Exhibit 7

Gender Assignment Surgery and Gender Reassignment Surgery with Related Services

Number: SUR717.001

Effective Date: 12-01-2021

Coverage:

CAREFULLY CHECK STATE REGULATIONS AND/OR THE MEMBER CONTRACT

I. GENDER ASSIGNMENT SURGERY

Gender assignment surgery for patients with ambiguous genitalia diagnosed at birth or in infancy is considered reconstructive surgery and **may be considered medically necessary.**

II. GENDER REASSIGNMENT SURGERY

NOTE: State Legislation may apply. Carefully check for legislative mandates that may apply for each plan.

ILLINOIS Legislative Mandate: 50 Illinois. Administrative. Code 2603.35 provides that a group health insurance plan that is neither a grandfathered plan nor a plan offering excepted benefits shall not discriminate on the basis of an insured's or prospective insured's actual or perceived gender identity, or on the basis that the insured or prospective insured is a transgender person.

Pursuant to the above, Gender Reassignment Surgery would be a covered benefit for Illinois insured policies subject to the coverage criteria set forth below.

CAREFULLY REVIEW the member's benefit contract for gender reassignment surgery and related services provisions. If there is a discrepancy between this medical policy and the member's benefit contract, the contract will govern.

Refer to Coding section for information on CPT codes to report female-to-male breast/chest surgery.

Gender reassignment surgery -- also known as transsexual surgery or sex reassignment surgery -- and related services **may be considered medically necessary** when meeting the criteria for gender dysphoria listed below.

Otherwise, gender reassignment surgery and related services **are considered not medically necessary.**

A. Gender Reassignment Surgery and Related Services for Children and Adolescents:

The following services **may be considered medically necessary** for the treatment of gender dysphoria for children and adolescents:

- Hormone therapy (such as, puberty-suppressing hormones or masculinizing/feminizing hormones);
- Psychological services, including but not limited to psychotherapy, social therapy, and family counseling; and/or
- Chest surgery for female-to-male (FtM) individuals.

The individual being considered for surgery and related services must meet ALL the following criteria. The individual must have:

- Been diagnosed with persistent, well-documented gender dysphoria; **and**
- The required referrals prior to any surgery or related service(s):

- Prior to feminizing or masculinizing hormonal therapy, one required referral from the individual's qualified mental health professional (**see NOTE 2**) competent in the assessment and treatment of gender dysphoria; **and/or**
- Prior to breast/chest surgery, e.g., mastectomy, chest reconstruction, or breast augmentation, one required referral from the individual's qualified mental health professional (**see NOTE 2**) competent in the assessment and treatment of gender dysphoria.

NOTE 1: The 2012 World Professional Association for Transgender Health (WPATH) Version 7, Standards of Care (SOC) (6) state that adolescent individuals seeking irreversible interventions, such as genital surgery:

"Genital surgery should not be carried out until (i) patients reach the legal age of majority to give consent for medical procedures in a given country, and (ii) patients have lived continuously for at least 12 months in the gender role that is congruent with the gender identity. The age threshold should be seen as a minimum criterion and not an indication in and of itself for active intervention."

B. Criteria for Coverage of Gender Reassignment Surgery and Related Services for Adults:

The individual being considered for surgery and related services must meet ALL the following criteria. The individual must have:

- Reached the age of majority; **and**
- The capacity to make a fully informed decision and to consent for treatment; **and**
- Been diagnosed with persistent, well-documented gender dysphoria; **and**
- The required referrals prior to any surgery or related service(s):
  - Prior to feminizing or masculinizing hormonal therapy, one required referral from the individual's qualified mental health professional (**see NOTE 2**) competent in the assessment and treatment of gender dysphoria; **and/or**
  - Prior to breast/chest surgery, e.g., mastectomy, chest reconstruction, or breast augmentation, one required referral from the individual's qualified mental health professional (**see NOTE 2**) competent in the assessment and treatment of gender dysphoria; **and/or**
  - Prior to any genital surgery, e.g., hysterectomy, salpingo-oophorectomy, orchiectomy, and/or other genital reconstructive procedures, two separate required independent referrals (or one signed by both referring providers) from the individual's qualified mental health professionals (**see NOTE 2**) competent in the assessment, treatment of gender dysphoria, and addressing the identical/same surgery to be performed.

NOTE 2: Psychotherapy and Mental Health Services:

Psychotherapy is not required for gender reassignment services except when a mental health professional recommends psychotherapy based on initial assessment prior to gender reassignment surgery. The recommendation for psychotherapy must specify the goals of treatment along with estimates of the frequency and duration of therapy throughout the individual's experience living in one's affirmed gender.

C. Gender Reassignment Pharmaceutical Services:

Continuous hormone replacement therapy **may be considered medically necessary** prior to gender reassignment of either male-to-female (MtF) or FtM surgical services or following gender reassignment MtF or FtM surgical services.

Continuous hormone replacement therapy may include the following services:

- Hormone injections by the medical provider, such as during an office visit; and/or
- Self-administered oral and injectables obtained from a pharmacy.

NOTE 3: It is not uncommon for an individual to receive continuous hormone replacement therapy for 12-months or more.

Pharmaceutical agents to treat hair loss or growth, sexual performance post-gender reassignment genital surgery (e.g., Viagra or Cialis), and/or cosmetic enhancements, including collagen and/or botulinum toxin injections, **are considered not medically necessary.**

D. Gender Reassignment Laboratory Services:

Laboratory testing to monitor continuous hormonal replacement therapy for treatment of gender dysphoria **may be considered medically necessary.**

E. Primary Sexual Characteristic Gender Reassignment Chest and/or Genital Surgeries:

MtF surgical procedures performed as part of gender reassignment services for an individual who has met the above criteria for gender dysphoria **may be considered medically necessary** and include the following:

- Breast modification, including but not limited to breast enlargement, breast augmentation, mastopexy, implant insertion, and silicone injections, and nipple or areola reconstruction;
- Clitoroplasty;
- Coloproctostomy;
- Colovaginoplasty;
- Labioplasty;
- Orchiectomy;
- Penectomy;
- Penile skin inversion;
- Repair of introitus;
- Vaginoplasty with construction of vagina with graft; and/or
- Vulvoplasty.

Female-to-Male (FtM) surgical procedures performed as part of gender reassignment services for an individual who has met the above criteria for gender dysphoria **may be considered medically necessary** and include the following:

- Hysterectomy;
- Metoidioplasty;
- Phalloplasty;
- Placement of an implantable erectile prostheses;
- Placement of testicular prostheses;
- Salpingo-oophorectomy;
- Scrotoplasty;
- Subcutaneous mastectomy, including nipple or areola reconstruction;
- Vaginectomy (colpectomy);
- Urethroplasty; and/or
- Urethromeatoplasty.

F. Secondary Sexual Characteristic (Masculinizing or Feminizing) Gender Reassignment Surgeries and Related Services:

Procedures or services to create and maintain gender specific characteristics (masculinization or feminization) as part of the overall desired gender reassignment services treatment plan **may be considered medically necessary for the treatment of gender dysphoria ONLY.** These procedures may include the following:

- Abdominoplasty;
- Blepharoplasty;
- Brow lift;
- Calf implants;
- Cheek implants;
- Chin or nose implants;
- External penile prosthesis (vacuum erection devices);
- Face lift (rhytidectomy);
- Facial bone reconstruction/sculpturing/reduction, includes jaw shortening;
- Forehead lift or contouring;
- Hair removal (laser hair removal or electrolysis) which may include donor skin sites; or hair transplantation (hairplasty);
- Laryngoplasty;
- Lip reduction or lip enhancement;
- Liposuction/lipofilling or body contouring or modeling of waist, buttocks, hips, and thighs reduction;
- Neck tightening;
- Pectoral implants;
- Reduction thyroid chondroplasty or trachea shaving (reduction of Adam's apple);
- Redundant/excessive skin removal;
- Rhinoplasty (nose correction);
- Skin resurfacing;
- Testicular expanders;
- Voice modification surgery; and/or
- Voice (speech) therapy or voice lessons.

NOTE 4: Preparatory and ancillary procedures (such as anesthesia, tissue harvesting for skin, fat, nerve or muscle grafting, etc.) and supplies or equipment (such as stents, prosthesis, implants, etc.) that are required for the procedures listed above are considered an integral part of the MtF or FtM transition process.

NOTE 5: Surgical repairs or revisions related to MtF or FtM procedures may be required, such as removal and replacement of prostheses.

G. Gender Primary or Secondary Sexual Characteristic Revision Surgeries

When there is documented evidence of physical functional impairment, gender primary or secondary sexual characteristic revision procedures or services **are considered medically necessary.**

When there is **no** documented evidence of physical functional impairment, gender primary or secondary sexual characteristics revision services **are considered not medically necessary** (refer to appropriate procedure-specific policy).

H. Gender Reassignment Reproductive Services:

Procurement, cryopreservation/freezing, storage/banking, and thawing of reproductive tissues, such as oocytes, ovaries, embryos, spermatozoa, and testicular tissue **may be considered medically necessary** for individuals with gender dysphoria because gender reassignment services, such as long-term cross-sex hormone therapy or surgical procedures, may render an individual infertile whether or not the individual has reproduced in the past.

I. Reversal of Gender Reassignment Surgical Procedures

For reversal of any of the prior gender reassignment surgical procedure(s) or service(s) for gender primary or secondary sexual characteristics, the patient must meet the same criteria for gender dysphoria to have those reversal procedures **considered medically necessary**.

If the criteria for gender dysphoria is not met, then reversal of any prior gender reassignment surgical procedure(s) or service(s) for gender primary or secondary sexual characteristics **is considered not medically necessary.**

J. Preventive Medicine Gender Reassignment Services:

Preventive medicine services **considered medically necessary** in conjunction with gender reassignment services include:

- Breast cancer screening for FtM individuals; or
- Cervical cancer screening for FtM individuals; or
- Prostate cancer screening for MtF individuals; or
- Contraception pharmaceuticals for FtM individuals at risk of pregnancy.

Description:

Gender Assignment Surgery

Gender assignment surgery (GAS), also known as genitoplasty, is genital reconstruction of ambiguous genitalia in newborns or infants difficult to classify as a male or female. The extent of the ambiguity varies. In very rare instances, the physical appearance may be fully developed as the opposite of the genetic sex (e.g., a genetic male may have developed the appearance of a typical female). (1) To the lay person the determination of an infant's sex can easily be identified as male or female, by virtue of outward genital anatomy, secondary sexual characteristics and behavior within their relevant cultural context. Arriving at a satisfactory scientific definition is more difficult as gender reflects the outcome of complex interactions occurring from the time of conception and extending throughout pre- and postnatal life. (2)

Intersex anomalies associated with ambiguous genitalia may result from major chromosomal abnormalities or from specific gene mutations as in congenital adrenal hyperplasia. (2) Typically, the ambiguous genitalia in genetic females (babies with two X chromosomes) include an enlarged clitoris that has the appearance of a small penis. The urethral opening can be anywhere along, above, or below the surface of the clitoris. The labia may be fused, resembling a scrotum. The infant may be thought to be a male with undescended testicles. Sometimes a lump of tissue is felt within the fused labia, further making it look like a scrotum with testicles. (3, 4)

In a genetic male (babies with one X and one Y chromosome), the ambiguous genitalia typically include a small penis (less than 2-3 centimeters or 0.8-1.2 inches) that may appear to be an enlarged clitoris (the clitoris of a newborn female is normally somewhat enlarged at birth). The urethral opening may be anywhere along, above, or below the penis; it can be placed as low as the

peritoneum, further making the infant appear to be female. There may be a small scrotum with any degree of separation, resembling labia. Undescended testicles commonly accompany ambiguous genitalia. (3, 4)

Disorders which include ambiguous genitalia, which are usually not life threatening, have serious and potentially lifelong consequences for the affected child and, depending on the underlying cause, are likely to entail surgery in childhood and in later life, for example endocrine replacement therapy in conjunction with steroid replacement for those with congenital adrenal hyperplasia. (1) Making a correct determination of gender is both important for treatment purposes, as well as the emotional well-being of the child. Some children born with ambiguous genitalia may have normal internal reproductive organs.

The incidence of a child with a disorder of sexual development (DSD) is approximately 1 in 1000 to 4500 live births. (21-22) The most frequently occurring etiology was congenital adrenal hyperplasia (CAH) followed by androgen insensitivity and mixed gonadal dysgenesis. A list of the most common causes is listed below:

- Pseudohermaphroditism, the genitalia are of one sex, but some physical characteristics of the other sex are present.
- True hermaphrodism, a very rare condition in which both ovarian and testicular tissue is present. The child may have parts of both male and female genitalia.
- Mixed gonadal dysgenesis, an intersex condition in which there appears to be some male structures (gonads, testis), as well as a uterus, vagina, and fallopian tubes.
- Congenital adrenal hyperplasia, a potentially life-threatening condition, has several forms, but the most common form causes the genetic female to appear male.
- Chromosomal abnormalities, including Klinefelter's syndrome (XXY) and Turner's syndrome (XO).
- Maternal ingestion of certain medications (including androgenic steroids) may cause a genetic female to look more male.
- Lack of production of specific hormones can cause the embryo to develop with a female body type regardless of genetic sex, such as the lack of testosterone cellular receptors. (1)

Regulatory Status

Gender assignment surgical procedures are surgical interventions and, as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA).

Gender Reassignment Surgery

Gender dysphoria (formerly known as 'gender identity disorder') is a condition recognized by the Diagnostic and Statistical Manual (DSM) of Mental Disorders and commonly known as transsexualism. (5) The diagnostic criteria describe many individuals who experience dissonance between their sex at birth and personal gender identity, which is not the same as having ambiguous genitalia. According to the American Academy of Pediatrics, based on population surveys completed in 2014 of 19 states, it suggested that the number of adults who identify as "gender non-conforming" or transgender is 0.6% (1.4 million). (7) On the basis of that data, it is estimated that 0.7% of youth, ages 13 to 17 years (~150,000) identify as transgender.

Gender reassignment surgery (GRS) is also known as sex reassignment surgery; genital reconstruction surgery; sex affirmation surgery; sex realignment surgery; intersex surgery, or sex-change operation. It is a term used for the culmination of a series of surgical procedures and treatments by which a person's physical appearance and the function(s) of existing sexual characteristics are altered or even irreversibly changed to that of the opposite sex. Gender reassignment generally consists of several treatment plans, which include the diagnostic phase (mostly supported through mental health professional interaction) followed by continuous hormonal therapy (through an endocrinologist). It includes living openly in a manner consistent with the affirmed gender or completed with the GRS itself. (5)

Other terms are used to describe these procedures. These include sex reconstruction surgery; gender confirmation surgery; feminizing genitoplasty or penectomy, orchidectomy and vaginoplasty for trans women, with masculinizing genitoplasty or phalloplasty for trans men. (Definitions of these procedures can be found later in this Description section.) These procedures and services are used to treat individuals diagnosed with gender dysphoria in transsexual or transgender people. (1, 2, 6)

Guidelines for GRS and related services have been developed by the World Professional Association for Transgender Health (WPATH) (1), formerly known as the Harry Benjamin International Gender Dysphoria Association. WPATH is an international, multispecialty, professional

association whose mission is to promote evidence-based care, education, research, advocacy, public policy, and respect for transgender health. In May 2010, WPATH urged de-psychopathologization of gender nonconformity worldwide by stating, "The expression of gender characteristics, including identities, that are not stereotypically associated with one's assigned sex at birth is a common culturally-diverse human phenomenon [that] should not be judged as inherently pathological or negative." WPATH clarified the related procedures and services when an individual is considering surgical transformation from male-to-female (MtF) or female-to-male (FtM), as well as how the treatment differs for gender dysphoria and transsexualism. (1)

WPATH Standards of Care (SOC)

The WPATH SOC document provides an overview of surgical procedures to treat patients with gender dysphoria, otherwise known as gender affirming surgeries. (6, 7)

"For the MtF (male-to-female) patient, surgical procedures may include the following:

1. Breast/chest surgery: augmentation mammoplasty (implants/lipofilling);
2. Genital surgery: penectomy, orchiectomy, vaginoplasty, clitoroplasty, vulvoplasty;
3. Non-genital, non-breast surgical interventions: facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal augmentation (implants/lipofilling), hair reconstruction, and various aesthetic procedures."

"For the FtM (female-to-male) patient, surgical procedures may include to following:

1. Breast/chest surgery: subcutaneous mastectomy, creation of male chest;
2. Genital surgery: hysterectomy/salpingo-oophorectomy, reconstruction of the fixed part of the urethra, which can be combined with a metoidioplasty or with a phalloplasty (employing a pedicle or free vascularized flap), vaginectomy, scrotoplasty, and implantation of erection and/or testicular prostheses;
3. Non-genital, non-breast surgical interventions: voice surgery (rare), liposuction, lipofilling, pectoral implants, and various aesthetic procedures."

SOC criteria for surgical services were introduced as a guide to decision making for breast/chest and genital surgery. (6) However, the SOC does not include criteria for other surgical procedures, such as masculinizing or feminizing facial surgery. The SOC does not stipulate the number, sequence, and/or timing of surgical procedures because they will vary from patient to patient, according to an individual patient's clinical needs and expectations, in collaboration with mental health and surgical professionals. (6)

Terminology in Relationship to Gender Reassignment Surgery and Related Services

Health care terminology for transsexual, transgender, and gender nonconforming individuals is rapidly evolving; new terms are being introduced and definitions of existing terms are changing. This tends to create misunderstanding, debate, or disagreement about the language used in this field.

For the purposes of this policy document, we have defined terms that may be unfamiliar or that have specific meanings in the "SOC." Although others may adopt these definitions, WPATH has acknowledged that the terms they use may be defined differently in different cultures, communities, and contexts. (1)

- Affirmed gender is when an individual's true gender identity, or concern about their gender identity, is communicated to and validated from others as authentic. (7)
- Agender is an individual who does not identify as having a particular gender. (7)
- Bioidentical hormones are structurally identical to those found in the human body and generally derived from plant sources. The hormones used in bioidentical hormone therapy (BHT) need to be commercially processed to become bioidentical. (6)
- Bioidentical compounded hormone therapy (BCHT) are prepared, mixed, assembled, packaged, or labeled as a drug by a pharmacist and custom-made for an individual according to a physician's specifications. (6)
- Cisgender or cissexual describes related types of gender identity perceptions, where the individuals' experiences of their own gender agree with the sex they were assigned at birth. Cisgender may be a complement to transgender. (6)
- Cross-sex hormone therapy, transgender hormone therapy or medical affirmation refers to a form of hormone replacement therapy in which sex hormones and other hormonal medications are administered for the purpose of more closely aligning with the individual's secondary sexual characteristics. (7)
- Disorders of sex development are the congenital conditions in which the development of chromosomal, gonadal, or anatomic sex is atypical. Some people strongly object to the

"disorder" label and instead view these conditions as a matter of diversity (1), preferring the terms intersex and intersexuality.

- Female-to-Male (FtM) describes individuals assigned female at birth who are changing or who have changed their body and/or gender role from birth-assigned female to a more masculine body or role. (6)
- Feminizing hormone therapy for transgender women or transfeminine individuals consists of estrogens and antiandrogens/androgen inhibitor. (7)
- Gender diverse is an umbrella term to describe an ever-evolving array of labels that individuals may apply when their gender identity, expression, or even perception does not conform to the norms and stereotypes others expects of their assigned sex. (7)
- Gender dysphoria, formerly known as gender identity disorder, is characterized by strong persistent cross-gender identification or a discrepancy between with the continuous discomfort or distress about one's anatomic sex (person's sex assigned at birth) or, by a sense of inappropriateness in the gender role of that sex. (1, 2) This includes inappropriateness, clinically caused impairment in social, occupational, or other important areas of functioning. (2)
- Gender identity is the intrinsic sense of knowing to which sex one belongs—that is the awareness that 'I am female" (a girl or woman), or "I am male" (a boy or a man). Gender identity is the private experience of gender role, and gender role is the public expression of gender identity. Gender role can be defined as everything one says and does, including sexual arousal, to indicate to others or to oneself the degree to which one is male or female. Some individuals describe themselves not as gender-nonconforming, but as unambiguously cross-sexed or unique/transitional. Such individuals no longer consider themselves to be either male or female. An individual may never fully embrace the gender role they were assigned at birth or an individual may actualize their gender identity, role, and expression in a way that does not involve a change from one gender to another gender. (1, 6) Gender identity and sexual orientation (see below) are distinct but interrelated constructs. Therefore, being transgender does not imply a sexual orientation, and individuals who identify still identify as straight, gay, bisexual, etc., on the basis of their attractions. (7)
- Gender identity disorder is a psychiatric diagnosis defined previously in the DSM-IV (changed to "gender dysphoria" in the DSM-5). This diagnosis is no longer appropriate for use and may lead to stigma, but the term may be found in older research. (7)
- Gender non-conforming is an adjective to describe individuals whose gender identity, role, or expression differs from what is normative for their assigned sex in a given culture and historical period or the individual differs from the cultural norms prescribed for people of a particular sex. (1)
- Gender role or expression are characteristics in personality, appearance, and behavior that in a given culture and historical period are designated as masculine or feminine (that is, more typical of the male or female social role). While most individuals present socially in clearly masculine or feminine gender roles, some people present in an alternative gender role such as "genderqueer" or specifically transgender. All people tend to incorporate both masculine and feminine characteristics in their gender expression in varying ways and to varying degrees. (1)
- Gender perception is the way others interpret an individual's gender expression. (7)
- "Genderqueer" is the identity label that may be used by individuals whose gender identity and/or role does not conform to a binary understanding of gender as limited to the categories of man or woman, male or female. (6)
- Genital phenotype is largely determined by androgenic stimulation of the external genitalia in embryonic and fetal life and depends on the presence of the appropriate receptors in the target tissues. (2)
- Gonadal phenotype is defined by the internal genitalia and the external morphology and microanatomy of the gonads (testis or ovary). (2)
- Hormones that express the sexual differentiation in humans include estrogens, progesterone, and androgens, such as testosterone. (6)
- Internalized transphobia describes the discomfort with one's own transgender feelings or identity as a result of internalizing society's normative gender expectations.
- Legal affirmation refers to the changing of gender and name recorded on birth certificate, school records, passports, and other documents. (7)
- Masculinizing hormone therapy for transgender men or transmasculine individuals consists of androgens, such as testosterone. (7)
- Male-to-Female (MtF) describes individuals assigned male at birth who are changing or who have changed their body and/or gender role from birth-assigned male to a more feminine body or role. (6)
- Natural hormones are derived from natural sources such as plants and animals. Natural hormones may or may not be bioidentical. (6)

- Puberty blockers are gonadotropin-releasing hormone (GnRH) analogues, such as leuprolide and histrelin. (7)
- Sex is assigned at birth as male or female, usually based on the appearance of the external genitalia, also known as "natal gender". When the external genitalia are ambiguous, other components of sex (internal genitalia, chromosomal and hormonal sex) are considered in order to assign sex. For most people, gender identity and expression are consistent with their sex assigned at birth; for transsexual, transgender, and gender nonconforming individuals, gender identity or expression differ from their sex assigned at birth. (1)
- Sexual characteristics are the physical and behavioral traits of an organism. In humans, sex organs or primary sexual characteristics are those an individual is born with. These traits are distinguished from secondary sex characteristics that develop later in life usually during puberty. The development of primary and secondary sexual characteristics is controlled by sex hormones produced in the body after the initial fetal stage, dependent on the presence or absence of the Y-chromosome and/or the testis-determining factor/gene to determine development. (6)
- Sexual orientation refers to an individual's identity relation to the gender(s) to which they are sexually and romantically attracted. (7)
- Social affirmation refers to adopting gender-affirming hairstyles, clothing, name, gender pronouns, and restrooms, including other facilities. (7)
- Surgical affirmation are the surgical/procedural approaches to feminize or masculinize physical features of an individual. (7)
- Transgender describes a diverse group of individuals who cross or transcend culturally-defined categories of gender. The gender identity of transgender people differs to varying degrees from the sex they were assigned at birth. (6)
- Transition is the period of time when individuals change from the gender role associated with their sex assigned at birth to a different gender role. For many people, this involves learning how to live socially in another gender role; for others this means finding a gender role and expression that is most comfortable for them. Transition may or may not include feminization or masculinization of the body through hormones or other medical procedures. The nature and duration of transition is variable and individualized. (1, 6)
- Trans men assume male gender identities. Trans men have an internal sense of being male and generally seek to make their maleness known socially and legally along with conforming their primary and secondary sex characteristics to a more typical male appearance. (1)
- Transsexualism is a gender dysphoria disorder in which the person manifests, with constant and persistent conviction, the desire to live as a member of the opposite sex and progressively takes steps to live in the opposite sex role full-time. These individuals who seek to change or who have changed their primary and/or secondary sex characteristics through feminizing or masculinizing medical interventions (hormones and/or surgery), typically accompanied by a permanent change in gender role. (2)
- Transvestism or cross-dressing describes the individual clothing and adopting a gender role presentation that, in a given culture, is more typical of the other sex. (5)
- Trans women assume female gender identities. Trans women have an internal sense of being female and generally seek to make their femaleness known socially and legally along with conforming their primary and secondary sex characteristics to a more typical female appearance. (11)

Definitions of Irreversible Chest and Genital Surgical Procedures for Gender Reassignment

- Augmentation mammaplasty – insertion of breast implants or lipofilling (suctioning of body fat from one body area and filling into another body area) to create the female chest.
- Clitoroplasty – creation of a clitoris, utilizing the penile glans.
- Genitoplasty – genital reconstruction or modification of genitalia.
- Hysterectomy/salpingo-oophorectomy – removal of the uterus with or without ovaries and fallopian tubes.
- Metoidioplasty – following testosterone replacement therapy, the clitoris enlarges to be separated from the labia minora to create a penis.
- Orchiectomy – both testicles are removed.
- Penectomy – removal of the penis.
- Phalloplasty – construction or reconstruction of the penis.
- Reconstruction of the fixed part of the urethra – associated surgical reconstruction with the scrotoplasty to create a scrotal complex.
- Scrotoplasty – creation of a penis from external genitalia, such as the labia majora, with or without testicular prosthesis insertion or implant.

- Subcutaneous mastectomy – removal of breast tissue, sparing the nipple-areola complex to create the male chest.
- Vaginectomy – removal of part or the entire vagina.
- Vaginoplasty – construction or reconstruction of the vaginal canal and may include neovaginoplasty, the partial or total construction of the vulvo-vaginal complex.
- Vulvoplasty – a reduction of the labia and may be known as a labiaplasty.

Regulatory Status

Gender reassignment surgical procedures are surgical interventions and, as such, are not subject to regulation by the FDA. The devices and medications/combinations of medications used in the treatment of gender dysphoria are subject to FDA approval or clearance. Refer to the FDA web site at <https://www.fda.gov> for additional information on devices and medications that may be utilized for treatment.

Rationale:

This policy was originally created in 2006 and has updated regularly with searches of the MedLine database and the current World Professional Association for Transgender Health (WPATH) Standards of Care (SOC). The most recent literature search was performed through July 2021. The following is a summary of the key literature to date.

Gender Assignment Surgery

The ability to diagnose infants born with intersex conditions has advanced rapidly in recent years. In most cases today, clinicians can promptly make an accurate diagnosis and counsel parents on therapeutic options. However, the paradigm of early gender assignment has been challenged by the results of clinical and basic science research, which show that gender identity development likely begins in utero. While the techniques of surgical genital reconstruction have been mastered, the understanding of the psychological and social implications of gender assignment is poor. (1-3)

Treatment of ambiguous genitalia is controversial. No one debates the need to treat underlying physiologic problems such as those associated with congenital adrenal hyperplasia or tumors in the gonads. However, treatment for ambiguous genitalia depends on the type of disorder but will usually include corrective surgery to remove or create reproductive organs appropriate for the gender of the child. Treatment may also include hormone replacement therapy. Controversy revolves around issues of gender assignment by the physician and family which may not correlate with gender preference by the patient in adulthood. (1-4)

For example, Reilly and Woodhouse interviewed and examined 20 patients with the primary diagnosis of micropenis in infancy and concluded, “[A] small penis does not preclude a normal male role and a micropenis or microphallus alone should not dictate a female gender reassignment in infancy.” More particularly, these doctors found that when parents “were well counseled about the diagnosis they reflected an attitude of concern but not anxiety about the problem, and they did not convey anxiety to their children. They were honest and explained problems to the child and encouraged normality in behavior. They believed that this is the attitude that allows these children to approach their peers with confidence. (2-4, 8)

From a medico-legal standpoint, the best approach to managing these cases is to provide parents with as much information as possible so that they can make informed decisions. Adequate counseling and support for parents is vital. The ideal management method is a team approach including neonatologists, geneticists, endocrinologists, surgeons, counselors, and ethicists. (2, 3, 9)

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in July 2021 did not identify any ongoing or unpublished trials that would likely influence this policy.

Professional Guidelines and Position Statements

There are no professional guidelines and position statements that would likely influence this policy.

Section Summary: Gender Assignment Surgery

The available evidence supports the conclusion that psychological, medical, and/or surgical services are required for the treatment of ambiguous genitalia; therefore, considered medically necessary.

Gender Reassignment Surgery

Within the past decade, addressing transgender health care concerns has come to the forefront for inclusion and diversity worldwide. (10) These concerns have transcended to all facets of the lesbian, gay, bisexual, or transgender (LGBT) community, including initiating changes in the health care services offered to transgender individuals.

In January 2016, ECRI published a report on gender dysphoria. (12) Their review included 10 publications of systematic reviews and primary studies targeting puberty suppression therapy, cross-sex hormonal therapy, and sexual reassignment surgery. The following is a summary of their review:

- *Puberty Suppression Therapy*: ECRI did not identify any studies that met their review inclusion criteria addressing this topic in the adolescent population.
- *Cross-Sex Hormonal Therapy*: ECRI reviewed 1 systematic review and 3 primary studies. The systematic review reported on 28 studies of 1833 patients (1093 MtF [male-to-female]; 801 FtM [female-to-male]) who received endocrine therapy as part of their sex reassignment treatment -- 80% of the patients demonstrated significant improvements in gender dysphoria; 78% of the patients demonstrated significant improvements in psychological symptoms; 80% of the patients reported significant improvement in quality of life; and 72% of the patients reported significant improvement in sexual function. The primary studies focused on specific issues and resolutions following hormonal therapy: 1) psychological functioning following testosterone treatment for FtM patients; 2) incidence of breast cancer following androgen deprivation and estrogen treatment for MtF; and 3) mood disorders following hormonal treatment starting by age 32.
- *Sexual Reassignment Surgery*: ECRI evaluated 2 systematic reviews and 4 primary studies. One review included 25 studies of patients having undergone MtF penile skin inversion and the bowel vaginoplasty technique, in which the sexual function and patient satisfaction were considered “overall acceptable.” The second review indicated that sexual satisfaction was “high”; however, quality of life was not reported. The primary studies focused on patient satisfaction, postoperative complications, psychosocial and sexual well-being, mortality, morbidity, and criminal rates. One study reported higher overall mortality, increased risk of suicide attempts, psychiatric inpatient care, and higher risk of criminal conviction rates. Other studies reported overall satisfaction with surgical procedures, improved mental health, and better quality of life. Postoperative complications were noted in 2 of the studies.

Later in 2016, ECRI released a summary of hormonal treatment with gonadotropin-releasing hormone (GnRH) analogues that can suppress the secretion of luteinizing hormone and follicle-stimulating hormone, being used as a puberty blocker in transgender children and adolescents. (13) The ECRI review indicated the evidence is consistent in showing that GnRH analogues benefit this transgender population by improving symptoms of depression, anxiety, body image, emotional and behavioral problems, and quality of life.

Revisions Following Initial GRS Treatment

Revisions to primary or secondary sexual characteristics should always be interpreted in the context of specific benefit language. The requirement of the presence of a functional impairment for a specific etiology may vary as applied to any physiological condition. It should be noted that the presence of a functional impairment would render treatment medically necessary and thus not subject to contractual definitions of reconstructive or cosmetic.

Reversal Following Regret of GRS Treatment

Misdiagnosed gender dysphoric patients may regret any gender reassignment treatments. Regret following hormonal and surgical treatment was reported at 1.83% in an 8-year case series reported by Judge et al., in 2014, of 218 patients of both transgender sexes. (14) In 2014, Dhejne et al. reported 2.2% (n=15) of the 767 patients over 50 years experienced regrets, but over time, the number of regrets has significantly declined. (15) This study was inclusive of both transgender sexes. Two other studies were reviewed from Krege et al. (16), and Nelson et al. (17), all of which found that 0% reported no regrets following gender reassignment surgery (GRS) treatments.

Seven patients who regretted their decision to undergo MtF sexual reassignment surgery were studied by Djordjevic et al. (18) Following 3 independent psychiatric evaluations for each patient, reversal surgeries were planned: 4 patients completed all steps of reversal, 2 are partially completed and awaiting completion, and 1 patient has declined a portion of the reversal. The reviewers concluded understanding the characteristics of patients regretting GRS will assist future patients opting for these services.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in November 2022 did not identify any ongoing or unpublished trials that would likely influence this policy.

Professional Guidelines and Position Statements

World Professional Association for Transgender Health (WPATH)

WPATH, formerly the Harry Benjamin International Gender Dysphoria Association, is the most widely recognized SOC and have been recognized by national medical and mental health organizations. (1, 5, 6, 10) WPATH states their overall goal to provide clinical guidance for health professionals to assist transsexuals, transgenders, and gender-nonconforming individuals with safe and effective pathways to achieve lasting personal comfort with their gendered selves, in order to maximize their overall health, psychological well-being, and self-fulfillment. (5)

In the 2012 WPATH SOC Seventh Version, clarifies the recommended medically necessary GRS and related services as the following: (6)

"In a June 2008 Clarification Statement, WPATH reiterated the procedures which are considered components of sex reassignment by the Standards of Care and specifically stated that these services are considered medically necessary when clinically indicated. WPATH underscores the clinical significance of the full range of reconstructive interventions including non-genital procedures (e.g., breast augmentation, mastectomy and chest reconstruction, facial feminization surgeries, and facial hair removal).

To ensure treatment effectiveness, WPATH emphasizes that individuals must have access to the procedures which match their clinical needs. Individuals may have a clinical need for specific procedures, although not every individual will require surgery or every possible intervention. Coverage must extend to include the variations which may exist for a given surgery type, and permit a multiple stage surgical process, to ensure clinical appropriateness for the individual." (6, 10)

In November 2015, the International Journal of Transgenderism published recommendations for speech-language therapy for individuals seeking the development of voice and communication that reflects their unique sense of gender. (19) The authors acknowledge the WPATH SOC recognition of speech-language congruency of inner and outer self. Davies et al. expand the speech-language recommendations to include the clinical care by professionals that require trans-specific voice-and-communication assessments, voice feminization protocols-and-voice feminizing surgeries, and voice masculinization protocols. (19)

American Psychiatric Association (APA)

In 2012, the APA Task Force published a report on the treatment of gender identity disorder. (20) The APA stated the following:

"There are some level B studies examining satisfaction/regret following sex reassignment (longitudinal follow-up after an intervention, without a control group); however, many of these studies obtained data retrospectively and without a control group (APA level G). Overall, the evidence suggests that sex reassignment is associated with an improved sense of well-being in the majority of cases, and also indicates correlates of satisfaction and regret. No studies have directly compared various levels of mental health screening prior to hormonal and surgical treatments on outcome variables; however, existing studies suggest that comprehensive mental health screening may be successful in identifying those individuals most likely to experience regrets."

American Academy of Pediatrics (AAP)

In 2018, the AAP released a policy statement, with recommendations focused on children and youth that identify as transgender rather than the larger LGBTQ (lesbian, gay, bisexual, transgender, queer) population. (7) The AAP stated that any discrimination based on

gender identity or expression, real or perceived, is damaging to the socio-emotional health of children, families, and society. In particular, the AAP recommends the following, which includes the psychosocial, healthcare insurer, medical/mental health provider, community, family, auxiliary service, educational, workforce, legal, and federal government aspects of a child or youth seeking gender reassignment services: (7)

1. "That youth who identify as TGD [transgender and gender diverse] have access to comprehensive, gender-affirming, and developmentally appropriate health care that is provided in a safe and inclusive clinical space";
2. "That family-based therapy and support be available to recognize and respond to the emotional and mental health needs of parents, caregivers, and siblings of youth who identify

as TGD";

3. "That electronic health records, billing systems, patient-centered notification systems, and clinical research be designed to respect the asserted gender identity of each patient while maintaining confidentiality and avoiding duplicate charts";
4. "That insurance plans offer coverage for health care that is specific to the needs of youth who identify as TGD, including coverage for medical, psychological, and, when indicated, surgical gender-affirming interventions";
5. "That provider education, including medical school, residency, and continuing education, integrate core competencies on the emotional and physical health needs and best practices for the care of youth who identify as TGD and their families";
6. "That pediatricians have a role in advocating for, educating, and developing liaison relationships with school districts and other community organizations to promote acceptance and inclusion of all children without fear of harassment, exclusion, or bullying because of gender expression";
7. "That pediatricians have a role in advocating for policies and laws that protect youth who identify as TGD from discrimination and violence";
8. "That the health care workforce protects diversity by offering equal employment opportunities and workplace protections, regardless of gender identity or expression"; and
9. "That the medical field and federal government prioritize research that is dedicated to improving the quality of evidence-based care for youth who identify as TGD".

Centers for Medicare and Medicaid Services (CMS)

In the CMS Proposed Decision Memo for Gender Dysphoria and GRS released in June 2016, CMS stated the following: (23)

"While we are not issuing a NCD [National Coverage Determination], CMS encourages robust clinical studies that will fill the evidence gaps and help inform the answer to the question posed in this proposed decision memorandum. Based on the gaps identified in the clinical evidence, these studies should focus on which patients are most likely to achieve improved health outcomes with gender reassignment surgery, which types of surgery are most appropriate, and what types of physician criteria and care setting(s) are needed to ensure that patients achieve improved health outcomes."

Section Summary: Gender Reassignment Surgery

The criteria in the 2012 World Professional Association for Transgender Health (WPATH) Seventh Version Standards of Care (SOC) are supported by evidence-based peer-reviewed scientific literature. Long-term trials of continuous hormonal therapy and living in one's affirmed gender, as well as social support, acceptance by family and peers, contribute to the improvements to the individual's well-being and health, following GRS procedures. Multi-disciplinary mental, medical, surgical, and speech-therapy professionals are crucial towards the best results to match the gender body identity to the intended gender identity role. Therefore, applicable GRS procedures and related services may be considered medically necessary when meeting the coverage criteria and the member's Benefit Contract allowance for these services.

Summary of Evidence

Gender Assignment Surgery

For individuals requiring gender assignment services following birth as a newborn or infant when ambiguity varies to identify their specific sexual gender, the evidence includes a variety of studies over the years, including a statement from the U.S. National Institute of Health. Relevant outcomes following corrective surgery, which may or may not correlate with the patient in adulthood. The evidence is sufficient to provide the psychosocial, medical, and/or surgical services for treatment of ambiguous genitalia.

Gender Reassignment Surgery

For individuals seeking gender reassignment surgery (GRS) with related services, the evidence primarily includes a globally accepted standard of care, which is supported by evidence-based peer-reviewed scientific literature. Relevant outcomes must include multi-disciplinary mental, medical, surgical, and speech-therapy professionals to achieve the best results to match the individual's gender identity. In accordance with the member's Benefit Contract allowances for these services or Legislative directives, the evidence is sufficient to determine these services result in a meaningful improvement in the individual's net health outcome.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coding:

CODING:

The CPT codes for mastectomy (19303 and 19304) are for breast cancer and should not be used to bill for reduction mammaplasty for female to male (transmasculine) gender affirmation surgery. A more appropriate code to report this service is 19318, as it includes the work that is necessary to create a more aesthetically pleasing result.

Disclaimer for coding information on Medical Policies

Procedure and diagnosis codes on Medical Policy documents are included only as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, device or diagnosis codes in a Medical Policy document has **no** relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a medical policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT/HCPCS/ICD-9/ICD-10 Codes
The following codes may be applicable to this Medical policy and may not be all inclusive.
CPT Codes
11950, 11951, 11952, 11954, 11980, 11981, 11982, 11983, 15780, 15781, 15782, 15783, 15786, 15787, 15788, 15789, 15792, 15793, 15820, 15821, 15822, 15823, 15824, 15825, 15826, 15828, 15830, 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, 15876, 15877, 15878, 15879, 17380, 19301, 19303, 19304, 19316, 19318, 19324, 19325, 19340, 19342, 19350, 21120, 21121, 21122, 21123, 21125, 21127, 30400, 30410, 30420, 30430, 30435, 30450, 53430, 54125, 54400, 54401, 54405, 54406, 54408, 54410, 54411, 54415, 54416, 54417, 54520, 54660, 54690, 55175, 55180, 55970, 55980, 56625, 56800, 56805, 56810, 57106, 57107, 57110, 57111, 57291, 57292, 57295, 57296, 57335, 57426, 58150, 58180, 58260, 58262, 58275, 58280, 58285, 58290, 58291, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58661, 58720, 90845, 90846, 90847, 90849, 90853, 90863
HCPCS Codes
J1071, J2320, J3121, J3145, S0189
ICD-9 Diagnosis Codes
Refer to the ICD-9-CM manual
ICD-9 Procedure Codes
Refer to the ICD-9-CM manual
ICD-10 Diagnosis Codes
Refer to the ICD-10-CM manual
ICD-10 Procedure Codes
Refer to the ICD-10-CM manual

Medicare Coverage:

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. CMS has issued a decision memo and coverage may be subject to an individual claim review.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

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Policy History:

Date	Reason
12/1/2021	Document updated with literature review. The following change was made to Coverage: Modified statement on hair removal. No new references added.
1/15/2021	Document updated with literature review. Coverage unchanged. Added references 21 and 22.
5/1/2019	Document updated with literature review. Coverage unchanged. Several definitions added in Description section. Reference 7 added; none removed.
3/15/2018	Document updated with literature review. The following changes were made to coverage: 1) Clarification of the required referrals prior to any surgery or related service(s); 2) The new coverage statements for gender primary or secondary sexual characteristic revision surgeries – "When there is documented evidence of physical functional impairment, gender primary or secondary sexual characteristic revision procedures or services are considered medically necessary. When there is no documented evidence of physical functional impairment, gender primary or secondary sexual characteristics revision services are considered not medically necessary (refer to appropriate procedure-specific policy)"; and, 3) The new coverage statements for reversal of gender reassignment surgical procedures – "Reversal of any of the prior gender reassignment surgical procedure(s) or service(s) for gender primary or secondary sexual characteristics, the patient must meet the same criteria for gender dysphoria to have those reversal procedures considered medically necessary. If the criteria for gender dysphoria is not met, then reversal of any prior gender reassignment surgical procedure(s) or service(s) for gender primary or secondary sexual characteristics is considered not medically necessary." The following was removed from coverage: 1) "See related medical policies below for information regarding related procedures or services for non-gender reassignment services because other exclusions may apply"; and 2) the listing of all medical policies addressing non-surgical related services and surgical related services.
10/1/2016	Document updated with literature review. Coverage unchanged. Speech-language therapy recommendations included in Rationale.
11/6/2015	Document updated with literature review. Multiple coverage changes from experimental, investigational and/or unproven to medically necessary for primary and secondary gender reassignment surgeries and related services. Coverage statements added for those individuals reaching the age of majority. Rationale and References updated and reorganized.
7/1/2014	Document updated with literature review. Coverage unchanged. CPT/HCPCS code(s) updated.

3/15/2013	Document updated with literature review. Coverage unchanged. The following was added: Gender reassignment surgery and related services, for those members with a contract or a certificate of coverage that would allow for gender reassignment surgery, when specific criteria are met. Title changed from Gender Reassignment Surgery to Gender Assignment Surgery and Gender Reassignment Surgery with Related Services. Policy removed from no further review status.
4/1/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
5/1/2006	New medical document

Archived Document(s):

Title:	Effective Date:	End Date:
Gender Assignment Surgery and Gender Reassignment Surgery with Related Services	01-15-2021	11-30-2021
Gender Assignment Surgery and Gender Reassignment Surgery with Related Services	05-01-2019	01-14-2021
Gender Assignment Surgery and Gender Reassignment Surgery with Related Services	03-15-2018	04-30-2019
Gender Assignment Surgery and Gender Reassignment Surgery with Related Services	10-01-2016	03-14-2018
Gender Assignment Surgery and Gender Reassignment Surgery with Related Services	11-06-2015	09-30-2016
Gender Assignment Surgery (GAS) and Gender Reassignment Surgery (GRS) with Related Services	07-01-2014	11-05-2015
Gender Assignment Surgery (GAS) and Gender Reassignment Surgery (GRS) with Related Services	03-15-2013	06-30-2014
Gender Reassignment Surgery	04-01-2008	03-14-2013
Gender Reassignment Surgery	05-01-2006	03-31-2008

Exhibit

21-2875

IN THE

United States Court of Appeals

FOR THE EIGHTH CIRCUIT

DYLAN BRANDT, et al.,

Plaintiffs-Appellees,

—v.—

LESLIE RUTLEDGE,
in her official capacity as the Arkansas Attorney General, et al.,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS

BRIEF FOR *AMICI CURIAE* STONEWALL UK, ET AL. IN SUPPORT OF PLAINTIFFS-APPELLEES

ANDREW RHYS DAVIES
Counsel of Record
JUSTIN L. ORMAND
STEVEN W. SHULDMAN
ALLEN & OVERY LLP
1221 Avenue of the Americas
New York, New York 10020
Telephone: (212) 610-6300
Facsimile: (212) 610-6399
andrewrhys.davies@allenovery.com

Counsel for Amici Curiae

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and 29(c), *amici curiae* (1) Stonewall UK, (2) the Swedish Federation for Lesbian, Gay, Bisexual, Transgender, Queer and Intersex Rights, (3) the Australian Professional Association for Trans Health, (4) the Professional Association for Transgender Health Aotearoa New Zealand, (5) LGBT+ Denmark, (6) Bundesverband Trans* e.V., (7) the Federación Estatal de Lesbianas, Gais, Trans, Bisexuales, Intersexuales y más, (8) Fundación Colectivo Hombres XX, AC, and (9) the Norwegian Organization for Sexual and Gender Diversity each state that they have no parent corporation and that no publicly-held corporation owns 10% or more of their stock.

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TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes and Rules

Other Authorities

IDENTITY OF AMICI CURIAE AND STATEMENT OF INTEREST[1]

Amici curiae (1) Stonewall UK, (2) the Swedish Federation for Lesbian, Gay, Bisexual, Transgender, Queer and Intersex Rights, (3) the Australian Professional Association for Trans Health, (4) the Professional Association for Transgender Health Aotearoa New Zealand, (5) LGBT+ Denmark, (6) Bundesverband Trans* e.V., (7) the Federación Estatal de Lesbianas, Gais, Trans, Bisexuales, Intersexuales y más, (8) Fundación Colectivo Hombres XX, AC, and (9) the Norwegian Organization for Sexual and Gender Diversity (together, the "*Amici* Organizations") are non-profit organizations dedicated in whole or in part to securing and protecting the rights of transgender people. The *Amici* Organizations respectfully submit this *amicus curiae* brief to assist the Court in understanding the availability of gender-affirming healthcare for adolescents in each of the *Amici* Organizations' respective home countries.

A more detailed statement of interest for each of the *Amici* Organizations is included in Appendix A.

[1] All parties consented to the filing of this brief. Pursuant to Fed. R. App. P. 29(a)(4)(E), *amici* state that no party's counsel authored this brief in whole or in part, and that no party or person other than *amici*, their members, and their counsel contributed money towards the preparation or filing of this brief.

PRELIMINARY STATEMENT

Arkansas law, 2021 Ark. Acts 626 (the "Arkansas Healthcare Ban"), prohibits gender-affirming healthcare for adolescents in the State of Arkansas. This Court should affirm the district court's order preliminarily enjoining this damaging act of legislative overreach.

Arkansas seeks to defend the Arkansas Healthcare Ban as an appropriate reaction to what it describes as a "worldwide controversy surrounding gender-transition procedures." Brief for Appellant ("Appellant's Br.") at 16–17, 46. Arkansas and its *Amici* States[2] even suggest that the Arkansas Healthcare Ban is consistent with and supported by the approach adopted by developed nations, including the United Kingdom, Sweden, Finland, Australia, and New Zealand. *Id.* at 16–17, 46*;* Br. of *Amici Curiae* State of Alabama, *et al*. ("*Amici* States Br.") at 3–5, 10–15, 19–22. It assuredly is not.

The *Amici* Organizations submit this brief to correct the record, so that this Court has the benefit of accurate information about the gender-affirming healthcare that is available to adolescents in the five countries that Arkansas and its *Amici* States have referenced. This brief also provides information about the availability of

[2] The term "*Amici* States" refers to the States of Alabama, Alaska, Arizona, Georgia, Idaho, Indiana, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, South Carolina, South Dakota, Tennessee, Texas, Utah and West Virginia, each of which joined an *amicus curiae* brief filed on November 23, 2021, in support of the State of Arkansas.

gender-affirming healthcare to adolescents in several other developed countries: Denmark, Germany, Spain, Mexico, and Norway.

As shown in this brief, the Arkansas Healthcare Ban is an outlier. In all of the countries surveyed, adolescent patients, together with their physicians and parents and/or legal guardians, make decisions about what gender-affirming healthcare is appropriate. In all of those countries, when it is deemed medically appropriate, adolescent patients have access to treatment that is prohibited under the Arkansas Healthcare Ban. Unlike Arkansas, these sovereigns leave these important decisions principally to the medical community. The district court's order preliminarily enjoining the Arkansas Healthcare Ban should be affirmed.

ARGUMENT

I. Adolescents Have Access to Appropriate Gender-Affirming Healthcare in the United Kingdom, Sweden, Finland, Australia, and New Zealand

Arkansas and its *Amici* States cite to materials referencing the United Kingdom, Sweden, Finland, Australia, and New Zealand, in support of the argument that there is an international controversy surrounding the issue of allowing adolescents to access critical gender-affirming healthcare. Appellant's Br. at 11–15, 46; *Amici* States Br. at 4–5, 10–16, 20–21. What Arkansas and its *Amici* States neglect to say, however, is that whatever debates may exist over how best to care for transgender adolescents, the governments in these countries—unlike the State of Arkansas—have not sought to prohibit clinicians from treating their patients.

Therefore, in all of those countries, adolescents have access to appropriate gender-affirming healthcare, including forms of care that the Arkansas Healthcare Ban prohibits.

A. United Kingdom

Arkansas and the *Amici* States create a misleading impression of adolescents' access to gender-affirming healthcare in the United Kingdom with citations to publications from the United Kingdom that they characterize as "skeptical of gender-transition procedures" or "not inspir[ing] much confidence in the procedures." Appellant's Br. at 12–14; *Amici* States Br. at 10–12. The State of Arkansas equally misplaces its reliance on a decision from a trial court in the United Kingdom that has since been reversed, in which the court concluded that judicial approval was required prior to the use of puberty blockers to treat gender dysphoria in individuals under the age of sixteen. Appellant's Br. at 16–17 (discussing *Bell v. Tavistock & Portman NHS Found. Tr.*, [2020] EWHC 3274 (Admin.)). Arkansas emphasizes the trial court's statements about uncertainties and complexities associated with gender-affirming healthcare, *id.*, which is what Arkansas claims motivated its enactment of the Arkansas Healthcare Ban. Arkansas, however, ignores the fact that, notwithstanding the publications and decision it cites, where medically indicated, gender-affirming healthcare is available to adolescents in the United Kingdom.

First, Arkansas and its *Amici* States misconstrue the review by the U.K. National Institute for Health and Care Excellence ("NICE"), from which they selectively quote. Appellant's Br. at 13; *Amici* States Br. at 10-12. Although NICE concluded that the evidence of the effectiveness of treatment with puberty blockers was of "very low certainty,"[3] it nevertheless recommended that gender dysphoria should be treated with "management plans [that] are tailored to the individual."[4] According to NICE, treatment plans may include "psychological support and exploration and, for some individuals, the use of GnRH analogues [*i.e.*, puberty blockers] in adolescence to suppress puberty; this may be followed later with gender-affirming hormones of the desired sex."[5] In any event, NICE's review is just one of many inputs that will be considered as part of an ongoing study commissioned by

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[3] NICE, *Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria* (Mar. 11, 2021) at 4-6 (2021), https://www.evidence.nhs.uk/document?id=2334888&returnUrl=search%3Fq%3Dtransgender%26s%3DDate (follow link to review) ("NICE Evidence Review").

[4] *Id.* at 3.

[5] *Id.*

the publicly-funded National Health Service,[6] which, notably, provides gender-affirming healthcare free of charge to adolescents.[7]

Second, contrary to what Arkansas and the *Amici* States imply, the *Bell* case in the United Kingdom was not about whether gender-affirming healthcare should be available to minors; it was about whether minors can independently consent to such care without their parents or guardians. In the United Kingdom, minors can validly consent to a medical procedure, provided they have so-called *Gillick* competence.[8] Under *Gillick*, a minor's capacity to make medical decisions depends on their having sufficient intelligence and understanding to make a decision regarding medical treatment, without regard to a judicially-fixed age limit.[9] It is not

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[6] NICE Evidence Review at 1; *see also* The Independent Review of Gender Identity Services for Children and Young People (The Cass Review), Terms of Reference, https://cass.independent-review.uk/about-the-review/terms-of-reference/ (last visited Jan. 14, 2022).

[7] *See generally* NHS Standard Contract for Gender Identity Service for Children and Adolescents (Dec. 30, 2019), https://www.england.nhs.uk/wp-content/uploads/2017/04/gender-development-service-children-adolescents.pdf, as amended, Amendments to Service Specification for Gender Identity Development Service for Children and Adolescents (Oct. 6, 2021), https://www.england.nhs.uk/wp-content/uploads/2020/12/amendment-to-cyp-gender-dysphoria-service-specification.pdf.

[8] *See Gillick v. West Norfolk & Wisbech Health Authority* [1986] 1 AC 112 (HL).

[9] *Id.* ¶ 188B ("[A] minor's capacity to make his or her own decision depends upon the minor having sufficient understanding and intelligence to make the decision and is not to be determined by reference to any judicially fixed age limit.").

the role of the court to intercede into the authority of a clinician in determining whether to recommend treatment, or of a competent minor in determining whether to undergo such treatment.[10]

Applying these principles, the Court of Appeal for England and Wales reversed the trial court decision that Arkansas references, establishing that an adolescent's ability to consent to gender-affirming healthcare—like other healthcare—is a matter for adolescents and their clinicians and parents/legal guardians, not the government.[11] To clarify what Arkansas does not, the trial court's decision was never about the *availability* of gender-affirming healthcare; the "sole legal issue" in the case was the circumstances in which an adolescent could *consent* to such care.[12]

The Court of Appeal roundly rejected the trial court's conclusion that adolescents under the age of sixteen were generally incapable of providing such consent, and that judicial involvement in the medical decision-making process was therefore needed.[13] The Court of Appeal acknowledged that the provision of gender-

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10 *Id.*

11 *Bell v. Tavistock & Portman NHS Found. Tr.*, [2021] EWCA 1363 (Civ) ¶¶ 86-87.

12 *Bell v. Tavistock & Portman NHS Found Tr.*, [2020] EWHC 3274 (Admin.) ¶ 9.

13 *Id.* ¶¶ 147, 151.

affirming healthcare is a complex topic, noting that clinicians should take "great care" before recommending gender-affirming treatment to an adolescent,[14] but concluded that, as far as a minor's *Gillick* competence to consent to such care is concerned, "[n]othing about the nature or implications of the treatment with puberty blockers allows for a real distinction to be made" between that and any other medical treatment.[15] In the Court of Appeal's judgment, "the [trial] court was not in a position to generalise about the capability of persons of different ages to understand what is necessary for them to be competent to consent to the administration of puberty blockers."[16] The State of Arkansas is likewise in no such position.

In short, despite the picture Arkansas attempts to paint, gender-affirming healthcare is available to any adolescent in the United Kingdom whose clinician recommends it, as long as the required clinical, patient, and parental consents are obtained.

B. Sweden

Arkansas and its *Amici* States also cite to a review article from Sweden and a Swedish hospital's decision to stop providing gender-affirming healthcare to adolescents under the age of sixteen outside of the clinical trial setting. Appellant's

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14 *Bell v. Tavistock & Portman NHS Found. Tr.*, [2021] EWCA 1363 (Civ) ¶ 92.

15 *Id.* ¶ 76.

16 *Id.* ¶ 85.

Br. at 11–12; *Amici* States Br. at 13–14. In the *Amici* States' view, these events in Sweden support the Arkansas Healthcare Ban by showing that there is not enough evidence regarding the outcomes of gender-affirming healthcare. Arkansas and the *Amici* States again fail to inform the Court that gender-affirming healthcare is available to adolescents in Sweden, and that the Swedish government has not inserted itself into this medical decision-making in the way that the State of Arkansas has done through the Arkansas Healthcare Ban.

In Sweden, access to healthcare is governed by the Health and Medical Services Act.[17] Under the framework of that law, medical treatment is valid so long as it comprises treatment that can relieve or alleviate pain or illness. Gender-affirming healthcare, as with all medical practice, needs to be performed within the framework of the law, based on medical evidence and well-known practice. Sweden also follows the United Nations Convention of the Rights of the Child, which recognizes a child's right to have a say in their medical treatment, and that this right increases with age.[18]

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[17] Hälso- och sjukvårdslag (Health and Medical Services Act (2017)) [SFS] 2017:30 (Swed.), https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/halso--och-sjukvardslag-201730_sfs-2017-30.

[18] *Convention on the Rights of the Child will become Swedish law*, Government Offices of Sweden, Ministry of Health and Social Affairs (June 14, 2018), https://www.government.se/articles/2018/03/new-legislative-proposal-on-the-convention-on-the-rights-of-the-child/.

For over twenty years, adolescent patients in Sweden have had access to gender-affirming healthcare. The Swedish National Board of Health and Welfare promulgates national guidelines to support clinicians in making decisions concerning the healthcare needs of their patients.[19] Since 2015, the guidelines have addressed hormone treatment for gender dysphoria. The guidelines state that if adolescent patients suffer due to their gender dysphoria, clinicians may prescribe both puberty blockers and gender-affirming hormones.

Ultimately, in Sweden, a clinician's professional judgment provides the basis on which treatment is or is not recommended. In Sweden, the decision to undergo gender-affirming healthcare is made between patients, their parents, and their clinicians. For example, some medical providers in Sweden have recently reconsidered the decision to administer hormones or hormone blockers to patients that have not already started them, but other medical providers continue to provide gender-affirming treatment based on the national guidelines and their own professional judgment. Critically, any decision regarding whether to prescribe gender-affirming treatment remains between clinicians and their patients. The government is not involved in that decision-making process.

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[19] God vård av barn och ungdomar med könsdysfori (Good care of children with gender dysphoria) (April 2015), https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2015-4-6.pdf.

C. Finland[20]

Arkansas and the *Amici* States cite to recommendations promulgated by the Council for Choices in Health Care in Finland ("COHERE Finland") in support of their position that uncertainty regarding treatment outcomes justifies Arkansas' actions here. Appellant's Br. at 12; *Amici* States Br. at 14-15. But Arkansas seeks to do something Finland has never done—ban treatment—and Arkansas and its *Amici* States misconstrue the contours of the COHERE Finland recommendations they cite.

COHERE Finland is a permanent body appointed by the Finnish government that works in conjunction with Finland's Ministry of Social Affairs and Health.[21] In 2011, Finland created an avenue for adolescents to seek treatment for trauma caused by gender dysphoria. Although adolescents cannot access surgical treatment for gender dysphoria until age eighteen, they can begin the diagnostic process at age thirteen.[22] COHERE Finland's recommendations recognize a treatment protocol for transgender adolescents as part of the Finnish healthcare system.

Patients whose puberty has not started and who experience long term or severe gender dysphoria-related anxiety can be sent for consultation at the university

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[20] The *Amici* Organizations thank Seta ry / Seta rf /Seta Lgbtiq Rights in Finland for its assistance with this section.

[21] *See* Background Memorandum and Recommendations, COHERE Finland, https://palveluvalikoima.fi/sukupuolidysforia-alaikaiset (last visited Jan. 5, 2022).

[22] *See id.*

hospitals in Helsinki or Tampere.[23] There, after conducting diagnostics to confirm medical necessity with no contraindications, clinicians can treat a patient with puberty blockers upon the onset of puberty.[24] It is also possible to access medication to block menstruation.[25]

COHERE Finland's recommendations also state that an adolescent who has already begun puberty can be referred to a university hospital for gender-identity examinations and treatment if the patient's gender identity variation and related dysphoria appear stable over the long term.[26] Gender-affirming hormonal interventions can be prescribed for patients commencing at age sixteen, absent contraindications, if the patient's gender dysphoria is considered permanent and severe and the patient has the capacity to understand the impact of the non-reversible aspects of treatment and the pros and cons of hormonal treatment.[27]

D. Australia & New Zealand

The *Amici* States briefly reference a statement by the Royal Australian & New Zealand College of Psychiatrists in support of their assertion that there is a lack of evidence regarding the outcomes of gender-affirming healthcare. *Amici* States Br. at

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23 *Id.*

24 *Id.*

25 *Id.*

26 *Id.*

27 *Id.*

5. But nowhere does the statement say that gender-affirming healthcare should not be made available to adolescents, as Arkansas seeks to do here. In fact, the statement makes recommendations on how to "support the mental health needs of people experiencing Gender Dysphoria/Gender Incongruence," including assessment and treatment "based on the best available evidence."[28] In any event, both Australia and New Zealand allow adolescents to access gender-affirming healthcare, where medically appropriate.

In Australia, a parent generally has power to consent to medical treatment, but the parental power to consent diminishes as the patient's capacities and maturities grow.[29] The Australian High Court has adopted *Gillick* competence, *supra* at 6, holding that a minor is capable of giving informed consent, and a parent is no longer capable of consenting on the minor's behalf, when the minor achieves *Gillick* competence—a sufficient understanding and intelligence to enable them to understand fully what treatment is proposed.[30]

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[28] Royal Australian & New Zealand College of Psychiatrists, Recognising and addressing the mental health needs of people experiencing Gender Dysphoria / Gender Incongruence (Aug. 2021), https://www.ranzcp.org/news-policy/policy-and-advocacy/position-statements/gender-dysphoria.

[29] *Secretary, Department of Health and Community Services v. JWB & SMB* ("*Marion's case*"), (1992) 175 CLR 218 (Austl.).

[30] *Id.* at 237 (Mason CJ, Dawson, Toohey and Gaudron JJ) (citing *Gillick v West Norfolk & Wisbech Area Health Authority*, [1986] AC 112).

The Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents ("ASOCT Guidelines"), promulgated by AusPATH, recommend that clinicians prescribe puberty blockers, hormone treatment, and psychological support where, following a diagnosis of adolescent gender dysphoria and a medical assessment, the patient agrees that hormone therapy or puberty blockers is in their best interest.[31] The ASOCT Guidelines rely on empirical evidence and clinical consensus, and were developed in consultation with professionals working with transgender and gender diverse communities across Australia and New Zealand.[32]

Legal access to gender-affirming healthcare for patients under eighteen was most recently clarified in 2020 by the Australian Family Court in *Re Imogen*.[33]

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[31] *Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents*, AusPATH, https://auspath.org.au/2018/02/01/australian-standards-of-care-and-treatment-guidelines-for-trans-and-gender-diverse-children-and-adolescents/ (last visited Jan. 14, 2022).

[32] *Id.* Australia is also home to clinical research affirming the medical benefit of puberty blockers for transgender youth. One published Australian study identified that, although limited, available evidence points to the safety of puberty blockers and the psychological benefits of suppressing puberty before the possible future commencement of hormone therapy. *See* Simone Mahfouda et al., *Puberty suppression in transgender children and adolescents*, 5 The Lancet Diabetes & Endocrinology 816 (2017), https://www.sciencedirect.com/science/article/pii/S2213858717300992?via%3Dihub#!.

[33] *Re Imogen (No. 6)*, [2020] FamCA 761 (Austl.).

Adolescent patients can legally receive hormone treatment, but there must be no dispute between parents (or those with parental responsibility), the medical practitioner, and the patient with regard to the patient's *Gillick* competence, diagnosis of gender dysphoria, or the proposed treatment for alleviating the suffering caused by the gender dysphoria.[34] Any dispute requires an application to the Family Court.[35] But where the adolescent, their parents, and their clinician are all in agreement about the need for treatment, care is available and there are no governmental barriers.

In New Zealand, the Care of Children Act 2004 empowers adolescents aged sixteen and older to consent to medical care.[36] With respect to medical care generally, including gender-affirming care, adolescents under sixteen years of age may consent to treatment on their own provided they meet the standard for competence in *Gillick*, *supra* at 6, which the New Zealand Court of Appeal has cited with approval.[37] Family support is however considered an important aspect of

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34 *Id.*

35 *Id.*

36 Care of Children Act 2004, Public Act 2004 No. 90, https://legislation.govt.nz/act/public/2004/0090/latest/DLM317233.html.

37 *Re J (An Infant): B and B v Director-General of Social Welfare*, [1996] 2 NZLR 134 (N.Z.).

gender-affirming care for all adolescents in New Zealand, with families involved in care wherever possible.

New Zealand has provided gender-affirming healthcare to adolescents for over fourteen years. Clinicians in New Zealand also consider the ASOCT Guidelines, the promulgation of which, as noted, involved a review by New Zealand adolescent health clinicians. In addition, in 2018, the University of Waikato published guidelines for gender-affirming healthcare for gender diverse and transgender patients.[38] These guidelines allow for puberty blockers to be prescribed depending on the stage of puberty, and also allow for hormone treatment.[39]

II. Gender-Affirming Healthcare Is Available to Adolescents in Other Developed Countries As Well

A review of the status of gender-affirming healthcare access in other countries reveals a common thread. With appropriate consultation and diagnoses, adolescents can access various forms of gender-affirming care, including treatment that the Arkansas Healthcare Ban prohibits.

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[38] J. Oliphant et al., *Guidelines for gender affirming healthcare for gender diverse and transgender children, young people and adults in Aotearoa, New Zealand*, Transgender Health Research Lab, University of Waikato (2018), https://researchcommons.waikato.ac.nz/handle/10289/12160.

[39] *Id.* at 29–31.

A. Denmark

In Denmark, hormone therapy for adolescents is available through the Danish public healthcare system, after consultation with a multidisciplinary team of doctors including pediatric, psychiatric, and endocrinology specialists.[40] For patients under the age of fifteen, parental consent is required for treatment in the Danish healthcare system.

B. Germany

Gender-affirming healthcare for patients under the age eighteen is available in various forms throughout Germany. Medical associations in Germany are in the process of developing guidelines for gender-affirming healthcare relating to teenage patients.

In February 2020, the German Ethics Council addressed healthcare for transgender teenagers.[41] The Council's statement acknowledged the tension created by the potentially irreversible consequences of both administering treatment and withholding treatment.[42] The Council's statement declared that it is not an option to

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[40] *See* Guidelines on healthcare concerning gender identity matters, part 9 (2018), https://www.retsinformation.dk/eli/retsinfo/2019/9060.

[41] Press Release, German Ethics Council, *Ethics Council publishes ad hoc recommendation on transgender identity in children and adolescents* (Feb. 2020), https://www.ethikrat.org/mitteilungen/mitteilungen/2020/deutscher-ethikrat-veroeffentlicht-ad-hoc-empfehlung-zu-trans-identitaet-bei-kindern-und-jugendlichen/.

[42] *Id.*

limit access to gender-affirming healthcare for adolescents who understand the consequences of their decision to undergo treatment.[43] The Council noted that where "the child is sufficiently capable of insight and judgement to understand the scope and significance of the planned treatment, to form his own judgement and to decide accordingly, his will must be decisively taken into account."[44]

C. Spain

In Spain, patients over the age of sixteen can validly consent to medical care, including gender-affirming healthcare.[45] Access to gender-affirming healthcare is generally available throughout the country for patients under the age of sixteen, and specific laws governing availability vary among the seventeen autonomous regions in the country. For example, in the Community of Madrid, adolescent patients have the right to treatment by pediatric physicians and to receive puberty blockers and hormone therapy upon the onset of puberty.[46] In the Region of Murcia, patients over twelve can access gender-affirming healthcare with consent of the minor's legal

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43 *Id.*

44 *Id.*

45 Access to Transgender Hormone Therapy, European Union Agency for Fundamental Rights, https://fra.europa.eu/en/content/access-transgender-hormone-therapy (last visited Jan. 18, 2022).

46 Law 2/2016 (July 1, 2016) (Community of Madrid, Spain).

representative.[47] Throughout Spain, gender-reassignment surgery is prohibited before the age of majority.

D. Mexico

Transgender healthcare in Mexico is guided by the Protocol for Access without Discrimination to Health Care Services for Lesbian, Gay, Bisexual, Transsexual, Transvestite, Transgender and Intersex Persons and Specific Care Guidelines.[48] The Protocol is observed in healthcare facilities administered by the Mexican federal government. The Protocol acknowledges that the process of defining one's sexual orientation, gender identity and/or expression may occur at early ages.[49] The Protocol therefore advises that medical facilities err in favor of providing medical care,[50] and recommends that the use of puberty blockers and hormone treatment be considered.[51]

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47 Law 8/2016 (May 27, 2016) (Region of Murcia, Spain).

48 Protocolo para el Acceso sin Discriminación a la Prestación de Servicios de Atención Médica de las Personas Lésbico, Gay, Bisexual, Transexual, Travesti, Transgénero e Intersexual y Guías de Atención Específicas, Government of Mexico, Secretary of Health (2020), https://www.gob.mx/cms/uploads/attachment/file/558167/Versi_n_15_DE_JUNIO_2020_Protocolo_Comunidad_LGBTTI_DT_Versi_n_V_20.pdf.

49 *Id.* at 35.

50 *Id.* at 36.

51 *Id.*

In addition to the Protocol, various Mexican states have reformed their civil codes to recognize the right to gender-affirming healthcare for patients under eighteen.

E. Norway

In Norway, both puberty blockers and hormone therapy are available to adolescent patients, although surgical treatment is generally not available before the age of majority. Access to gender-affirming healthcare, including hormone therapy and mental health support, for adolescent patients is defined in the National Guidelines on the Treatment of Gender Incongruence, promulgated by the Norwegian Directorate of Health.[52] Puberty blockers are administered to patients based on their pubertal development stage. Any patient over the age of sixteen may access puberty blockers and hormone therapy upon prescription by a clinician; parental consent is not required.

For adolescents under sixteen, puberty blockers are available with parental consent on a case-by-case basis after an evaluation by medical experts, either through the clinician specialist team at Oslo University Hospital or via a health

[52] Helsedirektoratet, https://www.helsedirektoratet.no/retningslinjer/kjonnsinkongruens (last visited Jan. 14, 2022).

service organized under the Municipality of Oslo which specializes in services for gender non-confirming and LGBTQI youth.[53]

* * *

The Arkansas Healthcare Ban finds no support in the practices of other developed nations—either those identified by the State of Arkansas and its *Amici* States, or the additional developed nations whose practices are described above. In all of those jurisdictions, adolescents have access to gender-affirming healthcare, when medically indicated. As with many forms of medicine, debate exists over how to improve the quality of care and over the need for more evidence of long-term efficacy and impact. That debate has prompted other developed nations to study the care and improve conditions for its delivery, not to ban it.

[53] Oslo universitetssykehus, https://oslo-universitetssykehus.no/behandlinger/kjonnsinkongruens-utredning-og-behandling-av-barn-og-unge-under-18-ar (last visited Jan. 14, 2022); Oslo kommune, https://www.oslo.kommune.no/helse-og-omsorg/helsetjenester/helsestasjon-og-vaksine/helsestasjon-for-ungdom-hfu/helsestasjon-for-kjonn-og-seksualitet-hks/#gref (last visited Jan. 14, 2022).

CONCLUSION

For all of these reasons, the district court's order preliminarily enjoining the Arkansas Healthcare Ban should be affirmed.

Dated: January 19, 2022

Respectfully submitted,

/s/ Andrew Rhys Davies
Andrew Rhys Davies
Counsel of Record
Justin L. Ormand
Steven W. Shuldman
ALLEN & OVERY LLP
1221 Avenue of the Americas
New York, New York 10020
Telephone: (212) 610-6300
Facsimile: (212) 610-6399
andrewrhys.davies@allenovery.com

Counsel for Amici Curiae

APPENDIX A

Stonewall UK has fought since 1989 to create transformative change in the lives of LGBTQ+ people across communities in the United Kingdom and around the world. Stonewall UK seeks to drive positive change in public attitudes and public policy, and to ensure that LGBTQ+ people can thrive throughout their lives by building deep, sustained change programs with the institutions that have the biggest impact on them. Stonewall UK's work includes supporting legal efforts to ensure that trans young people have access to gender-affirming medical treatment.

The Swedish Federation for Lesbian, Gay, Bisexual, Transgender, Queer and Intersex Rights ("RFSL") is a non-profit community organization that has been advocating for the rights of LGBTQIA persons in Sweden and internationally since its founding in 1950. RFSL engages support and educational services, political advocacy, lobbying initiatives, and community space in furtherance of its mission supporting LGBTQIA persons. Since 2001, RFSL has formally included transgender people within the communities it serves. RFSL's key initiatives today include transgender rights advocacy, asylum rights, and family law.

The Australian Professional Association for Trans Health ("AusPATH") is Australia's principal body representing, supporting, and connecting those working to strengthen the health, rights, and wellbeing of all transgender people—binary and non-binary.

The AusPATH membership comprises over 350 experienced professionals working across Australia. AusPATH firmly believes that all young people who desire puberty suppression should be able to access such care in a timely manner under appropriate supervision and assessment by a multidisciplinary team. AusPATH advocates for access to timely, culturally-safe and person-centered gender-affirming healthcare as critical to protect transgender children, adolescents, and adults from negative health and well-being implications.

The Professional Association for Transgender Health Aotearoa New Zealand ("PATHA NZ") is an incorporated society established in May 2019 to be an interdisciplinary professional organization working to promote the health, well-being, and rights of transgender people. PATHA NZ comprises over 200 members who work professionally for transgender health in clinical, academic, community, legal, and other settings.

As a society committed to supporting gender-affirming care, PATHA NZ's role includes advocacy both within New Zealand and internationally. PATHA NZ views gender-affirming care for children and adolescents as an essential part of healthcare and views the denial of access to care until the age of eighteen in any country or state as a violation of human rights.

LGBT+ Denmark is Denmark's largest and oldest political organization for LGBT+ people in Denmark. LGBT+ Denmark fights for everyone to be able to live

their life in full compliance with their own identity through rights, safe communities, and social change—locally, nationally and globally.

Bundesverband Trans* e.V. (BVT*) is the largest transgender association in Germany. The association's common endeavor is the commitment to gender diversity and self-determination. BVT* is committed to human rights and to the respect, recognition, equality, social participation and health of transgender and non-binary people.

The Federación Estatal de Lesbianas, Gais, Trans, Bisexuales, Intersexuales y más ("FELGBTI+") is the largest LGBTI+ organization in Spain and one of the largest in Europe, with fifty-seven nongovernmental organizations and associations collaborating as member entities. It is one of only eight LGBTI+ organizations in the world that has consultative status with the United Nations. With thirty years of history, FELGBTI+ is one of the reference organizations in the promotion and defense of rights for LGBTI+ people.

FELGBTI+'s mission is to defend and promote human rights and equality for lesbian, gay, transgender, bisexual, and intersex people and their families in all areas of life (social, health, work, educational, cultural, etc.). In addition, FELGBTI+ works to strengthen and unify the LGBTI associative movement in the Spanish territory from a networking approach and a secular, feminist, nonpartisan, and non-unionist perspective.

Fundación Colectivo Hombres XX, AC (the "Fundación") is a non-profit community LGBTI organization with a particular focus on men in Mexico who were assigned a female gender at birth. The Fundación has operated since 2012 as a collective and since 2018 as a Civil Association, and has extensive lobbying experience. The Fundación participated in the drafting of the Protocol for Access without Discrimination to Health Care Services for Lesbian, Gay, Bisexual, Transsexual, Transvestite, Transgender and Intersex Persons and Specific Care Guidelines, which provides guidance for the administration of healthcare to transgender individuals in Mexico.

The Norwegian Organization for Sexual and Gender Diversity ("FRI") is a membership-based nongovernmental organization with local chapters throughout Norway. FRI's vision is a society free from harassment and discrimination based on sexual orientation, gender identity, and/or gender expression. FRI's key activities include national-level advocacy for the rights of LGBTI people, building competency of government institutions and employees within different sectors (education, health, social welfare, justice) to include LGBTI people in a non-discriminatory way, and engaging in international solidarity by partnering with LGBTI organizations in Europe, Asia and Africa.

As a membership and community-based organization, FRI has firsthand experience of the impact that gender-affirming healthcare—or the lack thereof—has

on transgender people. FRI is deeply concerned that a law seeking to restrict access to gender-affirming care will be detrimental to the lives of transgender people in Arkansas.

CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limit of Fed. R. App. P. 29(a)(5) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this brief contains 4,920 words.

2. This document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-Point Times New Roman font.

3. This document has been scanned for viruses and is virus-free.

Dated: January 19, 2022

/s/ Andrew Rhys Davies
Andrew Rhys Davies

CERTIFICATE OF SERVICE

I hereby certify that on this day the foregoing brief was served electronically on all parties via CM/ECF.

Dated: January 19, 2022

/s/ Andrew Rhys Davies
Andrew Rhys Davies

Exhibit

From: Ele Hamburger
To: Payton, Gwendolyn; Bedard, Stephanie
Cc: Omar Gonzalez-Pagan; Jenny Pizer; Daniel Gross
Subject: RE: Expert disclosure
Date: Wednesday, June 15, 2022 9:37:08 AM

Hi Gwendolyn,

I'm so sorry - I hope you feel better soon. We will work with you on whatever you need.

If you want to reschedule the deposition tomorrow, that's fine. We will file the reply on the Motion to Compel on Thursday along with a placeholder Motion to Seal/Redact. We are happy to renote the placeholder motions to any date that works for you, and you can renote your motion to seal/redact to that same date. Just let me know the preferred date.

Ele

-----Original Message-----
From: Payton, Gwendolyn <GPayton@kilpatricktownsend.com>
Sent: Wednesday, June 15, 2022 9:15 AM
To: Ele Hamburger <ele@sylaw.com>
Subject: [External] Expert disclosure

I am really sick. Can we have a one week extension? Of course it can be mutual.

Gwendolyn Payton
Kilpatrick Townsend & Stockton LLP
Suite 3700 | 1420 Fifth Avenue | Seattle, WA 98101 office 206 626 7714 | fax 206 299 0414 gpayton@kilpatricktownsend.com | https://urldefense.proofpoint.com/v2/url?u=http-3A__www.kilpatricktownsend.com&d=DwIFAg&c=euGZstcaTDllvimEN8b7jXrwqOf-v5A_CdpgnVfiiMM&r=ZQ1zc62mnZGFngGQVI3Iog&m=_Jz110DOrQh7i9GcJ_O91VmAVz3DOiUYxei_SlHp2f8&s=uPnHvlXLtfetGhGH7Ezga1s_o9FggqERpt07PSxXBsM&e=

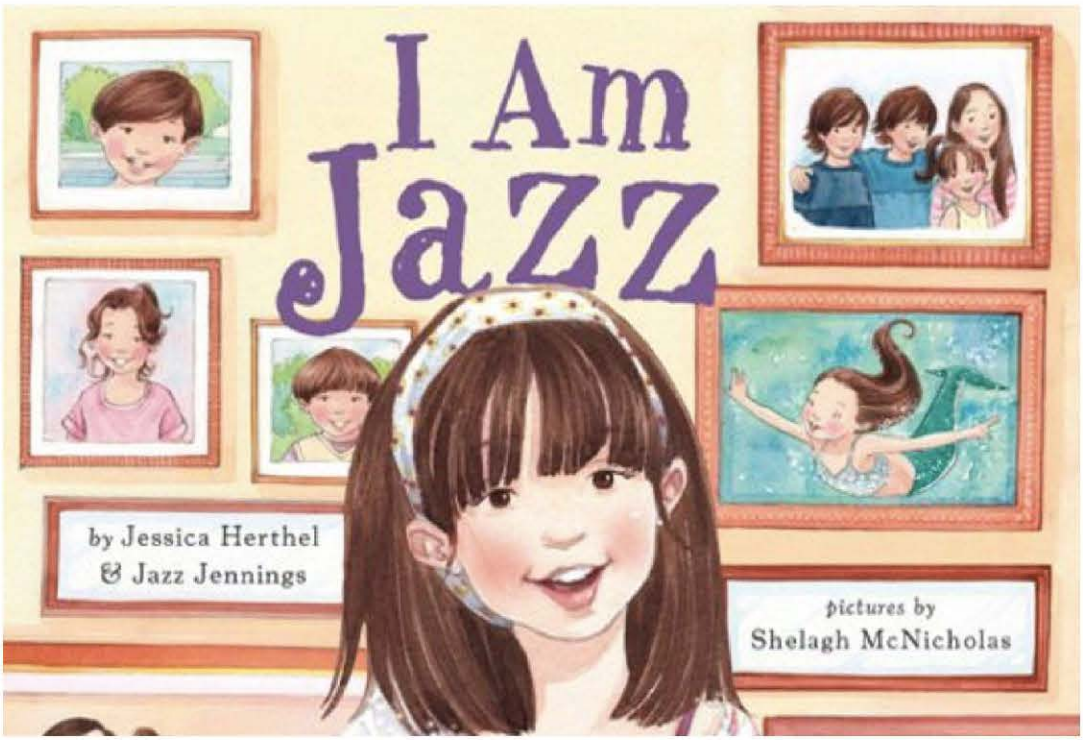
Exhibit

Book Reviews, Healthcare, Sexuality

Gender Dysphoria and Children: An Endocrinologist's Evaluation of *I am Jazz*

April 5, 2018 By Michael K. Laidlaw

I Am Jazz contains both false information and very troubling omissions. Children who are experiencing gender dysphoria will likely be harmed by this book, as will children who do not have the condition.



Recently, a group of parents asked me to review the book *I Am Jazz* to determine whether, from a medical point of view, it is suitable for children to read. They also asked this for the benefit of their school district, given that the topic of childhood gender dysphoria would be discussed at their upcoming school board meeting.

I have read the book *I Am Jazz* and examined the book's relationship to childhood gender dysphoria and its implications for adolescence and adulthood. I am a board-certified physician in Rocklin, California specializing in Endocrinology, Diabetes, and Metabolism. Broadly, endocrinology is the study of hormones and glands and the diagnosis and treatment of diseases involving these hormones and glands. The following essay is a detailed presentation of my findings regarding this important topic.

Introduction

Children with gender dysphoria deserve our compassion and deserve to be treated with dignity and kindness, just like all other children. Their unique condition makes integrating in the school a challenge. Particularly when dealing with bathrooms and locker rooms, it would be advantageous for schools to have a comprehensive policy to address children with gender dysphoria.

To some degree, children who share a class with a gender-dysphoric child will need to be educated about what that means and how to address that situation. This should be done by parents and guardians primarily, but ideally in cooperation with teachers and staff.

Unfortunately, *I Am Jazz* actually works against educating children about gender dysphoria. In this essay, I use the book *I Am Jazz* and the TLC show of the same name to help illustrate medical facts about childhood gender dysphoria and adult transgenderism. I believe that if we know the facts about this condition, we will be much more compassionate and understanding toward people with this condition. This will also help in dealing with the parents of children without gender dysphoria who have to explain to their children how to cope with this condition.

The book *I Am Jazz,* by Jazz Jennings and Jessica Herthel, contains a number of factual inaccuracies and very significant omissions. I am very concerned

that children or even adults who read these books will be given false ideas about transgenderism. This will lead to the harm of children, as has already happened at Rocklin Academy.

For context, I would highly recommend watching and listening to the *I Am Jazz* book being read by Jazz Jennings, which is available freely on Youtube. Throughout this essay, for the sake of clarity, I use the pronouns of Jazz's biological sex.

Factual Inaccuracies in *I Am Jazz*

Inaccuracy #1: About a quarter of the way through *I Am Jazz*, the author states: "I have a girl brain in a boy body." Jazz later goes to the doctor and relates: "Afterwards, the doctor spoke to my parents and I heard the word 'transgender' for the very first time."

The Facts: The book is written in a way to make you believe that Jazz was diagnosed as transgender. But this is not a diagnosis. The medical diagnosis is gender dysphoria. A biological male feeling and believing himself to be a girl and the distress that accompanies these feelings and beliefs is an example of gender dysphoria (previously known as gender identity disorder). Gender dysphoria is never mentioned in the book.

As a younger child, when Jazz went to see this doctor, he actually had the condition of gender dysphoria. He was not transgender at that point in time. In fact, most children who suffer from gender dysphoria will no longer experience it by the time they become adults. In other words, about 90 percent of biologically male children who believe they are female as young children, when allowed to go through normal puberty and enter adulthood as men, will identify as biological males.

Even the 2017 Endocrine Clinical Practice Guidelines for gender transition state flatly: "With current knowledge, we cannot predict the psychosexual

outcome [whether or not a person eventually identifies as transgender] for any specific child."

This is not to say that the dysphoria is not a real condition for Jazz. It certainly has been, and that is very troubling for numerous reasons, not the least of which is the high prevalence of psychiatric conditions that may accompany gender dysphoria, such as depression, which Jazz also suffers from. This is discussed further below.

Inaccuracy #2: According to Jazz, "I have a girl brain but a boy body. This is called transgender. I was born this way!"

The Facts: The "born this way" narrative contradicts known medical facts involving twin studies. Gender identity has been defined as the innate sense that one feels one is male or female (or some combination of the two).

If gender identity is determined only by genes, then we would expect that identical twins would profess having the same gender identity nearly 100 percent of the time. This is not the case. In fact, the largest transexual twin study ever conducted included seventy-four pairs of identical twins. They were studied to determine in how many cases both twins would grow up to identify as transgender. In only twenty-one of the seventy-four pairs (28 percent) did both identical twins identify as transgender. This is consistent with the fact that multiple factors play a role in determining gender identity, including psychological and social factors. This study in fact shows that those factors are more important than any potential genetic contribution. Furthermore, no genetic studies have ever identified a transgender gene or genes.

Inaccuracy #3: Jazz says: "I have a girl brain."

The Facts: As to Jazz having a "girl brain," consider, what does the brain comprise? There are billions of neurons that make up this magnificent

structure. Neurons are very specialized cells that transmit and store information. The control center, if you will, of every cell in the body is the nucleus, which contains DNA. The DNA is wound up into specialized units called chromosomes. There are 46 chromosomes in every human cell. Two of these are specialized chromosomes called sex chromosomes. Assuming normal development, females have two X chromosomes, and males have one X and one Y chromosome. These sex chromosomes are present in every cell in the body. They remain in the cells from conception until death and do not change.

It follows from this that since Jazz is male, every cell of his brain has an X and a Y chromosome (whereas a girl brain would have two X chromosomes). Therefore Jazz in fact has a "boy brain" right down to the very level of the DNA.

There is further development of the male body at 8 weeks' gestation within the womb. At this point testosterone is involved in a very intricate process that changes tissues in the pelvis into male genitalia. And we know from the "I am Jazz" show that Jazz has male genitalia. Since the hormone testosterone is carried by the bloodstream throughout the whole body—including the pelvic region as well as the brain—we know that Jazz's brain was also filled with testosterone for development at that time.

This is further evidence that Jazz does not in fact have a "girl brain." He has a boy brain. It is his mind that is giving him the trouble. This is a psychological condition, rather than a biological one.

The authors of the book present false information to children and parents. Kids with gender dysphoria are not born that way. Jazz was born with a male brain that has not changed physically into a female brain. There are numerous psychological and social factors that account for the condition of gender dysphoria in children, some of which are discussed below.

Troubling Omissions

I Am Jazz contains a large number of glaring and very troubling omissions.

Omission #1: The authors fail to mention that Jazz suffers from depression.

At least 70 percent of people with gender dysphoria suffer from mental illness currently or in their lifetime. The most common comorbid mental illnesses include depression, anxiety, bipolar disorder, and dissociative disorder. Jazz has depression, as he has discussed on the TLC program *I Am Jazz.*

Sadly, many people who identify as transgender never find out until it is too late that their gender dysphoria is actually closely tied in with a mental health condition. Walt Heyer is an author who has journeyed from male to female and back to male again. He had surgical and hormonal therapy to become "Laura" and lived that way for many years.

The first physician he saw for this condition sadly never looked further into his psychiatric conditions. Walt was eventually diagnosed with dissociative disorder. He also had problems with substance abuse and was abused as a child. In other words, numerous psychological and social factors contributed to his gender dysphoria. Had these been seriously investigated and treated by his physicians, there is a good chance he could have avoided his life-changing genital surgery.

Omission #2: The suicide rate of transgender individuals is alarmingly high.

Ninety percent of suicides are associated with a psychiatric condition. The risk of suicide coincides of course with the high prevalence of mental illness in this group of people. Depression, for example, is present in at least 50 percent of those who commit suicides.

The American public has been led to believe that the primary cause of transgender suicide is bullying and mistreatment by society. The facts are quite different.

A landmark government study in sexually liberal Sweden showed that people who identify as transgender have about eight times the risk of attempting suicide above the general population. Their risk of death by suicide is nineteen times higher. And *the risk does not decline after surgery and hormonal therapy*. Although the study was designed to simply analyze patients in their government database and not to study the effects of treatment, people who have had sex reassignment procedures remain at high risk for suicide both before and after therapy.

It seems that many people with gender dysphoria are being given surgical and hormonal treatment for a psychological condition or conditions.

Radical political activists apparently do not want the truth to be known about the association of transgender suicide with mental illness. If we care about people who identify as transgender, we must bring these facts to light.

Omission #3: Jazz is currently being given hormone blockers to stop him from going through normal pubertal development. These powerful hormones arrest the normal development of boys into fully developed men and of girls into fully developed women. In other words, Jazz is now a teenager who has not been allowed to go through puberty.

Many physicians and therapists from across the political spectrum are critical of affirming children as transgender and of the use of puberty blockers. This includes organizations such as the "left-leaning, open-minded, and pro-gay rights" group youthtranscriticalprofessionals.org and the right leaning American College of Pediatricians.

By current protocol, children with gender dysphoria are given these powerful hormones at around age eleven. This is too young for them to understand the implications of what will happen to their minds and bodies. Time is required for maturity of the developing adolescent mind, and hormones play an important role in this development. For Jazz, allowing normal production of testosterone would further the development of his adolescent brain and very likely lead him to different conclusions regarding his gender.

Again, in some 90 percent of children with gender dysphoria, the condition will have resolved by the time of going through normal pubertal development.

Warning: Omission #4 contains a graphic description of transgender surgery.

Omission #4: Jazz will need to have his child-sized penis surgically destroyed to create a false vagina.

What type of surgical procedure(s) is Jazz considering for the treatment of gender dysphoria? Typically, surgery turning a male into a trans-female involves dissecting the penis, turning the skin inside out, and placing it into a surgically created cavity to create a false vagina. After surgery, a dilator has to be placed in this artificial vagina to keep it from collapsing.

But Jazz has a problem. Since he still has a small child-sized penis (because of puberty blockers), he does not have enough skin to line the false vagina. Potential remedies include sewing in a section of intestine along with the penis skin to make the false vagina. In one episode, Jazz is actually offered two different surgeries: one surgery to create the false vagina and a second surgery two months later to attempt to form the labia. The need for two dangerous surgeries instead of one is directly related to the effects of puberty blockers.

Omission #5: Jazz currently suffers from sexual dysfunction and will likely have permanent damage.

The effects of puberty-blocking agents (started in early adolescent development) on long-term sexual function seem to be largely unstudied. However, from interviews with Jazz's surgeons, one can deduce the almost certain loss of sexual function. Or more accurately, the sexual development of the genitalia has not been allowed to occur in Jazz and never will occur under the current circumstances.

There are five pubertal development stages, which are known as Tanner Stages. They go from 1 (no development, prepuberty) to 5 (full adult development). This is what a pediatrician would use to determine the level of a child's development.

Current guidelines recommend starting puberty blockers at Tanner stage 2 (sparse pubic hairs, minimal testicular growth). This will reduce testosterone to very low levels. Because of this, Jazz's male genitalia are "locked in" at Tanner stage 2. There is by definition "no enlargement of the penis" to that point. That accounts for Jazz's child-size penis and the problems with surgery discussed earlier.

In an episode where Jazz visits a surgeon and has a discussion about sexual function, Jazz states: "I haven't experienced any sexual sensation." Regarding orgasm, Jazz says: "I don't know, I haven't experienced it." The male genitalia are awaiting testosterone to change from a pre-pubescent state to an adult state in which sexual function is possible.

In the normal adult state, there is full sexual function. In one episode, Jazz's pediatric endocrinologist states that Jazz has adult female levels of estrogen. This, however, has not given Jazz "any sexual sensation." This makes sense physiologically, as the male genitalia (penis, scrotum, testicles, etc.) are awaiting testosterone to develop, not estrogen.

Because of this, for adolescent males similar to Jazz who are receiving puberty blockers, I can see little to no sexual function occurring either now or into adulthood. They will not achieve even the equivalent sexual function of, say, an adult male who has gone through hormone treatment and sex reassignment surgery as an adult.

Omission #6: Jazz will very likely be rendered permanently infertile.

Again, because of puberty blockers, Jazz's male genitalia are stuck at Tanner stage 2. The estrogen he is receiving will allow for breast development to the level of an adult female. However, his testicles are unable to produce sperm capable of fertilizing an ovum. In fact, it is not even possible to store sperm for use in future fertility, because it has never been given the opportunity to develop within Jazz's testicles.

Once he has surgery to remove his testicles, Jazz will be forever infertile, with no chance to produce biological offspring.

Is this a decision that any adolescent child has the maturity and insight to make? I do not believe so. This is another reason that the use of puberty blocking agents in adolescents is highly unethical.

Omission #7: There is a high level of substance abuse among people who identify as transgender.

Fortunately, Jazz does not appear to use alcohol or other substances. Even when his family inexplicably takes him to a "drag queen" club for his sixteenth birthday, Jazz does not consume alcohol.

Studies show that people who identify as transgender are at increased risk of drug and alcohol abuse and that LGBT people "enter treatment with more severe substance abuse problems, greater psychopathology, and greater medical service utilization when compared with heterosexual clients." Again, this is understandable when one considers the degree of mental illness in gender dysphoric individuals. These substances may be

used as coping mechanisms. Additionally, some children who grow up to identify as transgender have been physically, emotionally or sexually abused, which again is correlated with substance abuse disorders.

Omission #8: There are a number of serious health risks associated with taking cross-sex hormones.

For biological males to take female hormones, such as estrogen, or biological females to take a male hormone, such as testosterone, is not without considerable health risk, particularly at the doses suggested. Males taking female hormones are at high risk for blood clots, which may be fatal if lodged in the lungs. They are also at increased risk for breast cancer, coronary artery disease, cerebrovascular disease, gallstones, and high levels of the lactation hormone prolactin. Females taking male hormones are at high risk for erythrocytosis (having a higher than normal number of red blood cells). They are also at increased risk for severe liver dysfunction, coronary artery disease, cerebrovascular disease, hypertension and breast or uterine cancer.

Furthermore, the use of puberty-blocking drugs in adolescents has been associated with incomplete mineralization of bone, meaning these children may be at future risk for osteoporosis. There is very little information on the use of these blockers on brain development, but the studies we do have show potential for cognitive impairment.

Omission #9: The mortality rate of those who identify as transgender is three times higher than that of the general population.

This should be a cause for alarm. Much of the increased risk of death has to do with the suicide rate, as detailed above. But the multitude of other health risks just mentioned play a role as well.

Entities such as the FDA demand rigorous studies to be done of medications and devices before they come to market. Many treatments

never come to market because of poor study outcomes. Of those treatments that are made available, many are still pulled from the market or receive changes in labeling on account of serious adverse reactions. It is very likely that if such rigorous studies were performed on transgender hormonal therapy and surgery then these therapies would never be approved for use because of the severe health outcomes including death.

Conclusion

Primum non nocere is the Latin phrase for "first, do no harm" and is an admonition to physicians to seriously consider the risks of any treatment before applying it. Given the multitude of health risks, potential infertility, and sexual dysfunction associated with the hormonal and surgical treatment of gender dysphoria, I could not in good conscience recommend these treatments to any child or adolescent.

I Am Jazz contains false information and very troubling omissions. For these reasons, I believe that the book is not appropriate for children of any age to read. Children who are experiencing gender dysphoria will likely be harmed by this book, as will children who do not have the condition.

This harm has already occurred at Rocklin Academy in a kindergarten class where the book was read. A number of children in the class were emotionally harmed. It is unclear to me whether any of the teachers or authority figures at Rocklin Academy have recommended that the male child who dresses as a girl should be evaluated by qualified therapists and counselors for psychosocial factors or mental illness that may be leading to the gender dysphoria. If this has not happened, it should.

It is possible that with proper therapy the child's gender dysphoria could be alleviated. He could then be allowed to regain his masculine identity and therefore not suffer the very troubling life of transgenderism, with all its risks of increased mortality, suicide, mental illness, substance abuse, infertility, and other grave conditions detailed above.

Thank you very much for reading this essay. I hope that it will benefit not only the parents in the community requesting this information, but also the students suffering from gender dysphoria and the families, friends, teachers, and administrators who care for them.

About the Author

MICHAEL K. LAIDLAW

Michael K. Laidlaw, MD is a board-certified physician in Rocklin, California specializing in Endocrinology, Diabetes, and Metabolism.