologic modifiers (rituximab and tumor necrosis factor inhibitors). Janus kinase inhibitors have shown promise. Overall, mortality has decreased to 2.5%. However, even today, between 30% and 40% of the patients manifest a chronic disease course with functional impairments and develop calcinosis, and they require long-term immunosuppressive therapy with many potential complications.[3] Thus, despite the improvement in prognosis, there is a still a long way to optimize treatment of this rare disease. Precision medicine, using specific myositis autoantibodies and analysis of immune pathways in individual patients, may further improve the outcome of our patients.[3] In addition, early diagnosis and treatment are key!

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Appendix

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Table II. Weighted frequencies or means for sociodemographic and study variables (n = 173)

Variables	Value
Age, n ($\%_{weighted}$)	
10-11 y	17 (8.5)
12-13 y	37 (22.6)
14-15 y	119 (68.9)
Ethnoracial background,* n ($\%_{weighted}$)	
Indigenous	33 (18.4)
Nonindigenous visible minority†	10 (6.6)
Nonindigenous white	128 (75.0)
Immigration background, n ($\%_{weighted}$)	
1 or more immigrant parent	126 (28.7)
No immigrant parents	44 (71.3)
Living environment, n ($\%_{weighted}$)	
City	87 (55.2)
Suburb	59 (33.9)
Rural	27 (10.9)
Gender identity, n ($\%_{weighted}$)	
Male or primarily a boy	125 (75.7)
Female or primarily a girl	32 (15.9)
Nonbinary‡	14 (8.3)
Mental health scales, $mean_{weighted}$ (SD)	
Anxiety severity/impairment (OASIS)	8.842 (4.548)
Depressive symptoms (MDS)	15.077 (4.030)
Psychological distress (K6)	10.746 (5.100)
Record of diagnosis with mental health disorder,§ n ($\%_{weighted}$)	92 (51.6)
Record of diagnosis with neurodevelopmental disorder,¶ n ($\%_{weighted}$)	44 (25.9)
Gender dysphoria/distress (TYC-GDS), $mean_w$ (SD)	4.048 (0.557)
Mental health related behaviors, n ($\%_{weighted}$)	
Self-harm, past year	110 (67.9)
Marijuana use, past year	29 (20.0)
Past-year suicide attempt	24 (16.9)
Social connection indicators,** n ($\%_{weighted}$)	
Reports having online friends supportive of gender	109 (69.9)
Indicates online friends as source of general support	79 (49.3)
Indicates trans friends as source of general support	92 (55.8)
All parents supportive of gender identity/expression	109 (61.8)

K6, Kessler-6 Scale; *MDS*, Modified Depression Scale; *OASIS*, Overall Anxiety Severity and Impairment Scale; *TYC-GDS*, Trans Youth CAN! Gender Distress Scale.

*Coded to match Statistics Canada categories of Indigenous, visible minority, and white. Nonwhite, nonindigenous ethnoracial backgrounds were indicated by the following numbers of participants: 6 Black Canadian or African American, 2 Black African, 4 Latin American, 4 East Asian, 1 Indo-Caribbean, 3 Black Caribbean, 1 Middle Eastern, and 1 Southeast Asian (participants could indicate more than 1).

†The Canadian government defines visible minorities as "persons, other than Aboriginal peoples, who are non-Caucasian in race or nonwhite in color."[26]

‡Response option was "nonbinary or something other than male or female."

§Extracted from medical record: any diagnosis from clinic or referrer of anxiety, depression, personality disorder, eating disorder. Personality disorder diagnoses were uncommon (n = 2) and no youth had a record of eating disorder diagnosis.

¶Extracted from medical record: any diagnosis from clinic or referrer of attention deficit hyperactivity disorder, obsessive compulsive disorder, or autism.

**Hypothesized by other authors based on a survey of parents.[10]

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN; ZACHARY MARTELL; and **BRIAN MCNEMAR,** Individually and on behalf of all others similarly situated,

Plaintiffs,

Civil Action No. 3:20-cv-00740
Hon. Robert C. Chambers, Judge

v.

WILLIAM CROUCH, in his official capacity as Cabinet Secretary of the West Virginia Department of Health and Human Resources; **CYNTHIA BEANE,** in her official capacity as Commissioner for the West Virginia Bureau for Medical Services; **WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES; TED CHEATHAM,** in his official Capacity as Director of the West Virginia Public Employees Insurance Agency; and **THE HEALTH PLAN OF WEST VIRGINIA, INC.,**

Defendants.

DEFENDANTS' RESPONSE TO PLAINTIFF'S SECOND SET OF INTERROGATORIES TO DEFENDANTS WILLIAM CROUCH, CYNTHIA BEANE, AND WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES

INTERROGATORIES

8. Identify all conditions, diagnostic codes, or instances where coverage for hysterectomy and/or oophorectomy surgical procedures is available under the Health Plans offered through West Virginia's Medicaid Program. Include in that identification:

a. Diagnostic code(s);

b. Procedure code(s);

c. Medical necessity criteria.

RESPONSE: Objection, this Interrogatory seeks information regarding procedures for which Plaintiff Fain is not seeking relief. Therefore, this request is not relevant, is not proportional to the matters in issue, and is outside the scope of permissible discovery. Without waiving this objection, multiple factors go into the review of any particular request, including past medical history, surgical history, and diagnosis. In addition, we have requested documents which are used as part of the review process and these will be supplemented upon receipt.

9. Identify all conditions, diagnostic codes, or instances where coverage for vaginoplasty procedures is available under the Health Plans offered through West Virginia's Medicaid Program. Include in that identification:

a. Diagnostic code(s);

b. Procedure code(s);

c. Medical necessity criteria.

RESPONSE: Objection, this Interrogatory seeks information regarding procedures for which Plaintiff Fain is not seeking relief. Therefore, this request is not relevant, is not proportional to the matters in issue, and is outside the scope of permissible discovery. Without waiving this objection, multiple factors go into the review of any particular request, including past medical history, surgical history, and diagnosis.

10. Identify all conditions, diagnostic codes, or instances where coverage for orchiectomy, penectomy, and/or phalloplasty procedures is available under the Health Plans offered through West Virginia's Medicaid Program. Include in that identification:

    a. Diagnostic code(s);

    b. Procedure code(s);

    c. Medical necessity criteria.

RESPONSE: Objection, this Interrogatory seeks information regarding procedures for which Plaintiff Fain is not seeking relief. Therefore, this request is not relevant, is not proportional to the matters in issue, and is outside the scope of permissible discovery. Without waiving this objection, multiple factors go into the review of any particular request, including past medical history, surgical history, and diagnosis.

11. Taking necessary steps to comply with applicable privacy laws, for each year since 2016 through the present identify the number of Health Plan participants who have submitted one or more claims with a diagnosis code for Gender Dysphoria or Gender Incongruence. This includes, but is not limited to, the following diagnosis: F64.0, Transsexualism (ICD-10-CM); F64.2, Gender identity disorder of childhood (ICD-10-CM); F64.8, Other gender identity disorders (ICD-10-CM); F64.9, Gender identity disorder, unspecified(ICD-10-CM); HA60, Gender incongruence of adolescence or adulthood (ICD-11); and HA61, Gender incongruence of childhood (ICD-11).

RESPONSE: Upon information and belief:

2016 30 members
2017 50 members
2018 243 members
2019 439 members
2020 602 members
2021 (through 9/30) 686 members.

WILLIAM CROUCH,
CYNTHIA BEANE, and
WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES,
BUREAU FOR MEDICAL SERVICES,
By counsel

/s/Kimberly M. Bandy
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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN; ZACHARY MARTELL; and **BRIAN MCNEMAR,** Individually and on behalf of all others similarly situated,

Plaintiffs,

Civil Action No. 3:20-cv-00740
Hon. Robert C. Chambers, Judge

v.

WILLIAM CROUCH, in his official capacity as Cabinet Secretary of the West Virginia Department Of Health and Human Resources; **CYNTHIA BEANE,** in her official capacity as Commissioner for the West Virginia Bureau for Medical Services; **WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES; TED CHEATHAM,** in his official Capacity as Director of the West Virginia Public Employees Insurance Agency; and **THE HEALTH PLAN OF WEST VIRGINIA, INC.**

Defendants.

CERTIFICATE OF SERVICE

Now come Defendants William Crouch, Cynthia Beane and West Virginia Department of Health and Human Resources, by counsel, and do hereby certify that on the 25th day of October, 2021, a true and exact copy of **DEFENDANTS' RESPONSE TO PLAINTIFF'S SECOND SET OF INTERROGATORIES TO DEFENDANTS WILLIAM CROUCH, CYNTHIA BEANE, AND WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES** was served on counsel via electronic means as follows:

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

B.P.J. by her next friend and mother, HEATHER JACKSON,

Plaintiff,

vs. No. 2:21-cv-00316

WEST VIRGINIA STATE BOARD OF EDUCATION, HARRISON COUNTY BOARD OF EDUCATION, WEST VIRGINIA SECONDARY SCHOOL ACTIVITIES COMMISSION, W. CLAYTON BURCH in his official capacity as State Superintendent, DORA STUTLER, in her official capacity as Harrison County Superintendent, and THE STATE OF WEST VIRGINIA,

Defendants,

LAINEY ARMISTEAD,

Defendant-Intervenor.

VIDEOTAPED DEPOSITION OF
STEPHEN LEVINE
Wednesday, March 30, 2022
Volume I

Reported by:
ALEXIS KAGAY
CSR No. 13795
Job No. 5122884
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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

B.P.J. by her next friend and mother, HEATHER JACKSON,

Plaintiff,

vs.

No. 2:21-cv-00316

WEST VIRGINIA STATE BOARD OF EDUCATION, HARRISON COUNTY BOARD OF EDUCATION, WEST VIRGINIA SECONDARY SCHOOL ACTIVITIES COMMISSION, W. CLAYTON BURCH in his official capacity as State Superintendent, DORA STUTLER, in her official capacity as Harrison County Superintendent, and THE STATE OF WEST VIRGINIA,

Defendants,

LAINEY ARMISTEAD,

Defendant-Intervenor.

Remote videotaped deposition of STEPHEN LEVINE, Volume I, taken on behalf of Plaintiff, with all participants appearing remotely, beginning at 9:09 a.m. and ending at 5:46 p.m. on Wednesday, March 30, 2022, before ALEXIS KAGAY, Certified Shorthand Reporter No. 13795.

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Also Present:

MITCH REISBORD - VERITEXT CONCIERGE

Videographer:

KIMBERLEE DECKER

Q Why don't you give me your estimate of how many prepubertal children you've ever seen as patients, and then we can ask more questions.

A I would say a handful. Six.

Q And how many of those -- of those approximately six did you see more than one time? 11:15:35

A I can't recall one.

Q And then I'll ask the same question about adolescents, which I'll mean minors from puberty through being a minor. 11:16:00

How many adolescent patients have you had in your career, approximately?

A 50.

Q And how many of those have you seen more than once? 11:16:14

A Most.

Q And were most of those, of the adolescent patients you've seen, late adolescence?

A No.

Q Turning back to your CV, you list yourself -- you're listed as a clinical professor at Case Western Reserve University School of Medicine; correct? 11:16:27

A Yes.

Q Do you work at Case Western Reserve University School of Medicine full-time? 11:16:51

three months because I'm part of a committee to plan the curriculum on sexuality and gender.

Speaking of education, the university -- other -- other institutions also asked me to teach about this subject. And on August -- on April 7th, I'm going to Akron to teach -- or virtually I'm going to teach a three -- a two-and-a-half-hour seminar. 12:07:39

And I forgot to mention to you before, and I'd like you to hear this, that when you were questioning me about my credentials or not having a certificate about -- in child psychiatry, you should know, I forgot to tell you that Cleveland Clinic, department of child psychiatry, and the University Hospitals, the department of child psychiatry, sends residents to be with me as part of their training in child development and child clinical issues, child and adolescent clinical issues. 12:07:57 12:08:18

So I think -- I just forgot to mention that.

Q Are you familiar with the University Hospitals' LGBTQ and gender care program? 12:08:48

A I'm aware that it exists, yes.

Q Have you ever talked to any clinicians in that practice?

A No one has ever talked to me in that practice. The only time I have interaction with them is when -- 12:09:00

if I present grand rounds, some of those people ask me a question. But they've never consulted me whatsoever in the formation of their clinic and in the ongoing work of their clinic.

Although, Cleveland Clinic has a very similar program, and they have called me up and -- for some advice sometimes. 12:09:20

But my -- my, quote, own University Hospitals' place I don't really think has any people from child psychiatry in it, but I'm not sure because they have kept me away. 12:09:38

Q What do you mean they have kept you away?

A Just what I explained. They have never communicated with me. It is -- you know, other people know me as being published in this area. You know, I think I've written 20 articles on this -- you know, I have 20 or so publications in this area. You would think that they would invite me or consult with me or ask me questions, but I think they recognized that they are part of what is called affirmative care and what I would say, rapidly affirmative care, and -- and they sense that I'm not so interested in rapid, that -- that I believe that -- that I have long believed that people who have this kind of dilemma need some patient time in talking about this matter. 12:09:54 12:10:18 12:10:45

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN and SHAUNTAE ANDERSON; individually and on behalf of all others similarly situated,

Plaintiffs,

v.

WILLIAM CROUCH, *et al.*,

Defendants.

CIVIL ACTION NO. 3:20-cv-00740
HON. ROBERT C. CHAMBERS

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF STEPHEN B. LEVINE, M.D.

TABLE OF CONTENTS

I. INTRODUCTION

The issue in this case is whether Defendants' policy of not providing insurance coverage for gender-confirming surgical care (the "Exclusion")[1] violates the Equal Protection Clause, Section 1557 ("Section 1557") of the Patient Protection and Affordable Care Act ("ACA" or "Affordable Care Act"), and the Medicaid Act's Comparability and Availability Requirements. Yet, Defendants have put forward an expert, Dr. Stephen Levine, whose opinions other federal courts have resoundingly dismissed. Moreover, Dr. Levine has not and cannot opine on the actual issue in this case. His opinions are (1) irrelevant because they are largely aligned with the relief Plaintiffs seek; (2) fail to create any material disputes of fact because the relevance of his opinions are outside the scope of the issue in this case and, regardless, cover topics the Fourth Circuit has already addressed; and (3) are unreliable, not based on scientific methodology, and devoid of probative value, thus risking unfair prejudice, confusion, undue delay and needless presentation of cumulative evidence. The Court should exclude Dr. Levine's opinions.[2]

II. LEGAL STANDARD

Federal Rule of Evidence 702 places "a special gatekeeping obligation" on a trial court to ensure that an expert's testimony is "relevant to the task at hand" and "rests on a reliable foundation." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993); *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021). The party offering the expert carries the burden of establishing admissibility by a preponderance of the evidence. *Cooper v. Smith & Nephew, Inc.*,

[1] To the extent Defendants omit coverage for other gender-confirming care, that is also part of the Exclusion. For example, as to puberty-delaying treatment, while Defendants have denied this care at least once, BMS's Medical Director agrees that it is "standard of care" for gender dysphoria, and Defendants have previously covered it. *See* Pls.' SJ Mem. at Pt. II(C), n.38.

[2] Expert Disclosure of Stephen B. Levine, M.D., signed February 18, 2022, is attached as Exhibit A to the concurrently filed Declaration of Carl S. Charles ("Charles Decl.").

259 F.3d 194, 199 (4th Cir. 2001). But "[t]he district court is the gatekeeper. It is an important role: 'Expert witnesses have the potential to be both powerful and quite misleading [;]" the court must "ensure that any and all scientific testimony … is not only relevant, but reliable." *Tyree v. Bos. Sci. Corp*., 54 F. Supp. 3d 501, 516 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014) citing *Cooper*, 259 F.3d at 199.

In determining whether the proposed expert is qualified, a trial court considers their "full range of experience and training." *Belk, Inc. v. Meyer Corp., U.S.,* 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (cleaned up). If the purported expert lacks the knowledge, skill, experience, training or education on the issue for which the opinion is proffered, the trial court must exclude the expert. *See, e.g., Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989); *Mod. Auto. Network, LLC v. E. All. Ins. Co.*, 416 F. Supp. 3d 529, 537 (M.D.N.C. 2019) (Biggs, J.), *aff'd*, 842 F. App'x 847 (4th Cir. 2021); *Tyree,* 54 F. Supp. 3d at 561. Even if the expert is deemed qualified, the trial court must consider the relevancy of the expert's testimony as "a precondition to admissibility." *Sardis,* 10 F.4th at 282 (cleaned up). Simply put, "if an opinion is not relevant to a fact at issue, Daubert requires that it be excluded." *Id*. at 281.

If deemed relevant, the trial court will inquire if the opinion is reliable, which focuses on "the principles and methodology" employed by the expert to assess whether it is "based on scientific, technical, or other specialized *knowledge* and not on belief or speculation." *Id*. at 281, 290 (cleaned up). When evaluating reliability, a court considers, among other things:

> (1) whether the expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4) whether the technique is generally accepted in the scientific community.

Id.; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149-150 (1999); *Daubert,* 509 U.S. at 593-94. While trial courts have "broad latitude" to determine reliability, they must engage

in the gatekeeping process and not simply "delegate the issue to the jury." *Sardis*, 10 F.4th at 281. Even when an expert relies upon their experience and training in forming opinions, "[p]roposed testimony must be supported by appropriate validation—i.e., 'good grounds' based on what is known." *Tyree,* 54 F. Supp. 3d at 526 (citing *Daubert* 509 U.S. at 590). An expert cannot purport to have "considered the scientific literature" in forming their opinions but be unable to provide scientific support for some opinions. *Id*. Even though an expert "has experience, he must still base his opinions on a reliable, scientific method." *Id*. ("[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method.").

Finally, because "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it…[T]he judge in weighing possible prejudice against probative force under Rule 403…exercises *more* control over experts than over lay witnesses." *Daubert,* 509 U.S. at 595 (cleaned up) (emphasis added). As such, "the importance of [the] gatekeeping function cannot be overstated." *Sardis*, 10 F.4th at 283 (cleaned up).

III. ARGUMENT

As a preliminary matter, Plaintiffs note other federal courts' decisive dismissal of Dr. Levine's opinions about transgender people and the treatment of gender dysphoria. This began several years ago with the holding in *Norsworthy v. Beard*, that "the Court gives very little weight to the opinions of Levine, whose report misrepresents the Standards of Care; overwhelmingly relies on generalizations about gender dysphoric prisoners, rather than an individualized assessment of Norsworthy; contains illogical inferences; and admittedly includes references to a fabricated anecdote." 87 F. Supp. 3d 1164, 1188 (N.D. Cal. 2015). This holding was echoed in *Edmo v. Idaho Dep't of Corr*., 358 F. Supp. 3d 1103, 1125-1126 (D. Idaho 2018) (vacated in part on other grounds in *Edmo v. Corizon, Inc.*, 935 F.3d 757 (9th Cir. 2019)) (holding that Dr. Levine

"is considered an outlier in the field of gender dysphoria" and gave "virtually no weight" to his opinions).

Dr. Levine's opinions were further diminished in *Hecox v. Little,* where the Court dismissed his opinion that "gender-affirming policies… are… harmful to transgender individuals," and instead "accept[ed] Plaintiffs' evidence regarding the harm forcing transgender individuals to deny their gender identity can cause." 479 F. Supp. 3d 930, 977 n.33 (D. Idaho 2020). And in just the last year alone, two more federal courts strongly discounted his proffered testimony by granting preliminary injunction motions against laws banning gender-confirming medical care and participation in school athletics, respectively, despite his testimony supporting those laws. *Brandt v. Rutledge*, 551 F. Supp. 3d 882 (E.D. Ark. 2021); *B. P. J.* v. *W. Va. State Bd. of Educ.*, 550 F. Supp. 3d 347 (S.D.W. Va. 2021). Against this backdrop, the deficiencies in Dr. Levine's opinions discussed below are all the more striking.

A. Many Of Dr. Levine's Opinions Will Not Help the Trier of Fact Because They Support Plaintiffs' Position.

Nearly all of Dr. Levine's opinions will not help the "trier of fact to understand the evidence or to determine a fact in issue," because, with very limited exception, he simply does not oppose the relief Plaintiffs seek. *Nease*, 848 F.3d 219, 229 (4th Cir. 2017) (cleaned up). For that reason, Dr. Levine's opinions do not "fit" with the facts relevant to resolving Plaintiffs' claims. *Bourne v. E.I. DuPont de Nemours & Co.*, 85 F. App'x 964, 966 (4th Cir. 2004).

Overwhelmingly, Dr. Levine's opinions and testimony are not contrary to the relief Plaintiffs seek in this case: that WV Medicaid participants with gender dysphoria receive coverage for gender-confirming surgery. Charles Decl., Ex. B at 86:25-87:19; 87:14-22; Ex. at C at 66:21-67:3; 69:18-70:2. Indeed, Dr. Levine testified that in just the last seven months, he has provided several letters of approval for gender-confirming surgeries for transgender people incarcerated at

Framingham, a correctional institution in Massachusetts. Charles Decl. Ex. B at 84:4-85:4. Dr. Levine has previously written similar letters for surgery in accordance with the medical community's widely accepted and authoritative guidance for transgender care, World Professional Association of Transgender Health ("WPATH") Standards of Care ("SOC"). Charles Decl., Ex. B. at 139:14-19; Ex. C at 55:13-17; 56:2-5; 112:16-21; 176:8-16; Ex. D at 1-100:15-22. He also recently testified that he does not provide such letters unless he has sufficiently informed his patients of possible risks and received a reasonable assurance that they understand. Charles Decl., Ex. C at 176: 8-16; 225:24-226:17. In fact, for almost fifty years, Dr. Levine's clinical practice has generally adhered to the WPATH SOC. Charles Decl. Ex. B at 136:8-11. And, as the WPATH's former Chairman of the SOC Committee, Dr. Levine helped to write Version 5 of the SOC, recognized his own writing in Version 7, and asked if he could help draft the forthcoming Version 8. Charles Decl., Ex. A at ¶67; Ex. B at 147:12-149:18. He testified at deposition in this case, and under oath previously, that he "is not advocating denying endocrine treatment or surgical treatment" to transgender people, a position he described as "draconian."[3]

Dr. Levine testified at deposition that he is not offering *any* opinions in this case about whether Defendants should have an exclusion in their Medicaid program for coverage of gender-confirming surgery. Charles Decl. Ex. B at 86:25-87:19. He also testified that he does not feel his

[3] Charles Decl., Ex. B 88:10-13; Ex. C at 73:4-7 ("Q: Is the worrisomeness about a patient's future health, is that a reason to ban all medical care for gender dysphoria? A: Absolutely not."); 84:21-85:1 ("Q: Given all those concerns you have, is that a reason to deny all medical interventions to people with gender dysphoria? A: No …."); 85:4-11 ("Q: Are those concerns you raised justifications in your mind for denying medical interventions to people who have gender dysphoria? A: You know, I'm not advocating denying endocrine treatment or surgical treatment."); 152:1-6 ("Q: Do you think because that study showed that some people committed suicide after gender affirming surgery that no patient should be able to access gender affirming surgery? A: That would be illogical"); 154:3-5 ("Q: But you're not recommending total bans on gender affirming surgery? A: I'm not recommending total bans."); 160:23-25 ("I did not say that gender affirming treatment in general should be stopped. I've never said that.").

"expertise extends to how the insurance industry works and how governments and legislatives work," nor "does he consider himself an expert" on whether Defendants' Exclusion should exist. Charles Decl., Ex. B at 87:14-22. These admissions contradict one of Dr. Levine's "key opinions" in his report, i.e., whether West Virginia's Medicaid Program should cover gender-confirming surgery, fundamentally undermining his credibility. Charles Decl., Ex. A at ¶10; Ex. B at 74:12-19. At bottom, Dr. Levine has repeatedly testified that he does not support banning gender-confirming medical care including surgery, which is the heart of Defendants' Exclusion. His opinions in this regard are thus consistent with the relief Plaintiffs seek and will not assist the trier of fact.

B. Certain Opinions Of Dr. Levine Have No Relevance To This Case Because They Address Issues Beyond The Scope Of The Dispute Or Have Already Been Addressed By The Fourth Circuit.

Dr. Levine's opinions fail to create any material disputes of fact because the relevance of Defendants' binding admissions refute his opinions. For example, Dr. Levine proposes to offer the opinion that "the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic and physiologic characteristics..." Charles Decl., Ex. A at ¶18. But this case is simply a dispute asking whether a state Medicaid plan's categorical exclusion of gender-confirming care for transgender Medicaid participants that is covered for cisgender Medicaid participants discriminates based on sex and transgender status. The Court need not resolve questions about whether it is "biologically attainable" for transgender people to become "complete men or women," or whether sex is a binary concept. *Id*. at ¶17. The Court here need only decide whether Defendants can deny the same kinds of treatments to transgender Medicaid participants that it affords to cisgender Medicaid participants. Defendants' own Rule 30(b)(6) witness, Commissioner Cynthia Beane, testified that individuals enrolled in the Medicaid Program

can, she assumes, change their sex identification marker in Medicaid records. Charles Decl., Ex. E at 119:17-120:11. Therefore, even Defendants take no position on the issues in Dr. Levine's report about the etiology of sex, and instead use participants' self-reported gender identity as evidence of sex designation for the purposes of WV Medicaid enrollment and coverage.

Dr. Levine also offers the opinion, supported only by anecdotal narrative articles, that "gender exploratory" therapy can and has led to a resolution of gender dysphoria. Charles Decl. Ex. A at ¶37. But Commissioner Beane also testified that she was aware of the concept of "conversion therapy" and that no one, including transgender children, should be subjected to "that therapy." Charles Decl. Ex. E at 157:14-23. Significantly, Dr. Levine admits in his report that "quality evidence proving long-term effectiveness of psychotherapy interventions" such as those he advocates "is missing." *Id.* at ¶160. Defendants thus disagree with Dr. Levine's opinion, rendering it irrelevant, and he further admits it has no scientific basis.

Dr. Levine's opinions also do not help this Court because Fourth Circuit precedent informs review of the relevant issues. *See Grimm v. Gloucester Cnty. Sch. Bd.* 972 F.3d 586, 595 (4th Cir. 2020); *Kadel v. N. C. State Health Plan for Tchrs. and State Emps.*, 12 F.4th 422, 427 (4th Cir. 2021). His attempts to disparage the credibility of the WPATH and diminish the SOC as ideological and unscientific are directly contrary to the Fourth Circuit's reasoning in *Grimm*:

> Fortunately, we now have modern accepted treatment protocols for gender dysphoria. Developed by the World Professional Association for Transgender Health (WPATH), the Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (7th Version 2012) (hereinafter "WPATH Standards of Care") represent the consensus approach of the medical and mental health community, Br. of Medical Amici 13, and have been recognized by various courts, including this one, as the authoritative standards of care, *see De'lonta v. Johnson*, 708 F.3d 520, 522–23 (4th Cir. 2013); *see also Edmo*, 935 F.3d at 769; *Keohane v. Jones*, 328 F. Supp. 3d 1288, 1294 (N.D. Fla. 2018), *vacated sub nom. Keohane v. Fla. Dep't of Corrs. Sec'y*, 952 F.3d 1257 (11th Cir. 2020). "There are no other competing, evidence-based standards that are accepted by any nationally or internationally recognized medical professional groups."

> *Edmo*, 935 F.3d at 769 (quoting *Edmo v. Idaho Dep't of Corr.*, 358 F. Supp. 3d 1103, 1125 (D. Idaho 2018)).

Grimm, 972 F.3d at 595-596. Further irreconcilable with available data and the consensus of the medical community, Dr. Levine suggests that the "high burden of mental illness" may be a "result" and/or "cause" of being transgender. Charles Decl., Ex. A at ¶35. The Fourth Circuit disagrees, reasoning that: "Being transgender is also not a psychiatric condition, and implies no impairment in judgment, stability, reliability, or general social or vocational capabilities." *Grimm*, 972 F.3d at 594 (cleaned up); *see also Kadel*, 12 F.4th at 427. Dr. Levine has previously testified at deposition that he believes that gender dysphoria, or being transgender, is a "product of other things," including possibly familial sexual abuse, distress over "their body changing," growing up in a single-parent home, or having an autism diagnosis. Charles Decl., Ex. C. at 154:5-8; 235:23-25; 137:10-13; 235:20-22; 235:17-20. The Fourth Circuit has also found that "[j]ust like being cisgender, being transgender is natural and is not a choice." *Kadel*, 12 F.4th at 427 (quoting *Grimm*, 972 F.3d at 594). Dr. Levine has previously admitted to practicing, and currently advocates for, the use of psychotherapy to "alleviate" gender dysphoria while withholding medical care,[4] but the Fourth Circuit has acknowledged that "mental health practitioners' attempts to convert transgender people's gender identity to conform with their sex assigned at birth did not alleviate dysphoria, but rather caused shame and psychological pain." *Grimm*, 972 F.3d at 595. Essentially, Fourth Circuit precedent renders much of Dr. Levine's testimony irrelevant to this case.

C. Dr. Levine's Opinions That Do Not Support Plaintiffs' Position Are Methodologically Unreliable and Unsupported by Science or Medicine.

Expert testimony should only be admitted if its methodology is sufficiently reliable. *Sardis*, 10 F.4th at 281. Dr. Levine's opinions fall far short of each prong of this reliability standard. Dr.

[4] Charles Decl., Ex. A at ¶37, ¶90

Levine admitted in his report and at deposition in this and other recent cases that theories upon which he relies lack *any* scientific support and have not been tested or subjected to peer review or publication. Charles Decl., Ex. A at ¶37, ¶160; Ex. B at 140:12-143:2, 145:19-25; Ex. C at 109:20-25; 116:4-7; 122:8-124:22; 131:11-132:1; 200:11-201:25. Even putting the *Daubert* reliability factors aside, although Dr. Levine claims his "experience" is sufficient foundation for his opinions, he fails to address how this purported experience leads to his conclusions and how such experience is reliably applied to the facts here. *See*, *e.g.*, *Cooper,* 259 F.3d at 200 (affirming the exclusion of an expert because he "asserted what amounted to a wholly conclusory finding based upon his subjective beliefs rather than any valid scientific method."); *Tyree,* 54 F. Supp. 3d at 526 (excluding an expert witness when the only support offered for an opinion was clinician's experience and not any reliable data); *SAS Inst., Inc. v. World Programming Ltd.,* 125 F. Supp. 3d 579, 589; *see also Nat'l Ass'n. for Rational Sexual Offense L. v. Stein*, No. 17-CV-53, 2021 WL 736375, at *3 (M.D.N.C. Feb. 25, 2021) (excluding expert where offering party failed to establish how expert's "experience leads to his conclusions nor how those experiences have been reliably applied to the facts").

1. Dr. Levine's Assertion that the WPATH SOC and Endocrine Society Guidelines Are Not the Authoritative Treatment Protocols for Gender Dysphoria Is Wrong.

Chief among Dr. Levine's many unreliable opinions is his assertion that the widely-accepted and utilized WPATH SOC and Endocrine Society Guidelines ("ESG") are not the authoritative treatment protocols for gender dysphoria. Seemingly contradicting *himself*, Dr. Levine has repeatedly testified, however, that he generally adheres to the WPATH SOC in his own clinical practice. Charles Decl., Ex. B at 136:8-11; Ex. C at 55:13-17; 56:2-5; 112:16-21; 176:8-16; 225:24-226:17; Ex. F at 29:10-18; 37:2-13; 47:22-49:3; 103:11-19. Nevertheless, Dr. Levine

attempts to undermine WPATH SOC by misrepresenting sources in his report and failing to include contrary information—undermining the admissibility and reliability of his opinions.

First, Dr. Levine alleges that the SOC are "very low quality and unfit tools for clinical decision-making," identifying one article by Dahlen et al. – but nowhere in that article does it characterize the WPATH SOC that way. Charles Decl., Ex. A at ¶21; Ex. G. The article concludes that the SOC are due for an update and acknowledges that evaluations of clinical practice guidelines in other medical areas including cancer, diabetes, pregnancy, and depression "tend to show room for improvement," and that "finding poor quality CPGs is not confined to this area of healthcare." Charles Decl., Ex. G at 8. In the same paragraph and without evidence, Dr. Levine makes a similar assertion about the ESG for treating gender dysphoria. Charles Decl., Ex. A at ¶21. Dr. Levine's report also mischaracterized the ESG's explanation of its "strong" versus "weak" recommendations related to gender-confirming care, something he admitted at deposition that he had no support for, reflected his own editorializing, and was not a quote from the Endocrine Society. *Id*. at ¶104; Charles Decl., Ex. B at 174:10-175:17

Second, Dr. Levine quotes from a *blog post* which mischaracterized comments from the incoming president of WPATH, Dr. Marci Bowers. Charles Decl., Ex. A at ¶23. Wholly absent from Dr. Levine's report was any acknowledgment of Dr. Bower's subsequent public statement released on her website that her comments were "taken out of context and used to cast doubt upon trans care," and her hope that those comments "will not be excerpted to weaponize ongoing attacks upon transgender persons." Charles Decl. Ex. H at 2. Third, Dr. Levine makes sweeping and inaccurate statements about WPATH SOC that other countries' protocols related to the treatment of gender dysphoria in transgender youth is evidence of a shift away from the WPATH SOC. Charles Decl., Ex. A at ¶¶22, 49. But again, Dr. Levine misrepresents even the content of non-peer

reviewed, non-scientific sources he uses to support this opinion. Both posts he cites to for this contention are from an advocacy group's website and plainly admit *in the text of the posts* that both Finland and Sweden allow youth to access medical interventions for the treatment of gender dysphoria, a fact Dr. Levine admitted at deposition. Ex. B at 106:4-108:8. Dr. Levine also acknowledged that the United Kingdom's Cass Review, which is currently underway, begins from the premise that some youth do experience gender dysphoria and will need clinical support and medical interventions, which are not prohibited in their health system. Charles Decl., Ex I; Ex. B at 191:20-192:16. Overwhelmingly, Dr. Levine's methodology and evidence for his opinions about the WPATH SOC do not meet the burden under *Daubert* or related standards articulated by this court for admissibility of expert witness testimony.

2. Dr. Levine's Opinions That Gender-Confirming Care Is Inadequate, Risky, and Without Lasting Benefit are Inaccurate and Unsupported.

Dr. Levine alleges that gender-confirming care is experimental, risky, and without lasting benefit. Charles Decl., Ex. A at ¶¶23, 39, 51, 118-122 This opinion cannot satisfy the reliability standard because Dr. Levine authorizes this care for his own patients and either ignores studies contrary to his belief or distorts their findings beyond the authors' explicit intentions or design. Significantly, he omits recent studies demonstrating that medical treatments for transgender adolescents and adults have favorable outcomes across many measures. Charles Decl., Ex. J. at ¶55. A plethora of studies also show that trans people experience pervasive stigma and discrimination, resulting in health disparities. But Dr. Levine omits any reference to those studies and instead implies that receiving gender-confirming care *causes* those disparities, such as increased risk of suicide and suicide attempts, relying most heavily on two articles which do not support this assertion. Charles Decl., Ex. A at ¶119-124. First, he relies on a study by Cecilia Dhejne, a scholar in the field who has publicly and specifically said Dr. Levine's assertion is a

mischaracterization of her work. Charles Decl., Ex. K at 65. Her study also does not support his assertion because *the study itself* states it is not designed to "address whether sex reassignment is an effective treatment or not." Charles Decl., Ex. L at 2. And when confronted at a recent deposition, he admitted the study design created a serious limitation in drawing any conclusions about the efficacy of the care. Charles Decl., Ex. C at 156:7-11. Dr. Levine makes similar implications in his report about the second study, Simonsen et al., suggesting that the article demonstrates higher death rates among people who received gender-confirming surgery. But again, the article states precisely the opposite, that "the present study design does not allow for determination of causal relations between HT (hormone therapy) and SRS (sex reassignment surgery) and somatic morbidity or mortality." Charles Decl., Ex. M at e65-e66.

Ultimately, Dr. Levine fails to cite any literature that supports this belief, and regardless, he confirmed that this should not prevent Plaintiffs or the class from receiving the relief they seek. When asked recently if he believes that because a study showed that some people committed suicide *no patient* should be able to access gender-confirming surgery, Dr. Levine responded, "that would be illogical." Charles Decl., Ex. C at 151:25-152:6. And when asked if all the concerns he has are justifications for denying medical interventions to all people with gender dysphoria, he responded "I'm not advocating denying endocrine treatment or surgical treatment." *Id*. at 85:4-11.

3. Dr. Levine's Opinions About Gender Dysphoria "Naturally Resolving" in Transgender Children and Adolescents Are Not Based In Fact.

Another unreliable opinion presented by Dr. Levine is that "the majority" of pre-pubescent children diagnosed with gender dysphoria will, absent intervention, cease to be transgender (or "desist") by adulthood. Charles Decl., Ex. A at ¶90. This opinion is unreliable and methodologically unsound for several reasons. First, Dr. Levine recently conceded that some

children are and will continue to be transgender and that as they progress into adolescence and adulthood, and that they would need medical care that he has, and would, authorize. Charles Decl., Ex. C. at 173:7-15; 137:14-23; 173:22-174:5; 53:16-54:7. Second, for this opinion, Dr. Levine cites to three articles that share the same core methodological flaw: they discuss studies that only include children whose gender non-conforming behavior was diagnosed under the obsolete and overly broad diagnostic criteria for "Gender Identity Disorder in Children" of the Diagnostic Statistical Manuals ("DSM") III, III-R, IV, and IV-R. Charles Decl., Ex. A at ¶90 nn.130-132. Under these sweeping, outdated diagnostic criteria, and the thinly veiled anti-gay attitudes of many clinicians at the time who viewed being gay as a disorder, most of the children diagnosed with Gender Identity Disorder in Children were not actually transgender but were gay or bisexual. Because of the years of initial visits in the study samples (1952-2008) none of these children were diagnosed under the diagnostic criteria for "Gender Dysphoria in Children," contained within the current and authoritative DSM-V, released in 2013, which requires "a strong desire to be of the other gender or an insistence that one is the other gender" and "clinically significant distress or impairment in social, school, or other important areas of functioning." Charles Decl., Ex. N at 452. Therefore, the "desistance rates" from the studies upon which Dr. Levine bases his opinion reflect children who, while they might have exhibited cross gender behaviors, would not satisfy the current diagnostic criteria and were likely not even transgender, or suffering from gender dysphoria. This clear implication undercuts other of Dr. Levine's conclusions but most importantly underscores that Dr. Levine cannot be established as a reliable expert because he manipulates available research and "cite[s] papers that do not provide the support asserted." *Tyree*, 54 F. Supp. 3d at 520 (cleaned up).

Dr. Levine also attempts to undercut the validity of the authoritative and widely used

diagnostic criteria for gender dysphoria in the DSM V. Charles Decl., Ex. A at ¶86. Without any evidence, Dr. Levine characterizes the International Classifications of Diseases Version 11 ("ICD-11") as a "diagnostic category [sic]," "which is expected to supersede DSM-V in determining eligibility for transgender interventions." *Id*. Setting aside that Dr. Levine again provides no citation or scientific proof of this assertion, the truth is that the ICD-11 has not even been adopted in the United States. Charles Decl., Ex. O at 108:10-18. Dr. Levine's claim that the "conflict" between the two precludes being able to determine medical necessity is an exercise in fiction. Indeed, the screening tool that BMS uses to determine medical necessity has issued policies clearly indicating when this care is medically indicated. Charles Decl., Ex. P. Such hypothetical and scientifically unsupported ideas cannot be the basis for reliable expert testimony.

4. Dr. Levine's Assertion that "Rapid Onset Gender Dysphoria," as a Cause of Gender Dysphoria or the Concept of "Detransition" Justifies Denying Treatment to Transgender WV Medicaid Recipients Who Need It Is Unsupported By Scientific Evidence.

A stark example of Dr. Levine's opinions failing to meet methodological reliability is his assertion that the untested and scientifically unsupported hypothesis of "rapid onset gender dysphoria" justifies denying Medicaid coverage of medical interventions to Plaintiffs and the proposed class. Charles Decl., Ex. A at ¶79. "While hypothesis is essential in the scientific community because it leads to advances in science, speculation in the courtroom cannot aid the fact finder in making a determination …." *Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 684 (M.D.N.C. 2003). Just seven months ago, the only article Dr. Levine could name regarding "rapid onset gender dysphoria" was withdrawn and republished with a significant correction that Dr. Levine confessed he had not read. Charles Decl., Ex. C at 116:22-117:9. The correction admitted that: "rapid onset gender dysphoria is not a formal mental health diagnosis," "the report did not collect data from adolescents and young adults or clinicians and therefore does not validate

the phenomenon," and "the use of the term, 'rapid onset gender dysphoria' should be used cautiously by clinicians and parents to describe youth." Charles Decl., Ex. Q at 1. Indeed, several months later, Dr. Levine does not cite to any new peer reviewed sources or studies that establish evidence of such a phenomenon, but instead to *one* article merely suggesting research should be performed. Charles Decl. Ex. A at ¶79. Despite this, at deposition Dr. Levine attempted to conflate an increased number of transgender young people presenting to clinics for care with the theory of "rapid onset gender dysphoria" and asserted, without evidence, it is not a hypothesis but "a fact," that he "assumes everyone understands [this] is true." Charles Decl. Ex. B at 151:18-152:6, 152:22-153:5. When pressed to provide peer-reviewed articles, sources, or studies as scientific support he referenced presentations without title or date, admitted he could not remember the names of "authors from Europe" but asserted it had been documented by "DiAngelo and Clayton in Australia." To date, the *only* peer-reviewed study that interrogates this hypothesis using adolescent clinical data "did not support the ROGD hypothesis." Charles Decl., Ex. R at 1.

Similarly, when confronted at deposition about his opinion that there is "evidence that *a growing number* of young people regret transition and wish to reverse it," Dr. Levine admitted he lacked any scientific support for such an opinion. Charles Decl., Ex. A at ¶79; Ex. B at 158:8-159:2; 160:25-161:9; 163:9-24. Dr. Levine did not point to his own experience as a basis and conceded three times that the sources he cited in his report did not provide relevant evidence. *Id.* Even if Dr. Levine had relied on his own experience for this opinion, "a reliable expert would not … misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." *Tyree*, 54 F. Supp. 3d at 520 (cleaned up).

Seven months ago, when confronted about the same "detransition subreddit" that Dr. Levine cites in his report here, he admitted he had no evidence that *even one* of the then 16,000

members of the subreddit had actually "detransitioned." Charles Decl., Ex. C at 200:6-201:25. Nothing has changed in the intervening months except that now Dr. Levine concedes in his report that "it would be wrong to assert that each of the members have detransitioned." Charles Decl., Ex. A at ¶91. Despite this concession, he asserts without citation or evidence that "it is reasonable to assume that many are considering it, and many have accomplished some degree of it." *Id*. Why Dr. Levine believes it is "reasonable" for an expert witness to make unsupported assumptions is unclear, but this does not pass *Daubert* muster. Given that these hypotheses about "rapid onset gender dysphoria" and ideas about "detransition" are entirely unverified or unsupported, Dr. Levine cannot claim that they use any reliable methodology. His reliance on his own *ipse dixit* fails to establish a basis upon which to assert this opinion.

D. Dr. Levine Is Not Qualified To Offer Opinions About the Cost of Gender-Confirming Care, Or About Puberty-Delaying Treatment Or the Treatment of Pre-Pubescent Transgender Children Generally.

Although Dr. Levine opines about the cost of gender-confirming care, he admits that—whatever his skills may be— "economic analysis is not one of them. Others must be relied upon to answer the question." Charles Decl. Ex. A at ¶55. Dr. Levine's candid admission that he is unqualified to render this opinion alone should disqualify it, but his analytical errors end all doubt.

Dr. Levine begins his analysis by stating that "the data already show that the numbers of individuals seeking transgender interventions on West Virginia Medicaid increased from 30 individuals in 2016, to 686 individuals through the end of September in 2021." Charles Decl. Ex. A ¶54. He relies on a discovery response by Defendants providing those figures, suggesting that this increase over a 5-year period supports his ideas about a "rapid rise in transgender identification, especially among youth." Charles Decl. Ex. A at ¶53. But he makes two fatal omissions.

First, he fails to disclose that the increase may be because West Virginia Medicaid began covering hormone therapy for gender-affirming care in 2017, one year into that period, as described in Plaintiffs' motion for summary judgment. Accordingly, this supplies no reliable basis to infer a "rapid rise in transgender identification."

Second, Defendants were asked in Plaintiffs' Second Set of Interrogatories to "identify the number of Health Plan participants who have submitted one or more claims with a diagnosis code for Gender Dysphoria or Gender Incongruence." Charles Decl. Ex. S at ¶11. Significantly, Defendants did not specify, and Dr. Levine does not purport to know, how many claims were for services like psychotherapy and hormone replacement therapy, and which were for services barred by the Exclusion. To this point, Dr. Levine admitted at deposition that not only does he not know which of the 686 Medicaid participants need which kinds of "interventions", but he also does not know which participants need surgery. Charles Decl. Ex. B at 213:20-25; 212:15-17.

Dr. Levine also provides no evidence of how many of the 686 participants claims are from youth or adults. But he suggests, without evidence or any basis upon which to opine, that "the majority" of transgender people will choose to undergo medical interventions, and that the proportion will increase "when such interventions are provided at no cost to the patient" or, as he implies, if WV Medicaid removes the Exclusion. Charles Decl., Ex. A at ¶53. Similarly, and without evidence or scientific methodology used to reach this conclusion, Dr. Levine wildly suggests that "as many as 30,000 West Virginia youth could be identifying as transgender." *Id*. at ¶54. What this has to do with West Virginia's Exclusion of gender-confirming surgery and its cost is murky at best and is certainly an opinion that should be excluded from testimony before this court. At bottom, Dr. Levine disclaimed at deposition that he was offering any opinions about how

the WV Medicaid program is subsidized by the federal government, about the cost of puberty blockers under the West Virginia Medicaid Program, or about the cost of surgical care for the treatment of gender dysphoria under the West Virginia Medicaid Program. Charles Decl. Ex. B at 211:17-21; 210:13-19; 211:6-10. The Court should accept Dr. Levine's own admissions that he is neither qualified to opine, nor opining about, the cost of gender-confirming care, and exclude such testimony as unfounded and irrelevant.

Dr. Levine also offers unsupported personal beliefs about the impact of puberty delaying treatment, for which he lacks clinical, and as his report admits, scientific evidence. Charles Decl. Ex. A at ¶132. Without citation, Dr. Levine raises the specter of puberty delaying medication causing transgender children "diminished sexual response," and extrapolates his unsupported opinion even further to suggest that youth will experience "social, psychosocial, and interpersonal impacts" of "not being in puberty for 2-5 years." *Id*. at ¶131, 132, 134. But Dr. Levine admits he lacks published data for these theories which, "have not been systematically studied." *Id*. at ¶132, ¶135. In fact, Dr. Levine's only consistent citations for these opinions are two of his own publications, which do not contain research, studies, or data that he has collected or analyzed. *Id*. at nn. 207, 208, 211, 213, 215. Dr. Levine again suggests that it is "reasonable to assume" that puberty delaying treatments "increase the adolescent's sense of isolation otherness or being an outsider." *Id*. at ¶136. Contrary to Dr. Levine's suggestion, unsupported assumptions are not an acceptable basis for expert testimony by this Court and fall far short of the standard for reliability.

Unsurprisingly, this is the norm for Dr. Levine's proffered opinions in other cases. He recently testified that puberty delaying treatment should not be available to any transgender adolescents because in the cases he has seen, such treatment was "like a treatment for the mother's pathology, not for the child." Charles Decl., Ex. C at 184:25-185:2. If it were up to Dr. Levine, he

would "consider banning puberty blocking hormones even for children who have been cross-gender identified for four years to give them a chance to desist." Charles Decl., Ex. C at 186:20-25. Even Dr. Levine acknowledges the unscientific nature of this opinion, as he recently admitted he does not know where it comes from or "to what extent it's from my politics, or from my being a parent or a doctor, I don't know." Charles Decl., Ex. C at 187:20-24.

Dr. Levine has also repeatedly admitted at depositions for the last year—as he must—that he has no experience performing research or publishing studies about pre-pubescent transgender children, and virtually no experience administering psychiatric treatment to them. Charles Decl., Ex. A at ¶5; Ex. B at 26:10-13; Ex. C at 23:1-8. When asked whether he has treated any children with gender dysphoria, he admitted, "I have only on rare occasion personally treated or directly or indirectly treated a child." Charles Decl. Ex. B at 28:23-29:6; 62:6-14. Dr. Levine also confirmed his testimony from March 30, 2022, that over the course of his nearly 50-year career, he had only seen an estimated six pre-pubertal children, and not for more than one visit. Charles Decl., Ex. T at 87:1-7. When asked about more recent experience treating children with gender dysphoria, Dr. Levine confirmed his testimony from seventh months ago was correct and that in the intervening months he had not treated any children. Charles Decl., Ex. B at 77:24-78:6; Ex. C at 51:14-18; 52:14-22. When asked if Dr. Levine had helped to develop guidelines for the treatment of transgender children or adolescents with gender identity issues he responded "the answer is no." Charles Decl., Ex. B at 51:10-16. Dr. Levine is not recognized as an expert in providing treatment to transgender children by his private employer who by his own admission does not refer children to him as patients, nor by the University Hospitals' LGBTQ and Gender Care Program--the Cleveland hospital affiliated with Case Western Reserve University Medical School where Dr. Levine is a clinical professor—which he previously admitted did not consult with him as part of

its formation or their ongoing work. Charles Decl., Ex. T at 113:19-114:4. He does not write or research about providing treatment to transgender children, nor does he deliver any psychiatric care to them in his day-to-day practice. Dr. Levine is not qualified under the *Daubert* standards to offer opinions on matters relating to the care of transgender children, and he cannot use his personal beliefs as methodologically reliable evidence.

E. Dr. Levine's Report, Opinions, And Testimony Lack Probative Value And Are Thus Inadmissible Under Federal Rule Of Evidence 403.

Finally, the Court should exclude evidence if its introduction will result in unfair prejudice, confusion of the issues, or result in misleading testimony. Fed. R. Evid. 403. As noted above, Dr. Levine offers no opinions on any factual dispute in this case, and, in any event, the opinions he offers are irrelevant and unreliable. Consideration of his testimony would waste time and create confusion. The testimony would also result in prejudice, as the testimony seeks to sow confusion about the veracity of Plaintiffs' gender identity, gender dysphoria diagnosis, and other experiences—issues unrelated to whether the WV Medicaid Program can deny coverage of the same kinds of treatments to transgender people that it provides cisgender people. Accordingly, Dr. Levine's testimony fails to satisfy the requirements of Fed. R. of Evid. 403 and should be excluded.

IV. CONCLUSION

Plaintiffs respectfully request that this Court grant the instant motion and exclude all of Dr. Levine's purported expert testimony as inadmissible under *Daubert* and the Rules of Evidence.

Dated: May 31, 2022

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN, *et al.*, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

WILLIAM CROUCH, *et al.*,

Defendants.

CIVIL ACTION NO. 3:20-cv-00740
HON. ROBERT C. CHAMBERS

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, and any attachments, were served electronically on May 31, 2022 on the following counsel for Defendants in this case:

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WILLIAM CROUCH, *et al.*,

Defendants.

CIVIL ACTION NO. 3:20-cv-00740
HON. ROBERT C. CHAMBERS

ORDER GRANTING JOINT MOTION TO FILE EXHIBITS UNDER SEAL

The Parties, through counsel, filed a Joint Motion to File Exhibits Under Seal in the above-captioned matter to protect sensitive personal identifying information, personal health information, and other confidential information. The Court finds that Plaintiffs' personal identifying information, personal health information, and other confidential information should not be in the public realm.

Having considered the Parties' Joint Motion, IT IS HEREBY ORDERED that the Parties' Joint Motion to Seal is GRANTED and that paragraphs 47-93 of the Exhibit A and paragraphs 3(a)-(v) and 5(a)-(q) of the Exhibit B to the Parties' motion are ACCEPTED UNDER SEAL.

Dated: 06/01/2022

Honorable Robert C. Chambers
U.S. District Court Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN, *et al.*, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

WILLIAM CROUCH, *et al.*,

Defendants.

CIVIL ACTION NO. 3:20-cv-00740

HON. ROBERT C. CHAMBERS, JUDGE

CORRECTED STIPULATION OF PLAINTIFFS AND DEFENDANTS

Pursuant to Local Rule of Civil Procedure 11.2, Plaintiffs and Defendants hereby stipulate as follows:

1. This stipulation corrects and supersedes the stipulation between the parties entered on the docket in this case at ECF No. 228, and the parties hereby withdraw the stipulation entered at ECF No. 228.

2. On March 30, 2022, Dr. James Becker provided deposition testimony on certain topics in this case as an organizational representative for the Department of Health and Human Resources, Bureau of Medical Services, pursuant to Federal Rule of Civil Procedure 30(b)(6). Plaintiffs and Defendants enter this stipulation to clarify the testimony that Dr. Becker provided in that capacity.

3. Defendants stipulate there are no documents of which they are aware that were considered in adopting and/or maintaining the Exclusion of gender-confirming care in the West Virginia Medicaid program.

4. Defendants' response to Plaintiffs' Request for Production 6, which was served on

Plaintiffs on March 25, 2022, and which was marked as Plaintiffs' Exhibit 4 during the deposition of Dr. Becker as an organizational representative, provides the complete list of the materials considered in connection with appeals of denials of coverage for Gender-Confirming care or reviewed as background research by individuals who considered those appeals.

5. The deposition testimony that Dr. Becker provided on March 30, 2022 regarding other materials he considered, which were not identified in the responses to Request for Production 6 in Plaintiffs' Exhibit 4 to this deposition, relates solely to materials Dr. Becker considered while reviewing appeals of services denied for treatment of gender dysphoria or for other reasons, but not for purposes of adopting and/or maintaining the Exclusion in the Health Plans in the West Virginia Medicaid program.

* * *

Dated: June 10, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing document on June 10, 2022 with the Clerk of the Court using the CM/ECF system, which will send notification of filing, and a copy of the same, to the following CM/ECF participants:

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Dated: June 10, 2022

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
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CHRISTOPHER FAIN, *et al.*,
Plaintiffs,

Civil Action No. 3:20-cv-00740
Hon. Robert C. Chambers, Judge

v.

WILLIAM CROUCH, *et al.*,
Defendants.

DEFENDANTS' RESPONSE IN OPPOSITION TO
PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

Now come Defendants, by counsel, Lou Ann S. Cyrus, Roberta F. Green, Caleb B. David, Kimberly M. Bandy, and Shuman McCuskey Slicer PLLC, and respond in opposition to Plaintiffs' Motion for Class Certification (ECF Nos. 248, 249) ("Class Motion") on the basis that the evidence as adduced in discovery has demonstrated the inappropriateness of these claims for class treatment and, therefore, the saliency of WVDHHR's initial arguments against class certification.

Background.

In its Memorandum Opinion and Order,[1] this Court relied upon *Wal-Mart Stores, Inc., v. Dukes* in finding that "'plaintiff shows that the class members have suffered the same injury,' and that the common injury arises from 'a common contention.'"[2] The Court further stated that "Plaintiffs allege that the class members suffer from a common injury which arises from a general policy of discrimination: the denial of coverage for '[t]ranssexual surgery' in the WVDHHR Medicaid Policy Manual. *Compl.* ¶ 61. As alleged, this denial generally affects the proposed class, which includes '[a]ll transgender people who are or will be enrolled in West Virginia 'Medicaid and who are seeking or will seek gender-confirming care barred by the Exclusions.' *Id.* at ¶ 108.[5]" In so finding, the Court held as follows:

Based on this common contention, Plaintiffs have appropriately framed the

[1] ECF No. 57.
[2] ECF No. 57 at 11.

> common questions as follows: (1) whether WVDHHR's Exclusion facially, and as applied to the proposed Class, violates the U.S. Constitution, the ACA, and the federal Medicaid Act; and (2) whether WVDHHR should be enjoined from enforcing the Exclusion and denying Mr. Fain and members of the proposed Medicaid Class coverage for and access to gender-confirming care. *See Compl*. ¶¶ 118-56. These questions are primarily legal and have the potential to relieve the common injury "in one stroke." *See Wal-Mart*, 564 U.S. at 350.
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> * * *
>
> These claims are purely legal and require little to no fact development. Having failed to identify any ground upon which the Parties will be required to make particularized and individualized factual findings, WVDHHR's argument must be rejected. The Court denies WVDHHR's Motion for Partial Dismissal of Plaintiffs' Class Action Complaint (ECF No. 23) and Motion to Dismiss (ECF No. 32).[3]

Per the Court's holding, Plaintiffs have proceeded through discovery relative to, *inter alia,* the Class Claims, yet the course of that discovery has proven that the majority of gender-confirming care is indeed available to these Plaintiffs and was available even prior to and absent this litigation, despite Plaintiffs' erroneous assertion in both the Complaint and the First Amended Complaint to the contrary. Further, through discovery, Plaintiffs' experts have opined that the determinations of when and whether gender-confirming surgery is appropriate is a highly individualized determination, with multiple predicates to reaching any conclusion that such care is medically indicated and/or medically necessary. Indeed, where the Court's initial holding was based in part upon a "fail[ure] to identify any ground upon which the Parties will be required to make particularized and individualized factual findings," Plaintiffs' experts have demonstrated that the claims are inherently, inescapably, individualized, based in each individual's mental health and health background and condition. Indeed, Plaintiffs' expert Dan H. Karasic, M.D., dedicates almost sixty paragraphs of his expert report to particularizing just the mental health and psycho-social background of the proposed class representatives.[4] That evaluation does not include medical assessments or pre-surgical assessments. Each of Plaintiffs' experts relies upon and emphasizes

[3] ECF No. 57 at 11-12, 13.
[4] Expert Report of Dan H. Karasic, M.D. (ECF No. 250-20) at 15ff.

the individual nature of the presentation and response. Therefore, Plaintiffs have identified the grounds upon which the Parties will be required to make particularized and individualized factual findings and allow for the mandated particularized and individualized defense. Plaintiff's Class Motion must be denied, as these claims are inherently poorly suited for class handling.

Argument.

The parties agree that class action claims constitute a deviation from the general rule that litigation must be conducted by and on behalf of the individual named parties only[5] and that the deviation is justified only to the extent the class representatives possess, *inter alia,* the same interests and suffer the same injury as the proposed class members.[6] After all, pursuant to Rule 23, a plaintiff may bring suit on behalf of a class of individuals

> only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.[7]

A motion for class certification must be subjected to rigorous analysis, especially in the instance of medical claims such as these, which Plaintiffs' discovery has proven finally are not 'cohesive enough' to gain economies through class action and conversely are incohesive enough to mandate individualized defenses.[8] Because by Plaintiffs' case (as now fully demonstrated through discovery) the majority of the factual, and, therefore, legal questions both for Plaintiffs and Defendants are unique to each class member, Plaintiffs' Class Motion must be denied. Plaintiffs' discovery confirmed that a class of transgender individuals is too broad a category, as that process

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[5] *Wal-Mart Stores, Inc., v. Dukes,* 564 U.S. 338, 349 (2011), *quoting Califano v. Yamasaki,* 442 U.S. 682, 700-01 (1979).
[6] *Dukes,* 564 U.S. at 349, *quoting East Tex. Motor Freight System, Inc. v. Rodriguez,* 431 U.S. 395, 403 (1977) (*quoting Schlessinger v. Reservists Comm. To Stop the War,* 418 U.S. 208 (1974)).
[7] Fed. R. Civ. P. 23(a).
[8] *Rhodes v. E.I. DuPont de Nemours & Co.,* 253 F.R.D. 365, 367, 370 (SD WV 2008).

and determination have been expressed by Plaintiffs' experts here.

Now, at the close of discovery, Plaintiffs' proposed class of "[a]ll transgender people who are or will be enrolled in West Virginia Medicaid and who are seeking or will seek gender-confirming care barred by the Exclusions"[9] is unsupported by the facts and law of the case, as Plaintiffs' discovery has demonstrated that class treatment of those precise claims is inappropriate and unworkable. As demonstrated by Plaintiffs' retained experts, the availability of the relief Plaintiffs seek is limited to individuals who undergo particularized assessment and approval prior to being a potential treatment recipient. Thereafter, in mounting their defense to the class claim, Defendants would need to conduct the same sort of careful evaluation of each particularized assessment and approval, making this claim and this litigation inappropriate for class treatment.

Plaintiffs have not established Numerosity.

Plaintiffs do not meet the numerosity requirement. While Plaintiffs Fain and Anderson each assert that they seek gender-confirming surgery, Plaintiffs do not have any evidence that any other Medicaid beneficiary seeks gender-confirming surgery. Instead, Plaintiffs acknowledge that the record does not reveal the number of Medicaid participants who may seek gender-confirming surgery.[10] Because the policy at issue only potentially affects those individuals who are diagnosed with gender dysphoria, seeking gender-confirming surgery, are determined to be candidates for surgery, approved for surgery, and who actually submit a claim for such services to Medicaid, this is a much smaller group of people than all Medicaid members who have a transgender identity. The "class" based on the evidence is comprised of Mr. Fain and Ms. Anderson, the two individual Plaintiffs. Numerosity of class membership is completely absent.

[9] *First Amended Compl.* ¶108.
[10] ECF 255 at 19.

Plaintiffs' characterization of the number of Medicaid members seeking gender-confirming care is also not entirely accurate. Plaintiffs allege that "the number of West Virginia Medicaid participants who submit claims related to a diagnosis of gender dysphoria alone exceeds 600 people annually."[11] However, as explained by the Medicaid employee that compiled the information, the number 686 captures all individuals who made claims for any reason during the first nine months of 2021 who also had a diagnosis code for one or more of the following: transsexualism, gender identity disorder of childhood, other gender identity disorders, or gender identity disorder, unspecified.[12] The number captured those who had made claims whether or not the transsexualism or gender identity disorder diagnosis was the primary diagnosis or the reason for the requested service.[13] Thus, 686 represents the number of members with a diagnosis related to gender dysphoria who made claims (not necessarily for gender-confirming care) during the first nine months of 2021.

Even assuming the claims were appropriate for class treatment (which they are not), Plaintiffs' discovery has proven that even the proposed class as initially crafted is unworkable. That is, while Plaintiffs continue in their efforts to certify a class populated by "[a]ll transgender people who are or will be enrolled in West Virginia Medicaid and who are seeking or will seek gender-confirming care barred by the Exclusions,"[14] Plaintiffs' experts have opined that not all transgender people are affected by the policy. As Plaintiffs' experts have expressly stated, not all

[11] ECF No. 249 at 3.
[12] ECF No. 252-14 at 32-35.
[13] ECF 252-14, Tr. pp. 32-35.
[14] Plaintiffs have not demonstrated that Medicaid has any exclusion of coverage that pertains categorically to transgender individuals. All services that are considered covered services by Medicaid are covered for transgender participants to the same extent and based on the same criteria as cisgender participants. ECF 257-1 at 34, 100. No evidence has been adduced in discovery indicating that any covered services are denied to members on the basis of transgender identity. Plaintiffs' discovery indicates that the determination of services available and the determination of medical necessity are both individualized. ECF No. 182 at 15ff.

transgender individuals are diagnosed with gender dysphoria. Plaintiffs' evidence is that there is a difference between a transgender identity and gender dysphoria.[15] Being transgender is an identity.[16] Gender dysphoria can result in a DSM-V disorder in some transgender individuals.[17] According to Plaintiffs' expert Dan Karasic, M.D., roughly one in 200 people identifies as transgender.[18] About one in a thousand is in clinical care for gender dysphoria.[19] Even though the numbers have not been precisely established [or established for West Virginia], only a fraction of individuals who identify as transgender actually receive care for gender dysphoria, according to Dr. Karasic.[20] Although Plaintiffs alleged in their First Amended Complaint that the Defendants herein had a "categorical exclusion" that denied coverage for "gender-confirming care," defined by Plaintiffs as "including but not limited to, counseling, hormone therapy, and surgical care," discovery established that several forms of gender-confirming care, including counseling and hormone therapy, and many others, are indeed covered by Medicaid, by and through its existing programs.[21] Further, through Plaintiffs' discovery, it was confirmed that any class made up of transgender individuals generally who are seeking the gender-confirming care not currently available would be overly broad. Plaintiffs' evidence is that the proposed class of transgender individuals is actually a group of differently situated persons who must be individually assessed and their propriety determined on a case-by-case basis prior to inclusion.[22] Per Plaintiffs' experts,

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[15] ECF 252-8 at 8.
[16] ECF 252-8 at 8.
[17] ECF 252-8 at 8-9.
[18] ECF No. 252-8 at 10.
[19](ECF No. 252-8 at 10..
[20] ECF No. 252-8 at 10-11.
[21] ECF No. 1 at 1-2; ECF No 140 at 1-2. *See also* Memorandum of Law in Support of Defendants' Motion for Summary Judgment (5.31.22) (ECF No. 253) at 2 stating that "[i]t is undisputed that Medicaid does not exclude, but in fact covers, psychiatric diagnostic evaluation, psychotherapy, psychological evaluation, counseling, office visits, hormones, and lab work as treatment related to gender-confirming care. (Ex. 4 pp. 142, 146, 151, 161-162, 164; Ex. 5 pp. 62-63, 65, 71, 73; Ex. 6; Ex.7 pp. 28-30; Ex. 1 pp. 168-169)."
[22] Expert Disclosure Report of Dan H. Kurasic (ECF No. 182) at ¶ 34, 41.

"[f]or a person to be diagnosed with [gender dysphoria], there must be a marked difference between the individual's expressed/experienced gender and their assigned sex at birth, present for at least six months."[23] Then, beyond the diagnosis, "for gender-confirming medical care, there is the additional safeguard of the assessment by a mental health professional, who, in addition to diagnosing gender dysphoria, also assesses capacity to consent and reviews the risks and benefits of treatment with the patient."[24]

Plaintiffs have not established Commonality or Typicality.

And as the law drives the class, so, too, the law drives the defenses, which are equally individualized and impossible to accomplish with any of the efficiencies that mitigate in favor of or would support class treatment (as opposed to individual claims).[25] Defendants must be allowed to raise individual affirmative defenses to whether Plaintiffs and any putative class members would qualify for the gender-confirming care they seek. For these reasons and those set out further below, Plaintiffs' Class Motion fails to meet the commonality and typicality requirements of Rule 23.

Beyond the fact that, in their First Amended Complaint, Plaintiffs particularized their claims to their precise diagnoses, their precise medical needs, and their precise claims histories,[26] Plaintiffs' experts have done likewise, even conducting detailed evaluations of the proposed Class Representatives, which evaluations were appended to the expert's report.[27] Indeed, the detailed, personalized assessments are affixed to the expert's opinions, inextricably bound as a portion of the support the expert provides here – the detailed, individualized assessments without which the

[23] Expert Rebuttal Report of Dr. Johanna Olson-Kennedy, M.D., M.S. (ECF No. 250-22) at ¶ 26.
[24] Expert Disclosure Report of Dan H. Kurasic (ECF No. 182) at ¶ 41.
[25] *Dukes,* 564 U.S. at 362, citing in pertinent part *Teamsters v. United States,* 431 U.S. 324, 361 (1977), for the proposition that a class cannot be certified if that certification precludes the defendant from litigating its defenses to individual claims.
[26] First Am. Compl. (ECF No. 140) at ¶¶ 75-156.
[27] Expert Disclosure Report of Dan H. Karasic (ECF No. 182) at 15ff.

experts' opinions are incomplete. Beyond that, it is important to note that Plaintiffs' discovery has been that the sole remaining gender-confirming care not currently available as such (gender-confirming surgery) mandates predicates: a more precise, particularized diagnosis than simply having a transgender identity and mental health assessments prior to any individual's being considered for the only gender-confirming care not currently provided by Defendants.[28] For these reasons, Plaintiffs' case reflects the reality that Rule 23 offers no economies to what must become multiple, separate determinations, joined only in the broadest sense. As clarified by the Supreme Court of the United States in *Wal-Mart Stores, Inc., v. Dukes,* if plaintiffs generalize their claims broadly enough, certainly any and all persons could qualify as class members so as to meet the commonality mandate.[29] However, "'[w]hat matters to class certification is not the raising of common 'questions'--even in droves--but, rather the capacity of a classwide proceeding to generate common answers apt to drive the resolution of the litigation. Dissimilarities within a proposed class are what have the potential to impede the generation of common answers.'"[30] Finally, in *Dukes,* the Court found that even a close assessment of the millions of employment decisions made by Wal-Mart could not result in the answer to the question of 'why was I disfavored.'[31] In determining the propriety of class certification, the Court was searching for the 'glue' that would hold the members to the class; finally, the Court found that employment decisions are multifactorial, such that a related claim would not be workable as a class.[32]

Likewise here, the evaluations/interviews Plaintiffs' expert conducted of the proposed class representatives are lengthy and detailed, with 26 paragraphs of detailed social, psycho-social,

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[28] *See* ECF No. 253 at 2.
[29] *Dukes,* 564 U.S. at 348.
[30] *Dukes,* 564 U.S. at 350, quoting Naguerenda, Class Certification in the Age of Aggregate Proof, 84 N.Y.U. L. Rev. 97, 132 (2009).
[31] *Dukes,* 564 U.S. at 352.
[32] *See, e.g., Dukes,* 564 U.S. at 352.

psychological and physical history and assessment of Mr. Fain alone.[33] Plaintiffs' expert expends additional paragraphs on Ms. Anderson with the same sort of analysis. All of this rigorous, detailed assessment aside, none of these individuals has undergone the pre-surgical assessment and clearance mandated per the testimony of yet another of Plaintiffs' experts. Even assuming that the individuals were approved through this detailed mental healthcare process, the gender-confirming surgical procedures would need to be determined by healthcare professionals to be medically indicated and necessary for the Plaintiffs and/or for the putative class members through a series of evaluations[34] and, in fact, finally, are medically indicated and necessary to only the segment of gender dysphoric individuals approved through the individualized assessments that are a universal prerequisite for same, based upon the Standards of Care relied upon by Plaintiffs:

> [T]he [SOC] note that "[t]he number and sequence of surgical procedures may vary from patient to patient, according to their clinical needs." (Standards of Care at 58.) Evidence shows that while some transgender individuals do not require surgery, "for many others surgery is essential and medically necessary to alleviate their gender dysphoria.[35]
>
> The accepted protocols for the treatment of transgender people with gender dysphoria provide for mental-health assessments, including of co-occurring conditions; criteria for eligibility for each treatment; and an informed consent process before medical interventions are initiated.[36]
>
> Medical and surgical treatment interventions are determined by the care team (usually a medical and mental health professional) in collaboration with the patient, and the patient's family. These medical decisions are made by the care team in conjunction with the patient and the patient's family and consider the patient's social situation, the level of gender dysphoria, developmental stage, chronological age, existing medical conditions and other relevant factors.[37]

Therefore, even assuming that this Court were to find the scope of Defendants' coverages

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[33] Expert Report of Dan H. Karasic, M.D. (ECF No. 250-20) at 15.
[34] *See, e.g.,* Expert Disclosure Report of Dan Karasic, MD (ECF No. 250-20) at ¶ 2; Expert Disclosure Report of Loren S. Schechter, MD (ECF No. 250-23) at ¶ 23.
[35] Expert Disclosure Report of Loren S. Schechter, MD (ECF No. 250-23) at ¶ 23 (partial).
[36] Expert Disclosure Report of Dan Karasic, MD (ECF No. 250-20) at ¶ 2 (partial).
[37] Expert Rebuttal Report of Johanna Olson-Kennedy, M.D., M.S. (ECF No. 250-26) at ¶ 39 (partial).

discriminatory and/or unconstitutional, a finding Defendants oppose, nonetheless, particularized determinations mitigate against use of the class form here. Determining class membership would require the detailed mental health and surgical healthcare assessments set out by Plaintiffs' experts for each putative class member – and Defendants would need to conduct the same particularized challenge in their defense.

As a matter of law, individualized claims necessitate individualized defenses, and the Defendants will have the right to raise any individual affirmative defenses they may have and to "'demonstrate that the individual applicant was denied an . . . opportunity for lawful reasons.'" *Dukes*, 564 U.S. at 366-67. The Supreme Court has considered ingenuous workarounds for accomplishing detailed discovery and providing the opportunity for detailed defenses when the class is large and has individualized and particularized situations. In *Dukes*, the Court of Appeals suggested just such a workaround to fast-track the detailed determination of defenses. Specifically, in recognition of the size of the class and the particularized assessment that could be indicated relative to the hiring decision-making process (which would need detailed discovery to demonstrate class inclusion and to provide opportunities for meaningful defense), the *Dukes* Appeals Court suggested Trial by Formula, where a "sample set of the class members would be selected, as to whom liability for sex discrimination and the backpay owing as a result would be determined in depositions supervised by a master." In disapproving of this shortcut, the Supreme Court stated as follows:

> We disapprove that novel project. Because the Rules Enabling Act forbids interpreting Rule 23 to 'abridge, enlarge or modify any substantive right,' 28 U.S.C. § 2072(b); see *Ortiz*, 527 U.S., at 845, 119 S. Ct. 2295, 144 L. Ed. 2d 715, a class cannot be certified on the premise that Wal-Mart will not be entitled to litigate its statutory defenses to individual claims. And because the necessity of that litigation will prevent backpay from being 'incidental' to the classwide injunction, respondents' class could not be certified even assuming, *arguendo*, that 'incidental'

monetary relief can be awarded to a 23(b)(2) class.[38]

Further, the class representatives do not possess, *inter alia,* the same interests and suffer the same injury as the proposed class members.[39] As the Supreme Court of the United States has held, class form is appropriate only where economical to combine the claims and that determination as to whether it is economical is a practical one – when a common injury can be addressed and resolved by a class litigation without doing damage to either. Here, the economies of the class form are unavailable, as particularized discovery would be necessary to determine the individualized facts relative to each class member. In *Dukes,* the Supreme Court recognized, *inter alia,* that, if plaintiffs generalize their claims broadly enough, certainly any and all persons could qualify as class members so as to meet the commonality mandate. The Supreme Court considered common questions that, finally, were generalized to the point that they no longer meaningfully constituted a basis of commonality: "Do all of us plaintiffs indeed work for Wal-Mart? Do our managers have discretion over pay? Is that an unlawful employment practice? What remedies should we get?"[40] While all of the *Dukes* plaintiffs truly had these questions at the heart of their claims, the *Dukes* Court found the questions too broad to provide meaningful class inquiry or relief – and that the workaround proposed to fast-track discovery and defense was unacceptable. [41]

While the class is "[a]ll transgender people who are or will be enrolled in West Virginia Medicaid and who are seeking or will seek gender-confirming care barred by the Exclusion," the procedures are only potentially medically necessary and therefore medically indicated in the

[38] *Dukes,* 564 U.S. at 367.
[39] ECF No. 25, relying in part on *Dukes,* 564 U.S. 338, 349 (2011), quoting *Califano v. Yamasaki,* 442 U.S. 682, 700-01 (1979), *East Tex. Motor Freight System, Inc. v. Rodriguez,* 431 U.S. 395, 403 (1977) (quoting *Schlessinger v. Reservists Comm. To Stop the War,* 418 U.S. 208 (1974)).
[40] *Dukes,* 564 U.S. at 349.
[41] *Dukes,* 564 U.S. at 349.

instance of a diagnosis of gender dysphoria. [42] Therefore, while the Plaintiffs' class has been and remains now at the close of discovery 'transgender people,' Plaintiffs' experts only support a class that would be transgender persons with a diagnosis of gender dysphoria who seek gender-confirming surgery and qualify for such care. "For a person to be diagnosed with [gender dysphoria], there must be a marked difference between the individual's expressed/experienced gender and their assigned sex at birth, present for at least six months."[43] Then, beyond the diagnosis, "for gender-confirming medical care, there is the additional safeguard of the assessment by a mental health professional, who, in addition to diagnosing gender dysphoria, also assesses capacity to consent and reviews the risks and benefits of treatment with the patient."[44]

> The surgeon receives in writing one or more assessments of the patient's diagnosis and medical necessity of the care by one or more mental health professionals, as required for the relevant procedure under the Standards of Care. But that is only one step in the assessment for surgical interventions. The surgeon remains ultimately responsible for deciding whether a particular surgical intervention is medically indicated. The surgeon evaluates the patient and makes the final decision about whether it is safe and medically indicated to proceed. This includes an evaluation of the patient's understanding of the condition, their self-awareness, and their goals and expectations for the intervention. The surgeon also evaluates other health factors that would affect the patient's fitness for the surgery, and determines whether additional studies might be required, such as x-rays or laboratory work. The surgeon also typically obtains an assessment from their primary care physician about their overall health. In my own clinical practice, I have had occasion to decline to perform a requested intervention based on my exercise of professional judgment.[45]

In *Dukes,* the Supreme Court held that when a plaintiff seeks individualized relief, "'a district court must usually conduct additional proceedings . . . to determine the scope of individual relief.' *Teamsters, 431 U.S., at 361, 97 S. Ct. 1843, 52 L. Ed. 2d 396.* At this phase, the burden of proof will shift to the [defendant], but it will have the right to raise any individual affirmative

[42] Expert Disclosure Report of Loren S. Schechter, MD (ECF No. 250-23) at ¶ 21.
[43] Expert Rebuttal Report of Dr. Johanna Olson-Kennedy, MD, MS (ECF No. 250-26) at ¶ 26.
[44] Expert Disclosure Report of Dan H. Karasic, M.D. (ECF No. 250-20) at ¶ 41.
[45] Expert Rebuttal Report of Loren S. Schechter, M.D. (ECF No. 250-24) at 51.

defenses it may have, and to 'demonstrate that the individual applicant was denied an . . . opportunity for lawful reasons.' *Id., at 362, 97 S. Ct. 1843, 52 L. Ed. 2d 396*."[46] Relying upon the Rules Enabling Act's prohibition against interpreting any rule (here Rule 23) so as to "'abridge, enlarge or modify any substantive right,' *28 U.S.C. § 2072(b)*; see *Ortiz, 527 U.S., at 845, 119 S. Ct. 2295, 144 L. Ed. 2d 715*," the Supreme Court found that a class cannot be certified if that certification precludes the defendant from litigating its defenses to individual claims.

Here, based on the evidence adduced by Plaintiffs during discovery by and through each of the Plaintiffs' experts, Defendants must be allowed to raise individual affirmative defenses to whether Plaintiffs and any putative class members would have qualified for the gender-confirming care they seek. After all, even Plaintiff Fain concedes that he is not ready or willing to undergo gender-confirming surgery until he has "completely kicked" his smoking habit, and he is a smoker.[47] Thus, even Mr. Fain's circumstance is particularized in that he is not currently in a position to undergo the surgery he desires based upon his stated understanding of the risks. Plaintiffs' experts and Mr. Fain's testimony both indicate that the coverage process, the process of determining medical necessity, and the process of determining whether the care is medically indicated all are highly individual. While that is the standard of care (as Plaintiffs suggest), it nonetheless renders the determination inappropriate for class treatment.

Further, the particularized, individualized course of Plaintiffs' discovery has proven germane the guidance of the United States District Court for the Northern District of West Virginia when it clarified that

> "[a] common question is one that can be resolved for each class member in a single hearing, such as the question of whether an employer engaged in a pattern and practice of unlawful discrimination against a class of its employees. A question is not common, by contrast, if its resolution turns on a consideration of the individual

[46] *Dukes*, 564 U.S. at 366-67.
[47] ECF No. 252-5 at 87-88.

> circumstances of each class member." "The common questions must be dispositive and over-shadow other issues."[48]

Plaintiffs' claims by necessity focus on mental health assessments, medical clearances, and coverage determinations – all under particularized policies and procedures. Plaintiffs' discovery has proven Plaintiffs' claims inherently poorly suited for class treatment in a post-*Dukes* world.[49]

Here, Plaintiffs' experts have demonstrated that Plaintiffs' claims by necessity will involve a particularized determination of each Plaintiff and putative plaintiff and will require careful and particularized determinations of the applicability of the care and coverage sought. Defendants must have the right to raise their individual affirmative defenses they have and must have the right to demonstrate whether each individual applicant was denied and/or would have been denied or will be denied or was never an appropriate applicant for coverage —all for lawful reasons.

By their precise nature, Plaintiffs' claims mitigate against class treatment.

The inefficiencies of class form also are demonstrated by the claims raised in Plaintiffs' First Amended Complaint[50] itself. Count I alleges violation of the Equal Protection Clause (EPC) of the 14th Amendment; Plaintiffs assert both facial and as-applied challenges. A facial challenge does not require class treatment, such that the Court need not consider whether the deviation from the general rule that litigation must be conducted by and on behalf of the individual named parties only would be unnecessary and unjustified.[51] An as-applied challenge would require 1) a request

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[48] *Paulino v. Dollar Gen. Corp.,* 2014 U.S. Dist. LEXIS 64233 (3:12-CV-75) (ND WV 2014) (citations omitted).

[49] Further, in *General Telephone Co. of Southwest v. Falcon, 457 U.S. 147 (1982)*, the Court considered the "existence of a class of persons who have suffered the same injury as that individual, such that the individual's claim and the class claims will share common questions of law or fact and that the individual's claim will be typical of the class claims."

[50] ECF No. 140.

[51] *Dukes,* 564 U.S. 338, 349 (2011), *quoting East Tex. Motor Freight System, Inc. v. Rodriguez,* 431 U.S. 395, 403 (1977) (*quoting Schlessinger v. Reservists Comm. To Stop the War,* 418 U.S. 208 (1974)), *Califano v. Yamasaki,* 442 U.S. 682, 700-01 (1979).

for coverage, 2) a denial of coverage, 3) a review of the reason for denial.[52] While the defense's expert has disputed whether the gender-confirming surgeries are ever medically necessary procedures,[53] Plaintiffs' experts agree that coverage should only be provided for medically necessary procedures and medical necessity is based upon history, physical examination, review of mental health assessments, basis for request for surgery, goals, expectations, and discussions with primary care and mental health providers.[54] These individualized assessments and determinations predominate over the putative class members' being "transgender," as the class definition requires, because being transgender does not entitle the class members to gender-confirming surgery. Indeed, not all transgender individuals are diagnosed with gender dysphoria and not all individuals diagnosed with gender dysphoria seek gender-confirming surgery and not all individuals who seek gender-confirming surgery meet the criteria Plaintiffs' experts opine are mandatory for a finding of medical necessity.[55] Therefore, Count I does not reach the requisite level to allow class claims to take the place of individualized claims as a matter of law and fact.

Count II alleges violation of Section 1557 of the Affordable Care Act (ACA), which prohibits discrimination on the basis of sex.[56] Again, Plaintiffs assert a facial challenge to Medicaid's policy and as-applied challenges on behalf of themselves and each member of the putative class. For all of the reasons set out relative to Count I, class treatment of Count II is unnecessary and/or inappropriate. However, whereas Count II no longer seeks compensatory damages, nonetheless, Defendants' decision-making may include a review of utilization control procedures, as discussed below. As a result, each Plaintiff and putative plaintiff will need to first

[52] *See, e.g. Lewis v. Thompson,* 252 F.3d 567 (2d Cir. 2001); *Cook v. Barry,* 718 F. Supp. 632 (S.D. OH 1989); *Hillspring Health Care Center v. Dungey,* 2018 U.S. Dist. Lexis 13317 (S.D. OH 2018).
[53] Expert Disclosure Report of Dr. Stephen B. Levine, M.D. (ECF No. 252-11) at 7.
[54] Deposition of Loren S. Schechter (3.8.22) (ECF NO. 252-15) at 194.
[55] *See, e.g.,* Expert Disclosure Report of Dan H. Karasic, M.D. (ECF No. 250-20) at 6ff.
[56] ECF No. 140.

prove the medical necessity of the care and the availability of the care for that patient – along with the relevant costs. For example, Christopher Fain is a transgender man and only desires double mastectomy, not phalloplasty.[57] Shauntae Anderson is a transgender woman and seeks both mammoplasty and vaginoplasty,[58] but not all transgender women will seek these same procedures. Additionally, some individuals may seek any number of procedures, including electrolysis, facial feminization, chest masculinization, tracheal shave, hair implants, and so forth. Thus, an analysis of the medical necessity of each type of procedure for each individual claimant is required (along with the opportunity for a particularized defense of same) and predominates over the broad class-defining term of "transgender."

Count III alleges violation of the Medicaid Act's availability requirements.[59] "The Medicaid Act states, in relevant part, "[a] State plan for medical assistance must … (10) provide—(A) for making medical assistance available, including at least the care and services listed in paragraphs (1) through (5), (17), (21), (28), (29), and (30) of section 1905(a) [42 USCS § 1396d(a)] …." 42 U.S.C. § 1396a(a)(10)(A)." While Plaintiffs' First Amended Complaint fails to identify which provision of Section 1396d they assert provides for gender-confirming surgery, regardless, "nothing in the statute suggests that participating States are required to fund every medical procedure that falls within the delineated categories of medical care." *Beal v. Doe*, 432 U.S. 438, 444 (1977). "Indeed, the statute expressly provides: 'A State plan for medical assistance must… include reasonable standards… for determining eligibility for and the extent of medical assistance under the plan which… are consistent with the objectives of this [Title]….' 42 U.S.C. § 1396a (a)(17) (1970 ed., Supp. V)." *Id.*[60] The Supreme Court's decision in *Beal* is consistent with the

[57] Deposition of Christopher Fain (ECF No. 250-10) at 128.
[58] Deposition of Shauntae Anderson (ECF No. 250-11) at 167-68.
[59] ECF No. 140.
[60] This language appears in the current version of 42 U.S.C. § 1396a(a)(17), although additional language

Medicaid Act's accompanying regulations. The regulations set forth the criteria for availability:

> (a) The plan must specify the amount, duration, and scope of each service that it provides for—
> (1) The categorically needy; and
> (2) Each covered group of medically needy.
> (b) Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.
> (c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition.
> (d) **The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures.**[61]

Thus, the regulations expressly permit a State Medicaid plan to place limits on services even if those services are required to be covered. *See Casillas v. Daines*, 580 F. Supp. 2d 235, 245-46 (S.D.N.Y. 2008) ("Thus, … § 1396a(a), permits a state plan to place 'appropriate limits' upon a 'service' regardless of an individual medical doctor's view of the appropriateness of the categorical limitation."). Therefore, Count III not only mandates particularized proof but also must allow for a particularized defense – all of which mitigates against class treatment.

Count IV alleges violation of the Medicaid Act's comparability requirements.[62] If Plaintiffs' interpretation of this law is correct, then Medicaid would be required to cover all procedures for all people no matter the diagnosis. The Medicaid Act states, in relevant part,

> [a] State plan for medical assistance must … (10) provide … (B) that the medical assistance made available to any individual described in subparagraph (A)—
> (i) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual, and
> (ii) shall not be less in amount, duration, or scope than the medical assistance made available to individuals not described in subparagraph (A)[.][63]

Like the availability requirements, the comparability requirements of the Medicaid Act also have

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has been added to this section of the statute.
[61] 42 C.F.R. § 440.230 (emphasis added).
[62] ECF No. 140.
[63] 42 U.S.C. § 1396a(a)(10)(B).

accompanying regulations:

> Except as limited in § 440.250—
> (a) The plan must provide that the services available to any categorically needy beneficiary under the plan are not less in amount, duration, and scope than those services available to a medically needy beneficiary; and
> (b) The plan must provide that the services available to any individual in the following groups are equal in amount, duration, and scope for all beneficiaries within the group:
> (1) The categorically needy.
> (2) A covered medically needy group.[64]

Thus, the plain language of the regulations prohibits three types of discrimination: (1) against the categorically needy, (2) among the categorically needy, and (3) among the medically needy.[65]

Here, Plaintiffs allege that Defendants violate the comparability requirements, presumably by discriminating among the categorically needy, because Defendants do not provide coverage for gender-confirming surgery "while the same or similar services and treatments are covered for cisgender Medicaid beneficiaries." Defendants do not cover gender-confirming surgeries for cisgender Medicaid beneficiaries; thus, Defendants assume that Plaintiffs are alleging that, because Defendants do provide coverage for mastectomy for patients with breast cancer, Medicaid is required to provide coverage for mastectomy for any and all diagnoses, including gender dysphoria. This allegation is not discrimination among categorically needy beneficiaries. Indeed, Plaintiffs have provided no evidence that mastectomy for breast cancer has been denied to any transgender individual. Rather, in Plaintiffs' view, any treatment that is reimbursable for one diagnosis must be a reimbursable treatment for a different diagnosis if it were deemed by the patient's doctor to be a medical necessity. While Defendants assert that gender-confirming care is

[64] 42 C.F.R. § 440.240.

[65] *See Schott v. Olszewski*, 401 F.3d 682, 686 (6th Cir. 2005) ("Under the Act, states must provide comparable medical assistance to all Medicaid recipients within each classification, so long as the medically needy do not receive greater benefits than the categorically needy (although the reverse is permitted).").

covered in all but surgical instances and that the surgical care is not medically necessary,[66] nonetheless, to the extent that Plaintiffs prevail, these distinctions and determinations mitigate against class treatment, as Defendants must be allowed to raise particularized defenses to claims for services on, *inter alia,* these particularized grounds.

Further, the Medicaid Act causes of action require us again to look at every possible procedure that could be considered a "gender-confirming surgery" to determine whether that procedure 1) has been requested by a transgender individual with an associated indication of gender dysphoria, 2) has been provided to a cisgender individual for another indication, or 3) has some similarity with another procedure that could lend itself to a claim for lack of comparability between transgender and cisgender individuals. This individualized determination process would not only require Defendants to look at the putative class members' claims but also the claims of cisgender non-class members to determine whether other procedures have been requested and covered. For example, it is possible that Medicaid provided hair implants to a cisgender individual who was a burn victim. Defendants would be required to look at that individual's claim history to confirm claimant's gender identity, gender assigned at birth, and indication for the procedure. Then, Defendants would have to compare those findings to the hypothetical transgender woman who has male pattern baldness to determine whether the denial of her claim violates the Medicaid Act. Each of these processes would be allowed under the law as part of Defendants' particularized defense – all of them mitigating against class treatment.

Plaintiffs have not established Adequacy of Representation.

While not included in the Amended Complaint, Plaintiffs now argue that a policy of excluding puberty-delaying treatment would also violate the law and is "part of the Exclusion."

[66] Expert Disclosure Report of Dr. Stephen B. Levine, M.D. (ECF No. 252-11) at 7.

(ECF 251 p. 8 FN 38). Plaintiffs have not presented any facts that an "exclusion" for puberty-delaying treatment exists, or the terms of any such "exclusion." Most importantly, the individual Plaintiffs have not sought and do not seek puberty-delaying treatment. They not only lack standing to assert such a challenge, but they also fail to adequately represent any potential class member who would potentially seek relief based upon any alleged policy regarding coverage for puberty-delaying treatment. The record is silent with respect to whether any such potential class members even exist, but if they did, Plaintiffs do not adequately represent their interests.

Conclusion.

Because Plaintiffs' experts have demonstrated unequivocally that the claims here mandate individualized, particularized assessments prior to determining that any Plaintiff and/or any putative class member would be appropriate to include, Plaintiffs have succeeded in proving that these claims cannot be proven on the basis of class. Further, because no substantive right can be compromised in the conversion to class, Defendants must be allowed to conduct discovery and develop defenses, all of which will be an individualized, particularized process. Plaintiffs' discovery has unequivocally identified grounds upon which the Parties will be required to make particularized and individualized factual findings and build factual defenses, such that Plaintiffs' Motion for Class Certification must be denied.

WILLIAM CROUCH, CYNTHIA BEANE, and WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES, By counsel

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN and **SHAUNTAE ANDERSON;** individually and on behalf of all others similarly situated,

Plaintiffs,

Civil Action No. 3:20-cv-00740
Hon. Robert C. Chambers, Judge

v.

WILLIAM CROUCH, in his official capacity as Cabinet Secretary of the West Virginia Department of Health and Human Resources; **CYNTHIA BEANE,** in her official capacity as Commissioner for the West Virginia Bureau for Medical Services; and **WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES,**

Defendants.

CERTIFICATE OF SERVICE

Now come Defendants William Crouch, Cynthia Beane and West Virginia Department of Health and Human Resources Bureau for Medical Services, by counsel, and do hereby certify that on the 14th day of June, 2022, a true and exact copy of **"DEFENDANTS' RESPONSE IN OPPOSITION TO MOTION FOR CLASS CERTIFICATION"** was served on counsel via electronic means as follows:

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN, *et al.*,
Plaintiffs,

Civil Action No. 3:20-cv-00740
Hon. Robert C. Chambers, Judge

v.

WILLIAM CROUCH, *et al.*,
Defendants.

DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE EXPERT TESTIMONY OF STEPHEN B. LEVINE, M.D.

NOW COME the Defendants, by counsel, Lou Ann S. Cyrus, Roberta F. Green, Caleb B. David, Kimberly M. Bandy, and Shuman McCuskey Slicer PLLC, and, for their Response to Plaintiffs' Motion to Exclude Expert Testimony of Stephen B. Levine, M.D., state as follows:

INTRODUCTION AND SUMMARY OF ARGUMENTS

Plaintiffs have moved this Court to exclude all of Stephen B. Levine, M.D.'s opinions, not because he is unqualified to provide them but because his opinions allegedly lack probative value. Pls.' Mot. to Exclude, p. 20.[1] Plaintiffs also move to exclude certain opinions expressed by Dr. Levine in his report on various grounds. Plaintiffs oddly seek exclusion on the grounds that some of Dr. Levine's opinions align with Plaintiffs' own experts' opinions. Pls.' Mot. to Exclude, p. 4. Plaintiffs seek exclusion of certain opinions on relevancy grounds. Pls. 'Mot. to Exclude, p. 6. Plaintiffs seek exclusion of certain opinions because the medical literature their experts cite is inapposite to the medical literature cited by Dr. Levine. Pls.' Mot. to Exclude, p. 8. Finally, Plaintiffs seek exclusion of Dr. Levine's opinions regarding costs of gender-confirming care,

[1] It is impossible to determine from Plaintiffs' Motion whether Plaintiffs seek to exclude Dr. Levine's testimony in this case or his testimony from other cases. Dr. Levine only intends to offer the opinions disclosed in this civil action.

regarding puberty-delaying treatment, and regarding the treatment of pre-pubescent transgender children on the grounds that Dr. Levine is not qualified to offer opinions in these areas. Pls.' Mot. to Exclude, p. 16. Defendants will address each of Plaintiffs' arguments in turn; however, a brief analysis of Plaintiffs' burden of proof for each of their claims is required.

Plaintiffs have asserted four causes of action: (1) alleged violation of the Equal Protection Clause of the Fourteenth Amendment, (2) alleged violation of Section 1557 of the Affordable Care Act, (3) alleged violation of the Medicaid Act's availability requirements, and (4) alleged violation of the Medicaid Act's comparability requirements. Am. Compl. ¶¶ 157 – 195 (ECF 140). Regarding Plaintiffs' equal protection claim, to the extent the Court finds that Defendants' policy is subject to rational basis review, it is Plaintiffs' burden "to negate every conceivable basis which might support" the alleged unequal treatment. *Giarratano v. Johnson*, 521 F.3d 298, 303 (4th Cir. 2008) (additional citation omitted). This includes the basis of medical necessity. If intermediate scrutiny is applied to Plaintiffs' equal protection claim, the challenged classification must serve an important governmental purpose, and the means employed must be substantially related to that purpose. *U.S. v. Virginia*, 518 U.S. 515, 524, 532-33 (1996). Medical necessity may be an important governmental purpose. To prevail on their Section 1557 discrimination claim, Plaintiffs must prove that Defendants discriminated against them on the basis of sex rather than made a determination based on factors such as medical necessity.

To prevail on their claim for alleged violation of the Medicaid Act's availability requirements, Plaintiffs must prove that Defendants have failed to make available to them care that is required to be covered by the Act. 42 U.S.C. § 1396a(a)(10)(A). The regulations associated with the availability requirements permit an agency to place appropriate limits on a service based on criteria such as medical necessity or on utilization control procedures. 42 C.F.R. § 440.230(d).

Finally, to prevail on their claim for alleged violation of the Medicaid Act's comparability requirements, Plaintiffs must prove that Defendants' policy discriminates among categorically needy beneficiaries. *See Schott v. Olszewski*, 401 F.3d 682, 686 (6th Cir. 2005) ("Under the Act, states must provide comparable medical assistance to all Medicaid recipients within each classification, so long as the medically needy do not receive greater benefits than the categorically needy (although the reverse is permitted)."). Because Plaintiffs' claim is based upon the argument that procedures such as mastectomy are covered for breast cancer but not for gender dysphoria, medical necessity is again a consideration that the jury must undertake.

Because each of Plaintiffs' causes of action requires the jury to consider policy motives and/or medical necessity, it is essential that the jury be provided expert testimony regarding the medical necessity of gender-affirming surgeries. Thus, it is important that the jury be provided with information explaining the etiology of gender dysphoria, diagnostic criteria for gender dysphoria, treatment modalities for gender dysphoria, the efficacy of those treatment modalities, and the risks, benefits, and alternatives of those treatment modalities. To assist the jury with these issues, Defendants have retained Stephen B. Levine, M.D., who thoroughly discusses and explains these issues in his expert report and in his deposition. *See generally* Levine Report (ECF 252-11); Levine Dep. (ECF 252-20 to 252-22).

LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert witness testimony. Rule 702 states as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;

> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. "Nothing in the text of this Rule establishes 'general acceptance' as an absolute prerequisite to admissibility." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 588 (1993). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Id.* at 596 (citing *Rock v. Arkansas*, 483 U.S. 44, 61, 97 L. Ed. 2d 37, 107 S. Ct. 2704 (1987)). "These conventional devices, rather than wholesale exclusion under an uncompromising 'general acceptance' test, are the appropriate safeguards where the basis of scientific testimony meets the standards of Rule 702." *Id.*

"Implicit in the text of Rule 702, the *Daubert* Court concluded, is a district court's gatekeeping responsibility to 'ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand.'" *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017) (quoting *Daubert*, 509 U.S. at 597) (emphasis in original). "Relevant evidence, of course, is evidence that helps 'the trier of fact to understand the evidence or to determine a fact in issue.'" *Id.* (quoting *Daubert*, 509 U.S. at 591) (internal question marks omitted). "To be relevant under *Daubert*, the proposed expert testimony must have 'a valid scientific connection to the pertinent inquiry as a precondition to admissibility.'" *Id.* (quoting *Daubert*, 509 U.S. at 592).

"With respect to reliability, the district court must ensure that the proffered expert opinion is 'based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods.'" *Id.* (quoting *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999)). "*Daubert* offered a number of guideposts to help a district court determine if expert testimony is sufficiently reliable to be admissible. First,

'a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested.'" *Id.* (quoting *Daubert*, 509 U.S. at 593). "A second question to be considered by a district court is 'whether the theory or technique has been subjected to peer review and publication.'" *Id.* (quoting *Daubert*, 509 U.S. at 593). "Publication regarding the theory bears upon peer review; '[t]he fact of publication (or lack thereof) in a peer reviewed journal will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.'" *Id.* (quoting *Daubert*, 509 U.S. at 594). "[D]espite the displacement of *Frye*, 'general acceptance' is nonetheless relevant to the reliability inquiry." *Id.* (quoting *Daubert*, 509 U.S. at 594). "*Daubert's* list of relevant considerations is not exhaustive; indeed, the Court has cautioned that this 'list of specific factors neither necessarily nor exclusively applies to all experts or in every case,' and that a trial court has 'broad latitude' to determine whether these factors are 'reasonable measures of reliability in a particular case[.]'" *Id.* (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141, 153, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999)).

ARGUMENT

Dr. Levine is eminently qualified to provide opinions regarding the issues germane to this case. Dr. Levine's testimony in this case is well-supported by the medical literature and by his education, training, experience, knowledge, and skill. Plaintiffs' arguments go to the weight of Dr. Levine's testimony, not its admissibility; therefore, Plaintiffs' Motion must be denied.

I. Dr. Levine is qualified to testify regarding the issues germane to this case.

Dr. Levine is eminently qualified to testify regarding the etiology of gender dysphoria, diagnostic criteria for gender dysphoria, treatment modalities for gender dysphoria, the efficacy of those treatment modalities, and the risks, benefits, and alternatives of those treatment modalities.

Dr. Levine is a clinical professor of psychiatry at Case Western Reserve University School of Medicine and a private clinician. Levine Report, ¶ 1 (ECF 252-11). Dr. Levine has been practicing psychiatry for nearly 50 years. Levine Report, ¶ 2 (ECF 252-11). Dr. Levine founded Case Western's Gender Identity Clinic in 1974 and has served as its Co-Director since that time. Levine Report, ¶ 3 (ECF 252-11). Dr. Levine has treated several dozens of patients with transgender identities. Levine Report, ¶ 3 (ECF 252-11). Dr. Levine was an early member of the Harry Benjamin International Gender Dysphoria Association, now known as the World Professional Association for Transgender Health ("WPATH"), and he served as the Chairman of the committee that developed the fifth version of WPATH's "Standards of Care." Levine Report, ¶ 3 (ECF 252-11). Dr. Levine is a Distinguished Life Fellow of the American Psychiatric Association and an inductee in the Case Western's Department of Psychiatry's Hall of Fame. Levine Report, ¶ 2 (ECF 252-11). Dr. Levine has served and continues to serve as a peer reviewer for dozens of journals. Levine Report, ¶ 4 (ECF 252-11). He has served as the editor of psychiatric textbooks, has authored books, and has published 180 articles and book chapters, 19 of which focus specifically on the issues relevant to this case. Levine Report, ¶ 4 (ECF 252-11). Dr. Levine is frequently invited to lecture to professional groups and organizations in the field of psychiatry and regarding the mental health professional's role in treating gender dysphoria. Levine Report, ¶ 6 (ECF 252-11).

Thus, there is no question that Dr. Levine is qualified as an expert by knowledge, skill, experience, training, and/or education. Because Dr. Levine possesses Rule 702's qualifications to opine regarding the etiology of gender dysphoria, diagnostic criteria for gender dysphoria, treatment modalities for gender dysphoria, the efficacy of those treatment modalities, and the risks, benefits, and alternatives of those treatment modalities, Dr. Levine must be permitted to provide testimony regarding the same so long as the other requirements of Rule 702 are met.

As discussed in detail above, the issues upon which Dr. Levine opines are relevant to the elements of Plaintiffs' causes of action. Thus, Dr. Levine's opinions and specialized knowledge will help the trier of fact to understand the evidence and to determine facts in issue, namely the medical necessity of gender-affirming surgery. Dr. Levine's opinions are based on sufficient facts or data. Dr. Levine's opinions are supported by 242 citations to relevant medical literature, studies, and commentaries, as well as Dr. Levine's own education, training, experience, and knowledge, which includes nearly 50 years of clinical practice. Dr. Levine's opinions are the product of reliable principles and methods. In addition to his own education, training, experience, and knowledge, Dr. Levine relies upon peer-reviewed medical literature and systematic reviews of the literature to support his opinions. Finally, Dr. Levine has reliably applied the principles and methods to the facts of this case. Dr. Levine has synthesized the literature, studies, and commentaries to provide opinions regarding the medical necessity of gender-affirming surgery, which is a crucial fact in this case. Therefore, Dr. Levine's opinions generally meet the Rule 702 standard for admissibility. Defendants will address each of Plaintiffs' specific arguments regarding specific opinions in turn.

II. Dr. Levine's opinions are not supportive of Plaintiffs' claims; regardless, however, agreement on issues is not grounds for exclusion.

Plaintiffs claim that Dr. Levine's opinions are supportive of their claims for relief because Dr. Levine has provided "letters of approval for gender-confirming surgeries for transgender people incarcerated at Framingham, a correctional institution in Massachusetts." Pl.'s Mot. to Exclude, pp. 4 – 5. Dr. Levine's provision of "letters of approval" is irrelevant to the issues in this case and is not an admission of medical necessity. Dr. Levine opines in his report that "[t]he right to bodily autonomy via 'gender-affirming' hormonal and surgical interventions should not be confused with medical necessity." Levine Report, ¶ 10 (ECF 252-11). Dr. Levine explains, "An objective test for medical necessity of transgender interventions does not exist. The diagnosis is

self-generated by the patient and merely recorded by the clinician. The choice of interventions is granted based on a patient's wish. In transgender healthcare, this is often wrongly equated with medical necessity." Levine Report, ¶ 10 (ECF 252-11). This is consistent with Dr. Levine's deposition testimony regarding the "letters of approval":

> Q. And if you were treating a patient and determined that they understood the risks and you and the patient agreed the treatment would be – actually, let me back up, sorry. When you authorize medical interventions for transgender patients, Dr. Levine, you don't use the word medically necessary, right?
> A. I generally do not.
> Q. Is it correct to say that you use the word psychologically beneficial?
> A. Yes, it may be psychologically beneficial.
> …
> Q. Let me ask the question again. If you were treating a patient and determined that they understood the risks and you thought the treatment would be psychologically beneficial and you provided letters of authorization to them, you would want the patient then to be able to access the care, right?
> A. If after getting the letter of authorization the patient still wanted to do it, then I had already said to the endocrinologist or the surgeon it's okay with me to go ahead, that I've done my due diligence in this case. But the reason I'm hesitating, Mr. Charles, is that I've had several experiences, more than several, where I write a letter of recommendation for a desired treatment and then the patient does not follow through as a reflection of ambivalence about what they're doing. So I don't want to say that if I wrote a letter of recommendation for a particular treatment that I would want him to have it. I would say that if the patient still wants to after they have the go-ahead from me who's worked with the patient for a long time, then they may go ahead and do it and they have my blessing. …
> …
> A. … So the answer to your question is not, is that I would not strongly want the person to have that. I have already done my work, I've already written my letter, I've explained the patient's circumstances as far as I understand them to the endocrinologist or to the surgeon, and then what happens is determined by the patient and is, is determined by the doctor, the, you know, the consultant or the endocrinologist or the surgeon.

Levine Dep. 69:9 – 71:1 (ECF 252-20). Thus, Dr. Levine testified that he has provided letters of approval based upon patients' bodily autonomy, desire for treatment, and that such treatment may be psychologically beneficial for the patient. Dr. Levine specifically testified that he does not use the phrase "medically necessary." Rather, he respects the patient's bodily autonomy and signs off

on medical and surgical interventions if he has determined that the patient has the capacity to consent to the intervention and desires the intervention. This is no way supports Plaintiffs' claims for relief under the Equal Protection Clause, Section 1557 of the ACA, or the Medicaid Act and has no bearing upon whether West Virginia Medicaid is required by law to afford coverage for gender-affirming surgeries.

Plaintiffs also suggest that, because Dr. Levine does not hold himself out to be an insurance expert and is not advancing a non-medical opinion regarding whether Medicaid should or should not cover gender-affirming surgeries, his opinions will not assist the trier of fact. Pl.'s Mot. to Exclude, pp. 5 – 6. Dr. Levine is a psychiatrist who has opined on the medical necessity of medical and surgical treatment for a psychiatric condition with which Plaintiffs have been diagnosed and for which Plaintiffs seek insurance coverage. Dr. Levine is not required to have insurance expertise to testify regarding medical necessity. Dr. Levine is also not required to have a personal opinion on Medicaid's policy to testify regarding medical necessity.

In short, Dr. Levine's opinions regarding the etiology of gender dysphoria, diagnostic criteria for gender dysphoria, treatment modalities for gender dysphoria, the efficacy of those treatment modalities, and the risks, benefits, and alternatives of those treatment modalities will assist the trier of fact to understand the evidence and to determine facts in issue. Dr. Levine is not required to opine on every issue germane to this case, and agreements among Dr. Levine and Plaintiffs, to the extent any exist, do not preclude Dr. Levine's testimony. Therefore, Plaintiffs' Motion must be denied.

III. Dr. Levine's opinions are relevant and within the scope of this dispute, and the Fourth Circuit's factual findings in *Grimm* are irrelevant to the facts of this case and to Plaintiffs' Motion.

Plaintiffs claim that certain of Dr. Levine's opinions have no relevance to Plaintiffs' claims and, therefore, must be excluded. Specifically, Plaintiffs seek to exclude as irrelevant Dr. Levine's opinion that "the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic and physiologic characteristics…." Pl.'s Mot. to Exclude, p. 6. Plaintiffs claim that this partial sentence removed from context has no bearing on this case; however, in context, this opinion is relevant to the issue of medical necessity. Dr. Levine's report states as follows:

> Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally defined sex. For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to the assertions of certain members of the medical community, the aspiration of some trans individuals to become "a complete man" or "a complete woman" is not biologically attainable. It is possible for some individuals to "pass" unnoticed as the opposite gender that they aspire to be—**but with limitations, costs, and risks**.

Levine Report, ¶ 18 (internal citations omitted) (emphasis added). This opinion is, therefore, relevant as a basis for Dr. Levine's opinion that gender-affirming surgeries do not and cannot fully achieve the results desired by patients and come with limitations, costs, and risks, all of which informs the issue of medical necessity. Additionally, Plaintiffs' experts assert similar opinions regarding sex and gender identity. Karasic Report, ¶¶ 20-21 (ECF 250-20); Schechter Report, ¶¶ 18-19 (ECF 250-23); Olson-Kennedy Report, ¶¶ 18-20 (ECF 250-26). Thus, if Dr. Levine's opinions regarding biological sex are irrelevant, then Plaintiffs' experts' opinions regarding the same are likewise irrelevant.

Plaintiffs also seek to exclude Dr. Levine's opinion that "'gender exploratory' therapy can and has led to a resolution of gender dysphoria." Pls.' Mot. to Exclude, p. 7. Plaintiffs attempt to

discredit Dr. Levine's opinion by claiming that it is supported only by "anecdotal narrative articles" and by likening psychotherapy to "conversion therapy." Pls.' Mot. to Exclude, p. 7. Plaintiffs' most recent attempt to make Dr. Levine a pariah is unfounded and is consistent with recent comments from the current president of WPATH, Dr. Marci Bowers, who stated, "There are definitely people [in WPATH] who are trying to keep out anyone who doesn't absolutely buy the party line that everything should be affirming, and that there's no room for dissent." Levine Report, ¶ 23 (ECF 252-11) (citation omitted). Plaintiffs are again demonstrating that there is no room for dissent and assert that, because Dr. Levine disagrees with them, he is labeled as a proponent of conversion therapy.

Dr. Levine's report actually states,

> In a growing number of instances, especially among gender-dysphoric youth, proper therapeutic exploration has led to a resolution of gender dysphoria. It is true that quality evidence proving long-term effectiveness of psychotherapy interventions is missing—just as they are lacking for the hormonal and surgical interventions. However, Dr. Karasic's attempts to stigmatize gender-exploratory psychotherapy as "gender identity change efforts," or to stigmatize as "unethical" appear to be politically motivated to maintain his beliefs with little concern for the patient's long-term outcomes in mind. Such efforts will only serve to limit access to quality healthcare for the already struggling and vulnerable group of gender dysphoric patients.

Levine Report, ¶ 37 (internal citations omitted). Nowhere in Dr. Levine's report does he state that therapeutic exploration resolves transgender identity. Rather, he states that therapeutic exploration has resolved gender dysphoria, which is purportedly the goal of the surgical treatment for which Plaintiffs seek coverage. Dr. Levine's opinion is supported by not only his own clinical experience but also by peer-reviewed literature in the Journal of Infant, Child, and Adolescent Psychotherapy, the Metalogos Systemic Therapy Journal, the Journal of Child Psychotherapy, Clinical Child Psychology and Psychiatry, the International Journal of Psychoanalysis, and the Archives of Sexual Behavior. Levine Report, ¶ 37 (ECF 252-11). Plaintiffs are correct that Dr. Levine admits

that psychotherapy, like medical and surgical interventions, is lacking in long-term evidence of results. Levine Report, ¶ 160 (ECF 252-11). Once again, however, Plaintiffs take a single sentence out of context and fail to cite to the rest of the paragraph:

> The results of alternative approaches, such as watchful waiting for children, or gender-psychotherapy, are likewise lacking in long-term evidence. However, **emerging evidence suggests that psychotherapy is a promising intervention for young people**. It should be noted that a key Finnish gender program recently announced that psychotherapy should be the first line of treatment for all gender dysphoric youth. **A growing list of European countries appear to be moving in the same direction**.

Levine Report, ¶ 160 (ECF 252-11) (internal citations omitted) (emphasis added). Thus, Dr. Levine recognizes that more research is required to fully understand the efficacy of psychotherapy as a treatment modality for gender dysphoria, but he also cites to peer-reviewed literature showing emerging evidence supportive of psychotherapy and a growing consensus supporting the use of psychotherapy as the first treatment modality for gender dysphoria.

Additionally, Plaintiffs attempt to conflate a transgender identity with gender dysphoria and to argue that, because the Fourth Circuit made certain findings in *Grimm*, Dr. Levine's opinions have no relevance. First, Fourth Circuit precedent is not found in factual findings. The District Court in *Grimm* admitted the submissions of *amici curiae* as "evidence of the views of the organizations that prepared them, and not as substantive evidence of the accuracy of such views." *Grimm v. Gloucester Cnty. Sch. Bd.*, 400 F. Supp. 3d 444, 455 (E.D. Va. 2019). The Fourth Circuit then quoted the *amici* briefs in the factual section of its opinion. *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 594-96 (4th Cir. 2020). Plaintiffs' quotes from *Grimm* are not holdings and lack any precedential value. Moreover, the *Daubert* Court recognized that "[s]cientific conclusions are subject to perpetual revision," and, as a result, "open debate is an essential part of both legal and scientific analyses." *Daubert*, 509 U.S. at 596-97. In reversing the Court of Appeals, the *Daubert*

Court noted that "[t]he inquiries of the District Court and the Court of Appeals focused almost exclusively on 'general acceptance,' as gauged by publication and the decisions of other courts." *Id.* at 597. Thus, *Daubert's* principles require the trial court to rely upon the factual record before it, not the "decisions of other courts." Therefore, Plaintiffs' Motion must be denied.

IV. Dr. Levine's opinions are methodologically reliable and supported by science and medicine.

Plaintiffs claim that Dr. Levine "admitted" that his opinions lack any scientific support and have not been tested or subjected to peer review or publication. This is wildly inaccurate and misleading. Dr. Levine's opinions are supported by 242 citations to relevant medical literature, studies, and commentaries, as well as Dr. Levine's own education, training, experience, and knowledge, which includes nearly 50 years of clinical practice. Dr. Levine's opinions are the product of reliable principles and methods. In addition to his own education, training, experience, and knowledge, Dr. Levine relies upon peer-reviewed medical literature and systematic reviews of the literature to support his opinions. Finally, Dr. Levine has reliably applied the principles and methods to the facts of this case. Dr. Levine has synthesized the literature, studies, and commentaries to provide his opinions. Plaintiffs identify four specific opinions they claim are not reliable, and, without explanation, Plaintiffs claim that Dr. Levine's methodology is unreliable. Defendants will address each of Plaintiffs' specific arguments in turn.

1. Dr. Levine's opinions regarding WPATH's treatment guidelines are accurate and reliable.

Plaintiffs take issue with Dr. Levine's accurate citations to medical literature and to WPATH's president's comments about the advocacy organization's refusal to consider opinions outside its core beliefs. First, Plaintiffs take issue with Dr. Levine's opinion that WPATH's "standards of care" are "very low quality and unfit tools for clinical decision-making[.]" Pls.' Mot.

to Exclude, p. 10. Again, Plaintiffs leave out important context. Dr. Levine's report fully states, "A recently published systematic review found the current WPATH SOC7 guidelines to be of very low quality and unfit tools for clinical decision-making, noting 'incoherence' within the recommendations." Levine Report, ¶ 21 (ECF 252-11). Dr. Levine cites directly to the systematic review that noted incoherence within the recommendations. Levine Report, ¶ 21 (ECF 252-11). The systematic review states,

> No statements were highlighted by the WPATH SOCv7 authors as key recommendations, and it proved impossible for all six reviewers independently performing data extraction to identify them. The total number of extracted recommendations ranged between 0 and 168 with little consistency or agreement on what passages were selected. **Some extracted statements might have been intended as recommendations or standards, but many were flexible, disconnected from evidence and could not be used by individuals or services to benchmark practice**. After discussion of this **incoherence** within WPATH SOCv7 and our inability therefore to compare recommendations across all [clinical practice guidelines], it was decided not to revisit inclusions post hoc but to abandon this protocol aim.

Levine Dep., Ex. SL10 (ECF 252-21) (emphasis added). Thus, Dr. Levine accurately and reliably stated the findings of the article cited to in his report.

Plaintiffs also take issue with Dr. Levine's citation to a blog post that included comments from Dr. Marci Bowers. Plaintiffs do not claim that Dr. Levine inaccurately cited to the blog post or that the blog post inaccurately quoted Dr. Bowers. Rather, Plaintiffs argue Dr. Levine should have also cited to a subsequent statement of Dr. Bowers. This has no bearing on whether Dr. Bowers was accurately quoted and has no bearing on the admissibility of Dr. Levine's opinions. Plaintiffs do not even attempt to explain how the failure to include other comments from Dr. Bowers is exclusionary.

Plaintiffs further claim that Dr. Levine's opinions regarding foreign countries moving away from WPATH's guidelines should be excluded. Again, Dr. Levine's report includes citations to

support his opinions. Levine Report, ¶ 22. Since his report, additional information has been published, including a statement from the Swedish National Board of Health and Welfare, which recommends restraint when it comes to hormone therapy, finds a lack of firm conclusions about the efficacy and safety of hormone and puberty-blocking treatments, and finds that the risks outweigh the benefits. Olson Kennedy Dep., Ex. 7 (ECF 252-18). Thus, again, while Plaintiffs may cross-examine Dr. Levine and present their own evidence, Plaintiffs lack any grounds for exclusion of Dr. Levine's opinions, which are based upon medical literature, government statements, and Dr. Levine's education, training, experience, and knowledge. Therefore, Plaintiffs' Motion must be denied.

2. Dr. Levine's opinions regarding gender-confirming care are reliable.

Plaintiffs claim that Dr. Levine's opinions that gender-confirming care is inadequate, risky, and without lasting benefit are inaccurate and unsupported. Plaintiffs specifically cite to Paragraphs 23, 39, 51, 55, and 118 through 124 of Dr. Levine's report as opinions that are not supported. Dr. Levine's report totals 161 paragraphs. Thus, Plaintiffs take issue with less than ten percent of Dr. Levine's opinions. Regardless, ample support is found throughout Dr. Levine's report. Paragraph 23 of Dr. Levine's Report discusses his own experience with WPATH and includes the previously discussed comments by Dr. Marci Bowers. There is no better source for Dr. Levine's own experience with WPATH than Dr. Levine. Thus, Plaintiffs' argument is unfounded. Paragraph 39 of Dr. Levine's Report rebuts Dr. Karasic's opinions regarding the Dutch Study and discusses the Dutch Study's failure to include the outcomes of several members of its study population in its statistical analysis. Dr. Levine does not invent the excluded members of the population; they are disclosed in the study's methodology section but not included in the statistical analysis. *See* de Vries ALC, et al., "Young Adult Psychological Outcome After Puberty

Suppression and Gender Reassignment," *Pediatrics*, 2014, 134(4): 696-704, attached hereto as **Exhibit A**. Thus, Dr. Levine's opinion is based on the very same article as the opinion he was criticizing. Thus, Plaintiffs' argument is unfounded.

Paragraph 51 of Dr. Levine's Report disputes Dr. Karasic's analysis of the costs of medical and surgical interventions. Dr. Levine cites to six sources to support his opinions. Levine Report, ¶ 51 (ECF 252-11). Again, Plaintiffs may disagree with Dr. Levine's opinions and may disagree with the literature and other sources he cites, but that disagreement does not render Dr. Levine's opinions inadmissible. Paragraphs 118 through 124 provide opinions regarding the risks of complications associated with gender-affirming hormonal and surgical interventions. Levine Report, ¶¶ 118-124 (ECF 252-11). Dr. Levine's opinions in these seven paragraphs are supported by citations to nine separate publications in the literature. Plaintiffs do not identify any specific opinions in these seven paragraphs that should be excluded and do not identify any specific opinions that are allegedly unsupported. Thus, the record demonstrates that Dr. Levine's opinions are well-supported by the literature, and Plaintiffs have failed to specify opinions that are allegedly unsupported. Therefore, Plaintiffs' Motion must be denied.

3. Dr. Levine's opinions regarding desistance are based in fact and in the literature.

Plaintiffs claim that Dr. Levine's opinions regarding desistance are not based in fact. Again, Plaintiffs attempt to mischaracterize his opinions in a fictional binary vacuum, stating that the opinions in his report are not based in fact because Dr. Levine "conceded" that some children persist in their transgender identity. Pls.' Mot. to Exclude, pp. 12 – 13. Dr. Levine's opinion is that "the majority (61-98%) of children who identify has transgender will reidentify with their sex before reaching maturity absent any interventions." Levine Report, ¶ 90 (citation omitted). Dr.

Levine does not claim that no children persist in their transgender identity, and Plaintiffs' attempt to mischaracterize his opinions is unsupported.

Plaintiffs do not and cannot claim that Dr. Levine's opinions on this topic are unsupported. Rather, they claim that the literature cited to by Dr. Levine used prior versions of the DSM-V, so the literature is unreliable. While some of the literature cited to by Dr. Levine did indeed analyze treatment outcomes using diagnostic criteria from the DSM-IV, much of the literature cited to by Dr. Levine is from 2020 and 2021, representing the most recent available literature in the field. Levine Report, ¶ 90 (ECF 252-11). Additionally, there is literature examining the outcomes of using various diagnostic criteria on the same patients. That literature found significant overlap of the diagnostic criteria: "Interrater agreement rates for each instrument ranged from 65% to 79% for the adolescence/adulthood diagnoses and from 67% to 94% for the childhood diagnoses and were comparable regardless of the system used." Karasic Dep., Ex. 9, de Vries, et al., "Reliability and Clinical Utility of Gender Identity-Related Diagnoses: Comparisons Between the ICD-11, ICD-10, DSM-IV, and DSM-5," *LGBT Health*, Volume 8, No. 2, 2021 (ECF 252-8; PageID 4389). Thus, Dr. Levine's opinions, which rely upon medical literature from the last two years, are not unreliable simply because some of the literature analyzed data under the DSM-IV's diagnostic criteria. Indeed, there is no significant statistical difference in the diagnosis rates for individuals under the DSM-IV and DSM-V. Thus, Plaintiffs' argument is unfounded.

Plaintiffs also attempt to characterize Dr. Levine's opinions as an attempt to "undercut the validity" of the DSM-V. Dr. Levine has no opinions that claim that the DSM-V is invalid. Rather, he opines that the ICD-11 criteria do not include a criterion requiring clinically significant distress for diagnosis. Levine Report, ¶ 86. This is, of course, true. In the draft eighth version of WPATH's "Standards of Care," WPATH states, "One important reconceptualization in comparison to the

DSM-5 Gender Dysphoria classification is that distress is not a required indicator of the ICD-11 Gender Incongruence classification (WHO, 2019)." Olson-Kennedy Dep., Ex. 6 (ECF 252-18; PageID 5925). Thus, Dr. Levine's opinion does not attempt to undercut the validity of the DSM-V and, instead, is critical of the ICD-11, which WPATH is eager to adopt. Thus, there is no "hypothetical." The ICD-11 exists, and, while not yet used in the United States, is included in WPATH's still-forthcoming updated guidelines. Thus, Plaintiffs' argument is unfounded, and Plaintiffs' Motion must be denied.

3. Dr. Levine's opinions regarding rapid-onset gender dysphoria and detransition are supported by the literature.

Plaintiffs claim that Dr. Levine has asserted an "unsupported hypothesis" regarding rapid-onset gender dysphoria. Dr. Levine's opinion is that WPATH's draft eighth version of their guidelines does not acknowledge rapid-onset gender dysphoria or detransition, both of which have been documented in the literature. Levine Report, ¶ 79 (ECF 252-11) (citing Hutchinson A, et al., "In Support of Research Into Rapid-Onset Gender Dysphoria," *Arch Sex Behav*. 2020;49(1)) (citing Vandenbussche E, "Detransition-Related Needs and Support: A Cross-Sectional Online Survey," *Journal of Homosexuality*, published online April 30, 2021) (citing Littman L, "Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners," *Arch Sex Behav*., published online October 19, 2021). Plaintiffs' expert Johanna Olson-Kennedy, M.D. testified that she has witnessed a change in her patient population from a majority of individuals assigned male at birth to a majority of individuals assigned female at birth and that this cohort of patients is currently being studied. Olson-Kennedy Dep. 55:8 – 57:12 (ECF 252-18). This is consistent with the Swedish National Board of Health and Welfare's February 2022 recommendations halting the use of hormone therapy for minors: "The National Board of Health and Welfare has previously

presented statistics showing that the group of young people seeking care for gender dysphoria has increased sharply. Between 2008 and 2018, the number of new cases of diagnosed gender dysphoria multiplied. Particularly large was the increase among those aged 13 to 17 years and with registered sex female at birth." Olson-Kennedy Dep., Ex. 7 (ECF 252-18). This is precisely the phenomenon described by Dr. Levine in his report.

Additionally, regarding detransition, Dr. Levine cited to literature in his report to support that detransition occurs, and a growing number of individuals are coming out publicly to discuss their own detransition. Two of these individuals were acknowledged by Dr. Olson-Kennedy in her deposition. Olson-Kennedy Dep. 48:9 – 49:10. Dr. Levine did not "concede" in his deposition that he lacks scientific support for his opinion. Rather, he pointed to the literature cited in his report, which documented 337 individuals who had detransitioned. Levine Dep. 158:8 – 160:24. Dr. Levine did admit that the Littman article did not compare historical rates of detransition, but his "concessions" stopped there. Thus, Dr. Levine's opinions are supported by the literature. Plaintiffs' arguments are unfounded, and Plaintiffs' Motion must be denied.

V. Dr. Levine is qualified to offer opinions regarding puberty-delaying treatment and treatment of pre-pubescent children.

Plaintiffs claim that Dr. Levine is unqualified to offer opinions regarding costs of care, puberty-delaying treatment, and treatment of pre-pubescent children. At the outset, it must be noted that neither Plaintiff is seeking puberty-delaying treatment, that neither Plaintiff is a pre-pubescent child, and that Plaintiffs are not adequate representatives of a class that includes pre-pubescent children and/or individuals seeking puberty-delaying treatment. Thus, Plaintiffs' experts' opinions regarding the same are entirely irrelevant to Plaintiffs' claims.

Regardless, Dr. Levine is qualified to offer opinions regarding puberty-delaying treatment and the treatment of pre-pubescent children. Plaintiffs' expert Dr. Karasic does not treat children

at all, yet he purports to be qualified to offer opinions regarding the treatment of children. Karasic Dep. 43:22 – 44:3 (ECF 252-8). Plaintiffs posit, however, that, because Dr. Levine only rarely treats pre-pubescent children with gender dysphoria, he is not qualified. Dr. Levine has education, training, experience, and knowledge in the field of psychiatry and treating gender dysphoric children and relies upon peer-reviewed literature for his opinions. Dr. Levine's citations include his own published works as well as the work of others, including the 2017 Endocrine Society Guidelines. Levine Report, ¶¶ 132 – 139 (ECF 252-11). Plaintiffs' repeated attempts to discredit Dr. Levine through excerpts of out-of-context partial sentences is likewise unavailing. Dr. Levine only intends to offer the opinions disclosed in this case, and Plaintiffs have failed to establish that Dr. Levine is unqualified to offer those opinions or that his opinions are unreliable. Therefore, Plaintiffs' Motion must be denied.

Finally, Dr. Levine does not intend to offer opinions regarding the costs of procedures outside of the literature and sources included in his report. Dr. Levine's opinions regarding costs are directed at Dr. Karasic's financial analysis, which he is not qualified to perform, and its lack of inclusion of numerous costs. Dr. Levine disputes the cost analysis of Dr. Karasic but does not offer additional cost opinions.

WHERFORE, Defendants respectfully request that this Honorable Court deny Plaintiffs' Motion to Exclude Expert Testimony of Stephen B. Levine, M.D. Defendants request all other and further relief this Honorable Court deems just and proper.

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN and **SHAUNTAE ANDERSON;** individually and on behalf of all others similarly situated,

Plaintiffs,

Civil Action No. 3:20-cv-00740
Hon. Robert C. Chambers, Judge

v.

WILLIAM CROUCH, in his official capacity as Cabinet Secretary of the West Virginia Department of Health and Human Resources; **CYNTHIA BEANE,** in her official capacity as Commissioner for the West Virginia Bureau for Medical Services; and **WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES,**

Defendants.

CERTIFICATE OF SERVICE

Now come Defendants William Crouch, Cynthia Beane and West Virginia Department of Health and Human Resources Bureau for Medical Services, by counsel, and do hereby certify that on the 14th day of June, 2022, a true and exact copy of **"DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE EXPERT TESTIMONY OF STEPHEN B. LEVINE, M.D."** was served on counsel via electronic means as follows:

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Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment

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KEY WORDS

gender dysphoria, transgenderism, adolescents, psychological functioning, puberty suppression, longitudinal outcomes

ABBREVIATIONS

ABCL—Adult Behavior Checklist
ASR—Adult Self-Report
BDI—Beck Depression Inventory
BIS—Body Image Scale
CBCL—Child Behavior Checklist
CGAS—Children's Global Assessment Scale
CSH—cross-sex hormones
GD—gender dysphoria
GnRHa—gonadotropin-releasing hormone analogs
GRS—gender reassignment surgery
SHS—Subjective Happiness Scale
STAI—Spielberger's Trait Anxiety Scale
SWLS—Satisfaction With Life Scale
TPI—Spielberger's Trait Anger Scale
UGDS—Utrecht Gender Dysphoria Scale
YSR—Youth Self-Report

Dr de Vries conceptualized the study, clinically assessed the participants, drafted the initial manuscript, and reviewed and revised the manuscript; Dr McGuire conceptualized the study, planned and carried out the analyses, assisted in drafting the initial manuscript, and reviewed and revised the manuscript; Dr Steensma conceptualized the study, coordinated and supervised data collection, and reviewed and revised the manuscript; Dr Wagenaar coordinated and invited participants for assessments and reviewed and revised the manuscript; Drs Doreleijers and Cohen-Kettenis conceptualized the study and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.

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(Continued on last page)

WHAT'S KNOWN ON THIS SUBJECT: Puberty suppression has rapidly become part of the standard clinical management protocols for transgender adolescents. To date, there is only limited evidence for the long-term effectiveness of this approach after gender reassignment (cross-sex hormones and surgery).

WHAT THIS STUDY ADDS: In young adulthood, gender dysphoria had resolved, psychological functioning had steadily improved, and well-being was comparable to same-age peers. The clinical protocol including puberty suppression had provided these formerly gender-dysphoric youth the opportunity to develop into well-functioning young adults.

abstract

BACKGROUND: In recent years, puberty suppression by means of gonadotropin-releasing hormone analogs has become accepted in clinical management of adolescents who have gender dysphoria (GD). The current study is the first longer-term longitudinal evaluation of the effectiveness of this approach.

METHODS: A total of 55 young transgender adults (22 transwomen and 33 transmen) who had received puberty suppression during adolescence were assessed 3 times: before the start of puberty suppression (mean age, 13.6 years), when cross-sex hormones were introduced (mean age, 16.7 years), and at least 1 year after gender reassignment surgery (mean age, 20.7 years). Psychological functioning (GD, body image, global functioning, depression, anxiety, emotional and behavioral problems) and objective (social and educational/professional functioning) and subjective (quality of life, satisfaction with life and happiness) well-being were investigated.

RESULTS: After gender reassignment, in young adulthood, the GD was alleviated and psychological functioning had steadily improved. Well-being was similar to or better than same-age young adults from the general population. Improvements in psychological functioning were positively correlated with postsurgical subjective well-being.

CONCLUSIONS: A clinical protocol of a multidisciplinary team with mental health professionals, physicians, and surgeons, including puberty suppression, followed by cross-sex hormones and gender reassignment surgery, provides gender dysphoric youth who seek gender reassignment from early puberty on, the opportunity to develop into well-functioning young adults. *Pediatrics* 2014;134:1–9

Transgender adolescents experience an incongruence between their assigned gender and their experienced gender and may meet the Diagnostic and Statistical Manual of Mental Disorders 5 criteria for gender dysphoria (GD).[1] Fifteen years ago, pubertal delay was introduced as an aid in the treatment of a gender dysphoric adolescent.[2] Although not without debate, blocking pubertal development has rapidly become more widely available[3–7] and is now part of the clinical management guidelines for GD.[8–12]

Gonadotropin-releasing hormone analogs (GnRHa) are a putatively fully reversible[13] medical intervention intended to relieve distress that gender dysphoric adolescents experience when their secondary sex characteristics develop. A protocol designed by Cohen-Kettenis and Delemarre-van de Waal[14] (sometimes referred to as "the Dutch model")[4,7] considers adolescents, after a comprehensive psychological evaluation with many sessions over a longer period of time, eligible for puberty suppression, cross-sex hormones (CSH), and gender reassignment surgery (GRS) at the respective ages of 12, 16, and 18 years when there is a history of GD; no psychosocial problems interfering with assessment or treatment, for example, treatment might be postponed because of continuous moving from 1 institution to another or repeated psychiatric crises; adequate family or other support; and good comprehension of the impact of medical interventions.[12] Puberty suppression is only started after the adolescent actually enters the first stages of puberty (Tanner stages 2–3), because although in most prepubertal children GD will desist, onset of puberty serves as a critical diagnostic stage, because the likelihood that GD will persist into adulthood is much higher in adolescence than in the case of childhood GD.[15,16]

Despite the apparent usefulness of puberty suppression, there is only limited evidence available about the effectiveness of this approach. In the first cohort of adolescents who received GnRHa, we demonstrated an improvement in several domains of psychological functioning after, on average, 2 years of puberty suppression while GD remained unchanged.[16] The current study is a longer-term evaluation of the same cohort, on average, 6 years after their initial presentation at the gender identity clinic. This time, we were not only interested in psychological functioning and GD, but added as important outcome measures objective and subjective well-being (often referred to as "quality of life"), that is, the individuals' social life circumstances and their perceptions of satisfaction with life and happiness.[17–19] After all, treatment cannot be considered a success if GD resolves without young adults reporting they are healthy, content with their lives, and in a position to make a good start with their adult professional and personal lives.[20] Because various studies show that transgender youth may present with psychosocial problems,[21,22] a clinical approach that includes both medical (puberty suppression) and mental health support (regular sessions, treatment when necessary, see Cohen-Kettenis et al[12]) aims to improve long-term well-being in all respects.

In the present longitudinal study, 3 primary research questions are addressed. Do gender dysphoric youth improve over time with medical intervention consisting of GnRHa, CSH, and GRS? After gender reassignment, how satisfied are young adults with their treatment and how do they evaluate their objective and subjective well-being? Finally, do young people who report relatively greater gains in psychological functioning also report a higher subjective well-being after gender reassignment?

METHODS

Participants and Procedure

Participants included 55 young adults (22 transwomen [natal males who have a female gender identity] and 33 transmen [natal females who have a male gender identity]) of the first cohort of 70 adolescents who had GD who were prescribed puberty suppression at the Center of Expertise on Gender Dysphoria of the VU University Medical Center and continued with GRS between 2004 and 2011. These adolescents belonged to a group of 196 consecutively referred adolescents between 2000 and 2008, of whom 140 had been considered eligible for medical intervention and 111 were prescribed puberty suppression (see de Vries et al[16]). The young adults were invited between 2008 and 2012, when they were at least 1 year past their GRS (vaginoplasty for transwomen, mastectomy and hysterectomy with ovariectomy for transmen; many transmen chose not to undergo a phalloplasty or were on a long waiting list). Nonparticipation (n = 15, 11 transwomen and 4 transmen) was attributable to not being 1 year postsurgical yet (n = 6), refusal (n = 2), failure to return questionnaires (n = 2), being medically not eligible (eg, uncontrolled diabetes, morbid obesity) for surgery (n = 3), dropping out of care (n = 1), and 1 transfemale died after her vaginoplasty owing to a postsurgical necrotizing fasciitis. Between the 55 participants and the 15 nonparticipating individuals, Student's t tests revealed no significant differences on any of the pretreatment variables. A similar lack of differences was found between the 40 participants who had complete data and the 15 who were missing some data.

Participants were assessed 3 times: pre-treatment (T0, at intake), during treatment (T1, at initiation of CSH), and post-treatment (T2, 1 year after GRS). See Table 1 for age at the different time points. The VU University Medical Center medical ethics committee approved the study, and all participants gave informed consent.

TABLE 1 Age at Different Treatment Milestones and Intelligence by Gender

Variable	All Participants[a] (*N* = 55)		Transwomen (Natal Males) (*N* = 22)	Transmen (Natal Females) (*N* = 33)
Age, y	Mean (SD)	Range	Mean (SD)	Mean (SD)
At assessment PreT	13.6 (1.9)	11.1–17.0	13.6 (1.8)	13.7 (2.0)
At start of GnRHa	14.8 (1.8)	11.5–18.5	14.8 (2.0)	14.9 (1.9)
At start of CSH	16.7 (1.1)	13.9–19.0	16.5 (1.3)	16.8 (1.0)
At GRS	19.2 (0.9)	18.0–21.3	19.6 (0.9)	19.0 (0.8)
At assessment PostT	20.7 (1.0)	19.5–22.8	21.0 (1.1)	20.5 (0.8)
Full-scale intelligence[b]	99.0 (14.3)	70–128	97.8 (14.2)	100.4 (14.3)

PostT, post-treatment; PreT, pre-treatment.

[a] Comparisons between those who had complete data (*n* = 40) and those who had missing data on the CBCL/ABCL (*n* = 15) reveal no significant differences between the groups in age at any point in the study or in natal sex.

[b] WISC-R, the WISC-III, or the WAIS-III at first assessment, depending on age and time.[45–47]

Measures

Time was the predominate independent variable. Other demographic characteristics were incorporated in some models, including, age, natal sex, Full Scale Intelligence, and parent marital status; where significantly different they are reported.

Gender Dysphoria/Body Image

There was 1 indicator measuring GD (Utrecht Gender Dysphoria Scale [UGDS]) and 3 indicators measuring body image (Body Image Scale [BIS] with primary, secondary, and neutral subscales). Higher UGDS (12 items, 1–5 range, total score ranging from 12–60) total scores indicate higher levels of GD, for example, "I feel a continuous desire to be treated as a man/woman."[23] There are separate versions of the UGDS for males and females with mostly different items, permitting no gender difference analyses. BIS (30 items, 1–5 range) higher scores indicate more dissatisfaction with primary sex characteristics (important gender-defining body characteristics, eg, genitals, breasts), secondary sex characteristics (less obvious gender-defining features, eg, hips, body hair), and neutral (hormonally unresponsive) body characteristics (eg, face, height).[24] The male and the female BIS are identical except for the sexual body parts. The UGDS and the BIS of the natal gender were administered at T0 and T1. At T1, we chose the UGDS of the assigned gender, because no physical changes had occurred yet and some were still treated as their assigned gender. This way, however, decreased GD caused by social transitioning was not measured. At T2 young adults filled out the versions of their affirmed gender.

Psychological Functioning

There were 10 indicators assessing psychological functioning. To assess global functioning, the Children's Global Assessment Scale (CGAS) was used.[25] The Beck Depression Inventory (BDI; 21 items, 0–3 range) indicates presence and severity of depressive symptoms.[26] Spielberger's Trait Anger (TPI) and Spielberger's Trait Anxiety (STAI; 10 and 20 items, respectively, 1–4 range) scales of the State-Trait Personality Inventory were administered to assess the tendency to respond with anxiety or anger, respectively, to a threatening or annoying situation.[27,28]

Behavioral and emotional problems were assessed by the total, internalizing, and externalizing T scores as well as clinical range scores for these 3 indices (T score >63) of the Child/Adult Behavior Checklist (CBCL at T0 and T1, ABCL at T2), the Youth/Adult Self-Report (YSR at T0 and T1, ASR at T2).[29–31] Items referring to GD in the CBCL/YSR and ABCL/ASR were scored as 0 (for more explanation, see Cohen-Kettenis et al[32]).

Objective and Subjective Well-Being (T2 Only)

A self-constructed questionnaire was used to ask the young adults about their current life circumstances, such as living conditions, school and employment, and social support (objective well-being), and satisfaction with treatment (subjective well-being). Three instruments further assessed subjective well-being. To measure quality of life, the WHOQOL-BREF (quality of life measure developed by the World Health Organization) was administered (24 items, 4 domains: Physical Health, Psychological Health, Social Relationships, and Environment, 1–5 range with higher scores indicating better quality of life).[17] The Satisfaction With Life Scale (SWLS, 5 items, 5–35 range, 20 being neutral) was used to assess life satisfaction.[18] Higher scores on the Subjective Happiness Scale (SHS, 4 items, 7-point Likert scale, average score 1–7) reflect greater happiness.[19]

Data Analyses

General Linear Models examined the repeated measures with an analysis of variance-based model, incorporating continuous and categorical predictors, and correcting for the unbalanced cell sizes. Linear and quadratic effects of the 14 indicators across 3 time points, with time as the within-subjects factor, and sex as a between-subjects factor in a second set of analyses are reported in Tables 2 and 3 and Fig 1. A linear effect signifies an overall change across T0 to T2. A quadratic effect signifies that the change was not continuous, such as when an indicator does not improve from T0 to T1 but improves from T1 to T2. It is possible to have both a significant linear and quadratic effect on the same

TABLE 2 Gender Dysphoria and Body Image of Adolescents at Intake (T0), While on Puberty Suppression (T1), and After Gender Reassignment (T2)

	N[a]	T0	T1	T2	T0–T2	Time	Time × Sex
					t test	Linear Effect Quadratic Effect	Linear Effect Quadratic Effect
		Mean (SD)	Mean (SD)	Mean (SD)	*P*	*P*	*P*
UGDS	33	53.51 (8.29)	54.39 (7.70)	15.81 (2.78)	<.001		
MtF	11	47.07 (11.05)	48.95 (10.80)	17.27 (2.57)	<.001	<.001 <.001	n/a
FtM	22	56.74 (3.74)	57.11 (3.40)	15.08 (2.64)	<.001	<.001 <.001	n/a
Body Image (BIS)							
Primary sex characteristics	45	4.13 (0.59)	4.05 (0.60)	2.59 (0.82)	<.001	<.001 <.001	.01 .45
MtF	17	4.03 (0.68)	3.82 (0.56)	2.07 (0.74)	<.001		
FtM	28	4.18 (0.53)	4.13 (0.60)	2.89 (0.71)	<.001		
Secondary sex characteristics	45	2.73 (0.72)	2.86 (0.67)	2.27 (0.56)	<.001	<.001 <.001	.10 <.001
MtF	17	2.63 (0.60)	2.34 (0.68)	1.93 (0.63)	<.001		
FtM	28	2.80 (0.72)	3.18 (0.43)	2.48 (0.40)	.05		
Neutral body characteristics	45	2.35 (0.68)	2.49 (0.53)	2.23 (0.49)	.29	.29 .01	.007 .01
MtF	17	2.57 (0.70)	2.29 (0.50)	2.09 (0.56)	.014		
FtM	28	2.21 (0.64)	2.61 (0.52)	2.32 (0.44)	.40		

FtM, female to male transgender; MtF, male to female transgender; n/a, not applicable.

[a] Participants who had complete data at all 3 waves were included. Some assessments were added to the study later, yielding fewer total participants for those scales.

indicator. Other potential between-subjects factors (age, total IQ, parental marital status) were examined but excluded owing to a lack of relationship with the 14 indicators at T0. The 1 exception, age predicting secondary sex characteristics, is described below in the findings. We compared T2 sample means to population norms for subjective well-being using 1-sample *t* tests from previously published validation studies. Finally, we examined T2 subjective well-being correlations with residual change scores from T0 to T2 on the 14 indicators (an indicator of who improved relatively more or less over time).

All measures used were self-reported, except the CGAS (attending clinician) and the CBCL/ASR (parents). Each participant was given all measures at each of 3 assessments. Numbers varied across indicators owing to the later inclusion of the YSR, CGAS, BDI, TPI, and STAI, yielding 8 persons who had missing data at T0 and a clinician error yielding missing data at T1 for 10 participants on the UGDS. Dutch versions were used (see de Vries et al[16]).

RESULTS

Gender Dysphoria and Body Satisfaction

Figure 1 and Table 2 show that GD and body image difficulties persisted through puberty suppression (at T0 and T1) and remitted after the administration of CSH and GRS (at T2) (significant linear effects in 3 of 4 indicators, and significant quadratic effects in all indicators). Time by sex interactions revealed that transwomen reported more satisfaction over time with primary sex characteristics than transmen and a continuous improvement in satisfaction with secondary and neutral sex characteristics. Transmen reported more dissatisfaction with secondary and neutral sex characteristics at T1 than T0, but improvement in both from T1 to T2. Age was a significant covariate with secondary sex characteristics (the only significant demographic covariate with any outcome indicator in the study), indicating that older individuals were more dissatisfied at T0, but the age gap in body satisfaction narrowed over time ($F(1, 42) = 8.18$; $P < .01$).

Psychological Functioning

As presented in Table 3, significant linear effects showed improvement over time in global functioning (CGAS), CBCL/ABCL total, internalizing and externalizing *T* scores, and YSR/ASR total and internalizing *T* scores. Quadratic effects revealed decreases from T0 to T1 followed by increases from T1 to T2 in depression and YSR/ASR internalizing *T* scores. Quadratic trends revealed decreases from T0 to T1, followed by increases from T1 to T2 in depression and YSR/ASR internalizing *T* scores. For all CBCL/ABCL and YSR/ASR indicators except YSR/ASR externalizing, the percentage in the clinical range dropped significantly (McNemar's test, *P* value <0.05) from T0 to T1, from T0 to T2, or from T1 to T2.

Over time, transmen showed reduced anger, anxiety, and CBCL/ABCL externalizing *T* scores, whereas transwomen showed stable or slightly more symptomatology on these measures. Transwomen improved in CBCL/ABCL total *T* scores in a quadratic fashion (all the improvement between T1 and T2),

TABLE 3 Psychological Functioning of Adolescents at Intake (T0), While on Puberty Suppression (T1), and After Gender Reassignment (T2)

	N[a]	T0	T1	T2	T0–T2	Time	Time × Sex
					t test	Linear Effect Quadratic Effect	Linear Effect Quadratic Effect
		Mean (SD)	Mean (SD)	Mean (SD)	*P*	*P*	*P*
Global functioning (CGAS)	32	71.13 (10.46)	74.81 (9.86)	79.94 (11.56)	<.001	<.001	.89
						.61	.68
MtF	15	74.33 (7.53)	78.20 (9.56)	82.40 (8.28)	<.001		
FtM	17	67.65 (11.87)	70.65 (9.89)	76.29 (14.48)	.02		
Depression (BDI)	32	7.89 (7.52)	4.10 (6.17)	5.44 (8.40)	.21	.23	.66
						.04	.49
MtF	12	4.73 (4.20)	2.25 (3.54)	3.38 (4.40)	.12		
FtM	20	10.09 (8.34)	5.05 (7.08)	6.95 (9.83)	.32		
Anger (TPI)	32	17.55 (5.72)	17.22 (5.61)	16.01 (5.28)	.20	.15	.04
						.52	.12
MtF	12	14.17 (3.01)	14.00 (3.36)	5.58 (3.92)	.18		
FtM	20	19.55 (5.96)	19.25 (5.69)	16.56 (6.06)	.05		
Anxiety (STAI)	32	39.57 (10.53)	37.52 (9.87)	37.61 (10.39)	.45	.42	.05
						.47	.52
MtF	12	31.87 (7.42)	31.71 (8.36)	35.83 (10.22)	.14		
FtM	20	44.41 (9.06)	41.59 (9.03)	39.20 (10.53)	.12		
CBCL–ABCL							
Total *T* score	40	60.20 (12.66)	54.70 (11.58)	48.10 (9.30)	<.001	<.001	.25
% Clinical		38_x	20_y	5_y		.68	.03
MtF	15	57.40 (12.76)	49.67 (12.29)	48.13 (12.58)	.002		
FtM	25	61.88 (12.56)	57.72 (10.23)	48.08 (6.95)	<.001		
Int *T* score	40	60.83 (12.36)	54.42 (10.58)	50.45 (10.04)	<.001	<.001	.91
% Clinical		30_x	12.5_y	10_y		.42	.33
MtF	15	59.40 (10.03)	50.93 (11.15)	48.73 (12.61)	<.001		
FtM	25	61.68 (13.70)	56.52 (9.86)	51.48 (8.25)	<.001		
Ext *T* score	40	57.85 (13.73)	53.85 (12.77)	47.85 (8.59)	<.001	<.001	.19
% Clinical		40_x	25_x	2.5_y		.43	.12
MtF	15	52.53 (14.11)	47.87 (12.07)	46.33 (10.95)	.10		
FtM	25	61.04 (12.71)	57.44 (12.01)	48.76 (6.89)	<.001		
YSR-ASR							
Total *T* score	43	54.72 (12.08)	49.16 (11.16)	48.53 (9.46)	.005	.005	.28
% Clinical		30_x	14_{xy}	7_y		.07	.75
MtF	17	50.65 (12.19)	45.94 (12.24)	47.24 (12.28)	.28		
FtM	26	57.38 (11.47)	51.27 (10.08)	49.38 (7.21)	.01		
Int *T* score	43	55.47 (13.08)	48.65 (12.33)	50.07 (11.15)	.03	.03	.87
% Clinical		30_x	9.3_y	11.6_{xy}		.008	.73
MtF	17	54.00 (12.31)	47.59 (14.26)	48.12 (12.54)	.04		
FtM	26	56.42 (13.86)	49.35 (11.13)	51.35 (10.19)	.17		
Ext *T* score	43	52.77 (12.47)	49.44 (9.59)	49.44 (9.37)	.14	.14	.005
% Clinical		21_x	11.6_x	7_x		.09	.14
MtF	17	46.00 (11.58)	44.71 (9.53)	50.24 (11.18)	.17		
FtM	26	57.16 (11.14)	52.54 (8.43)	48.92 (8.18)	.006		

FtM, female to male transgender; MtF, male to female transgender.

[xy] Percent clinical range, shared subscripts indicate no significant difference in values. In no case was an increase in percent in the clinical range significant from 1 time point to any other time point, indicating an overall decline or stability of clinical symptoms over time.

[a] Participants who had complete data at all 3 waves were included. Some assessments were added to the study later, yielding fewer total participants for those scales.

whereas transmen improved steadily across the 3 time points (linear effect only).

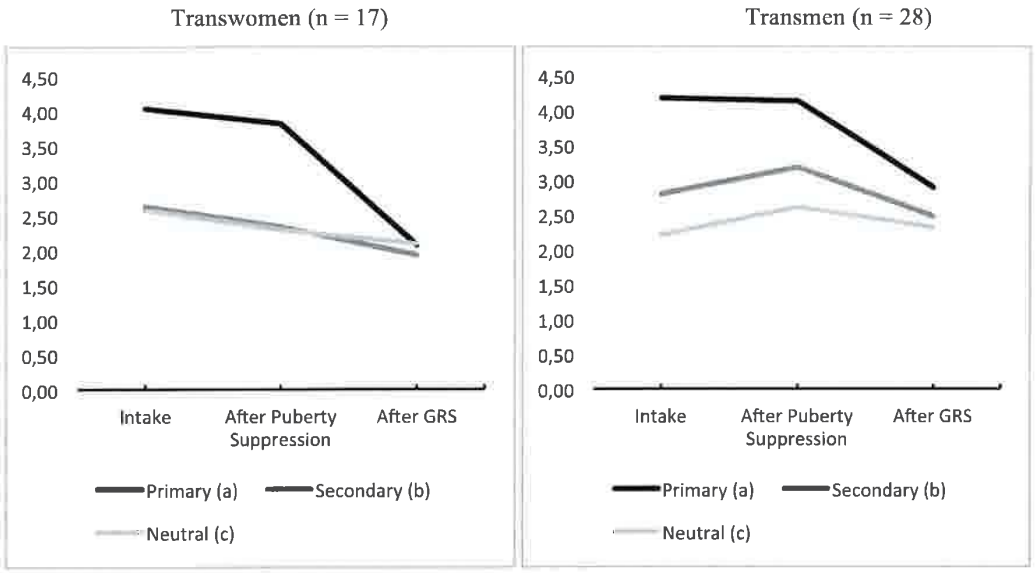
Objective Well-Being

At T2, the participants were vocationally similar to the Dutch population except they were slightly more likely to live with parents (67% vs 63%), and more likely, when studying, to be pursuing higher education (58% vs 31%).[33]

Families were supportive of the transitioning process: 95% of mothers, 80% of fathers, and 87% of siblings. Most (79%) young adults reported having 3 or more friends, were satisfied with their male (82%) and female peers (88%), and almost all (95%) had received support from friends regarding their gender reassignment. After their GRS, many participants (89%) reported having been never or seldom called names or harassed. The majority (71%) had experienced social transitioning as easy.

Subjective Well-Being

None of the participants reported regret during puberty suppression, CSH



Eta Squared for Linear and Quadratic Effects

(a) Primary sex characteristics
Time: .79 ($P < .001$), .66 ($P < .001$),
Time × sex: .14 ($P = .01$), .01 ($P = .45$),

(b) Secondary sex characteristics
Time: .31($P < .001$), .30 ($P < .001$),
Time × sex: .06 ($P = .10$), .22 ($P < .001$)

(c) Neutral body characteristics
Time: .07($P < .001$), .09 ($P = .29$)
Time × sex: .16 ($P = .007$), .15 ($P = .01$)

FIGURE 1
BIS[23] for transwomen and transmen at T0 (pretreatment, at intake), T1 (during treatment, at initiation of cross-gender hormones), and T2 (post-treatment, 1 year after GRS).

treatment, or after GRS. Satisfaction with appearance in the new gender was high, and at T2 no one reported being treated by others as someone of their assigned gender. All young adults reported they were very or fairly satisfied with their surgeries.

Mean scores on WHOQOL-BREF, the SWLS, and the SHS are presented in Table 4, together with scores from large validation and reliability studies of these measures,[17,19,34] revealing similar scores in all areas except WHOQOL-Environment subdomain, which was higher for the participants than the norm. There were some differences across gender; transwomen scored higher than transmen on the SWLS (mean = 27.7; SD = 5.0 vs mean = 23.2; SD = 6.0; t (52) = 2.82; $P < .01$) and on the psychological subdomain of the WHOQOL (mean = 15.77; SD = 2.0 vs mean = 13.92; SD = 2.5; t (53) = 2.95; $P < .01$).

Correlations With Residual Change Scores

The residual change scores of secondary sex characteristics, global functioning, depression, anger, anxiety, and YSR total, internalizing and externalizing from T0 to T2, were significantly correlated with the 6 T2 quality of life indicators. Most correlation coefficients were within the moderate to large magnitude (eg, 0.30–0.60), except depression, which was highly correlated (0.60–0.80) (see Table 5).

DISCUSSION

Results of this first long-term evaluation of puberty suppression among transgender adolescents after CSH treatment and GRS indicate that not only was GD resolved, but well-being was in many respects comparable to peers.

The effectiveness of CSH and GRS for the treatment of GD in adolescents is in line with findings in adult transsexuals.[35,36] Whereas some studies show that poor surgical results are a determinant of postoperative psychopathology and of dissatisfaction and regret,[37,38] all young adults in this study were generally satisfied with their physical appearance and none regretted treatment. Puberty suppression had caused their bodies to

TABLE 4 Subjective Well-Being: Quality of Life, Satisfaction With Life, and Subjective Happiness Mean Scores With Scores From Validation Studies

	N	Mean (SD)	Range	Validation Studies Scores Mean (SD)	Comparison *P*
WHOQOL[a] Physical	55	15.22 (2.49)	8.6–20.0	15.0 (2.9)[b]	.56
WHOQOL Psychological	55	14.66 (2.44)	6.67–20.0	14.3 (2.8)[b]	.24
WHOQOL Social Relations	55	14.91 (2.35)	9.3–20.00	14.5 (3.4)[b]	.18
WHOQOL Environment	55	15.47 (2.06)	10.5–20.00	13.7 (2.6)[b]	<.001
SWLS	54	24.98 (6.0)	9.0–35.0	26.18 (5.7)[c]	.16
SHS	54	4.73 (0.77)	2.75–6.0	4.89 (1.1)[d]	.17

[a] WHOQOL, Bref, Skevington et al.[16]
[b] International field trial, ages 21 to 30 years, Skevington et al.[16]
[c] Dutch young adults, Arindell et al.[53]
[d] US Public College Students, Lyubomirsky.[18]

not (further) develop contrary to their experienced gender.

Psychological functioning improved steadily over time, resulting in rates of clinical problems that are indistinguishable from general population samples (eg, percent in the clinical range dropped from 30% to 7% on the YSR/ASR[30]) and quality of life, satisfaction with life, and subjective happiness comparable to same-age peers.[17,19,34] Apparently the clinical protocol of a multidisciplinary team with mental health professionals, physicians, and surgeons gave these formerly gender dysphoric youth the opportunity to develop into well-functioning young adults. These individuals, of whom an even higher percentage than the general population were pursuing higher education, seem different from the transgender youth in community samples with high rates of mental health disorders, suicidality and self-harming behavior, and poor access to health services.[21,22,39,40]

In this study, young adults who experienced relatively greater improvements in psychological functioning were more likely to also report higher levels of subjective postsurgical well-being. This finding suggests value to the protocol that involves monitoring the adolescents' functioning, physically and psychologically, over many years, and providing more support whenever necessary.

This clinic-referred sample perceived the Environmental subdomain (with items like "access to health and social care" and "physical safety and security") of the WHOQOL-BREF as even better than the Dutch standardization sample.[17] Whereas in some other contexts transgender youth may experience gender-related abuse and victimization,[22,41,42] the positive results may also be attributable to supportive parents, open-minded peers, and the social and financial support (treatment is covered by health insurance) that gender dysphoric individuals can receive in the Netherlands.

Both genders benefitted from the clinical approach, although transwomen showed more improvement in body image satisfaction (secondary sex characteristics) and in psychological functioning (anger and anxiety). None of the transmen in this study had yet had a phalloplasty because of waiting lists or

TABLE 5 Correlations Between Residual Change in Psychological Functioning Over Time and Young Adult Subjective Well-Being

	WHOQOL BREF					
	Physical	Psychological	Social	Environment	SWLS	SHS
Gender dysphoria (UGDS)	0.01 (.97)	0.05 (.75)	−0.09 (.57)	−0.02 (.89)	0.06 (.71)	0.30 (.04)
Body image subscales (BIS)						
Primary sex characteristics	−0.22 (.14)	−0.25 (.09)	−0.35 (.02)	−0.04 (.78)	−0.22 (.14)	−0.21 (.17)
Secondary sex characteristics	−0.39 (.006)	−0.45 (<.001)	−0.47 (<.001)	−0.34 (.02)	−0.35 (.02)	−0.26 (.08)
Neutral body characteristics	−0.21 (.16)	−0.27 (.07)	−0.15 (.32)	−0.28 (.06)	−0.26 (.08)	−0.16 (.28)
Psychological functioning						
Global functioning (CGAS)	0.60 (<.001)	0.52 (.002)	0.52 (.002)	0.27 (.14)	0.58 (<.001)	0.50 (.004)
Depression (BDI)	−0.76 (<.001)	−0.72 (<.001)	−0.51 (.002)	−0.49 (.003)	−0.61 (<.001)	−0.77 (<.001)
Trait anger (TPI)	−0.37 (.03)	−0.18 (.31)	−0.22 (.20)	−0.29 (.09)	−0.33 (.07)	−0.35 (.05)
Trait anxiety (STAI)	−0.58 (<.001)	−0.64 (<.001)	−0.38 (.03)	−0.44 (.01)	−0.49 (.004)	−0.57 (<.001)
CBCL–ABCL						
Total *T* score	−0.20 (.20)	−0.12 (.45)	−0.07 (.65)	−0.14 (.35)	−0.32 (.03)	−0.16 (.29)
Internalizing *T* score	−0.29 (.06)	−0.29 (.06)	−0.23 (.14)	−0.12 (.44)	−0.48 (<.001)	−0.36 (.02)
Externalizing *T* score	−0.13 (.40)	−0.05 (.75)	0.16 (.29)	−0.20 (.19)	−0.15 (.36)	0.00 (.99)
Youth Self Report (YSR–ASR)						
Total *T* score	−0.53 (<.001)	−0.45 (.002)	−0.33 (.03)	−0.42 (.005)	−0.52 (<.001)	−0.55 (<.001)
Internalizing *T* score	−0.62 (<.001)	−0.61 (<.001)	−0.47 (<.001)	−0.40 (.007)	−0.66 (<.001)	−0.60 (<.001)
Externalizing *T* score	−0.23 (.13)	−0.10 (.53)	−0.07 (.67)	−0.37 (.02)	−0.22 (.15)	−0.35 (.02)

P values are in parentheses.

a desire for improved surgery techniques. This finding warrants further study of the specific concerns of young transmen.

Despite promising findings, there were various limitations. First, the study sample was small and came from only 1 clinic. Second, this study did not focus on physical side effects of treatment. Publications on physical parameters of the same cohort of adolescents are submitted or in preparation. A concurring finding exists in the 22-year follow-up of the well-functioning first case now at age 35 years who has no clinical signs of a negative impact of earlier puberty suppression on brain development, metabolic and endocrine parameters, or bone mineral density.[43] Third, despite the absence of pretreatment differences on measured indicators, a selection bias could exist between adolescents of the original cohort that participated in this study compared with nonparticipants.

Age criteria for puberty suppression and CSH are under debate, although they worked well for adolescents in the current study. Especially in natal females, puberty will often start before the age of 12 years. Despite the fact that developing evidence suggests that cognitive and affective cross-gender identification, social role transition, and age at assessment are related to persistence of childhood GD into adolescence, predicting individual persistence at a young age will always remain difficult.[44] The age criterion of 16 years for the start of CSH may be problematic especially for transwomen, as growth in height continues as long as cross-sex steroids are not provided (causing the growth plates to close). Therefore, psychological maturity and the capacity to give full informed consent may surface as the required criteria for puberty suppression and CSH[45] in cases that meet other eligibility criteria.

CONCLUSIONS

Results of this study provide first evidence that, after CSH and GRS, a treatment protocol including puberty suppression leads to improved psychological functioning of transgender adolescents. While enabling them to make important age-appropriate developmental transitions, it contributes to a satisfactory objective and subjective well-being in young adulthood. Clinicians should realize that it is not only early medical intervention that determines this success, but also a comprehensive multidisciplinary approach that attends to the adolescents' GD as well as their further well-being and a supportive environment.

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