

No. 21-11174

In the United States Court of Appeals for the Fifth Circuit

FRANCISCAN ALLIANCE, INCORPORATED; CHRISTIAN MEDICAL AND DENTAL
SOCIETY; SPECIALTY PHYSICIANS OF ILLINOIS, L.L.C.,
Plaintiffs-Appellees,

v.

XAVIER BECERRA, SECRETARY U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES; UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Defendants-Appellants,

v.

AMERICAN CIVIL LIBERTIES UNION OF TEXAS;
RIVER CITY GENDER ALLIANCE

Intervenor Defendants-Appellants

On Appeal from the United States District Court for the
Northern District of Texas
No. 7:16-cv-00108-O

**BRIEF OF *AMICUS CURIAE* ETHICS AND PUBLIC POLICY
CENTER IN SUPPORT OF PLAINTIFFS-APPELLEES AND
AFFIRMANCE**

RACHEL N. MORRISON
MARY RICE HASSON
Ethics & Public Policy Center
1730 M Street, N.W.
Suite 910
Washington, DC 20036
(202) 682-1200
rmorrison@eppc.org
Counsel for Amicus Curiae

CERTIFICATE OF INTERESTED PERSONS

Counsel of record certifies that the following persons and entities as described Fifth Circuit Rule 29.2 have an interest in the amicus brief.

Plaintiffs-Appellees	Counsel for Plaintiffs-Appellees
- Franciscan Alliance, Inc. - Christian Medical & Dental Society - Specialty Physicians of Illinois, LLC	<i>The Becket Fund for Religious Liberty:</i> Luke W. Goodrich Mark L. Rienzi Daniel L. Chen Joseph C. Davis

Defendants-Appellants	Counsel for Defendants-Appellants
- Xavier Becerra, in his official capacity as Secretary of the U.S. Department of Health and Human Services - U.S. Department of Health and Human Services	<i>U.S. Department of Justice:</i> McKaye Lea Neumeister Marleigh D. Dover Charles Wylie Scarborough Bradley Philip Humphreys Jack Starcher

Intervenor Defendants-Appellants	Counsel for Intervenor Defendants-Appellants
- American Civil Liberties Union of Texas - River City Gender Alliance	<i>American Civil Liberties Union Foundation:</i> Lindsey Kaley Joshua A. Block Brigitte Amiri James D. Esseks Louise Melling Daniel Mach <i>American Civil Liberties Union of Texas:</i> Andre Segura Brian Klosterboer <i>American Civil Liberties Union Foundation of Nebraska:</i> Scout Richters

<i>Amicus Curiae</i>	Counsel for <i>Amicus Curiae</i>
Ethics & Public Policy Center	<i>Ethics & Public Policy Center:</i> Rachel N. Morrison Mary Rice Hasson

/s/ Rachel Morrison
Rachel N. Morrison
Counsel for Amicus Curiae

CORPORATE DISCLOSURE STATEMENT

Amicus Curiae the Ethics and Public Policy Center is a non-profit 501(c)(3) organization and has no corporate parent and is not owned in whole or in part by any publicly held corporation.

TABLE OF CONTENTS

	Page
CERTIFICATE OF INTERESTED PERSONS	i
CORPORATE DISCLOSURE STATEMENT	iii
TABLE OF AUTHORITIES	v
STATEMENT OF INTEREST OF <i>AMICUS CURIAE</i>	1
ARGUMENT	3
I. There is no international or national medical consensus regarding an authoritative standard of care for gender dysphoria or gender-transition procedures.	4
A. There is no consensus within the medical profession.	5
B. The lack of medical consensus is reflected internationally.	10
C. The federal government has recognized the lack of medical consensus.	13
D. State action reflects the lack of medical consensus.	14
II. Gender-transition procedures can lead to serious harm, especially in minors.	17
CONCLUSION	22
CERTIFICATE OF SERVICE	23
CERTIFICATE OF COMPLIANCE	24

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Doe v. Snyder</i> , 28 F.4th 103 (9th Cir. 2022).....	7
<i>Franciscan All. v. Becerra</i> , No. 7:16-cv-00108 (N.D. Tex. Aug. 16, 2021)	3
<i>Gibson v. Collier</i> , 920 F.3d 212 (5th Cir. 2019)	5, 7
Statute	
42 U.S.C. § 18116(a).....	3
Other Authorities	
85 Fed. Reg. 37160	13
Abigail Shrier, <i>Top Trans Doctors Blow the Whistle on</i> <i>“Sloppy” Care</i> , Real Clear Politics (Oct. 5, 2021)	20
Ala. H.B. 266 (2022)	15
Ala. S.B. 184 (2022).....	15
Alison Clayton, <i>The Gender Affirmative Treatment Model for</i> <i>Youth with Gender Dysphoria: A Medical Advance or Dan-</i> <i>gerous Medicine?</i> , Archives Sexual Behav., (2022)	21
Am. Psychiatric Ass’n, Diagnostic and Statistical Manual of Mental Disorders: DMS-5 (5th ed. 2013)	5
Ariz. H.B. 2608 (2022).....	15
Ariz. S.B. 1138 (2022)	15
Ark. H.B. 1570 (2021)	15

Becky McCall, <i>NHS Makes Child Gender Identity Service Changes After High Court Ruling</i> , Medscape (Dec. 4, 2020).....	11
Becky McCall, <i>Psychiatrists Shift Stance on Gender Dysphoria, Recommend Therapy</i> , Medscape (Oct. 7, 2021).....	12
Cecilia Dhejne et al., <i>Long-term Follow-up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden</i> , PLoS ONE (2011)	17
Chantel M. Wiepjes et al., <i>Trends in Suicide Death Risk in Transgender People: Results from the Amsterdam Cohort of Gender Dysphoria Study (1972-2017)</i> , Acta Psychiatrica Scandinavica (2020)	17-18
CMS, Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (Aug. 30, 2016)	8, 13, 14
Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, Institute of Medicine of the National Academies, <i>Clinical Practice Guidelines We Can Trust</i> (2011)	9
<i>Correction to Bränström and Pachankis</i> , 177 Am. J. Psychiatry (2020).....	18
Dep’t of Defense, Report and Recommendations on Military Service by Transgender Persons (Feb. 22, 2018)	14
Devita Singh et al., <i>A Follow-Up Study of Boys with Gender Identity Disorder</i> , Front Psychiatry (2021)	18
<i>Fact-Checking the HHS</i> , Soc’y for Evidence Based Gender Med. (Apr. 7, 2022)	16
<i>Facts About Anti-Trans Youth Bills</i> , Fenway Health (2022).....	7

Florida Agency for Health Care Administration, Florida Medicaid: Generally Accepted Professional Medical Stand- ards Determination on the Treatment of Gender Dyspho- ria (June 2022).....	16
<i>Gender Dysphoria</i> , Am. Psychiatric Ass’n (2022).....	5
<i>Gender-Affirming Hormone in Children and Adolescents</i> , BJM EBM Spotlight (Feb. 25, 2019)	20
Hilary Cass, <i>Review of Gender Identity Services for Children and Young People</i> , BMJ (2022)	12
Institute of Medicine (US) Committee on Standards for De- veloping Trustworthy Clinical Practice Guidelines, Clini- cal Practice Guidelines We Can Trust (Robin Graham et al. eds., 2011)	8
Johanna Olson-Kennedy et al., <i>Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Co- horts</i> , JAMA Pediatrics (2018).....	21
Karl Gerritse et al., <i>Decision-Making Approaches in Transgender Healthcare: Conceptual Analysis and Ethical Implications</i> , 24 Med. Health Care & Phil. (2021)	6
Kenneth J. Zucker, <i>Adolescents with Gender Dysphoria: Re- flections on Some Contemporary Clinical and Research Is- sues</i> , Arch Sex Behav. (2019)	18
La. H.B. 570 (2022)	15
Lauren Lewis, <i>NHS’s Only Gender Service for Children Be- lieves All Girls Who Don’t Like ‘Pink Ribbons and Dollies’ Must Be Transgender, Whistleblower Claims</i> , Daily Mail (Nov. 22, 2021).....	11
Letter from Greg Abbott, Governor, State of Texas, to Jaime Masters, Commissioner, Texas Department of Family and Protective Services (Feb. 22, 2022).....	16

Lisa Littman, <i>Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners</i> , Arch Sex Behav. (2021)	19
Lisa Nainggolan, <i>Hormonal Tx of Youth with Gender Dysphoria Stops in Sweden</i> , Medscape (2021)	10
Madeline B. Deutsch et al., <i>What’s in a Guideline? Developing Collaborative and Sound Research Designs that Substantiate Best Practice Recommendations for Transgender Health Care</i> , AMA J. of Ethics (2016)	6, 7, 8
Madeline B. Deutsch, <i>Overview of Gender-Affirming Procedures</i> , Univ. Cal. San Fran. Transgender Care (June 17, 2016).....	7
Max Lichtenstein et al., <i>The Mount Sinai Patient-Centered Preoperative Criteria Meant to Optimize Outcomes Are Less of a Barrier to Care than WPATH SOC 7 Criteria Before Transgender-Specific Surgery</i> , Mary Ann Liebert, Inc. (2020).....	9, 10
Mo. H.B. 2649 (2022)	15
Mo. S.B. 843 (2022)	15
N.H. H.B. 1651 (2022).....	15
Nat’l Inst. for Health & Care Excellence, <i>Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria</i> (Mar. 11, 2021).....	11, 19
Office for Civil Rights, U.S. Dep’t of Health & Human Servs., <i>HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy</i> (Mar. 2, 2022).....	3
Office of Population Affairs, U.S. Dep’t of Health & Human Servs., <i>Gender-Affirming Care and Young People</i> (Mar. 2022).....	3

Office of the State Surgeon Gen., Fla. Dep’t of Health, Treatment of Gender Dysphoria for Children and Adolescents (Apr. 20, 2022)	16
Ohio H.B. 454 (2021).....	15
Okla. H.B 1076 (2022).....	15
Okla. H.B. 3240 (2022).....	15
Okla. S.B. 676 (2022)	15
Polly Carmichael et al., <i>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</i> , PLoS ONE (2021).....	19
Press Release, French National Academy of Medicine, Medicine and Gender Transidentity in Children and Adolescents (Feb. 25, 2022).....	12
Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland): Medical Treatment Methods for Dysphoria Related to Gender Variance In Minors (2020)	10-11
<i>Report Overview</i> , Florida Agency for Health Care Administration (2022)	17
Richard Bränström & John E. Pachankis, <i>Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study</i> , 177 Am. J. Psychiatry (2020)	17-18
Roberto D’Angelo et al., <i>One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria</i> , Archives Sexual Behav. (2020).....	17
S.C. S.B. 1259 (2022)	15

Sara Dahlen et al., <i>International Clinical Practice Guidelines for Gender Minority/Trans People: Systematic Review and Quality Assessment</i> , BMJ Open (2021)	8, 9
<i>Setting the Record Straight</i> , Florida Agency for Health Care Administration (2022)	16
Sonia Appleby, <i>NHS Gender Identity Clinic Whistleblower Wins Damages</i> , The Guardian (Sept. 4, 2021)	11
Stephen B. Levine, <i>Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria</i> , J. Sex & Marital Therapy (2018).....	20
Stephen B. Levine et al., <i>Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults</i> , J. of Sex & Marital Therapy (2022)	20
Tenn. H.B. 0578 (2021)	15
Tenn. H.B. 2835 (2022)	15
Tenn. S.B. 2696 (2022).....	15
Tex. Att’y Gen. Op. Letter No. KP-0401, from Ken Paxton, Attorney General, to Matt Krause, Chair, House Committee on General Investigating, Texas House of Representatives (Feb. 18, 2022)	15
U.S. Dep’t of Health & Human Servs., Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972 3 (May 10, 2021)	3
Video, Mission: Investigate: Trans Children (“Trans Train 4”) (Nov. 26, 2021)	21
William Malone, <i>Puberty Blockers for Gender Dysphoria: The Science is Far from Settled</i> , Lancet Child & Adolescent Health (2021)	19

World Prof'l Ass'n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People Version 7 (2012)	7
Wylie C. Hembree et al., <i>Endocrine Treatment of Gender- Dysphoric/Gender-Incongruent Persons: An Endocrine So- ciety Clinical Practice Guideline</i> , J. Clinical Endocrinology & Metabolism (2017)	10

STATEMENT OF INTEREST OF *AMICUS CURIAE*¹

The Ethics and Public Policy Center (“EPPC”) is a nonprofit research institution dedicated to applying the Judeo-Christian moral tradition to critical issues of public policy, law, culture, and politics. EPPC’s programs cover a wide range of issues, including specifically HHS accountability, governmental and judicial restraint, bioethics and human flourishing, and personhood and identity. EPPC has a strong interest in ensuring the proper interpretation and application of Section 1557 of the Affordable Care Act, promoting the Judeo-Christian vision of the human person, and responding to the challenges of gender ideology.

Gender ideology has permeated the culture with stunning speed, influencing medicine, government, and business, and creating an urgent need for clarity, education, and compassionate guidance. This is particularly true in healthcare, which is at issue in this case. EPPC’s brief demonstrates the lack of medical consensus regarding an authoritative standard of care for the treatment of gender dysphoria and gender-

¹ All parties have consented to this filing. No party’s counsel authored this brief in whole or in part, and no person or entity other than *Amicus Curiae* or their counsel made a monetary contribution intended to fund the brief’s preparation or submission.

transition procedures, and underscores the harms of gender-transition procedures, especially for minors.

ARGUMENT

The U.S. Department of Health and Human Services (HHS) under Secretary Xavier Becerra has interpreted and is enforcing Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116(a), to prohibit discrimination on the basis of “gender identity” in federally funded health programs and activities.² This interpretation requires healthcare organizations and professionals, including Plaintiffs and its members, to perform and insure “gender-transition procedures.”³ But Plaintiffs, in accordance with their medical judgments and religious beliefs, do not perform gender-transition procedures because such procedures cause lifelong harm to an otherwise healthy person.

As discussed below, there is no international or national medical consensus regarding an authoritative standard of care for the treatment of gender dysphoria or for the proper evaluation of the risks and benefits of

² See, e.g., U.S. Dep’t of Health & Human Servs., Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972 (May 10, 2021), <https://www.hhs.gov/sites/default/files/ocr-bostock-notification.pdf>; Office for Civil Rights, U.S. Dep’t of Health & Human Servs., HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy (Mar. 2, 2022), <https://www.hhs.gov/sites/default/files/hhs-ocr-notice-and-guidance-gender-affirming-care.pdf>; Office of Population Affairs, U.S. Dep’t of Health & Human Servs., Gender-Affirming Care and Young People (Mar. 2022), <https://opa.hhs.gov/sites/default/files/2022-03/gender-affirming-care-young-people-march-2022.pdf>.

³ The lower court’s order defines “gender-transition procedures” as including “surgery, counseling, provision of pharmaceuticals, or other treatments sought in furtherance of a gender transition.” *Franciscan All. v. Becerra*, No. 7:16-cv-00108, at *1 n.1 (N.D. Tex. Aug. 16, 2021). For purposes of this brief, “gender-transition procedures” is used as shorthand for surgical and pharmaceutical (puberty blockers and cross-sex hormones) interventions used to further a “gender transition.”

medically assisted “gender transitions.” HHS’s interpretation of Section 1557’s sex discrimination prohibition to require performance and insurance coverage of gender-transition procedures is an arbitrary determination by a government agency of the required medical standard of care. This “transgender mandate” forces healthcare professionals, including Plaintiffs, to violate their ethical obligations to render treatment according to their best medical judgment. The consequences affect not only the Plaintiffs but also the patients they serve. Gender-transition procedures can lead to significant and irreversible harms, especially for minors.

Without a permanent injunction, Plaintiffs, as they explain in their brief, will “face an untenable choice: sear their consciences and scar their patients, or risk losing their livelihoods and ministries.” Pls.-Appellees’ Br. at 6. The Court should affirm the district court’s permanent injunction.

I. There is no international or national medical consensus regarding an authoritative standard of care for gender dysphoria or gender-transition procedures.

HHS seeks to mandate gender-transition procedures as a standard of care under Section 1557, even though there is no consensus within the medical profession regarding an authoritative standard of care for gender dysphoria or gender-transition procedures. This lack of medical consensus is reflected internationally, has been recognized by the federal government, and is reflected in actions by the states.

A. There is no consensus within the medical profession.

Since the first gender-transition surgeries were performed in the U.S. in the mid-20th century to the present day, there has not been a medical consensus regarding the authoritative standard of care to treat gender dysphoria (previously called “gender identity disorder”) or the proper evaluation of the risks and benefits of medically assisted “gender transitions.” *Cf. Gibson v. Collier*, 920 F.3d 212, 216, 223, 224 (5th Cir. 2019) (finding it “indisputable” that “[t]here is no medical consensus that sex reassignment surgery is a necessary or even effective treatment for gender dysphoria” and that it “remains one of the most hotly debated topics within the medical community today”).

Historically, there are uneven and, at times competing, trajectories in the development of therapeutic responses to gender dysphoria—defined by the American Psychiatric Association as “psychological distress that results from an incongruence between one’s sex assigned at birth and one’s gender identity.”⁴ Gender dysphoria is an “inherently subjective

⁴ The Diagnostic and Statistical Manual of Mental Health (DSM-5) of the American Psychiatric Association (APA) has recognized the diagnosis of “gender dysphoria” since 2013. For a diagnosis of gender dysphoria, the individual must meet various criteria (two of six for adults and adolescents and six of eight for children) and experience clinically significant distress sufficient to interfere with daily life. Am. Psychiatric Ass’n, *Diagnostic and Statistical Manual of Mental Disorders: DMS-5* (5th ed. 2013). A list of relevant criteria may be accessed here: *Gender Dysphoria*, Am. Psychiatric Ass’n (2022), <https://www.psychiatry.org/patients-families/gender-dysphoria>.

phenomenon” and at the core of “gender medicine” and gender-transition procedures.⁵

“Transgender medicine presents a particular challenge for the development of evidence-based guidelines” in light of its thin evidence base, diverse clients and treatment goals, and “complex history.”⁶ Existing treatments for gender dysphoria rest on a “relatively slim (biomedical) evidence base”⁷ that is compounded by major gaps in research. This results in a “convoluted context” that complicates the development of clinical care guidelines and research, undermines the pursuit of evidence-based treatments, and heightens the risk of harm for vulnerable patients.⁸

Nevertheless, certain medical organizations and gender clinics cite to and promote World Professional Association for Transgender Health (WPATH) guidelines as a dispositive summary of the “professional con-

⁵ Karl Gerritse et al., *Decision-Making Approaches in Transgender Healthcare: Conceptual Analysis and Ethical Implications*, 24 Med. Health Care & Phil. 687 (2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8557156/>.

⁶ Madeline B. Deutsch et al., *What’s in a Guideline? Developing Collaborative and Sound Research Designs that Substantiate Best Practice Recommendations for Transgender Health Care*, 18 AMA J. of Ethics 1098 (2016), <https://doi.org/10.1001/journalofethics.2016.18.11.stas1-1611>.

⁷ Karl Gerritse et al., *supra* note 5.

⁸ *Id.*

sensus about the psychiatric, psychological, medical, and surgical management of gender dysphoria.”⁹ However, as this Court has recognized, WPATH guidelines do not reflect medical consensus. *See Gibson*, 920 F.3d at 223 (finding “WPATH Standards of Care do not reflect medical consensus”); *see also Doe v. Snyder*, 28 F.4th 103, 112 (9th Cir. 2022) (affirming district court’s reliance on “expert testimony that WPATH’s Standards of Care are not universally endorsed”).

While WPATH guidelines are styled as “Standards of Care” (SOC) and promoted as the “leading care model for gender-affirming care,”¹⁰ they do not qualify as an authoritative standard of care. Indeed version 7 of the WPATH SOC acknowledges that the so-called “standards of care” are actually “flexible clinical guidelines.”¹¹ In declining to endorse the use of WPATH SOC for Medicare coverage determinations, the Centers for

⁹ *Facts About Anti-Trans Youth Bills*, Fenway Health (2022), <https://fenwayhealth.org/the-fenway-institute/health-policy/transyouthmatter/> (Fenway describes the role of WPATH to “monito[r] current research and new knowledge about evidence-based medicine for transgender people. It publishes Standards of Care and Ethical Guidelines for health care providers ...”); *see also* Madeline B. Deutsch, *Overview of Gender-Affirming Procedures*, Univ. Cal. San Fran. Transgender Care (June 17, 2016), <https://transcare.ucsf.edu/guidelines/overview> (The University of California San Francisco Transgender Care program cites WPATH for authority in determining which gender affirming surgical procedures are “defined as medically necessary.”).

¹⁰ Deutsch et al., *supra* note 6.

¹¹ World Prof’l Ass’n for Transgender Health, *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People Version 7* (2012), <https://www.wpath.org/publications/soc>. WPATH Standards of Care were developed initially in 1979 and are updated at regular intervals. Version 8 of the SOC is expected to be released in summer 2022.

Medicare & Medicaid Services (CMS) cited the “flexible” nature of WPATH guidelines.¹² Moreover, the WPATH guidelines lack the rigor and evidence base necessary to qualify as authoritative standards of care or clinical practice guidelines (CPGs).¹³

A 2021 first-of-its-kind systematic analysis of international CPGs for “gender minority/trans health” (including WPATH guidelines) published in the British Medical Journal concluded that “WPATH SOCv7 *cannot* be considered ‘gold standard’” (emphasis added).¹⁴ In fact, none of the twelve international gender medicine guidelines assessed in the BMJ review met the rigorous standard for clinical practice guidelines (or standards of

¹² CMS, Decision Memo for Gender Dysphoria and Gender Reassignment Surgery, CAG-00446N (Aug. 30, 2016) [hereinafter “CMS Decision Memo”], <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282>.

¹³ Deutsch et al., *supra* note 6. Trustworthy CPGs “should be based on a systematic review of the existing evidence; be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups; consider important patient subgroups and patient preferences, as appropriate; be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest; provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations; and be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.” Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, *Clinical Practice Guidelines We Can Trust 3* (Robin Graham et al. eds., 2011), <https://www.ncbi.nlm.nih.gov/books/NBK209546/> (cleaned up).

¹⁴ Sara Dahlen et al., *International Clinical Practice Guidelines for Gender Minority/Trans People: Systematic Review and Quality Assessment*, 11 *BMJ Open* (2021), <https://pubmed.ncbi.nlm.nih.gov/33926984/>.

care).¹⁵ *All* failed to meet the required standards, with WPATH SOC7 singled out for particularly strong criticism.¹⁶ “Standards of Care,” such as WPATH’s, which rest on weak, ungraded evidence, fail to make evidence-based practice recommendations, decline to discuss alternative care options, and omit data on treatment outcomes, fall far short of an authoritative medical standard of care.¹⁷

A 2020 study from the Mount Sinai Center for Transgender Medicine and Surgery (CTMS), a leading center for transgender medical care, notes that WPATH guidelines “are often considered the standard of care for [transgender] people throughout the world,” but characterizes them as a “barrier to care,” “impractical,” unclear, and detrimental to patient wellbeing.¹⁸ Mount Sinai’s open disregard for WPATH guidelines proves the point that there is no operative standard of care for the treatment of gender dysphoria.¹⁹ Indeed, Mount Sinai eventually developed its own

¹⁵ *Id.* (describing an overall “paucity” of “high quality” clinical guidance pertaining to gender dysphoria and gender transition).

¹⁶ *Id.*

¹⁷ Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, Institute of Medicine of the National Academies, *Clinical Practice Guidelines We Can Trust* (2011), <https://www.ncbi.nlm.nih.gov/books/NBK209546/>.

¹⁸ Max Lichtenstein et al., *The Mount Sinai Patient-Centered Preoperative Criteria Meant to Optimize Outcomes Are Less of a Barrier to Care than WPATH SOC 7 Criteria Before Transgender-Specific Surgery*, 5 *Mary Ann Liebert, Inc.* 166 (2020), <https://doi.org/10.1089/trgh.2019.0066>.

¹⁹ Other guidelines governing treatment for gender dysphoria, such as the Endocrine Society’s 2017 guidelines, prove similarly inadequate. Like the WPATH “standards,” the Endocrine Society guidelines rely on “low” and “very low” quality evidence and

criteria for gender-transition procedures—criteria that diverged significantly from WPATH guidelines, with less than 10 percent of Mount Sinai patients meeting criteria for both WPATH and Mount Sinai assessments.²⁰

In short, there is no consensus within the medical community regarding the appropriate standard of care for gender dysphoria or gender-transition procedures.

B. The lack of medical consensus is reflected internationally.

Many countries that initially embraced gender-transition procedures, especially for minors, are now reversing course. For example, the leading gender clinic in Sweden has ended the use of puberty blockers in minors.²¹ Finland likewise has reversed course. After extensive evidence reviews, it issued new guidelines that prioritize psychotherapy as the first-line treatment for gender dysphoric minors.²²

includes a disclaimer stating that its “guidelines cannot guarantee any specific outcome, nor do they establish a standard of care.” Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. Clinical Endocrinology & Metabolism (2017), <https://academic.oup.com/jcem/article/102/11/3869/4157558>. Lacking “detailed clinical guidelines for professionals” and clear, measurable, evidence-based recommendations, no current guidelines for treating gender dysphoria qualify as an authoritative CPG or standard of care.

²⁰ Lichtenstein et al., *supra* note 18.

²¹ Lisa Nainggolan, *Hormonal Tx of Youth with Gender Dysphoria Stops in Sweden*, Medscape (2021), <https://www.medscape.com/viewarticle/950964>.

²² Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland): Medical Treatment Methods for Dysphoria Related to Gender

In the United Kingdom, whistleblower complaints exposed the National Health Service's (NHS) gender clinic's inadequate psychological care for gender dysphoric minors.²³ A landmark case against the NHS in 2020 by “detransitioner” Keira Bell found that minors lacked capacity to consent to gender-transition procedures that cause sterility and impair sexual function, causing the NHS to suspend the use of puberty blockers and institute new procedures to ensure better psychological care.²⁴ (The decision was later reversed on procedural grounds.)

A separate evidence review in the UK, by the National Institute for Health and Care Excellence (NICE), found little evidence of benefit and substantial risk of harm from gender affirming treatment in minors.²⁵ An independent review commissioned by NHS England (the “Cass report”), found that “[a]t present the professional community does not have a

Variance In Minors (2020), *available at* https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf. COHERE Finland works in conjunction with the Ministry of Social Affairs and Health.

²³ Sonia Appleby, *NHS Gender Identity Clinic Whistleblower Wins Damages*, The Guardian (Sept. 4, 2021), <https://www.theguardian.com/society/2021/sep/04/gender-identity-clinic-whistleblower-wins-damages>; Lauren Lewis, *NHS's Only Gender Service for Children Believes All Girls Who Don't Like 'Pink Ribbons and Dollies' Must Be Transgender, Whistleblower Claims*, Daily Mail (Nov. 22, 2021), <https://www.dailymail.co.uk/news/article-10231507/NHSs-gender-service-children-believes-girls-dont-like-pink-transgender.html>.

²⁴ Becky McCall, *NHS Makes Child Gender Identity Service Changes After High Court Ruling*, Medscape (Dec. 4, 2020), <https://www.medscape.com/viewarticle/941781>.

²⁵ Nat'l Inst. for Health & Care Excellence, Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria (2021) [hereinafter “NICE Evidence Review”].

shared understanding about the meaning of gender dysphoria in young people,” its cause, or best treatment approaches.²⁶ The report notes that “[m]uch of the research base is observational,” with little “longer term follow up data,” resulting in a “weak evidence base” for the use of puberty blockers.²⁷

Psychotherapists in Australia and New Zealand recently issued a new policy statement emphasizing mental health treatment for gender dysphoric minors, rather than “gender affirmation,” and stressing the importance of assessing the “psychological state and context in which gender dysphoria has arisen,” before any treatment decisions are made.²⁸ In February 2022, France’s National Academy of Medicine warned medical professionals that the increase in young people seeking to undergo medical gender transition may be due to social contagion and urged the medical community to approach this issue with “great medical caution.”²⁹

²⁶ Hilary Cass, *Review of Gender Identity Services for Children and Young People*, BMJ (2022), <https://www.bmj.com/content/376/bmj.o629>.

²⁷ *Id.*

²⁸ Becky McCall, *Psychiatrists Shift Stance on Gender Dysphoria, Recommend Therapy*, Medscape (Oct. 7, 2021), <https://www.medscape.com/viewarticle/960390>.

²⁹ Press Release, French National Academy of Medicine, *Medicine and Gender Transidentity in Children and Adolescents* (Feb. 25, 2022), <https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/?lang=en>.

C. The federal government has recognized the lack of medical consensus.

Despite the efforts of HHS under the current administration to push gender-transition procedures, including for minors, under Section 1557, HHS has never formally determined that such treatments are the appropriate standard of care.

As recently as June 2020, HHS acknowledged its 1557 regulations that “there is no medical consensus to support one or another form of treatment for gender dysphoria.” 85 Fed. Reg. 37160, 37198. The Department explained that prior HHS regulations regarding coverage and performance of gender-transition surgeries “relied excessively on the conclusions of an advocacy group (WPATH) rather than on independent scientific fact-finding,” such as the factfinding that CMS (an agency within HHS) undertook for its most recent National Coverage Determination. *Id.* After its factfinding, CMS declined to issue a National Coverage Determination on gender-transition surgeries for Medicare beneficiaries with gender dysphoria “because the clinical evidence is inconclusive.”³⁰ “Based on an extensive assessment of the clinical evidence,” CMS determined that “there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for

³⁰ CMS Decision Memo, *supra* note 12.

Medicare beneficiaries [which include non-seniors] with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively.”³¹

Similarly, in a 2018 Department of Defense (DOD) report on the diagnosis of gender dysphoria, which included input from both transgender individuals and medical professionals with experience in the care and treatment of individuals with gender dysphoria, DOD found that there is “considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related treatments, such as cross-sex hormone therapy and sex reassignment surgery—interventions which are unique in psychiatry and medicine—remedy the multifaceted mental health problems associated with gender dysphoria.”³² Indeed, none of the drugs used to block puberty and induce cross-sex masculine or feminine features are approved as safe or effective for such uses by the U.S. Food and Drug Administration (another HHS agency).

D. State action reflects the lack of medical consensus.

State actions reflect the lack of medical consensus for the appropriate standard of care for gender dysphoria and gender-transition procedures, especially for minors. For instance, several states have passed laws that

³¹ *Id.*

³² Dep’t of Defense, Report and Recommendations on Military Service by Transgender Persons 5 (Feb. 22, 2018).

prohibit providing minor children with puberty blockers, cross-sex hormones, or gender-transition surgeries.³³ Other states are currently considering similar bills.³⁴

Apart from state legislation, state executives have also weighed in on the issue. For example, in February 2022, the Texas Attorney General issued an opinion letter stating that sterilizing treatments and other permanent “sex-change procedures” “can constitute child abuse when performed on minor children.”³⁵ The treatments and procedures included: “(1) puberty-suppression or puberty-blocking drugs; (2) supraphysiologic doses of testosterone to females; and (3) supraphysiologic doses of estrogen to males,” as well as “(1) sterilization through castration, vasectomy, hysterectomy, oophorectomy, metoidioplasty, orchiectomy, penectomy, phalloplasty, and vaginoplasty; (2) mastectomies; and (3) removing from children otherwise healthy or non-diseased body parts or tissue.”³⁶ Texas’s governor subsequently directed the Texas Department of Family and Protective Services to “conduct a prompt and thorough investigation

³³ See, e.g., Ala. S.B. 184 (2022); Ariz. S.B. 1138 (2022); Ark. H.B. 1570 (2021); Tenn. H.B. 0578 (2021).

³⁴ See, e.g., Ala. H.B. 266 (2022); Ariz. H.B. 2608 (2022); La. H.B. 570 (2022); Mo. S.B. 843 (2022); Mo. H.B. 2649 (2022); N.H. H.B. 1651 (2022); Ohio H.B. 454 (2021); Okla. H.B. 3240 (2022); Okla. H.B. 1076 (2022); Okla. S.B. 676 (2022); S.C. S.B. 1259 (2022); Tenn. S.B. 2696 (2022); Tenn. H.B. 2835 (2022).

³⁵ Tex. Att’y Gen. Op. Letter No. KP-0401, from Ken Paxton, Attorney General, to Matt Krause, Chair, House Committee on General Investigating, Texas House of Representatives 1-2 (Feb. 18, 2022), <https://www.texasattorneygeneral.gov/sites/default/files/opinion-files/opinion/2022/kp-0401.pdf>.

³⁶ *Id.* at 1.

of any reported instances of these abusive procedures in the State of Texas.”³⁷

More recently, Florida’s Department of Health issued guidelines in response to an HHS document promoting “gender-affirming care” for young people. Florida’s DOH clarified that the treatment of gender dysphoria for children and adolescents should *not* include social gender transition, puberty blockers, cross-sex hormones, or gender-transition surgeries because of “the lack of conclusive evidence, and the potential for long-term, irreversible effects.”³⁸ The state Secretary of the Agency for Health Care Administration subsequently requested that the Florida Medicaid program review whether such treatments are “consistent with widely accepted professional medical standards.”³⁹ The report, completed on June

³⁷ Letter from Greg Abbott, Governor, State of Texas, to Jaime Masters, Commissioner, Texas Department of Family and Protective Services (Feb. 22, 2022), <https://gov.texas.gov/uploads/files/press/O-MastersJaime202202221358.pdf>.

³⁸ Office of the State Surgeon Gen., Fla. Dep’t of Health, Treatment of Gender Dysphoria for Children and Adolescents (Apr. 20, 2022), https://www.floridahealth.gov/_documents/newsroom/press-releases/2022/04/20220420-gender-dysphoria-guidance.pdf; cf. *Setting the Record Straight*, Florida Agency for Health Care Administration (2022), <https://ahca.myflorida.com/LetKidsBeKids/page3.shtml> (“detailing the lack of conclusive evidence in recent directives and ‘fact sheets’ issued by the US Department of Health and Human Services for the coverage of ‘gender affirming’ care, for children and adolescents”); *Fact-Checking the HHS*, Soc’y for Evidence Based Gender Med. (Apr. 7, 2022), <https://segm.org/fact-checking-gender-affirming-care-and-young-people-HHS> (finding HHS’s document contains “a number of errors and misrepresentations” and “many highly inaccurate” claims).

³⁹ Florida Agency for Health Care Administration, Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria 2 (June 2022), https://ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf.

2, 2022, found that gender-transition procedures for the treatment of gender dysphoria “are not consistent with widely accepted professional medical standards and are experimental and investigational with the potential for harmful long term affects [sic].”⁴⁰

II. Gender-transition procedures can lead to serious harm, especially in minors.

HHS is seeking to require Plaintiffs to perform and insure gender-transition procedures, which can lead to serious harms, especially in minors.

Long-term outcomes for individuals who undergo gender-transition procedures are not promising. Forty-one percent of all adults who identify as transgender attempt suicide at some point in their lives, and those who have had genital surgery are nineteen times more likely than the general population to die by suicide.⁴¹ Other recent studies of adults report similar findings after gender-transition surgeries: suicide risks and mental health issues remain high.⁴²

⁴⁰ *Report Overview*, Florida Agency for Health Care Administration (2022), <https://ahca.myflorida.com/letkidsbekids/>.

⁴¹ Cecilia Dhejne et al., *Long-term Follow-up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden*, 6 PLoS ONE (2011), <https://pubmed.ncbi.nlm.nih.gov/21364939/>.

⁴² Roberto D’Angelo et al., *One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria*, 50 Archives Sexual Behav. 7 (2020), <https://doi.org/10.1007/s10508-020-01844-2>; Chantel M. Wiepjes et al., *Trends in Suicide Death Risk in Transgender People: Results from the Amsterdam Cohort of Gender Dysphoria Study (1972-2017)*, 141 Acta Psychiatrica Scandinavica 486 (2020), <https://doi.org/>

Equally troubling, the number of children and adolescents diagnosed with gender dysphoria or identifying as “transgender” has risen dramatically over the past decade, becoming “an international phenomenon, observed across North America, Europe, Scandinavia, and elsewhere.”⁴³ The typical patient profile has changed markedly. In the past, patients seeking treatment for gender dysphoria were usually either adult males or very young children, mostly male. Today, the typical patient is an adolescent, usually female.⁴⁴

For years, gender dysphoria in children was addressed through “watchful waiting” or in family therapy. About eighty-eight percent of the time, the child’s gender dysphoria resolved naturally by puberty without gender-transition interventions.⁴⁵ The “gender-affirming” approach, however, changed that pattern dramatically. Most children affirmed in their transgender beliefs will persist in their transgender identification,

10.1111/acps.13164; *Correction to Bränström and Pachankis*, 177 Am. J. Psychiatry 734 (2020) (correcting Richard Bränström & John E. Pachankis, *Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study*, 177 Am. J. Psychiatry 727 (2020)).

⁴³ Kenneth J. Zucker, *Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues*, 48 Arch Sex Behav. 1983 (2019), <https://pubmed.ncbi.nlm.nih.gov/31321594/>.

⁴⁴ *Id.*

⁴⁵ Devita Singh et al., *A Follow-Up Study of Boys with Gender Identity Disorder*, 12 Front Psychiatry (2021), <https://pubmed.ncbi.nlm.nih.gov/33854450>.

leading many to pursue gender-transition procedures to modify their bodies—drastic measures that lead to regret.⁴⁶

Clinical concerns over the outcomes of gender-transition procedures have escalated.⁴⁷ Puberty blockers, originally described as safe and fully reversible, are now recognized to have negative effects on bone density, social and emotional maturation, and other aspects of development.⁴⁸ They generally fail to lessen the child's gender dysphoria, and results are mixed in terms of effects on mental health.⁴⁹ Long term effects remain unknown.

Nearly all children who begin puberty blockers go on to receive cross-sex hormones, the next step in gender transitions, with life-altering consequences.⁵⁰ Blocking a child's natural puberty (preventing maturation

⁴⁶ See, for example, this study from the Tavistock and Portman NHS Gender Identity Development Service (UK), which found ninety-eight percent of adolescents who underwent puberty suppression continued on to cross-sex hormones. Polly Carmichael et al., *Short-Term Outcomes of Pubertal Suppression in a Selected Cohort of 12 to 15 Year Old Young People with Persistent Gender Dysphoria in the UK*, 16 PLoS ONE (2021), <https://pubmed.ncbi.nlm.nih.gov/33529227/>. See also Lisa Littman, *Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners*, 50 Arch Sex Behav. 3353 (2021), <https://pubmed.ncbi.nlm.nih.gov/34665380/>.

⁴⁷ William Malone, *Puberty Blockers for Gender Dysphoria: The Science is Far from Settled*, 5 Lancet Child & Adolescent Health 33 (2021), <https://pubmed.ncbi.nlm.nih.gov/34418372/>.

⁴⁸ NICE Evidence Review, *supra* note 25.

⁴⁹ Polly Carmichael et al., *supra* note 46.

⁵⁰ *Id.*

of genitals and reproductive organs) and then introducing cross-sex hormones renders the child permanently sterile.⁵¹ Gender clinicians now admit that puberty blocking may impair the child's later sexual functioning as an adult as well.⁵² These losses cannot be fully comprehended by a child, precluding the possibility of informed consent.

Cross-sex hormones carry numerous health risks and cause many irreversible changes in adolescents' bodies, including genital or vaginal atrophy, hair loss (or gain), voice changes, and impaired fertility.⁵³ They also increase cardiovascular risks and cause liver and metabolic changes.⁵⁴ The flood of opposite sex hormones has variable emotional and psychological effects as well. Females who take testosterone experience an increase in gender dysphoria, particularly regarding their breasts, creating heightened demand for double mastectomies on teens as young

⁵¹ Stephen B. Levine, *Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria*, 44 J. Sex & Marital Therapy 29 (2018), <https://pubmed.ncbi.nlm.nih.gov/28332936/>.

⁵² Abigail Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, Real Clear Politics (Oct. 5, 2021), https://www.realclearpolitics.com/2021/10/05/top_trans_doctors_blow_the_whistle_on_sloppy_care_553290.html.

⁵³ Stephen B. Levine et al., *Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults*, J. of Sex & Marital Therapy (2022), <https://www.tandfonline.com/doi/full/10.1080/0092623X.2022.2046221>.

⁵⁴ *Gender-Affirming Hormone in Children and Adolescents*, BJM EBM Spotlight (Feb. 25, 2019), <https://blogs.bmj.com/bmjebmspotlight/2019/02/25/gender-affirming-hormone-in-children-and-adolescents-evidence-review/>.

as thirteen.⁵⁵ Far from an evidence-based standard of care, gender-transition procedures for gender dysphoria amount to unethical human experimentation—on *children*. One Swedish teen who underwent medical gender transition, suffered serious bodily harm, and then de-transitioned describes gender-transition procedures for gender dysphoria in stark terms: “They’re experimenting on young people ... we’re guinea pigs.”⁵⁶ Or, as psychotherapist Alison Clayton warns, this is nothing less than “dangerous medicine.”⁵⁷

* * *

Despite the harms of gender-transition procedures, especially for minors, and the lack of medical consensus regarding the treatment of gender dysphoria and gender-transition procedures, HHS is seeking to impose a medical standard of care through Section 1557, a nondiscrimination provision. But there is no standard of care that authoritatively re-

⁵⁵ Johanna Olson-Kennedy et al., *Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts*, 172 JAMA Pediatrics 431 (2018), <https://pubmed.ncbi.nlm.nih.gov/29507933/>.

⁵⁶ Video, Mission: Investigate: Trans Children (“Trans Train 4”) (Nov. 26, 2021), <https://www.svtplay.se/video/33358590/uppdrag-granskning/mission-investigate-trans-children-avsnitt-1>.

⁵⁷ Alison Clayton, *The Gender Affirmative Treatment Model for Youth with Gender Dysphoria: A Medical Advance or Dangerous Medicine?*, 51 Archives Sexual Behav. 691 (2022), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8888500/>.

views and appraises the evidence, assesses the risks and benefits of proposed treatments and alternative care options, and optimizes patient outcomes through evidence-based outcome measurement.

Without a permanent injunction, Plaintiffs will be forced choose between providing and insuring harmful gender-transition procedures, including for minors, or violating their medical judgments and religious beliefs. Plaintiffs' conscience should not be seared, and their patients should not be scarred.

CONCLUSION

The district court's judgment should be affirmed.

Respectfully submitted,

RACHEL N. MORRISON
MARY RICE HASSON
Ethics & Public Policy Center
1730 M Street, N.W.
Suite 910
Washington, DC 20036
(202) 682-1200
rmorrison@eppc.org

Counsel for Amicus Curiae

CERTIFICATE OF SERVICE

I certify that on June 17, 2022, an electronic copy of the foregoing brief was filed with the Clerk of Court for the U.S. Court of Appeals for the Fifth Circuit using the appellate CM/ECF system, and that service will be accomplished by the appellate CM/ECF system.

/s/ Rachel Morrison
Rachel N. Morrison
Attorney for Amicus Curiae

CERTIFICATE OF COMPLIANCE

This brief complies with the word limit of Fed. R. App. P. 29(a)(5) and 5th Cir. R. 29.3 because, excluding the parts exempted by Fed. R. App. P. 32(f), it contains 4,590 words. This brief complies with the requirements of Fed. R. App. P. 32(a)(5) and Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally-spaced typeface (Century Schoolbook 14 pt.) using Microsoft Word for Mac version 16.61.

/s/ Rachel Morrison
Rachel N. Morrison
Attorney for Amicus Curiae

Dated: June 17, 2022