No. 25-1279

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

PFLAG, INC., et al.,

Plaintiffs-Appellees,

v.

DONALD J. TRUMP,
in his official capacity as President of the United States, et al.,
Defendants-Appellants.

On Appeal from the United States District Court
for the District of Maryland
Case No. 8:25-cv-00337-BAH

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

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Civil Procedure 7.1 and Fourth Circuit Rule 26.1(b), the undersigned counsel for the American Academy of Pediatrics ("AAP"), the Academic Pediatric Association, the American Academy of Child & Adolescent Psychiatry ("AACAP"), the American Academy of Family Physicians ("AAFP"), the American Academy of Nursing ("AAN"), the American Association of Physicians for Human Rights, Inc. d/b/a GLMA: Health Professionals Advancing LGBTQ+ Equality ("GLMA"), the American College of Obstetricians and Gynecologists ("ACOG"), the American College of Osteopathic Pediatricians ("ACOP"), the American College of Physicians ("ACP"), the American Pediatric Society ("APS"), the Association of American Medical Colleges ("AAMC"), the American Psychiatric Association ("APA"), the Association of Medical School Pediatric Department Chairs, Inc. ("AMSPDC"), the Endocrine Society ("ES"), the Maryland Chapter of the American Academy of Pediatrics ("MDAAP"), the National Association of Pediatric Nurse Practitioners ("NAPNAP"), the Pediatric Endocrine Society ("PES"), the Pediatric Endocrinology Nursing Society ("PENS"), the Societies for Pediatric Urology ("SPU"), the Society for Adolescent Health and Medicine ("SAHM"), the Society of Pediatric Nurses ("SPN"), and the World Professional Association for Transgender Health ("WPATH") (collectively, "*amici*") certify that:

1. AAP, the Academic Pediatric Association, AACAP, AAFP, AAN, GLMA, ACOG, ACOP, ACP, AAMC, APS, APA, AMSPDC, ES, MDAAP, NAPNAP, PES, PENS, SPU, SAHM, SPN, and WPATH, respectively, have no parent corporation.

2. No corporations hold any stock in AAP, the Academic Pediatric Association, AACAP, AAFP, AAN, GLMA, ACOG, ACOP, ACP, AAMC, APS, APA, AMSPDC, ES, MDAAP, NAPNAP, PES, PENS, SPU, SAHM, SPN, and WPATH.

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STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici[1] 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 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.[2]

[1] "Amici" is defined in the Corporate Disclosure Statement.

[2] All parties consent to the filing of this brief. *Amici* affirm 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.

INTRODUCTION

On January 28, 2025, the President signed Executive Order No. 14187 (the "Healthcare Ban"), directing all federal agencies to "immediately take appropriate steps to ensure that institutions receiving Federal research or education grants end" gender-affirming medical care ("GAMC") for people under nineteen. GAMC refers to critical, medically necessary, evidence-based care for gender dysphoria.[3] Denying this care to adolescents who meet the requisite medical criteria puts them at risk of significant harm. Below, *amici* provide an accurate description of GAMC and the evidence that supports its use when medically indicated for adolescents with gender dysphoria.

Gender dysphoria is a condition 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 assigned at birth.[4] If not treated, or

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[3] In this brief, the term "gender-affirming medical care" or "GAMC" 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.

[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 (continued…)

treated improperly, gender dysphoria can result in debilitating anxiety, depression, and self-harm, and is associated with suicidality. The effective treatment of gender dysphoria saves lives.

The medical community, including the respected professional organizations participating as *amici*, widely recognizes that the appropriate treatment for transgender adolescents diagnosed with gender dysphoria is gender-affirming care.[5] Gender-affirming care 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 carefully evaluated 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 identity. Empirical evidence indicates that GAMC, including the prescription of puberty blockers and hormone therapy to

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Policy Statement"]. The American Academy of Pediatrics 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] *Id*. at 10.

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

carefully evaluated patients who meet diagnostic criteria, can alleviate clinically significant distress and lead to significant improvements in the mental health and overall wellbeing of adolescents with gender dysphoria.[7] This evidence supporting GAMC is of the same type and quality as the evidence supporting numerous medical treatments.

The Healthcare Ban disregards this medical evidence by effectively denying adolescents' access to treatments for gender dysphoria. *Amici* urge this Court to uphold the District Court's preliminary injunction.

ARGUMENT

This brief provides: (1) background on gender identity and gender dysphoria; (2) an overview of the general standards and best practices used by the medical community when developing clinical treatment recommendations; (3) a description of how such recommendations involving GAMC were developed in a manner consistent with the general standards and best practices used in other areas of medicine; (4) an explanation that the Healthcare Ban and its proponents rely on several inaccurate claims to support banning GAMC; and (5) an explanation of how

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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://perma.cc/BR4F-YLZS (providing an overview of the scientific basis underlying gender-affirming care and its demonstrated effectiveness).

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.

Being transgender is a normal variation of human identity.[13] However, many

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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/JJE6-XUNX.

[10] *See id.* at 832.

[11] *See* Jody L. Herman et al., *Ages of Individuals Who Identify as Transgender in the United States*, WILLIAMS INST., at 2 (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, 2021), https://perma.cc/BKS6-QFQ8; *see also* Am. Psychological Ass'n, *APA Resolution on Gender Identity Change Efforts*, 4 (Feb. 2021), https://perma.cc/M22K-PBUZ.

transgender people suffer 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 can lead to depression, anxiety, self-harm, and suicidality.[16] 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.[17] Even more troubling, more than 50% of this population reported having seriously considered attempting suicide,[18] and more than one in three transgender adolescents reported having attempted suicide in the preceding

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[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* 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.

[17] *See* Amit Paley, *The Trevor Project: National Survey on LGBTQ Youth Mental Health 2020*, at 1, https://perma.cc/JB6T-49XF.

[18] *See id*. at 2.

12 months.[19]

II. General Standards and Best Practices for the Development of Clinical Treatment Recommendations in Medicine

Healthcare providers, hundreds of thousands of whom are individual or institutional members of the respected medical organizations participating here as *amici*, are ethically and legally obligated to provide medical care in accordance with the accepted standards of care. To decide on treatment recommendations for their patients, healthcare providers rely—both directly and through clinical practice guidelines—on the best available evidence in the relevant medical fields, as well as a comparison of the potential benefits and risks of any potential treatments, their own clinical judgment as experienced healthcare professionals, their patients' own individual circumstances, and informed consent.[20] In weighing these considerations, healthcare providers may rely on various types of research and studies, each providing distinct insights into the safety and efficacy of medical treatments. Below,

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[19] *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.

[20] *See* National Academy of Medicine, *Clinical Practice Guidelines We Trust* at 109–112 (2011); Yael Schenker & Alan Meisel, *Informed Consent in Clinical Care: Practical Considerations in the Effort to Achieve Ethical Goals*, 305 JAMA 1130 (2011), https://pubmed.ncbi.nlm.nih.gov/21406651/.

amici provide an overview of various types of medical evidence relied on in the development of clinical treatment recommendations, the way that evidence is assessed, how those assessments influence treatment recommendations, and the importance of informed consent.

A. Categories of Medical Evidence

Clinical studies constitute the principal evidence considered by healthcare providers when considering treatment recommendations. Such studies are classified into two general types: observational studies and experimental studies, also known as clinical trials.[21] Broadly speaking, the main distinction between these types of studies is whether the investigators of the study: assign treatments to participants with the express purpose and design of testing a hypothesis (experimental study), or observe the effects of the participants' exposure to the treatment in question as a part of usual clinical practice (observational study).[22] Randomized controlled trials ("RCTs") are a form of experimental study wherein researchers randomly assign participants to either receive a particular treatment or a comparison intervention,

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[21] *See* David A. Grimes & Kenneth F. Schulz, *An Overview of Clinical Research: The Lay of the Land*, 359 LANCET 57, 58 (2002), https://pubmed.ncbi.nlm.nih.gov/11809203/; Ambika G. Chidambaram & Maureen Josephson, *Clinical Research Study Designs: The Essentials*, 3 PEDIATR. INVEST. 245 (2019), https://perma.cc/EP4E-FE7C.

[22] *Id.*

such as a different treatment or a placebo.[23]

When considering the evidence pertaining to a potential treatment for a patient, healthcare professionals may base their recommendations on both observational and experimental studies. Though experimental studies such as RCTs are highly regarded, they are not feasible in all contexts, may face difficult ethical considerations, and can be prohibitively costly.[24] Observational studies are conducted more frequently because they do not face these obstacles, and provide important data from clinical contexts on the long-term efficacy and safety of a treatment, and thus form an important pillar of medical evidence.[25]

In addition to clinical studies, secondary sources of support exist in the form of published reviews or analyses, such as systematic reviews. Systematic reviews do not provide any new clinical data and instead are summaries of preexisting studies

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[23] *Id.*

[24] In certain circumstances, RCTs would violate the principle of equipoise, which safeguards the rights of trial participants, where it would be unethical to withhold treatments with proven effects from a placebo group in need of medical intervention. *See* Richard J. Lilford & Jennifer Jackson, *Equipoise and the Ethics of Randomization*, 88 J. R. SOC. MED. 552, 552 (1995); Chidambaram & Josephson, *supra* note 20, at 251.

[25] *See* Ravi Thadhani, *Formal Trials Versus Observational Studies*, *in Fabry Disease: Perspectives From 5 Years of FOS* (2006).

based on the authors' criteria for which studies to include or exclude.[26]

B. Assessment of Evidence in the Development of Treatment Recommendations

To evaluate a potential treatment recommendation for a patient, healthcare providers must consider not just the scope of available evidence, but also the quality of available evidence. Although there is no universal framework for performing this assessment, Grading of Recommendations Assessment, Development and Evaluation (GRADE) is a commonly used system that provides guidance on assessing the quality of evidence and determining the strength of treatment recommendations.[27] Clinical practice guidelines promulgated by respected medical organizations commonly provide strength-rated treatment recommendations utilizing GRADE or similar frameworks, which healthcare providers often consider in determining a recommended plan of treatment for their patients.[28]

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[26] *See* Maria J. Grant & Andrew Booth, *A Typology of Reviews: An Analysis of 14 Review Types and Associated Methodologies*, 26 HEALTH INFO. LIBR. J. 91 (2009), https://perma.cc/C6QG-DYPN.

[27] *See* National Academy of Medicine, *supra* note 19, at 114–116; 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; David Atkins et al., *Grading Quality of Evidence and Strength of Recommendations*, 328 BMJ 1490 (2004).

[28] *Id.*

The GRADE system identifies four levels of evidence quality: high, moderate, low, and very low.[29] However, it is important to understand that these are terms of art; "low" does not mean that the evidence lacks value.

GRADE's levels of evidence are based on a complex assessment of factors that can influence how study data are interpreted. For example, if different proportions of participants complete a study depending on the treatment they received, this affects the interpretation of the results.[30] Also, if a participant is aware of the treatment because of its unique benefits, side effects, etc., this affects the interpretation of results.[31] Studies rated as "high quality" studies have fewer such factors, but it is well understood in the medical community that "low quality" studies still provide valuable and valid information about the benefits and safety of clinical practices. "[O]nly a minority of outcomes for health care interventions are supported by high quality evidence."[32] Indeed, clinical practice is commonly guided

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[29] Gordon H. Guyatt et al., *GRADE: What Is "Quality of Evidence" and Why Is It Important to Clinicians?*, 336 BMJ 995, 998 (2008), https://www.cpd-umanitoba.com/wp-content/uploads/2021/02/Guyatt-et-al.-GRADE-what-is-the-quality-of-evidence-and-why-it-is-important-to-clinicians.-BMJ-2008.pdf.

[30] *See* Holger Schünemann et al., *GRADE Handbook* at 5.2 (2013), https://perma.cc/B7EM-E73T.

[31] *Id.*

[32] Jeremy Howich et al., *The Quality of Evidence for Medical Interventions Does Not Improve or Worsen: A Metaepidemiological Study of Cochrane Reviews*, 126 J. CLIN. EPIDEMIOL. 154 (2020), https://perma.cc/TKB3-6ZNH.

by evidence that evidence grading systems might deem "low quality."[33] In addition, GRADE itself acknowledges the relevance of factors beyond the quality of evidence, such as "[t]he balance between desirable and undesirable outcomes and the application of patients' values and preferences," should inform treatment recommendations.[34]

In sum, healthcare providers carefully consider the best available evidence, alongside the relevant benefits and risks associated with a given treatment and their clinical experience, to tailor treatment recommendations to a patient's individual needs.

C. The Importance of Informed Consent

A final essential element of healthcare practice is securing a patient's informed consent for the treatment by discussing the potential benefits and risks

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[33] For example, the American Heart Association's guideline for Pediatric Basic and Advanced Life Support includes 130 recommendations, only 1 of which is predicated on Level A (akin to GRADE's "high quality") 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 (akin to GRADE's "low quality") evidence. *Id.*

[34] Guyatt et al. (2011), *supra* note 27, at 384, 86, 92; *see also* Mohammed T. Ansari et al., *Grading Quality of Evidence and Strength of Recommendations: A Perspective*, PLoS MEDICINE 6(9):e1000151, 2 (2009), https://perma.cc/4MUS-TBZM.

associated with the recommended treatment with patients[35]—and in the pediatric context,[36] with the patient's parents or guardians. Obtaining informed consent centers medical care around a patient's autonomy and dignity. Informed consent, combined with a careful analysis of the existing science and clinical experience, are key elements in enabling healthcare providers to adhere to national standards and practices to provide the best possible care to their patients.[37]

III. GAMC Was Developed Using the Same Standards and Best Practices as Other Types of Medical Treatments

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, GAMC is necessary.[38] This care greatly reduces the negative physical and mental health consequences that result when gender dysphoria is untreated.[39] As discussed below, the type and quality of evidence supporting these treatments, and the manner in which that evidence has been evaluated, is consistent with general best practices of the medical community in other clinical disciplines.

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[35] *See* Ruth R. Faden & Tom L. Beauchamp, *Foundations in Moral Theory*, *in* A History and Theory of Informed Consent (1986).

[36] *See* National Academy of Medicine, *supra* note 20, at 111.

[37] *See* National Academy of Medicine, *supra* note 20, at 111.

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

[39] *See id.*

A. The Widely Accepted Guidelines for Treating Adolescents With Gender Dysphoria Provide for GAMC When Indicated

For youths with gender dysphoria that continues into adolescence—after the onset of puberty—in certain circumstances GAMC may be indicated in addition to mental health care. The treatment recommendations for gender dysphoria are provided in evidence-based clinical guidelines: (i) the Endocrine Society Clinical Practice Guidelines for Clinical Treatment of Gender-Dysphoria/Gender Incongruent Persons, and (ii) the WPATH Standards of Care for the Health of Transgender and Gender-Diverse People.[40] These guidelines set forth an extensive list of requirements detailing the circumstances in which GAMC care may be prescribed to adolescents, including a robust diagnostic assessment, stringent guidelines regarding the qualifications of the medical professionals involved in that assessment, and strict patient criteria—including that the patient has demonstrated a

[40] *See* Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons*, 102(11) J. CLINICAL ENDOCRINOLOGY & METABOLISM 3869, at 3869, 3878, 80–85 (Nov. 2017); Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People*, 23 INT'L J. TRANSGENDER HEALTH S1, S48 (8th ed. 2022). *Amici* member American Psychiatric Association ("APA") also links to Coleman et al. on its website, which indicates that APA has reviewed these guidelines under the "AGREE" rating framework and scored them as "high quality." *See* American Psychiatric Association, *Clinical Practice Guidelines*, https://www.psychiatry.org/psychiatrists/practice/clinical-practice-guidelines (last visited Sept. 9, 2025); AGREE, *Appraisal of Guidelines for Research & Evaluation* (2017), https://perma.cc/UEX9-4KLK.

prolonged pattern of gender dysphoria.[41]

If, after careful evaluation, healthcare providers determine that an adolescent with gender dysphoria meets all criteria, and the patient and their parent provide informed consent, gonadotropin-releasing hormone (GnRH) analogues, or "puberty blockers," may be offered beginning at the onset of puberty.[42] The purpose of puberty blockers is to delay further pubertal development until adolescents are older and have had sufficient time to make more informed decisions about whether to pursue further treatments.[43] Puberty blockers also can make pursuing transition later in life easier, because they prevent bodily changes such as protrusion of the Adam's apple or breast growth.[44]

Puberty blockers have well-known efficacy and side-effect profiles.[45] Their effects are generally reversible, and when a patient discontinues their use, the patient typically resumes endogenous puberty.[46] In fact, puberty blockers have been used by pediatric endocrinologists for more than 40 years for the treatment of precocious

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[41] *See* Hembree et al., *supra* note 40 at 3869, 3878, 80–85; Coleman et al., *supra* note 40 at S48.

[42] *See id.*

[43] Martin, *supra* note 7, at 2.

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

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

[46] *See id.*

puberty.[47] The risks of any serious adverse effects from puberty blockers are exceedingly rare when provided under clinical supervision.[48]

Later in adolescence, if healthcare providers determine—after careful evaluation—that an adolescent with gender dysphoria meets all the treatment criteria,[49] hormone therapy may be used to initiate puberty consistent with the patient's gender identity.[50] Hormone therapy involves using hormones to allow adolescents to develop secondary sex characteristics consistent with their gender identity.[51] Although some of the changes caused by hormone therapy become irreversible after those secondary sex characteristics are fully developed, others are

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[47] *See* F. Comite et al., *Short-Term Treatment of Idiopathic Precocious Puberty with a Long-Acting Analogue of Luteinizing Hormone-Releasing Hormone — A Preliminary Report*, 305 NEW ENG. J. MED. 1546 (1981), https://pubmed.ncbi.nlm.nih.gov/6458765/.

[48] *See, e.g.*, Annemieke S. Staphorsius et al., *Puberty Suppression and Executive Functioning: An Fmri-Study in Adolescents with Gender Dysphoria*, 6 PSCYHONEUROENDOCRINOLOGY 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 (2020), https://perma.cc/VP47-UA9M (exceedingly low risk of delayed bone mineralization from hormone treatment).

[49] *See* Hembree et al., *supra* note 40, at 3878, 80–85; Coleman et al., *supra* note 40, at S48.

[50] Martin, *supra* note 7, at 2.

[51] *See* AAP Policy Statement, *supra* note 4, at 6.

partially reversible if the patient discontinues use of the hormones.[52]

B. The Available Evidence Supports Providing GAMC for Adolescents With Gender Dysphoria When Medically Indicated

Multiple studies have been published that investigated the use of puberty

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

blockers,[53] and/or hormones,[54] to treat adolescents with gender dysphoria. These

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[53] *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 ENDOCRINOLOGY 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(2) 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. 2206–2214 (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. 2276–2283 (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(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://perma.cc/2HAT-GGFV; Jack L. Turban et al., *Pubertal Suppression For Transgender Youth And Risk of Suicidal Ideation*, 145(2) PEDIATRICS e20191725 (2020), https://perma.cc/B2UZ-YR3Q; Anna I.R. van der Miesen et al, *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), https://pubmed.ncbi.nlm.nih.gov/32273193/; 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://perma.cc/SBF4-B4D4.

[54] *See, e.g.*, Achille, *supra* note 53**Error! Bookmark not defined.**, at 1–5; Luke R. Allen et al., *Well-Being and Suicidality Among Transgender Youth After Gender-Affirming Hormones*, 7(3) CLINICAL PRAC. PEDIATRIC PSYCH. 302 (2019), https://www.sciencegate.app/document/10.1037/cpp0000288; 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., (continued…)

studies find positive mental health outcomes for those adolescents who received GAMC, including statistically significant reductions in anxiety, depression, and suicidal ideation.[55]

A 2020 retrospective 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.[56] 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

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Psychosocial Assessment in Transgender Adolescents, 93(1) ANALES DE PEDIATRIA 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 52**Error! Bookmark not defined.**; Rittakerttu Kaltiala et al., *Adolescent Development And Psychosocial Functioning After Starting Cross-Sex Hormones For Gender Dysphoria*, 74(3) NORDIC J. PSYCHIATRY 213 (2020), https://doi.org/10.1080/08039488.2019.1691260; Kuper, *supra* note 52**Error! Bookmark not defined.**; 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://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. PLOS ONE (2022), https://doi.org/10.1371/journal.pone.0261039.

[55] The data likewise indicates that adults who receive GAMC 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*, 9 ANDROLOGY 1808–1816 (2021).

[56] *See* Turban, *supra* note 53.

demographic variables and level of family support.[57] Approximately *nine in ten* transgender adults who wanted puberty blocking treatment but did not receive it reported lifetime suicidal ideation.[58] 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.[59] 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.[60]

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.[61] 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

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[57] *See id*.

[58] *See id.*

[59] *See* Allen, *supra* note 54.

[60] *See* Chen et al., *supra* note 54.

[61] *See* de Vries et al., *Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study*, *supra* note 53.

associated with a statistically significant decrease in depression and anxiety.[62] Notably, this study demonstrated that the sense of well-being of these transgender adolescents and young adults was equivalent or superior to that observed in age-matched controls from the general population.[63]

As scientists and researchers, *amici* always welcome more research, including on this crucial topic. However, the available data indicate that the GAMC targeted by the Healthcare Ban is effective for the treatment of gender dysphoria in carefully evaluated patients.

C. The Evidence Supporting GAMC Recommendations, and the Evaluation of That Evidence, Is Consistent With Other Areas of Medicine

The Healthcare Ban incorrectly claims that GAMC is based on "junk science."[64] Proponents of the Healthcare Ban have criticized GAMC because it is based in part on evidence that may be deemed "low quality" under GRADE. Such an assertion misapprehends GRADE. As discussed in Section II.B, its term of art—"low quality"— does not mean that the evidence lacks value or should not be used to develop treatment recommendations.

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[62] de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, *supra* note 53.

[63] *Id.* at 696.

[64] Exec. Order No. 14187 § 3.

Widely-accepted clinical treatment recommendations across various medical fields commonly rely on evidence that is not considered "high quality."[65] Moreover, "high quality" evidence typically refers to RCTs, which often are infeasible or unethical to carry out, particularly in the pediatric context.

"[I]n transgender clinical research individual . . . RCTs . . . may not always be feasible or ethically acceptable."[66] With preexisting guidelines that recommend GAMC for those with gender dysphoria, RCTs would violate the principle of equipoise.[67] Moreover, the ability to perform blinded RCTs is complicated where participants may be able to easily discern trial placement due to biological changes from treatment.

Recently, the authors of several systematic reviews studying evidence related to GAMC—including Dr. Guyatt, one of the architects of GRADE—published a letter stating that it is "unconscionable" to deny GAMC based on evidence characterized as "low quality" within a specific GRADE category.[68] They wrote:

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[65] *See supra* note 33.

[66] Sari L. Reisner et al., *Advancing Methods for U.S. Transgender Health Research*, 23(2) CURR. OPIN. ENDOCRINAL DIABETES OBES. 198, 199 (2016), https://perma.cc/KR8Z-WJA3.

[67] Richard J. Lilford & Jennifer Jackson, *Equipoise and the Ethics of Randomization*, 88 J. R. SOC. MED. 552, 552 (1995), https://perma.cc/7458-SJSC.

[68] Gordon Guyatt et al., *Systematic Reviews Related to Gender-Affirming Care*, (continued…)

> We are concerned our findings will be used to justify denying care such as puberty blockers and hormone replacement therapy to [transgender] individuals.
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> . . .
>
> It is profoundly misguided to cast health care based on low-certainty evidence as bad care or as care driven by ideology, and low-certainty evidence as bad science. Many of the interventions we offer are based on low certainty evidence, and enlightened individuals often legitimately and wisely choose such interventions. **Thus, forbidding delivery of gender-affirming care and limiting medical management options on the basis of low certainty evidence is a clear violation of the principles of evidence-based shared decision-making and is unconscionable.** The appropriate use of our work is in ensuring patients receive needed care and in helping [transgender] patients and their clinicians in decision making.[69]

As these authors make plain, it is a grievous mischaracterization of evidence-based medicine to presume that GAMC is bad care, or should be banned because that care is supported, at least in part, by observational studies.

D. Informed Consent is a Core Requirement of GAMC

As with all other areas of medicine, treatment recommendations involving GAMC insist that healthcare providers receive informed consent before care is provided. Clinical practice guidelines for treating adolescent patients with GAMC include express and specific guidance on securing informed consent before treating

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https://hei.healthsci.mcmaster.ca/systematic-reviews-related-to-gender-affirming-care/.

[69] *Id.*

adolescent patients with GAMC.[70] GAMC is not recommended where informed consent is not given.

IV. The Healthcare Ban Proponents Make Factually Inaccurate Claims in an Attempt to Support Banning Care

In attempting to justify effectively denying access to GAMC, the Healthcare Ban and its proponents make inaccurate claims that are lacking in meaningful evidentiary support. These claims are discussed below.

A. GAMC is Not a Recommended Treatment for Prepubertal Children

The Healthcare Ban purports to protect "children."[71] However, it conflates prepubertal children with adolescents,[72] which is an important distinction. Prepubertal children are ***not*** eligible under the applicable clinical practice guidelines for the GAMC targeted in the Healthcare Ban.[73] For prepubertal children with

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[70] *See* Hembree et al., *supra* note 40, at 3878 (describing requirement of informed consent from patient and parent/guardian and ensuring that the adolescent has sufficient mental capacity to give informed consent to the treatments); Coleman et al., *supra* note 40, at S48 (describing requirement of informed consent and ensuring the adolescent has no mental health concerns that could impact the capacity to consent).

[71] Exec. Order No. 14187 § 1.

[72] *Id.* § 2.

[73] *See* Susan D. Boulware et al., *Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims*, 1, 18 (Apr. 28, 2022), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4102374.

gender dysphoria, it is recommended that clinicians provide only mental health care and support for the child and their family, such as through psychotherapy and social transitioning.[74]

B. The Vast Majority of Adolescents Diagnosed With Gender Dysphoria Will Persist Through Adulthood

The Healthcare Ban states that "[c]ountless children soon regret" receiving GAMC.[75] 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.[76] Rather, "[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."[77]

Moreover, while detransitioning may occur for many reasons, detransitioning

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[74] *See* Coleman et al., *supra* note 40, at S73–S74; Hembree et al., *supra* note 39, at 3877–78. "Social transition" refers to a process by which a child is acknowledged to have, and has the opportunity to live in, the gender identity they affirm. *See, e.g.*, Coleman et al., *supra* note 40, at S75.

[75] Exec. Order No. 14187 § 1.

[76] *See, e.g.*, Stewart L. Adelson, *Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Non-Conformity, and Gender Discordance in Children and Adolescents*, 51 J. AM. ACAD. CHILD & ADOLESCENT PSYCHIATRY 957, 964 (2012), https://pubmed.ncbi.nlm.nih.gov/22917211.

[77] Stephen M. Rosenthal, *Challenges in the Care of Transgender and Gender-Diverse Youth: An Endocrinologist's View*, 17(10) NATURE REV. ENDOCRINOLOGY 581, 585 (Oct. 2021), https://pubmed.ncbi.nlm.nih.gov/34376826.

is not the same as regret. The Healthcare Ban incorrectly assumes that an individual who detransitions—the definition of which varies from study to study[78]—must do so because they have come to identify with their sex assigned at birth. This ignores other, more commonly reported factors that contribute to a person's choice to detransition, such as pressure from parents and discrimination.[79]

C. There is No Evidence That Gender Dysphoria Can Be Caused by "Social Contagion" or "Rapid-Onset Gender Dysphoria"

Proponents of the Healthcare Ban have also claimed that gender dysphoria in adolescents can be attributed to "social contagion," or "rapid-onset gender dysphoria," from exposure to peer groups and social media.[80] There is no credible evidence to support this argument.

The term "rapid-onset gender dysphoria" was coined in 2018 by the author of an anonymous survey of parents of transgender youth, who were recruited from

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[78] Michael S. Irwig, *Detransition Among Transgender and Gender-Diverse People—An Increasing and Increasingly Complex Phenomenon*, J. Clinical Endocrinology & Metabolism 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.").

[79] *See id.* (discussing "largest study to look at detransition").

[80] *See* Greta R. Bauer et al., *Do Clinical Data from Transgender Adolescents Support the Phenomenon of "Rapid Onset Gender Dysphoria"?*, 243 J. PEDIATRICS 224, 225–26 (2022), https://pubmed.ncbi.nlm.nih.gov/34793826/; Exec. Order No. 14187 § 3.

websites that promote the belief that "social contagion" causes transgender identity.[81] The survey has been widely discredited.[82] Moreover, the journal in which the survey was published subsequently published an extensive correction stating, among other things, that "[r]apid-onset gender dysphoria (ROGD) is not a formal mental health diagnosis," and that the "report did not collect data from the adolescents and young adults (AYAs) or clinicians and therefore does not validate the phenomenon."[83] Subsequent peer-reviewed research has not found support for a new etiologic phenomenon of rapid-onset gender dysphoria during adolescence.[84]

D. GAMC Is Provided Infrequently to Adolescents

Proponents of the Healthcare Ban have falsely suggested that GAMC is

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[81] Lisa Littman, *Parent Reports of Adolescents and Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria*, 14(3) PLOS ONE e0214157, at 2, 8–9 (Aug. 2018), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0202330 (stating that survey participants were recruited from the websites YouthTransCriticalProfessionals.org, TransgenderTrend.com, and 4thWaveNow.com).

[82] *See, e.g.*, Susan D. Boulware et al., *Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims*, 1, 18 (Apr. 28, 2022), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4102374.

[83] Lisa Littman, *Correction: Parent Reports of Adolescents and Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria*, 14(3) PLOS ONE e0214157 (Mar. 2019), https://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0214157.

[84] *See, e.g.*, Bauer et al., *supra* note 80 at 224–27.

rampantly and carelessly provided to adolescents. As discussed in Section III.A, it is recommended that GAMC be provided to adolescents only after careful evaluation under an extensive list of specific criteria. Moreover, only a small fraction of transgender adolescents are prescribed GAMC.[85] Further, research supports that the increase in adolescents seeking care is very likely the result of reduced social stigma and expanded care options.[86]

E. The HHS Report Does Not Provide A Basis To Ban GAMC

As required by the Healthcare Ban, the U.S. Department of Health and Human Services ("HHS") recently published a report highly critical of GAMC that purports to provide "a review of evidence and best practices" for the treatment of gender dysphoria.[87] However, the HHS Report states that it is "not intended to serve as a clinical practice guideline" or "make any specific policy recommendations regarding

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[85] Landon D. Hughes et al., *Gender-Affirming Medications Among Transgender Adolescents in the US, 2018-2022*, JAMA Pediatr. (Jan. 6, 2025), https://pubmed.ncbi.nlm.nih.gov/39761053/ (finding less than 0.1% of transgender adolescents are prescribed GAMC by examining private insurance claims over 5 years).

[86] *See* Boulware, *supra* note 82, at 20.

[87] U.S. Department of Health and Human Services, *Treatment for Pediatric Gender Dysphoria – Review of Evidence and Best Practices* (2025), https://opa.hhs.gov/sites/default/files/2025-05/gender-dysphoria-report.pdf ("HHS Report").

the regulation of medicine."[88] Additionally, the HHS Report fails to disclose its authors, which precludes evaluating the qualifications of its drafters and any potential biases or conflicts of interest—fundamental requirements for any reliable review.[89] The HHS Report also relies heavily on media coverage, blogs, social media posts, and other sources lacking the necessary credibility to support policy recommendations.[90] As a result, the HHS Report does not provide a basis for banning GAMC.

F. GAMC is Provided Internationally

Proponents of the Healthcare Ban have suggested that a categorical ban of GAMC is consistent with treatment recommendations in other countries. This is simply untrue. For example, as recently as March 2025, an organization comprising over 150 German medical societies that promulgates healthcare guidelines in Germany published guidelines stating that the provision of GAMC to adolescents is

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[88] HHS Report at 261.

[89] *See* Cochrane, *Cochrane Handbook for Systematic Reviews of Interventions* at II.2.2, https://www.cochrane.org/authors/handbooks-and-manuals/handbook/current.

[90] *See* Nadia Dowshen et al., *A Critical Scientific Appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria*. 77 J ADOLESC HEALTH 342, 343 (2025), https://perma.cc/MH6N-PX2N (finding one in five references cited in HHS Report fall short of minimum evidentiary standard expected of a scientific review).

appropriate when medically indicated.[91]

Proponents of the Healthcare Ban have relied on a systematic review conducted for NHS England by Dr. Cass ("Cass Review") to argue international support for banning GAMC.[92] But the Cass Review does no such thing. Instead, NHS England continues to provide GAMC through research protocols, as recommended by the Cass Review.[93] Additionally, the Cass Review has been the subject of much criticism, including that it is not an accurate restatement of the medical evidence on the treatment of gender dysphoria.[94]

V. The Healthcare Ban Would Irreparably Harm Many Adolescents With Gender Dysphoria By Effectively Denying Them the Treatment They Need.

The Healthcare Ban will effectively prevent adolescents with gender dysphoria throughout the United States from accessing medical care designed to improve health outcomes and alleviate suffering, and that is grounded in science and

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[91] *See, e.g.*, *Geschlechtsinkongruenz und Geschlechtsdysphorie im Kindes- und Jugendalter – Diagnostik und Behandlung (S2k)*, AWMF (Mar. 2025), https://perma.cc/V623-FW2B (in German).

[92] Hilary Cass, *Independent Review of Gender Identity Services for Children and Young People: Final Report, Cass Review* (Apr. 2024), https://perma.cc/A8UR-Q2WD.

[93] Cass Review at 35; Meredithe McNamara et al., *An Evidence-Based Critique of the Cass Review on Gender-Affirming Care for Adolescent Gender Dysphoria* (2024) at 4, https://perma.cc/39RR-FAM6 ("Cass Critique").

[94] *Id.* at 35.

endorsed by the medical community. Clinicians who are members of the *amici* associations have witnessed the benefits of this treatment and the harm that results when such treatment is denied or delayed.

As discussed in Part III.B, research shows that adolescents with gender dysphoria who receive GAMC 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.[95] In light of this evidence supporting the connection between lack of access to GAMC and lifetime suicide risk, effectively banning such care can put patients' lives at risk.

CONCLUSION

For the foregoing reasons, this Court should affirm the preliminary injunction.

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[95] *See* Mohammad Hassan Murad et al., H*ormonal Therapy and Sex Reassignment: A Systematic Review and Meta-Analysis of Quality of Life and Psychosocial Outcomes*, 72(2) CLINICAL ENDOCRINOLOGY 214 (Feb. 2010), https://onlinelibrary.wiley.com/doi/10.1111/j.1365-2265.2009.03625.x; *see also* Turban, *supra* note 54.

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Respectfully submitted,

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2. In addition, this brief complies with the typeface and type style requirements of FRAP 32(a)(5) and (6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

/s/ D. Jean Veta
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I hereby certify that on September 26, 2025, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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COUNSEL FOR: American Academy of Pediatrics and Additional National and State Medical and Mental Health Organizations. See Attachment 1 for complete list. as the
(party name)

☐ appellant(s) ☐ appellee(s) ☐ petitioner(s) ☐ respondent(s) ☑ amicus curiae ☐ intervenor(s) ☐ movant(s)

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ATTACHMENT 1

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1. The American Academy of Pediatrics
2. The Academic Pediatric Association
3. The American Academy of Child and Adolescent Psychiatry
4. American Academy of Family Physicians
5. The American Academy of Nursing
6. The American Association of Physicians for Human Rights, Inc. d/b/a GLMA: Health Professionals Advancing LGBTQ+ Equality
7. The American College of Obstetricians and Gynecologists
8. The American College of Osteopathic Pediatricians
9. The American College of Physicians
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13. Association of Medical School Pediatric Department Chairs, Inc.
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15. The Endocrine Society
16. The National Association of Pediatric Nurse Practitioners
17. The Pediatric Endocrine Society
18. The Pediatric Endocrinology Nursing Society
19. The Society for Adolescent Health and Medicine
20. The Society of Pediatric Nurses
21. The Societies for Pediatric Urology
22. The World Professional Association for Transgender Health