No. 23-466

IN THE

Supreme Court of the United States

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

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

Cortlin H. Lannin
COVINGTON & BURLING LLP
Salesforce Tower
415 Mission Street
Suite 5400
San Francisco, CA 94105

D. Jean Veta
Counsel of Record
William R. Isasi
Emily Mondry
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, N.W.
Washington, DC 20001
jveta@cov.com
(202) 662-6000

Counsel for Amicus Curiae

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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, American Psychiatric Association, 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

[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 *amici*'s brief because it provides important expertise and addresses misstatements about the treatment of transgender adolescents.

SUMMARY OF ARGUMENT

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 the patient's gender identity (i.e., the innate sense of oneself as being a particular gender) and sex assigned at birth. This incongruence can lead to clinically significant distress and impair functioning in many

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[2] Tenn. Code Ann. § 68-33-102(5)(B) prohibits medical treatments that are administered for the purpose of treating gender dysphoria, including treatments that delay or stop puberty or include certain hormone therapy 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.

aspects of the patient's life.[4] If not treated, or treated improperly, gender dysphoria can result in debilitating anxiety, depression, and self-harm, and is associated with higher rates of suicide. As such, the effective treatment of gender dysphoria saves lives.

The widely accepted recommendation of the medical community, including that of the respected professional organizations participating here as *amici*, is that the well-accepted protocol for treating gender dysphoria 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,

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[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) [hereinafter, "AAP Policy Statement"], https://publications.aap.org/pediatrics/article/142/4/e20182162/37381/Ensuring-Comprehensive-Care-and-Support-for. The American Academy of Pediatrics recently voted to reaffirm the AAP Policy Statement. *See* Alyson Sulaski Wyckoff, American Academy of Pediatrics, *AAP Reaffirms Gender-Affirming Care Policy, Authorizes Systematic Review of Evidence to Guide Update* (Aug. 4, 2023), https://publications.aap.org/aapnews/news/25340/AAP-reaffirms-gender-affirming-care-policy. AAP's review and reaffirmation was undertaken as part of its normal procedures to perform such reviews on a five-year basis.

[5] *Id.* at 10.

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

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.

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

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[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.

I. Understanding Gender Identity and Gender Dysphoria

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

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[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,

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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]

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, gender-affirming medical

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[18] *See* Brayden N. Kameg & Donna G. Nativio, *Gender Dysphoria in Youth: An Overview for Primary Care Providers*. 30(9) J. Am. Assoc. Nurse Prac. 493 (2018), https://pubmed.ncbi.nlm.nih.gov/30095668.

[19] *See* Amit Paley, *The Trevor Project 2020 National Survey* at 1, https://perma.cc/JB6T-49XF.

[20] *See id.* at 2.

[21] *See* Michelle M. Johns et al., *Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students–19 States and Large Urban School Districts, 2017*, U.S. Dep't of Health and Human Servs., Centers for Disease Control & Prevention, 68 Morbidity & Mortality Wkly. Rep. 67, 70 (2019), https://perma.cc/7ZKM-F4SS.

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 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").[24] The Guidelines have been developed by expert clinicians and researchers who have worked with patients with gender dysphoria for many years.

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[22] *See, e.g.*, Endocrine Soc'y, *Transgender Health: An Endocrine Society Position Statement* (2020), https://perma.cc/7L4P-VWME.

[23] *See id.*

[24] Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons*, 102(11) J. Clin. Endocrinol. & Metabolism 3869 (Nov. 2017) [hereinafter, "Endocrine Soc'y Guidelines"], https://perma.cc/3L9J-428B; WPATH, *Standards of Care for the Health of Transgender and Gender Diverse People* (8th Version) [hereinafter "WPATH Guidelines"], https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644.

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.

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

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 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

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[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 areas relevant to gender diverse children, adolescents, and families.[27]

Prior to developing a treatment plan, the HCP should conduct a "comprehensive biopsychosocial assessment" of the adolescent patient.[28] 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.[29] This assessment must be conducted collaboratively with the patient and their caregiver(s).[30]

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[27] *See* WPATH Guidelines, *supra* note 24, at S49–50.

[28] *Id.* at S50.

[29] *Id.*

[30] *Id.*

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

For youths 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, the Guidelines collectively provide that a qualified HCP must determine that: (1) the adolescent meets the diagnostic criteria of gender dysphoria or gender incongruence according to an established taxonomy;[31] (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.[32] Further, a pediatric

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[31] Endocrine Soc'y Guidelines, *supra* note 24, at 3876; WPATH Guidelines, *supra* note 24, at S47, S48.

[32] WPATH Guidelines, *supra* note 24, at S59–65.

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.[33]

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.[34] The purpose of puberty blockers is to delay pubertal development until adolescents are old enough and have had sufficient time to make more informed decisions about whether to pursue further treatments.[35] 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.[36] Puberty blockers have well-known efficacy and side-effect profiles.[37] Their effects are generally reversible, and when a patient discontinues their use, the patient resumes endogenous puberty.[38] In fact, puberty blockers have been used by pediatric endocrinologists for more than 40 years for the treatment of precocious puberty.[39] The risks of any serious adverse effects

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[33] Endocrine Soc'y Guidelines, *supra* note 24, at 3878 tbl.5.

[34] WPATH Guidelines, *supra* note 24, at S61–62; Endocrine Soc'y Guidelines, *supra* note 24, at 3878 tbl.5; Martin, *supra* note 7.

[35] WPATH Guidelines, *supra* note 24, at S112.

[36] *See* AAP Policy Statement, *supra* note 4, at 5.

[37] *See* Martin, *supra* note 7, at 2.

[38] *See id.*

[39] *See* Florence Comite et al., *Short-Term Treatment of Idiopathic Precocious Puberty with a Long-Acting Analogue of Luteinizing*

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 Pscyhoneuroendocrinol. 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.*

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.[45]

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.[46] Decisions regarding the appropriate treatment for each patient with gender dysphoria are made in consultation with the patient, their parents or guardians, and the medical and mental health care team. There is "no one-size-fits-all approach to this kind of care."[47]

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

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[45] *See* AAP Policy Statement, *supra* note 4, at 5–6.

[46] *See* Endocrine Soc'y Guidelines, *supra* note 24, at 3871, 3876.

[47] Martin, *supra* note 7, at 1.

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

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[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. 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.[55] A number of studies have been published that investigated the use of puberty blockers on adolescents with gender dysphoria[56]

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[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

and/or the use of hormone therapy to treat adolescents with gender dysphoria.[57] These studies find positive

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Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134(4) 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(4) Pediatrics e20193006 (2020), https://pubmed.ncbi.nlm.nih.gov/32220906; Jack L. Turban et al., *Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation*, 145(2) Pediatrics e20191725 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7073269; Anna I.R. van der Miesen, *Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared with Cisgender General Population Peers*, 66(6) J. Adolescent Health 699–704 (2020); Diana M. Tordoff et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care*, 5(2) JAMA Network Open e220978 (2022), https://pubmed.ncbi.nlm.nih.gov/35212746/.

[57] *See, e.g.*, Achille, *supra* note 56; Luke R. Allen et al., *Well-Being and Suicidality Among Transgender Youth After Gender-Affirming Hormones*, 7(3) Clin. 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(3) New Eng. J. Med 240–50 (2023), https://www.nejm.org/doi/10.1056/NEJMoa2206297; Diego Lopez de Lara et al., *Psychosocial Assessment in Transgender Adolescents*, 93(1) Anales de Pediatria (English ed.) 41–48 (2020), https://perma.cc/AQ4G-YJ85; Vries, *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, *supra* note 56; Rittakerttu Kaltiala et al., *Adolescent Development and Psychosocial Functioning After Starting Cross-Sex Hormones for Gender Dysphoria*, 74(3) Nordic J. Psychiatry 213 (2020); Kuper, *supra* note 56; Amy E. Green et al., *Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth*, J. Adolescent Health (2021), https://www.jahonline.org/article/S1054-139X(21)00568-1/fulltext; Jack L. Turban et al., *Access to Gender-Affirming*

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 wanted puberty blocking treatment but did not receive it reported lifetime suicidal ideation.[61] Additionally, a longitudinal study of nearly 50 transgender adolescents found that suicidality was decreased by a statistically-significant degree after receiving gender-affirming hormone treatment.[62] A

Hormones During Adolescence and Mental Health Outcomes Among Transgender Adults, J. PLOS One (2022), https://perma.cc/Q96X-W2FK.

[58] The data likewise indicates 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).

[59] *See* Turban, *Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, supra* note 56.

[60] *See id.*

[61] *See id.*

[62] *See* Allen, *supra* note 57.

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.

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[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.

III. The Sixth Circuit's Opinion Relies on Factually Inaccurate Claims and Ignores Recommendations of the Medical Community

A. The Evidence Supporting Gender-Affirming Medical Care Is In-Line with Evidence Supporting Decisions in Other Clinical Contexts

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 supported by high-quality, long-term medical studies."[67] To conclude that gender-affirming medical care is not well-supported by the evidence is contrary to standard clinical practices.

When Respondents criticize the studies supporting gender-affirming medical care,[68] they refer to "high-quality" vs. "low-quality" studies under the GRADE system and the presence (or lack thereof) of randomized controlled trials.[69] Under the GRADE system, evidence may be assessed according to different categories, including "high," "moderate,"

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[67] Pet. App. 10a.

[68] 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).

[69] *Id*.

"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

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[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*, 328 BMJ 1490 (2004).

[71] 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., *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.*

[72] "[I]n transgender clinical research individual randomized controlled trials (RCTs) may not always be feasible or ethically acceptable." Sari L. Reisner et al., *Advancing Methods for U.S. Transgender Health Research*, 23(2) Curr. Opin. Endocrinal 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 RCT is complicated where participants may be able to easily discern trial placement due to biological changes from treatment.

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 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 for a finding of contraindication or unsafety.[77] Gender-affirming medications have been approved by the FDA. To suggest that using those medications to treat gender dysphoria is *disapproved*, or *should* be

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[73] Pet. App. 21a.

[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] American Academy of Pediatrics, *Policy Statement – Off-Label Use of Drugs in Children*, 133 Pediatrics 563, 564 (2014).

[77] *See id.*

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

B. Gender-Affirming Medical Care Is Provided Internationally.

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 Norway[79] 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

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[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 with regard to the circumstances under which gender-affirming medical care may be provided to adolescents. *See, e.g.*, NHS Services, *The Young People's Gender Service*, https://perma.cc/75AL-6KJD (gender-affirming care in Scotland). The National Health Service in England and Wales recently published an *interim* service specification that narrows some of their policies on gender-affirming medical care for adolescents to incorporate research protocols, but the interim specification does not contemplate a categorical ban on such care. *See* NHS Services, *Interim Service Specification for Specialist Gender Incongruence Services for Children and Young People*, https://perma.cc/5LU2-QBWN. A non-interim (i.e., "a national service specification") is not expected for several months.

medically necessary.[81] Finland also offers gender-affirming medical care to transgender adolescents through its national healthcare system.[82] Norway offers gender-affirming medical care to transgender adolescent patients as well.[83]

Transgender youth also have access to gender-affirming medical care in developed nations across the world including Australia,[84] Canada,[85] Denmark,[86]

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[81] *See Care of Children and Adolescents with Gender Dysphoria: Summary of National Guidelines,* Swedish Nat'l Bd. of Health & Welfare (2022), https://perma.cc/H7WD-T27P.

[82] *See Medical Treatment Methods for Dysphoria Associated with Variations in Gender Identity in Minors – Recommendation*, Council for Choices in Health Care in Finland (2020), https://perma.cc/J8PH-VSY9.

[83] *Kjønnsinkongruens: Nasjonal Faglig Retningslinje* (*Gender Incongruence: National Academic Guideline*), Norwegian Directorate of Health (2021), https://perma.cc/6HQU-P7PN (in Norwegian).

[84] *See Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents*, Royal Children's Hosp. Melbourne (Oct. 2021), https://perma.cc/4DXY-7E8Z.

[85] *See* Greta R. Bauer et al., *Transgender Youth Referred to Clinics for Gender-Affirming Medical Care in Canada*, 148(5) Pediatrics 1 (2021).

[86] *See* Vejledning om Sundhedsfaglig Hjælp ved Kønsidentitetsforhold (*Guidelines on Healthcare Concerning Gender Identity Matters*), Danish State Legal Information System (2018), https://perma.cc/6T3E-GZ4Z (in Danish).

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.

IV. The Healthcare Ban Would Irreparably Harm 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-

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[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 lntersexual 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 associated with reductions in the rate of suicide attempts and significant improvement in quality of life. 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.

CONCLUSION

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

Respectfully submitted,

Cortlin H. Lannin
COVINGTON & BURLING LLP
Salesforce Tower
415 Mission Street
Suite 5400
San Francisco, CA 94105

D. Jean Veta
Counsel of Record
William R. Isasi
Emily Mondry
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, N.W.
Washington, DC 20001
jveta@cov.com
(202) 662-6000

Counsel for Amicus Curiae

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