

No. 23-477

IN THE

Supreme Court of the United States

UNITED STATES OF AMERICA,

Petitioner,

v.

JONATHAN SKRMETTI, ET AL.,

Respondents.

On Writ of Certiorari to the United States
Court of Appeals for the Sixth Circuit

**BRIEF OF *AMICI CURIAE* AMERICAN
ACADEMY OF PEDIATRICS AND ADDITIONAL
NATIONAL AND STATE MEDICAL AND
MENTAL HEALTH ORGANIZATIONS IN
SUPPORT OF PETITIONER AND
RESPONDENTS IN SUPPORT OF PETITIONER**

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INTEREST OF *AMICI CURIAE*

Amici curiae are the American Academy of Pediatrics, the Academic Pediatric Association, the American Academy of Child & Adolescent Psychiatry, the Association of American Medical Colleges, the American Academy of Family Physicians, the American Academy of Nursing, the American Association of Physicians for Human Rights, Inc. d/b/a GLMA: Health Professionals Advancing LGBTQ+ Equality, the American College of Obstetricians and Gynecologists, the American College of Osteopathic Pediatricians, the American College of Physicians, the American Medical Association, the American Pediatric Society, the American Psychiatric Association, the Association of Medical School Pediatric Department Chairs, Inc., the Endocrine Society, the National Association of Pediatric Nurse Practitioners, the Pediatric Endocrine Society, the Tennessee Chapter of the American Academy of Pediatrics, the Societies for Pediatric Urology, the Society for Adolescent Health and Medicine, the Society for Pediatric Research, the Society of Pediatric Nurses, and the World Professional Association for Transgender Health (collectively, “*amici*”).¹

Amici are professional medical and mental health organizations seeking to ensure that all adolescents, including those with gender dysphoria, receive the optimal medical and mental health care they need and

¹ Pursuant to Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part and that no person other than *amici*, their staff, or their counsel made any monetary contributions intended to fund the preparation or submission of this brief.

deserve. *Amici* represent thousands of healthcare providers who have specific expertise with the issues raised in this brief. The Court should consider *amici's* brief because it provides important expertise and addresses misstatements about the treatment for transgender adolescents.

SUMMARY OF ARGUMENT

On March 23, 2023, the Governor of Tennessee signed S.B. 1 into law (the “Healthcare Ban”). The Healthcare Ban prohibits healthcare providers from providing patients under the age of 18 with critical, medically necessary, evidence-based care for gender dysphoria.² Denying such evidence-based medical care to adolescents who meet the requisite medical criteria puts them at risk of significant harm. Below, *amici* provide the Court with an accurate description of the relevant treatment guidelines and summarize the scientific evidence supporting the gender-affirming medical care for adolescents that is prohibited by the Healthcare Ban.³

Gender dysphoria is a condition that is characterized by clinically significant distress or impairment in social, occupational, or other important areas of functioning due to a marked incongruence between the patient’s gender identity (i.e., the innate sense of oneself as being a particular gender) and sex

² Tenn. Code Ann. §§ 68-33-102(5)(B), 68-33-103(a) prohibits medical treatments that are administered for the purpose of treating gender dysphoria—including treatments that delay or stop puberty, as well as certain hormone therapy treatments—which, as discussed in this brief, are medically necessary for certain adolescents with gender dysphoria.

³ In this brief, the term “gender-affirming medical care” refers to the use of gonadotropin-releasing hormone (GnRH) analogues and/or hormone therapy to treat gender dysphoria. Because this brief focuses primarily on adolescents, it does not discuss surgeries that are typically available to transgender adults.

assigned at birth.⁴ If not treated, or treated improperly, gender dysphoria can result in debilitating anxiety, depression, and self-harm, and is associated with suicidality. As such, the effective treatment of gender dysphoria saves lives.

The medical community, including the respected professional organizations participating here as *amici*, widely recognizes that the appropriate protocol for treating gender dysphoria in transgender adolescents is “gender-affirming care.”⁵ Gender-affirming care is care that supports an individual with gender dysphoria as they explore their gender identity—in contrast with efforts to change the individual’s gender identity to match their sex assigned at birth, which are known to be ineffective and harmful.⁶ For adolescents with persistent gender dysphoria that worsens with the onset of puberty, gender-affirming care may include medical care to align their physiology with their gender

⁴ See, e.g., Jason Rafferty, *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142(4) *Pediatrics* e20182162, at 2–3 tbl.1 (2018), <https://perma.cc/DB5G-PG44> [hereinafter, “AAP Policy Statement”]. The American Academy of Pediatrics recently voted to reaffirm the AAP Policy Statement. See Alyson Sulaski Wyckoff, Am. Acad. of Pediatrics, *AAP Reaffirms Gender-Affirming Care Policy, Authorizes Systematic Review of Evidence to Guide Update*, AAP News (Aug. 4, 2023), <https://perma.cc/XS4B-WBLH>. In addition, AAP has commissioned a systematic review of the existing research, which is part of its normal procedures to perform such reviews on a periodic basis to maintain up-to-date guidelines.

⁵ AAP Policy Statement, *supra* note 4, at 10.

⁶ See, e.g., Christy Mallory et al., *Conversion Therapy and LGBT Youth*, Williams Inst. (2019), <https://perma.cc/HXY3-UX2J>.

identity. Empirical evidence indicates that gender-affirming care, including the prescription of puberty blockers and hormone therapy to carefully evaluated patients who meet diagnostic criteria, can alleviate clinically significant distress and lead to significant improvements in the mental health and overall well-being of adolescents with gender dysphoria.⁷

The Healthcare Ban disregards this medical evidence by precluding healthcare providers from providing adolescent patients with treatments for gender dysphoria in accordance with the well-accepted protocol. Accordingly, *amici* urge this Court to vacate the decision below and remand for the application of heightened scrutiny, or reverse the judgment.

ARGUMENT

This brief first provides background on gender identity and gender dysphoria. It then describes the professionally accepted medical guidelines for treating gender dysphoria as they apply to adolescents, the scientifically rigorous process by which these guidelines were developed, and the evidence that supports the effectiveness of this care for adolescents with gender dysphoria. Finally, the brief explains how the Healthcare Ban irreparably

⁷ See Simona Martin et al., *Criminalization of Gender-Affirming Care—Interfering with Essential Treatment for Transgender Children and Adolescents*, 385(7) *New Eng. J. Med.* 579, 580 (2021), <https://perma.cc/BR4F-YLZS> (providing an overview of the scientific basis underlying gender-affirming care and its demonstrated effectiveness in “alleviat[ing] gender dysphoria”).

harms adolescents with gender dysphoria by denying crucial care to those who need it.

I. Understanding Gender Identity and Gender Dysphoria

Gender identity refers to a person's deep internal sense of belonging to a particular gender.⁸ Most people have a gender identity that aligns with their sex assigned at birth.⁹ However, transgender people have a gender identity that does not align with their sex assigned at birth.¹⁰ In the United States, approximately 1.6 million individuals identify as transgender.¹¹ Of these individuals, approximately 10% are teenagers aged 13 to 17.¹² Individuals often start to understand their gender identity during prepubertal childhood and adolescence.

Today, there is an increasing acceptance of being transgender as a normal variation of human identity.¹³ However, many transgender people suffer

⁸ AAP Policy Statement, *supra* note 4, at 2 tbl.1.

⁹ See Am. Psychological Ass'n, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70(9) *Am. Psychologist* 832, 862 (2015), <https://perma.cc/6VQK-S3F8>. Such individuals are referred to as "cisgender." See *id.* at 861.

¹⁰ See *id.* at 832.

¹¹ See Jody L. Herman et al., *How Many Adults and Youth Identify as Transgender in the United States?* at 2, Williams Inst. (2022), <https://perma.cc/UCB4-346Z>.

¹² See *id.* at 3.

¹³ James L. Madara, *AMA to States: Stop Interfering in Healthcare of Transgender Children*, *Am. Med. Ass'n* (Apr. 26, 2021), <https://perma.cc/BKS6-QFQ8>; see also *Am. Psychological*

from gender dysphoria, a serious medical condition in which the patient experiences significant distress that can lead to “impairment in peer and/or family relationships, school performance, or other aspects of their life.”¹⁴ Gender dysphoria is a formal diagnosis under the American Psychiatric Association’s Diagnostic and Statistical Manual (DSM-5-TR).¹⁵

If untreated or inadequately treated, gender dysphoria may lead to depression, anxiety, self-harm, and suicidality.¹⁶ In contrast, with treatment, transgender adolescents with gender dysphoria can mature into thriving adults.¹⁷

Ass’n, *APA Resolution on Gender Identity Change Efforts* at 4, (Feb. 2021) <https://perma.cc/M22K-PBUZ>.

¹⁴ AAP Policy Statement, *supra* note 4, at 3.

¹⁵ See Am. Psychiatric Ass’n, *Diagnostic and Statistical Manual of Mental Disorders: DSM-5-TR* at 512–13 (2022); see also World Health Org., *International Classification of Diseases, Eleventh Revision (ICD-11)* (2019/2021) (“Gender incongruence is characterised by a marked and persistent incongruence between an individual’s experienced gender and the assigned sex. Gender variant behaviour and preferences alone are not a basis for assigning the diagnoses in this group.”).

¹⁶ See Brayden N. Kameg & Donna G. Nativio, *Gender Dysphoria in Youth: An Overview for Primary Care Providers*, 30 *J. Am. Assoc. Nurse Prac.* 493 (2018), <https://pubmed.ncbi.nlm.nih.gov/30095668>.

¹⁷ See *infra* Section II.C.

II. The Widely Accepted Guidelines for Treating Adolescents with Gender Dysphoria Provide for Gender-Affirming Medical Care When Indicated.

The widely accepted view of the professional medical community is that gender-affirming care is the appropriate treatment for gender dysphoria and that, for some adolescents, puberty blockers and hormone therapy are necessary.¹⁸ Gender-affirming care greatly reduces the negative physical and mental health consequences that result when gender dysphoria is untreated.¹⁹

A. The Gender Dysphoria Treatment Guidelines Include Thorough Mental Health Assessments and, for Some Adolescents, Gender-Affirming Medical Care.

The treatment protocols for gender dysphoria are laid out in established, evidence-based clinical guidelines: (i) the Endocrine Society Clinical Practice Guideline for Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons, and (ii) the WPATH Standards of Care for the Health of Transgender and Gender Diverse People (together, the “Guidelines”).²⁰ The Guidelines have been

¹⁸ See, e.g., Endocrine Soc’y, *Transgender Health: An Endocrine Society Position Statement* (2020), <https://perma.cc/7L4P-VWME>.

¹⁹ See *id.*

²⁰ Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society*

developed by expert clinicians and researchers who have worked with patients with gender dysphoria for many years.

The Guidelines provide that all youth with gender dysphoria should be evaluated, diagnosed, and treated by a qualified health care professional (“HCP”).²¹ Further, the Guidelines provide that each patient who receives gender-affirming care should receive only medically necessary and appropriate care that is tailored to the patient’s individual needs and that is based on the best evidence possible along with clinical experience.²²

1. The Guidelines Do Not Recommend Gender-Affirming Medical Care for Prepubertal Children.

For prepubertal children with gender dysphoria, the Guidelines provide for mental health care and support for the child and their family, such as through psychotherapy and social transitioning.²³ The

Clinical Practice Guideline, 102 *J. Clin. Endocrinol. & Metab.* 3869 (2017) [hereinafter, “Endocrine Soc’y Guidelines”], <https://perma.cc/3L9J-428B>; Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People*, 23 *Int’l J. Transgender Health S1* (8th ed. 2022) [hereinafter “WPATH Guidelines”], <https://perma.cc/7SU3-RPK9>.

²¹ See *infra* Section II.A.2.

²² See WPATH Guidelines, *supra* note 20, at S16–S18; *Endocrine Soc’y Guidelines*, *supra* note 20, at 3872–73.

²³ See WPATH Guidelines, *supra* note 20, at S73–S76; *Endocrine Soc’y Guidelines*, *supra* note 20, at 3877–78. “Social transition” refers to a process by which a child is acknowledged by others and has the opportunity to live publicly, either in all situations

Guidelines do *not* recommend that prepubertal children with gender dysphoria receive puberty blockers, hormone therapy, or surgeries.²⁴

2. A Robust Diagnostic Assessment Is Required Before Gender-Affirming Medical Care Is Provided.

In contrast to prepubertal children, the Guidelines do contemplate the possibility that, for some transgender adolescents with gender dysphoria, gender-affirming medical care may be indicated, provided certain criteria are met. According to the Guidelines, puberty blockers and hormone therapy should be provided only after a thorough evaluation by a HCP who: (1) is licensed by their statutory body and holds a master's degree or equivalent in a relevant clinical field; (2) has expertise and received theoretical and evidence-based training in child, adolescent, and family mental health; (3) has expertise and received training in gender identity development, gender diversity in children and adolescents, can assess capacity to consent, and possesses knowledge about gender diversity across the life span; (4) has expertise and received training in autism spectrum disorders and other neurodevelopmental presentations, or collaborates with a developmental disability expert when working with neurodivergent patients; and (5) continues engagement in professional development in areas

or in certain situations, in the gender identity they affirm. *See, e.g.,* WPATH Guidelines, *supra* note 20, at S75.

²⁴ *See* WPATH Guidelines, *supra* note 20, at S64, S67; Endocrine Soc'y Guidelines, *supra* note 20, at 3871.

relevant to gender diverse children, adolescents, and families.²⁵

Prior to developing a treatment plan, the HCP should conduct a robust diagnostic assessment—specifically, a “comprehensive biopsychosocial assessment”—of the adolescent patient.²⁶ The HCP conducts this assessment to “understand the adolescent’s strengths, vulnerabilities, diagnostic profile, and unique needs,” so that the resulting treatment plan is appropriately individualized.²⁷ This assessment must be conducted collaboratively with the patient and their caregiver(s).²⁸

3. In Certain Circumstances, the Guidelines Provide for the Use of Gender-Affirming Medical Care to Treat Adolescents with Gender Dysphoria.

For youth with gender dysphoria that continues into adolescence—after the onset of puberty—the Guidelines provide that, in addition to mental health care, gender-affirming medical care may be indicated. Before an adolescent may receive any gender-affirming medical care for treating gender dysphoria, a qualified HCP must make a determination that such medical care is indicated. The Guidelines collectively provide that, before prescribing puberty blockers, the HCP must determine that: (1) the adolescent meets

²⁵ See WPATH Guidelines, *supra* note 20, at S49.

²⁶ *Id.* at S50.

²⁷ *Id.*

²⁸ *Id.*

the diagnostic criteria of gender dysphoria or gender incongruence according to an established taxonomy;²⁹ (2) the adolescent has demonstrated a sustained and persistent pattern of gender nonconformity or gender dysphoria; (3) the adolescent has demonstrated the emotional and cognitive maturity required to provide informed consent for treatment; (4) any coexisting psychological, medical, or social problems that could interfere with diagnosis, treatment, or the adolescent's ability to consent have been addressed; (5) the adolescent has been informed of the reproductive effects of treatment in the context of their stage in pubertal development and discussed fertility preservation options; and (6) the adolescent has reached Tanner stage 2 of puberty to initiate pubertal suppression.³⁰ Further, a pediatric endocrinologist or other clinician experienced in pubertal assessment must (7) agree with the indication for treatment, (8) confirm the patient has started puberty, and (9) confirm that there are no medical contraindications.³¹

If all of the above criteria are met, and the patient and their parents provide informed consent, gonadotropin-releasing hormone (GnRH) analogues, or “puberty blockers,” may be offered beginning at the onset of puberty.³² The purpose of puberty blockers is to delay the development of permanent secondary sex

²⁹ Endocrine Soc’y Guidelines, *supra* note 20, at 3876; WPATH Guidelines, *supra* note 20, at S47, S48.

³⁰ WPATH Guidelines, *supra* note 20, at S59–S65.

³¹ Endocrine Soc’y Guidelines, *supra* note 20, at 3878 tbl.5.

³² WPATH Guidelines, *supra* note 20, at S64; Martin et al., *supra* note 7.

characteristics—which may result in significant distress for transgender youth—until adolescents are old enough and have had sufficient time to make more informed decisions about whether to pursue further treatments.³³ Puberty blockers also can make pursuing transition later in life easier, because they prevent irreversible bodily changes such as protrusion of the Adam’s apple or breast growth.³⁴ Puberty blockers have well-known efficacy and side-effect profiles.³⁵ Their effects are generally reversible, and when a patient discontinues their use, the patient resumes endogenous puberty.³⁶ In fact, puberty blockers have been used by pediatric endocrinologists for more than 40 years for the treatment of precocious puberty.³⁷ The risks of any serious adverse effects from puberty blockers are exceedingly rare when provided under clinical supervision.³⁸

³³ WPATH Guidelines, *supra* note 20, at S112.

³⁴ See AAP Policy Statement, *supra* note 4, at 5.

³⁵ See Martin et al., *supra* note 7, at 2.

³⁶ See *id.*

³⁷ See Florence Comite et al., *Short-Term Treatment of Idiopathic Precocious Puberty with a Long-Acting Analogue of Luteinizing Hormone-Releasing Hormone: A Preliminary Report*, 305(26) *New Eng. J. Med.* 1546 (1981).

³⁸ See, e.g., Annemieke S. Staphorsius et al., *Puberty Suppression and Executive Functioning: An fMRI-Study in Adolescents with Gender Dysphoria*, 56 *Psychoneuroendocrinol.* 190 (2015), <https://pubmed.ncbi.nlm.nih.gov/25837854> (no adverse impact on executive functioning); Ken C. Pang et al., *Long-Term Puberty Suppression for a Nonbinary Teenager*, 145(2) *Pediatrics* e20191606 (2019), <https://perma.cc/VP47-UA9M> (exceedingly low risk of delayed bone mineralization from hormone treatment).

Later in adolescence—and if the criteria below are met—hormone therapy may be used to initiate puberty consistent with the patient’s gender identity.³⁹ Hormone therapy involves using gender-affirming hormones to allow adolescents to develop secondary sex characteristics consistent with their gender identity.⁴⁰ Hormone therapy is only prescribed when a qualified mental health professional has confirmed the persistence of the patient’s gender dysphoria, the patient’s mental capacity to consent to the treatment, and that any coexisting problems have been addressed.⁴¹ A pediatric endocrinologist or other clinician experienced in pubertal induction must also agree with the indication, and the patient and their parents must be informed of the potential effects and side effects and give their informed consent.⁴² Although some of the changes caused by hormone therapy become irreversible after those secondary sex characteristics are fully developed, others are partially reversible if the patient discontinues use of the hormones.⁴³

The Guidelines contemplate that the prescription of puberty blockers and/or hormone therapy be coupled with education on the safe use of such medications and close monitoring to mitigate any potential risks.⁴⁴ Decisions regarding the appropriate

³⁹ Martin et al., *supra* note 7, at 2.

⁴⁰ See AAP Policy Statement, *supra* note 4, at 6.

⁴¹ Endocrine Soc’y Guidelines, *supra* note 20, at 3878 tbl.5.

⁴² See *id.*

⁴³ See AAP Policy Statement, *supra* note 4, at 5–6.

⁴⁴ See Endocrine Soc’y Guidelines, *supra* note 20, at 3871, 3876.

treatment for each patient with gender dysphoria are made in consultation with the patient, their parents, and the medical and mental health care team. There is “no one-size-fits-all approach to this kind of care.”⁴⁵

B. The Guidelines for Treating Gender Dysphoria Were Developed Through a Robust and Transparent Process, Employing the Same Scientific Rigor That Underpins Other Medical Guidelines.

The Guidelines are the product of careful and robust deliberation following the same types of processes—and subject to the same types of rigorous requirements—as other guidelines promulgated by *amici* and other medical organizations.

For example, the Endocrine Society’s Guidelines were developed following a 26-step, 26-month drafting, comment, and review process.⁴⁶ The Endocrine Society imposed strict evidentiary requirements based on the internationally recognized Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.⁴⁷ That GRADE assessment was then reviewed, re-reviewed, and reviewed again by multiple,

⁴⁵ Martin et al., *supra* note 7, at 580.

⁴⁶ See, e.g., Endocrine Soc’y Guidelines, *supra* note 20, at 3872–73 (high-level overview of methodology).

⁴⁷ See Gordon H. Guyatt et al., *GRADE Guidelines: 1. Introduction - GRADE Evidence Profiles and Summary of Findings Tables*, 64 J. Clinical Epidemiology 383 (2011), <https://perma.cc/66FA-6MT6>; Gordon H. Guyatt et al., *GRADE: An Emerging Consensus on Rating Quality of Evidence and Strength of Recommendations*, 336 BMJ 924 (2008), <https://perma.cc/4J7F-3Z62>.

independent groups of professionals.⁴⁸ Reviewers were subject to strict conflict of interest rules, and there was ample opportunity for feedback and debate through the years-long review process.⁴⁹ Further, the Endocrine Society continually reviews its own guidelines and recently determined that the 2017 transgender care guidelines continue to reflect the best, most up-to-date available evidence.⁵⁰

First published in 1979, the WPATH Standards of Care are currently in their 8th Edition. The current Standards of Care are the result of a robust drafting, comment, and review process that collectively took five years.⁵¹ The draft guidelines went through rigorous review and were publicly available for discussion and debate, receiving a total of 2,688 comments.⁵² There were 119 authors ultimately involved in the final draft, including feedback from experts in the field as well as from transgender individuals and their families.⁵³

⁴⁸ Endocrine Soc’y, *Guideline Methodology* (2022), <https://perma.cc/9NK4-HNNX>.

⁴⁹ *See id.*

⁵⁰ *See* Endocrine Soc’y, *Endocrine Society Statement in Support of Gender-Affirming Care* (May 8, 2024), <https://perma.cc/J4Y2-RUJ2>.

⁵¹ *See* WPATH Guidelines, *supra* note 20, at S247–S251.

⁵² *See id.*

⁵³ *See id.* Inclusion of input from the relevant patient population during development of medical guidelines adheres to national standards and best practices. *See* National Academy of Sciences, *Clinical Practice Guidelines We Trust* at 89–92 (2011).

C. Scientific Evidence Indicates the Effectiveness of Treating Gender Dysphoria According to the Guidelines.

Multiple studies indicate that adolescents with gender dysphoria who receive gender-affirming medical care experience improvements in their overall well-being.⁵⁴ A number of studies have been published that investigated the use of puberty blockers on adolescents with gender dysphoria⁵⁵

⁵⁴ See Martin et al., *supra* note 7, at 580.

⁵⁵ See, e.g., Christal Achille et al., *Longitudinal Impact of Gender-Affirming Endocrine Intervention on the Mental Health and Well-Being of Transgender Youths: Preliminary Results*, 8 Int'l J. Pediatric Endocrinol. 1, 1–5 (2020), <https://perma.cc/K5SR-EE3G>; Polly Carmichael et al., *Short-Term Outcomes of Pubertal Suppression in a Selected Cohort of 12 to 15 Year Old Young People with Persistent Gender Dysphoria in the UK*, 16 PLOS One e0243894 (2021), <https://doi.org/10.1371/journal.pone.0243894>; Rosalia Costa et al., *Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria*, 12(11) J. Sexual Med. 2206–14 (2015), <https://pubmed.ncbi.nlm.nih.gov/26556015/>; Annelou L.C. de Vries et al., *Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study*, 8 J. Sexual Med. 2276–83 (2011), <https://pubmed.ncbi.nlm.nih.gov/20646177/>; Annelou L.C. de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 Pediatrics 696–704 (2014), <https://pubmed.ncbi.nlm.nih.gov/25201798/>; Laura E. Kuper et al., *Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy*, 145 Pediatrics e20193006 (2020), <https://perma.cc/2HAT-GGFV>; Jack L. Turban et al., *Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation*, 145 Pediatrics e20191725 (2020), <https://perma.cc/B2UZ-YR3Q>; Anna I.R. van der Miesen, *Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared with Cisgender*

and/or the use of hormone therapy to treat adolescents with gender dysphoria.⁵⁶ These studies find positive mental health outcomes for those adolescents who received puberty blockers or hormone therapy,

General Population Peers, 66 *J. Adolescent Health* 699–704 (2020); Diana M. Tordoff et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care*, 5 *JAMA Network Open* e220978 (2022), <https://perma.cc/SBF4-B4D4>.

⁵⁶ See, e.g., Achille et al., *supra* note 55, at 1–5; Luke R. Allen et al., *Well-Being and Suicidality Among Transgender Youth After Gender-Affirming Hormones*, 7 *Clinical Prac. Pediatric Psych.* 302 (2019), <https://psycnet.apa.org/record/2019-52280-009>; Diane Chen et al., *Psychosocial Functioning in Transgender Youth after 2 Years of Hormones*, 388 *New Eng. J. Med.* 240–50 (2023), <https://www.nejm.org/doi/10.1056/NEJMoa2206297>; Diego López de Lara et al., *Psychosocial Assessment in Transgender Adolescents*, 93 *Anales de Pediatría* 41–48 (English ed. 2020), <https://perma.cc/AQ4G-YJ85>; de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, *supra* note 55; Rittakerttu Kaltiala et al., *Adolescent Development and Psychosocial Functioning After Starting Cross-Sex Hormones for Gender Dysphoria*, 74 *Nordic J. Psychiatry* 213 (2020), <https://doi.org/10.1080/08039488.2019.1691260>; Kuper et al., *supra* note 55; Amy E. Green et al., *Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth*, 70(4) *J. Adolescent Health* 643 (2022), <https://doi.org/10.1016/j.jadohealth.2021.10.036>; Jack L. Turban et al., *Access to Gender-Affirming Hormones During Adolescence and Mental Health Outcomes Among Transgender Adults*, *J.* 17(1) *PLOS One* e0261039 (2022), <https://doi.org/10.1371/journal.pone.0261039>.

including statistically significant reductions in anxiety, depression, and suicidal ideation.⁵⁷

For example, a longitudinal study of nearly 50 transgender adolescents found that suicidality was decreased by a statistically significant degree after receiving gender-affirming hormone treatment.⁵⁸ A study published in January 2023, following 315 participants age 12 to 20 who received gender-affirming hormone treatment, found that the treatment was associated with decreased symptoms of depression and anxiety.⁵⁹ Additionally, a 2020 study analyzed survey data from 89 transgender adults who had access to puberty blockers while adolescents and from more than 3,400 transgender adults who did not.⁶⁰ The study found that those who received puberty blocking treatment had lower odds of lifetime suicidal ideation than those who wanted puberty blocking treatment but did not receive it, even after adjusting for demographic variables and level of family support.⁶¹ Approximately *nine in ten* transgender adults who wanted puberty blocking

⁵⁷ The data likewise indicate that adults who receive gender-affirming care experience positive mental health outcomes. See, e.g., Zoe Aldridge et al., *Long Term Effect of Gender-Affirming Hormone Treatment on Depression and Anxiety Symptoms in Transgender People: A Prospective Cohort Study*, 9 *Andrology* 1808–16 (2021), <https://perma.cc/543U-HL5P>.

⁵⁸ See Allen et al., *supra* note 56.

⁵⁹ See Chen et al., *supra* note 56.

⁶⁰ See Turban et al., *Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation*, *supra* note 55.

⁶¹ See *id.*

treatment but did not receive it reported lifetime suicidal ideation.⁶²

As another example, a prospective two-year follow-up study of adolescents with gender dysphoria published in 2011 found that treatment with puberty blockers was associated with decreased depression and improved overall functioning.⁶³ A six-year follow-up study of 55 individuals from the 2011 study found that subsequent treatment with hormone therapy followed by surgery in adulthood was associated with a statistically significant decrease in depression and anxiety.⁶⁴ “Remarkably, this study demonstrated that these transgender adolescents and young adults had a sense of well-being that was equivalent or superior to that seen in age-matched controls from the general population.”⁶⁵

As clinicians and scientific researchers, *amici* always welcome more research, including on this crucial topic. However, the available data indicate that the gender-affirming medical care prohibited by the Healthcare Ban is effective for the treatment of gender dysphoria.

⁶² *See id.*

⁶³ *See de Vries et al., Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study, supra note 55.*

⁶⁴ *de Vries et al., Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment, supra note 55.*

⁶⁵ Stephen M. Rosenthal, *Challenges in the Care of Transgender and Gender-Diverse Youth: An Endocrinologist’s View*, 17(10) *Nature Rev. Endocrinol.* 581, 586 (2021), <https://perma.cc/8BT8-G9QS>.

III. The Sixth Circuit’s Opinion and the State Rely on Factually Inaccurate Claims and Ignore Recommendations of the Medical Community.

Both the Sixth Circuit and the State make several inaccurate assertions regarding gender-affirming medical care that are inconsistent with the existing evidence and standard practices in medicine. Contrary to the State’s arguments, (1) the Guidelines’ reliance on evidence is consistent with international best practices and the development of standards of care for treating adolescents in other medical contexts, and (2) the Guidelines already carefully address the safety of gender-affirming medical care and provide recommendations for the mitigation of any potential risks, as is typical in every area of medicine.

First, the State of Tennessee posits that the use of puberty blockers and hormone therapy to treat gender dysphoria in adolescents is “experimental in nature and not supported by high-quality, long-term medical studies.”⁶⁶ To conclude that these treatments are not supported by evidence ignores a significant body of research.

When Respondents criticize the studies supporting gender-affirming medical care,⁶⁷ they refer

⁶⁶ Pet. App. 10a.

⁶⁷ While the Respondents broadly criticize the evidence supporting the Guidelines, the reports they rely upon do not evaluate, nor do they purport to evaluate, all of the evidence supporting the Guidelines. C.A. Dkt. 64, at 14 (citing to declarations discussing the 2020 NICE studies).

to “high-quality” vs. “low-quality” studies under the GRADE system and the presence (or lack thereof) of randomized controlled trials.⁶⁸ Under the GRADE system, evidence may be assessed according to different categories, including “high,” “moderate,” “low,” and “very low.”⁶⁹ These are terms of art. “Low quality,” which does not mean poor quality, generally refers to studies that were not randomized controlled clinical trials, which are generally considered “high quality.” To suggest that clinical practice predicated on anything but “high” quality evidence is unsafe or uncommon in the medical profession is simply false. Clinical practice across disciplines is commonly guided by evidence that various evidence grading systems might deem “lower quality.”⁷⁰ Moreover, with respect to randomized controlled trials, such trials are often impossible or unethical, especially in the pediatric context.⁷¹ In those instances, as here,

⁶⁸ *Id.*

⁶⁹ See Gordon H. Guyatt et al., *GRADE: What Is “Quality of Evidence” and Why Is It Important to Clinicians?*, 336 *BMJ* 995 (2008); David Atkins et al., *Grading Quality of Evidence and Strength of Recommendations*, 328 *BMJ* 1490 (2004).

⁷⁰ For example, the American Heart Association’s guideline for Pediatric Basic and Advanced Life Support includes 130 recommendations for pediatric care, only 1 of which is predicated on Level A (“high quality evidence from more than 1 RCT”) evidence. Alexis A. Topjian et al., *Pediatric Basic and Advanced Life Support: 2020 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care*, 142 *Circulation* S469 (2020). The majority of the recommendations rely on what was deemed Level C-LD (“limited data”) evidence. *Id.*

⁷¹ “[I]n transgender clinical research individual randomized controlled trials (RCTs) may not always be feasible or ethically

clinicians rely on the best evidence possible and clinical experience to provide treatment for their patients. The evidence supporting gender-affirming medical care is consistent with the type of evidence relied on in other clinical practices throughout the medical community.⁷²

In addition, the Sixth Circuit appears to conflate the use of FDA-approved medications for off-label uses with the use of *non*-FDA-approved medications.⁷³ According to the FDA, “once the FDA approves a drug,

acceptable.” Sari L. Reisner et al., *Advancing Methods for U.S. Transgender Health Research*, 23(2) *Curr. Opin. Endocrinol Diabetes Obes.* 198, 199 (2016). With preexisting guidelines that recommend gender-affirming care for those with gender dysphoria, randomized controlled trials would violate the principle of equipoise, which safeguards the rights of individual trial participants. Richard J. Lilford & Jennifer Jackson, *Equipoise and the Ethics of Randomization*, 88 *J. R. Soc. Med.* 552, 552 (1995). Moreover, the ability to perform RCTs is complicated where participants may be able to easily discern trial placement due to biological changes from treatment.

⁷² *Amici* also are aware of the systematic review conducted by Hilary Cass which was submitted to NHS England. See Hilary Cass, *Independent Review of Gender Identity Services for Children and Young People: Final Report*, Cass Review (Apr. 2024), <https://perma.cc/A8UR-Q2WD> (the “Cass Review”). However, the Cass Review, like other systematic reviews, is simply a summary of some of the existing research, as selected by the author. It does not purport to offer any new studies or findings regarding the efficacy and safety of prescribing gender-affirming medical care for adolescents that conflict with the recommendations in the Guidelines, which themselves are based on the available existing studies and research, as well as clinical experience. See Endocrine Soc’y, *Endocrine Society Statement in Support of Gender-Affirming Care* (May 8, 2024), <https://perma.cc/J4Y2-RUJ2>.

⁷³ Pet. App. 21a.

healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient.”⁷⁴ Such off-label drug use is common, particularly in disciplines such as pediatrics, where patients are less likely to be included in clinical trials.⁷⁵ “[I]n no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children.”⁷⁶ The FDA does not regulate the practice of medicine, and a lack of labeling should not be confused with a finding of contraindication or unsafety.⁷⁷ Medications used in providing gender-affirming care have been approved by the FDA. To suggest that using those medications to treat gender dysphoria is *disapproved*, or *should* be prohibited based on a lack of approval, is incorrect and contradicts common medical practices.

Second, the State claims that “the risks likely outweigh the benefits” of prescribing puberty blockers and hormone therapy to transgender adolescents.⁷⁸ *Amici* disagree, and observe that the State’s view is inconsistent with the existing research. This research, as well as the clinical experience of members of the *amici* who specialize in treating gender

⁷⁴ FDA, *Understanding Unapproved Use of Approved Drugs “Off Label”* (Feb. 5, 2018), <https://perma.cc/YW48-NZJS>.

⁷⁵ See, e.g., Christopher M. Wittich et al., *Ten Common Questions (and Their Answers) About Off-Label Drug Use*, 87(10) *Mayo Clin. Proc.* 982, 983 (2012) (reporting on study finding “78.9% of children discharged from pediatric hospitals were taking at least 1 off-label medication”).

⁷⁶ Am. Acad. of Pediatrics, *Policy Statement – Off-Label Use of Drugs in Children*, 133 *Pediatrics* 563, 564 (2014).

⁷⁷ See *id.*

⁷⁸ C.A. Dkt. 64 at 21.

dysphoria show that the use of these medications to treat adolescents is both safe and effective in appropriately identified individuals.⁷⁹

The State also justifies the Healthcare Ban based on the purported risk that patients may “regret their treatment decisions” and choose to “detransition[.]”⁸⁰ However, there are *no* studies to support the proposition that adolescents with gender dysphoria are likely to later identify as their sex assigned at birth, whether they receive treatment or not.⁸¹ On the contrary, “[l]ongitudinal studies have indicated that the emergence or worsening of gender dysphoria with pubertal onset is associated with a very high likelihood of being a transgender adult.”⁸²

Moreover, while detransitioning may occur for many reasons, detransitioning is not the same as regret. The State incorrectly assumes that an individual who detransitions—the definition of which

⁷⁹ See *supra* Section II.C (discussing the well-known efficacy and side-effects—which are exceedingly rare—of puberty blockers and the safe use of hormone therapy where indicated, including close monitoring to mitigate any potential risks).

⁸⁰ C.A. Dkt. 64 at 54–55.

⁸¹ See, e.g., Stewart L. Adelson, *Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents*, 51 J. Am. Acad. Child & Adolescent Psychiatry 957, 964 (2012), <https://perma.cc/S2Z4-DZMG> (“when gender variance with the desire to be the other sex is present in adolescence, this desire usually does persist through adulthood.”).

⁸² Rosenthal, *supra* note 65, at 585.

varies from study to study⁸³—must do so because they have come to identify with their sex assigned at birth. This ignores other, more common reported factors that contribute to a person’s choice to detransition, such as pressure from parents and discrimination.⁸⁴

IV. The Healthcare Ban Irreparably Harms Many Adolescents with Gender Dysphoria by Denying Them the Treatment They Need.

The Healthcare Ban denies adolescents with gender dysphoria in Tennessee access to medical care that is designed to improve health outcomes and alleviate suffering, and that is grounded in science and endorsed by the medical community. The gender-affirming medical care prohibited by the Healthcare Ban can be a crucial part of treatment for transgender adolescents with gender dysphoria and necessary to preserve their health. Clinicians who are members of the relevant amici associations have witnessed the benefits of this treatment as well as the harm that results when such treatment is denied or delayed.

As discussed above, research shows that adolescents with gender dysphoria who receive puberty blockers and/or hormone therapy experience

⁸³ Michael S. Irwig, *Detransition Among Transgender and Gender-Diverse People—An Increasing and Increasingly Complex Phenomenon*, *J. Clin. Endocrinol. & Metab.* 1, 1 (June 2022), <https://pubmed.ncbi.nlm.nih.gov/35678284> (“Detransition refers to the stopping or reversal of transitioning which could be social (gender presentation, pronouns), medical (hormone therapy), surgical, or legal.”).

⁸⁴ See *id.* (discussing “largest study to look at detransition”).

less depression, anxiety, and suicidal ideation. Several studies have found that hormone therapy is associated with reductions in the rate of suicide attempts and significant improvement in quality of life.⁸⁵ In light of this evidence supporting the connection between lack of access to gender-affirming medical care and lifetime suicide risk, banning such care can put patients' lives at risk.

⁸⁵ See M. Hassan Murad et al., *Hormonal Therapy and Sex Reassignment: A Systematic Review and Meta-Analysis of Quality of Life and Psychosocial Outcomes*, 72 *Clin. Endocrinol.* 214 (2010), <https://onlinelibrary.wiley.com/doi/10.1111/j.1365-2265.2009.03625.x>; see also Chen et al., *supra* note 56; Turban et al., *Access to Gender-Affirming Hormones During Adolescence and Mental Health Outcomes Among Transgender Adults*, *supra* note 56.

CONCLUSION

For the foregoing reasons, this Court should vacate the decision below and remand for the application of heightened scrutiny, or reverse the judgment.

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