

No. 23-466

IN THE

L.W., BY AND THROUGH HER PARENTS AND NEXT
FRIENDS, SAMANTHA WILLIAMS AND BRIAN WILLIAMS,
ET AL.,

Petitioners,

v.

JONATHAN SKRMETTI, ET AL.,

Respondents.

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

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

¹ In accordance with Rule 37.2, all counsel of record received timely notification of *amici's* intent to file this brief. 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.

optimal medical and mental health care they need and deserve. *Amici* represent thousands of healthcare providers who have specific expertise with the issues raised in this brief. The Court should consider *amicus*'s brief because it provides important expertise and

On March 23, 2023, the Tennessee Governor signed S.B. 1 into law (the “Healthcare Ban”). The Healthcare Ban prohibits healthcare providers from providing patients under 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 clinical condition that is marked by distress due to an incongruence between

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aspects of the patient's life.⁴ If not treated, or treated

gender-affirming care may include medical care to align their physiology with their gender identity. Empirical evidence indicates that gender-affirming care, including gender-affirming medical care provided 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 grant the petition.

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

⁷ See Simona Martin et al., *Criminalization of Gender-Affirming Care—Interfering with Essential Treatment for Transgender Children and Adolescents*, 385 *New Eng. J. Med.* 579, at 2 (2021), <https://www.nejm.org/doi/full/10.1056/NEJMp2106314> (providing an overview of the scientific basis underlying gender-affirming care and its demonstrated effectiveness in “alleviat[ing] gender dysphoria”).

brief explains how the Healthcare Ban would irreparably harm adolescents with gender dysphoria by denying crucial care to those who need it.

A person's gender identity is 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, it is estimated that approximately 1.4 million individuals are 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 understanding that being transgender is 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/6HR2-9KCM>.

¹⁰ See *id.* at 863.

¹¹ See Jody L. Herman et al., *Age of Individuals Who Identify as Transgender in the United States* at 2, Williams Inst. (Jan. 2017), <https://perma.cc/C4TA-NR25>.

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,

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

Adolescents with gender dysphoria are not expected to identify later as their sex assigned at birth.¹⁶ Instead, “[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.”¹⁷

If untreated or inadequately treated, gender dysphoria can cause depression, anxiety, self-harm,

2021), <https://perma.cc/BKS6-QFQ8>; see also Am. Psychological 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).

¹⁶ 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 (2020), <https://pubmed.ncbi.nlm.nih.gov/22917211> (“In contrast, when gender variance with the desire to be the other sex is present in adolescence, this desire usually does persist through adulthood”).

¹⁷ Stephen M. Rosenthal, *Challenges in the Care of Transgender and Gender-Diverse Youth: An Endocrinologist’s View*, 17(10) Nature Rev. Endocrinol. 581, 585 (Oct. 2021), <https://pubmed.ncbi.nlm.nih.gov/34376826>.

and suicidality.¹⁸ Indeed, over 60% of transgender adolescents and young adults reported having engaged in self-harm during the preceding 12 months, and over 75% reported symptoms of generalized anxiety disorder in the preceding two weeks.¹⁹ Even more troubling, more than 50% of this population reported having seriously considered attempting suicide,²⁰ and more than one in three transgender adolescents reported having attempted suicide in the preceding 12 months.²¹

care is necessary.²² Gender-affirming care greatly reduces the negative physical and mental health consequences that result when gender dysphoria is untreated.²³

A.

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”).²⁴ The Guidelines have been 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”). Further, the Guidelines provide that each patient who receives gender-affirming care should receive only evidence-based, medically necessary, and appropriate care that is tailored to the patient’s individual needs.

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.²⁵ The Guidelines do *not* recommend that prepubertal children with gender dysphoria receive gender-affirming medical care or surgeries.²⁶

In contrast to prepubertal children, the Guidelines do contemplate the possibility that transgender adolescents with gender dysphoria could receive gender-affirming medical care, provided certain criteria are met. According to the Guidelines, gender-affirming medical care should be provided

²⁵ See WPATH Guidelines, *supra* note 24, at S73–S74; Endocrine Soc’y Guidelines, *supra* note 24, at 3877–78.

²⁶ See WPATH Guidelines, *supra* note 24, at S64, S67; Endocrine Soc’y Guidelines, *supra* note 24, at 3871.

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

from puberty blockers are exceedingly rare when provided under clinical supervision.⁴⁰

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.⁴¹ Hormone therapy involves using gender-affirming hormones to allow adolescents to develop secondary sex characteristics consistent with their gender identity.⁴² 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.⁴³ A pediatric endocrinologist or other clinician experienced in pubertal induction must also agree with the indication, and the patient and their parents or guardians must be informed of the potential effects and side effects and give their informed consent.⁴⁴

Hormone-Releasing Hormone — A Preliminary Report, 305 New Eng. J. Med. 1546 (1981).

⁴⁰ See, e.g., Annemieke S. Staphorsius et al., *Puberty Suppression and Executive Functioning: An Fmri-Study in Adolescents with Gender Dysphoria*, 6 *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://pubmed.ncbi.nlm.nih.gov/31974217/> (exceedingly low risk of delayed bone mineralization from hormone treatment).

⁴¹ Martin, *supra* note 7 at 2.

⁴² See AAP Policy Statement, *supra* note 4, at 6.

⁴³ Endocrine Soc’y Guidelines, *supra* note 24, at 3878 tbl.5.

⁴⁴ See *id.*

drafting, comment, and review process.⁴⁸ The Endocrine Society imposes strict evidentiary requirements based on the internationally recognized Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.⁴⁹ That GRADE assessment is then reviewed, re-reviewed, and reviewed again by multiple, independent groups of professionals.⁵⁰ Reviewers are subject to strict conflict of interest rules, and there is ample opportunity for feedback and debate through the years-long review process.⁵¹ 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.

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.⁵² The draft guidelines went through

⁴⁸ See, e.g., Endocrine Soc'y Guidelines, *supra* note 24, at 3872–73 (high-level overview of methodology).

⁴⁹ See Gordon Guyatt et al., *GRADE Guidelines: 1. Introduction - GRADE Evidence Profiles and Summary of Findings Tables*, 64 J. Clin. Epidemiol. 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://pubmed.ncbi.nlm.nih.gov/18436948/>.

⁵⁰ Endocrine Soc'y, *Guideline Methodology*, <https://perma.cc/9NK4-HNNX>.

⁵¹ See *id.*

⁵² See WPATH Guidelines, *supra* note 24, at S247–51.

rigorous review and were publicly available for discussion and debate, receiving a total of 2,688 comments.⁵³ 119 authors were ultimately involved in the final draft, including feedback from experts in the field as well as from transgender individuals and their families.⁵⁴

C.

Multiple studies indicate that adolescents with gender dysphoria who receive gender-affirming medical care experience improvements in their overall well-being.⁵⁵ A number of studies have been published that investigated the use of puberty blockers on adolescents with gender dysphoria⁵⁶

⁵³ *See id.*

⁵⁴ *See id.*

⁵⁵ *See* Martin, *supra* note 7, at 2.

⁵⁶ *See, e.g.*, Christal Achille et al., *Longitudinal Impact of Gender-Affirming Endocrine Intervention on The Mental Health and Wellbeing of Transgender Youths: Preliminary Results*, 8 Int'l J Pediatric Endocrinol. 1–5 (2020), <https://pubmed.ncbi.nlm.nih.gov/32368216>; 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(2) PLOS One e0243894 (2021), <https://pubmed.ncbi.nlm.nih.gov/33529227>; Rosalia Costa et al., *Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria*, 12(11) J. Sexual Med. 2206–2214 (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(8) J. Sexual Med. 2276–83 (2011), <https://pubmed.ncbi.nlm.nih.gov/20646177>; Annelou L.C. de

mental health outcomes for those adolescents who received puberty blockers or hormone therapy, including statistically significant reductions in anxiety, depression, and suicidal ideation.⁵⁸

For example, 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.⁵⁹ 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.⁶⁰ Approximately *nine in ten* transgender adults who

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.⁶³

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.⁶⁴ 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.⁶⁵ “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.”⁶⁶

As scientists and 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.

⁶³ See Chen, *supra* note 57.

⁶⁴ See Vries, *Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study*, *supra* note 56.

⁶⁵ Vries, *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, *supra* note 56.

⁶⁶ Rosenthal, *supra* note 17, at 586.

A.

In its opinion, the Sixth Circuit relies on the State of Tennessee's assertion that gender-affirming medical care is "experimental in nature and not

“low,” and “very low.”⁷⁰ To suggest that clinical practice predicated on anything but “high” quality evidence is unsafe and unsupported by best medical practices is misleading at best. Clinical practice across disciplines is commonly guided by evidence that various evidence grading systems might deem “lower quality.”⁷¹ It is often the case, especially in the pediatric context, that randomized controlled trials are impossible or unethical.⁷² In such instances, as here, clinicians rely on the best evidence possible to provide treatment for their patients. The evidence

⁷⁰ 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*

supporting gender-affirming medical care is consistent with the type of evidence relied on in other clinical practices throughout the medical community.

In addition, the Sixth Circuit appears to conflate the use of FDA-approved medications for other indications with the use of *non*-FDA-approved medications.⁷³ According to the FDA, “once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient.”⁷⁴ 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

prohibited based on a lack of approval, is incorrect and contradicts common medical practices.

B.

The Sixth Circuit wrongly suggests that there is a vigorous international debate about whether to ban gender-affirming medical care.⁷⁸ The State of Tennessee attempts to rely on examples from Sweden, certain countries in the United Kingdom, Finland, and Norway⁷⁹ but, in fact, none of these countries—in contrast to Tennessee—categorically ban gender-affirming medical care. The United Kingdom provides gender-affirming medical care through its National Health Service.⁸⁰ Sweden offers gender-affirming medical care through its national health care system, and youth in Sweden are able to access gender-affirming medical care when their providers deem it

⁷⁸ See Pet. App. 28a.

⁷⁹ See C.A. Dkt. 64 (Br. of Defendants-Appellants) at 14.

⁸⁰ Policies vary throughout the countries of the United Kingdom

Germany,⁸⁷ Mexico,⁸⁸ New Zealand,⁸⁹ Norway,⁹⁰ and Spain,⁹¹ among others. Although some of these countries have debated how best to care for transgender patients, none has come close to banning gender-affirming medical care for all minors. The Healthcare Ban would make Tennessee an outlier in the international medical community, not the norm.

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-

⁸⁷ See *Ethics Council Publishes Ad Hoc Recommendation on Transgender Identity in Children and Adolescents*, German Ethics Counsel (Feb. 20, 2020), <https://perma.cc/KUJ6-W47M>.

⁸⁸ See *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 (Protocol for Access without Discrimination to Health Care Services for Lesbian, Gay, Bisexual, Transsexual, Transvestite, Transgender and Intersex Persons and Specific Care Guidelines)*, Gov't of Mex. (June 15, 2020), <https://perma.cc/2DTG-HKQY> (in Spanish).

⁸⁹ See *Transgender New Zealanders: Children and Young People*, New Zealand Ministry of Health (2020), <https://perma.cc/MBF9-QZ4J>.

⁹⁰ See *Gender Incongruence: National Academic Guideline*, Norwegian Directorate of Health (2020), <https://perma.cc/6HQU-P7PN>.

⁹¹ See López de Lara et al., *supra* note 57.

affirming medical care prohibited by the Healthcare Ban can be a crucial part of treatment for adolescents with gender dysphoria and necessary to preserve their health.

As discussed above, research shows that adolescents with gender dysphoria who receive puberty blockers and/or hormone therapy experience less depression, anxiety, and suicidal ideation. Several studies have found that hormone therapy is

For the foregoing reasons, this Court should grant the petition.

Respectfully submitted,

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