

No. 23-5053

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**UNITED STATES COURT OF APPEALS  
FOR THE SIXTH CIRCUIT**

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AMERICAN COLLEGE OF PEDIATRICIANS, on behalf of its members; and CATHOLIC  
MEDICAL ASSOCIATION, on behalf of its members,  
*Plaintiffs-Appellants,*

v.

XAVIER BECERRA, in his official capacity as Secretary of the United States Department  
of Health and Human Services; U.S. DEPARTMENT OF HEALTH AND HUMAN  
SERVICES; OFFICE FOR CIVIL RIGHTS OF THE U.S. DEPARTMENT OF HEALTH AND  
HUMAN SERVICES; and LISA J. PINO, in her official capacity as Director of the Office  
for Civil Rights of the U.S. Department of Health and Human Services,  
*Defendants-Appellees.*

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On Appeal from the United States District Court  
for the Eastern District of Tennessee (Chattanooga)  
Case No. 1:21-cv-00195

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

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April 6, 2023

## **CORPORATE DISCLOSURE STATEMENT**

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## STATEMENT OF INTEREST OF *AMICUS CURIAE*<sup>1</sup>

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 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 rights guaranteed by the Constitution, promoting the Judeo-Christian vision of the human person, and responding to cultural and legal challenges to constitutional rights and human flourishing.

Gender ideology has permeated the culture with stunning speed, influencing medical, government, and family decisions and creating an urgent need for clarity, education, and public discourse. 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 underscores the harms of gender-transition interventions, especially for minors.

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<sup>1</sup> 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 its counsel made a monetary contribution intended to fund the brief's preparation or submission.

## 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.<sup>2</sup> According to HHS, Section 1557’s sex discrimination prohibition requires performance, insurance coverage, and promotion of “gender-transition interventions.”<sup>3</sup> This “gender identity mandate” is an arbitrary determination by a government agency of the required medical standard of care and forces healthcare professionals, including Plaintiffs, to violate their religious beliefs and ethical obligations to render treatment according to their best medical judgment. 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 medically assisted “gender

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<sup>2</sup> See, e.g., HHS, 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, HHS, 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, HHS, 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>.

<sup>3</sup> For purposes of this brief, “gender-transition interventions” is used as shorthand for surgical and pharmaceutical (puberty blockers and cross-sex hormones) interventions used to further a “gender transition.”

transitions.” Gender-transition interventions can lead to significant and irreversible harms, especially for minors.

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

There is no consensus within the medical profession regarding an authoritative standard of care for treatment of gender dysphoria, nor in support of gender-transition interventions. This lack of consensus is reflected historically, internationally, in actions by the federal government and states, and in the continued controversy among medical professionals over gender-transition interventions.

**A. There is no consensus within the medical profession historically.**

Ever since the first gender-transition surgeries were performed in the U.S. in the mid-20th century, there has never been a medical consensus regarding the authoritative standard of care to treat gender dysphoria (previously, “gender identity disorder”) or regarding the risks and benefits of medically assisted “gender transitions.”

Historically, there have been uneven and, at times, competing trajectories in how the psychological and medical communities have responded to an individual’s experience of incongruence between perceived identity and the sexed body.

Diagnostic labels, criteria, and interventions have evolved significantly over a relatively

short time.<sup>4</sup> Until the late 20th century, “incongruence was taken to justify the need for psychiatric hospitalization and reparative psychotherapy,”<sup>5</sup> while more recently, the experience of incongruence or “gender dysphoria” has been variously classified as “a mental disorder” or “a condition related to sexual health.”<sup>6</sup> (The American Psychiatric Association defines gender dysphoria as “clinically significant distress or impairment related to gender incongruence, which may include desire to change primary and/or secondary sex characteristics.”<sup>7</sup>)

The treatment of gender dysphoria, an “inherently subjective phenomenon,” has been complicated by a “relatively slim (biomedical) evidence base” and a “unique” approach where “a mental health professional determines eligibility for medical treatment.”<sup>8</sup> Not surprisingly, this “convoluted context” results in situations where “experts, clinicians and clients may disagree when it is appropriate to initiate medical

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<sup>4</sup> The American Psychiatric Association’s (APA) Diagnostic and Statistical Manual (DSM) changed terminology and diagnostic criteria as follows: “transsexualism” (DSM-III), “gender identity disorder” (DSM-IV), and “gender dysphoria.” *Gender Dysphoria Diagnosis*, APA (2022),

<https://www.psychiatry.org/psychiatrists/diversity/education/transgender-and-gender-nonconforming-patients/gender-dysphoria-diagnosis>.

<sup>5</sup> Karl Gerritse et al., *Decision-Making Approaches in Transgender Healthcare: Conceptual Analysis and Ethical Implications*, 24 *Med. Health Care Philos.* 687, 687 (2021), <https://doi.org/10.1007/s11019-021-10023-6>.

<sup>6</sup> The APA classifies “gender dysphoria” under mental health disorders, while the World Health Organization classifies “gender incongruence” under “sexual health.” *Id.* at 688.

<sup>7</sup> Jack Turbian, ed., *What Is Gender Dysphoria?*, APA (Aug. 2022), <https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria>.

<sup>8</sup> Gerritse, *supra* note 5.

treatment, how to organize decision-making and how to serve the client’s best interests.”<sup>9</sup>

Over the past decade, another conflict has emerged, between the “gatekeeping” approach—which relies on mental health professionals to diagnose, and physicians to treat, the patient—and the “informed consent” model, which prioritizes “consumer” autonomy to choose a full range of medical interventions “without [a] mental health evaluation” or “formal diagnosis.”<sup>10</sup>

Activists now press for full “depathologization” of “transgender” identities, calling for “the removal of the diagnostic classification of gender transition processes as a mental disorder from the [Diagnostic and Statistical Manual] and the [International Classification of Diseases], [a change] from a psychiatric assessment process towards an informed decision-making approach ... [and] depathologization of gender diversity in childhood.”<sup>11</sup> The continued conflicts over basic issues of diagnosis, appropriate interventions, and even the validity of mental health assessments in connection with gender-transition interventions reflects the ongoing lack of medical consensus.

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<sup>9</sup> *Id.* at 688.

<sup>10</sup> *Id.*

<sup>11</sup> Amets Suess Schwend, *Trans Health Care from a Depathologization and Human Rights Perspective*, 41 *Pub. Health Rev.* 1, 4 (2020), <https://doi.org/10.1186/s40985-020-0118-y>.

The care for gender-dysphoric minors also has lacked medical consensus. A decade ago, responding to a child’s gender dysphoria with “watchful waiting” or family therapy was not controversial because, in most cases, the child’s gender incongruence resolves by puberty.<sup>12</sup> In contrast, the use of gender-transition interventions for minors has been controversial since its inception—and remains so.

The Dutch researchers who pioneered the use of puberty suppression for minors acknowledge persistent skepticism towards their work, including from providers concerned that gender dysphoria “can only be diagnosed with certainty in adulthood”; they feared “disapproval of the peer group, reactions of the correctional medical boards, or litigation.”<sup>13</sup>

In 2007, Dr. Norman Spack opened the first U.S. pediatric gender clinic at Boston Children’s Hospital and introduced puberty suppression for minors. With scant research available, he viewed “stopping puberty” as “a diagnostic test.”<sup>14</sup> If it brought relief, the diagnosis was right.

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<sup>12</sup> Devita Singh et al., *A Follow-Up Study of Boys with Gender Identity Disorder*, 12 *Front. Psychiatry* 632784 (2021), <https://pubmed.ncbi.nlm.nih.gov/33854450/>.

<sup>13</sup> Peggy Cohen-Kettenis et al., *The Treatment of Adolescent Transsexuals: Changing Insights*, 5 *J. Sexual Med.* 1892, 1893 (2008), <https://doi.org/10.1111/j.1743-6109.2008.00870.x>.

<sup>14</sup> Pagan Kennedy, *Q & A with Norman Spack*, Boston.com (archives Boston Globe), Mar. 30, 2008, [http://archive.boston.com/bostonglobe/ideas/articles/2008/03/30/qa\\_with\\_norman\\_spack/?page=full](http://archive.boston.com/bostonglobe/ideas/articles/2008/03/30/qa_with_norman_spack/?page=full).



No professional medical society recommended medically treating gender dysphoria in minors until 2009,<sup>15</sup> when the Endocrine Society released Clinical Practice Guidelines supporting puberty suppression and cross-sex hormones for minors—despite lacking “rigorous evaluation of the effectiveness and safety of endocrine protocols.”<sup>16</sup>

In 2012, the World Professional Association for Transgender Health (WPATH), an early promoter of gender-transition interventions for minors, noted that adoption of such interventions for minors “differs among countries and centers. Not all clinics offer puberty suppression.... The percentages of treated adolescents are likely influenced by the organization of health care, insurance aspects, cultural differences, opinions of health professionals, and diagnostic procedures offered in different settings.”<sup>17</sup> In short, no consensus.

Although a 2014 Dutch study reported positive psychological functioning for fifty-five patients who received medical transitioning treatments as adolescents and

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<sup>15</sup> Edwards-Leeper et al., *Psychological Evaluation and Medical Treatment of Transgender Youth in an Interdisciplinary “Gender Management Service” (GeMS) in a Major Pediatric Center*, 59 J. Homosexuality 321, 323 (2012), <https://pubmed.ncbi.nlm.nih.gov/22455323/>.

<sup>16</sup> Wylie C. Hembree et al., *Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline*, 94 J. Clinical Endocrinology & Metabolism 3132, 3134 (2009), <https://pubmed.ncbi.nlm.nih.gov/19509099/>.

<sup>17</sup> WPATH, Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, Version 7 13 (2012), [hereinafter “WPATH SOC7”], <https://www.wpath.org/publications/soc>.

surgery as adults,<sup>18</sup> subsequent studies failed to replicate those positive outcomes<sup>19</sup> and many have criticized the study’s methodology.<sup>20</sup> The Endocrine Society’s 2017 guidelines rely on the Dutch study but acknowledge the overall “low” and “very low” quality of supporting evidence generally<sup>21</sup> and note new concerns emerging since 2009, including “effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain.”<sup>22</sup>

In 2019, Boston Children’s opened the first pediatric center for gender-transition surgery, performing double mastectomies on minors.<sup>23</sup> The center reflects gender medicine’s expansion to younger and younger adolescents—controversial decisions unsupported by consensus.<sup>24</sup>

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<sup>18</sup> Annelou L.C. de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 *Pediatrics* 696, 702 (2014), <https://pubmed.ncbi.nlm.nih.gov/25201798/>.

<sup>19</sup> 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://doi.org/10.1371/journal.pone.0243894> (failing to replicate Dutch study).

<sup>20</sup> Stephen B. Levine et al., *Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults*, 48 *J. Sex & Marital Therapy* 706 (2022), <https://www.tandfonline.com/doi/full/10.1080/0092623X.2022.2046221>.

<sup>21</sup> Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 *J. Clinical Endocrinology & Metabolism* 3869, 3880 (2017), <https://doi.org/10.1210/jc.2017-01658>.

<sup>22</sup> *Id.* at 3874.

<sup>23</sup> *Center for Gender Surgery: Conditions & Procedures*, Boston Children’s Hospital, <https://www.childrenshospital.org/programs/center-gender-surgery-program/conditions-and-treatments>.

<sup>24</sup> See Hembree et al., *supra* note 2121, at 3872; Christine & Dan Karasic, *Age Is Just a Number: WPATH-Affiliated Surgeons’ Experiences and Attitudes Toward Vaginoplasty in*

In the sixteen years since U.S. gender clinicians began their controversial practice, the number of minors seeking and receiving gender-transition interventions has skyrocketed. Over 42,000 U.S. youth were diagnosed with gender dysphoria in 2021 alone.<sup>25</sup> The number of gender clinics for minors has grown from one in 2007 to over sixty today.<sup>26</sup> But market expansion does not mean medical consensus.

In 2022, WPATH released updated guidelines, “Standards of Care for the Health of Transgender and Gender Diverse People, Version 8,” claiming that “[t]he SOC-8 is based on the best available science and expert professional consensus.”<sup>27</sup> This supposed “expert professional consensus” was limited by design to clinicians who share WPATH’s activist commitment to promoting “gender-affirming” interventions.<sup>28</sup> The guidelines eliminated the ethics chapter and acknowledged that particular recommendations were based on “expert consensus only and are

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*Transgender Females Under 18 Years of Age in the United States*, 14 J. Sex Med. 624, 625 (2017), <https://pubmed.ncbi.nlm.nih.gov/28325535/> (urging lowering of recommended age for surgeries); Elizabeth R. Boskey et al., *Ethical Issues Considered when Establishing a Pediatric Gender Surgery Center*, 143 Pediatrics 1, 2 (2019), <https://pediatrics.aappublications.org/content/143/6/e20183053.figures-only>.

<sup>25</sup> *The Evidence to Support Medicalized Gender Transitions in Adolescents Is Worryingly Weak*, Economist (Apr. 5, 2023) [hereinafter “*The Evidence*”], <https://archive.ph/IaCvu#selection-1039.0-1039.88>.

<sup>26</sup> *Comprehensive Care Clinics*, Human Rights Campaign Found., <https://www.thehrcfoundation.org/professional-resources/comprehensive-care-clinics>.

<sup>27</sup> E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 Int’l J. Transgender Health S1, S3 (2022), <https://doi.org/10.1080/26895269.2022.2100644>.

<sup>28</sup> *Id.* at S247 (App. A: Methodology).

evidentiarily weak.”<sup>29</sup> After the initial release, the WPATH SOC-8 guidelines required major corrections and eliminated minimum ages for all gender-transition interventions.<sup>30</sup> WPATH is “an explicitly ideological organization” whose guidelines neither meet rigorous standards of review nor reflect an international medical consensus.<sup>31</sup>

**B. There is a lack of evidence to support gender-transition interventions.**

Gender specialists admit that “[t]ransgender medicine presents a particular challenge for the development of evidence-based guidelines” because of “limited” data, “lower-quality evidence,” retrospective study design, “lack of uniform data collection,” and limited research funding.<sup>32</sup> Experts admit that gender-transition interventions for gender dysphoria rest on a “relatively slim (biomedical) evidence base.”<sup>33</sup>

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<sup>29</sup> *Id.* at S150 (Statement 15.6).

<sup>30</sup> *WPATH Explained*, Genspect (Oct. 1, 2022), <https://genspect.org/wpath-explained/>.

<sup>31</sup> Leor Sapir, “*Trust the Experts*” *Is not Enough: U.S. Medical Groups Get the Science Wrong on Pediatric “Gender Affirming Care”*, Manhattan Inst. (Oct. 17, 2022), <https://www.manhattan-institute.org/how-to-respond-to-medical-authorities-claiming-gender-affirming-care-is-safe>.

<sup>32</sup> 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. Ethics* 1098, 1099 (2016), <https://doi.org/10.1001/journalofetics.2016.18.11.stas1-1611>.

<sup>33</sup> Gerritse et al., *supra* note 5, at 687.

In 2021, Dutch gender clinician Dr. Thomas Steensma acknowledged the need for “[m]ore research on sex changes in young people under the age of 18.... Doctors who provide transgender care in [the Netherlands] say they know too little about the target group and the long-term effects.”<sup>34</sup> Lawrence Tabak, acting director of the National Institutes of Health, told a U.S. Senate Committee in 2022 that “no long-term studies are available evaluating the effects of puberty blockers when used for gender dysphoria.”<sup>35</sup> Diane Chen, a leading psychologist with Lurie Children’s Hospital gender clinic, recently admitted that “a lot of the questions around long-term medical health outcomes we won’t be able to answer until the youth who started hormones at 13, 14, 15, are in their 50s, 60s, 70s.”<sup>36</sup>

Dr. Johanna Olson-Kennedy leads The Trans Youth Research Network, a multi-million-dollar research project involving four major gender clinics. In 2019, Olson-Kennedy justified the project, explaining “there is a consensus gap about the

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<sup>34</sup> *More Research Is Urgently Needed into Transgender Care for Young People: “Where does the Large Increase of Children Come From?”*, Voorzij, Feb. 27, 2021, <https://www.voorzij.nl/more-research-is-urgently-needed-into-transgender-care-for-young-people-where-does-the-large-increase-of-children-come-from/> (translation of Dutch newspaper).

<sup>35</sup> Florida Agency for Health Care Administration, Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria 14 (June 2022) [hereinafter Florida Medicaid Report], [https://ahca.myflorida.com/letkidsbekids/docs/AHCA\\_GAPMS\\_June\\_2022\\_Report.pdf](https://ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf).

<sup>36</sup> Frieda Klotz, *The Fractional Evolution of Pediatric Transgender Medicine*, Undark.org (Apr. 6, 2022), <https://undark.org/2022/04/06/the-evolution-of-pediatric-transgender-medicine/>.

best approach to the care of youth with gender dysphoria,” and “lack of consensus among professionals around timing of initiation of medical interventions, as well as optimal dosing regimens.”<sup>37</sup> After receiving over \$7.7 million in federal grants, the project’s renewal application in 2022 described a “scant evidence-base currently guiding the clinical care of [transgender/gender diverse] youth.”<sup>38</sup> A 2022 funding request by other gender clinicians to research the impact of puberty blockers in minors admits “[t]he overall impacts of [puberty suppression] have not been systematically studied.”<sup>39</sup> A multi-year grant application from Stanford researchers sought to study the use of cross-sex hormones “in early pubertal adolescents,” because clinicians need a “foundation for understanding the longitudinal impact of treatments that are *already being used* in clinical settings.”<sup>40</sup>

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<sup>37</sup> Johanna Olson-Kennedy et al., *Creating the Trans Youth Research Network: A Collaborative Research Endeavor*, 4 *Transgender Health* 304, 305 (2019), <https://liebertpub.com/doi/full/10.1089/trgh.2019.0024>.

<sup>38</sup> 2022 Renewal, *The Impact of Early Medical Treatment in Transgender Youth*, NIH Project No. 5R01HD082554-07, NIH REPORTER, [https://reporter.nih.gov/search/RiXZr\\_7vAECCgmmm-c\\_pjIw/project-details/10401756#similar-Projects](https://reporter.nih.gov/search/RiXZr_7vAECCgmmm-c_pjIw/project-details/10401756#similar-Projects) (multi-year, four-center study led by Dr. Johanna Olson-Kennedy received \$7,748,467 to date).

<sup>39</sup> Eric Nelson et al., *The Impact of Pubertal Suppression on Adolescent Neural and Mental Health Trajectories*, NIH RePORTER (2022), <https://reporter.nih.gov/search/Xr4WhUWe906AqRywwpsXVA/project-details/10442698>.

<sup>40</sup> David S. Hong et al., *Sex Hormone Effects on Neurodevelopment: Controlled Puberty in Transgender Adolescents*, NIH RePORTER (2020), <https://reporter.nih.gov/search/XPR7Y2lFAEC3glQp53hqPw/project-details/9940793> (emphasis added).

The original Dutch studies that formed the empirical basis for the “gender-affirming” approach have undergone new scrutiny. Scholars reviewing the underlying data and study methodology have sharply criticized the Dutch studies for their “methodological biases,” weak evidence base, and “profound limitations,” and concluded the studies “should never have been used as justification for propelling these interventions into general medical practice.”<sup>41</sup> Dr. Susan Bradley, a pioneering gender clinician in Canada, recently expressed regret for adopting the Dutch model and using puberty suppression in minors: “We were wrong.”<sup>42</sup> Over time she realized that gender-transition interventions are “not as irreversible as we always thought, and they have longer term effects on kids’ growth and development, including making them sterile and quite a number of things affecting their bone growth.”<sup>43</sup>

**C. WPATH and Endocrine Society guidelines are not the standard of care.**

Gender clinicians and activists promote WPATH guidelines as the dispositive summary of the “professional consensus about the psychiatric, psychological, medical,

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<sup>41</sup> E. Abbruzzese et al., *The Myth of “Reliable Research” in Pediatric Gender Medicine: A Critical Evaluation of the Dutch Studies—and Research that Has Followed*, J. Sex & Marital Therapy (2023).

<sup>42</sup> Laurel Duggan, “*We Were Wrong*”: Pioneer in Child Gender Swaps Makes Damning Admission, WND News Servs., Mar. 12, 2023, <https://www.wnd.com/2023/03/wrong-pioneer-child-gender-swaps-makes-damning-admission/>.

<sup>43</sup> *Id.*

and surgical management of gender dysphoria.”<sup>44</sup> WPATH guidelines, however, have consistently stated they are merely “flexible” guidelines.<sup>45</sup> Indeed, HHS’s Centers for Medicare & Medicaid Services (CMS) cited the “flexibility” of WPATH’s guidelines when it declined to endorse WPATH guidelines for Medicare coverage determinations.<sup>46</sup>

WPATH guidelines lack the rigor and evidence base necessary to qualify as authoritative standards of care or clinical practice guidelines (CPGs).<sup>47</sup> A 2021 first-of-its-kind systematic analysis of international CPGs for “gender minority/trans

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<sup>44</sup> *Facts About Anti-Trans Youth Bills*, Fenway Health (2022), <https://fenwayhealth.org/the-fenway-institute/health-policy/transyouthmatter/>; see also Madeline B. Deutsch, *Overview of Gender-Affirming Procedures*, Univ. Cal. S.F. Transgender Care (June 17, 2016), <https://transcare.ucsf.edu/guidelines/overview>.

<sup>45</sup> WPATH SOC 8, *supra* note 2717.

<sup>46</sup> 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>.

<sup>47</sup> Deutsch et al., *supra* note 20. 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).



health,”<sup>48</sup> published in the British Medical Journal (BMJ), reviewed WPATH SOC 7 guidelines, singled them out for particularly strong criticism, and concluded they “cannot be considered ‘gold standard.’”<sup>49</sup> Patrik Vankrunkelsven, the Director the Belgian Center for Evidence-Based Medicine (CEBAM), extended those criticisms to WPATH SOC 8 and called gender-transition interventions “a pure experiment on children, without any scientific evidence.”<sup>50</sup> From a professional standpoint, Vankrunkelsven pointed out that “if we had to review [the WPATH guidelines] at CEBAM, we would actually toss them in the bin [trash].”<sup>51</sup>

Similarly, the Endocrine Society’s guidelines are “fundamentally flawed” according to Gordon Guyatt, a professor at McMaster University and the co-developer of the GRADE “evidence-based” review protocol.<sup>52</sup> Before issuing its 2009 guidelines supporting gender-transition interventions for minors, the Endocrine Society conducted a substantive evidence review, using GRADE methodology. However, the review had “serious problems,” according to Guyatt, especially its focus

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<sup>48</sup> Sara Dahlen et al., *International Clinical Practice Guidelines for Gender Minority/Trans People: Systematic Review and Quality Assessment*, 11 *BMJ Open* 1, 8, 2021, <https://pubmed.ncbi.nlm.nih.gov/33926984/> (describing an overall “paucity” of “high quality” clinical guidance regarding gender dysphoria and transitioning treatments).

<sup>49</sup> *Id.* at 8 (emphasis added), referencing the “incoherence” of WPATH SOCv7).

<sup>50</sup> Lauwke Vandendriessche Pano, *Fierce Debate About Puberty Inhibitors and Male/Female Hormones: What You are Doing Is an Experiment on Children*, *VRT News*, Mar. 29, 2023, (translated).

<sup>51</sup> *Id.*; see also @segm\_ebm, Twitter (Mar. 31, 2023, 7:54 PM), [https://twitter.com/segm\\_ebm/status/1641952056088096769](https://twitter.com/segm_ebm/status/1641952056088096769).

<sup>52</sup> *The Evidence*, *supra* note 25.

on two side effects (cardiovascular and bone health), while failing to assess the main outcome desired (reducing gender dysphoria).<sup>53</sup> The Society also “paired strong recommendations—phrased as ‘we recommend’—with weak evidence,” in violation of GRADE protocols.<sup>54</sup>

Like WPATH’s “standards,” the Endocrine Society based its recommendations on “low” and “very low” quality evidence and included a disclaimer that its “guidelines cannot guarantee any specific outcome, nor do they establish a standard of care.”<sup>55</sup>

No current guidelines for treating gender dysphoria qualify as an authoritative CPG or standard of care, and clinicians with diverse perspectives recognize that no medical consensus exists. In practice, gender medicine freely disregards existing guidelines. A 2020 study from the Mount Sinai Center for Transgender Medicine and Surgery, 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.<sup>56</sup> Indeed, Mount Sinai eventually developed its own

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<sup>53</sup> J. Block, *Gender Dysphoria in Young People Is Rising—And so Is Professional Disagreement*, 380 *BMJ* 2-3 (2023), <https://www.bmj.com/content/380/bmj.p382>.

<sup>54</sup> *Id.* at 3.

<sup>55</sup> Hembree et al., *supra* note 2121.

<sup>56</sup> 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 *Transgender Health* 166, 170 (2020), <https://doi.org/10.1089/trgh.2019.0066>.

criteria for gender-transition interventions—criteria that diverged significantly from WPATH guidelines, with less than ten percent of Mount Sinai patients meeting criteria for both WPATH and Mount Sinai assessments.<sup>57</sup>

Although gender clinicians tout the “substantial” mental health evaluations occurring before transition, the role of mental health providers varies widely by clinic.<sup>58</sup> Seattle Children’s Gender Clinic, for example, offers “brief mental health support” but no ongoing mental health therapy,<sup>59</sup> while other clinics, such as Boston Children’s, conduct “comprehensive psychological and medical assessments.”<sup>60</sup> Two veteran gender clinicians, Dr. Erica Anderson and Dr. Laura Edwards-Leeper, have warned that some adolescents receive “sloppy care” from clinicians who start them on transitioning treatments with minimal psychological assessments.<sup>61</sup> Edwards-Leeper recently reiterated her concern, observing that “[m]ore providers do not value the mental health component,” which results in children being “pretty much fast tracked to medical intervention.”<sup>62</sup> De-transitioners (formerly trans-identified people who

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<sup>57</sup> *Id.* at 170.

<sup>58</sup> Block, *supra* note 53, at 4; *The Evidence*, *supra* note 25.

<sup>59</sup> *Services We Provide: Brief Mental Health Support*, Seattle Children’s Gender Clinic, <https://www.seattlechildrens.org/clinics/gender-clinic/>.

<sup>60</sup> *Gender Multispecialty Clinic (GeMS): Your Visit*, Boston Children’s Hospital, <https://www.childrenshospital.org/programs/gender-multispecialty-service/your-visit>.

<sup>61</sup> 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](https://www.realclearpolitics.com/2021/10/05/top_trans_doctors_blow_the_whistle_on_sloppy_care_553290.html).

<sup>62</sup> Block, *supra* note 53, at 4.

regret and discontinue gender-transition interventions) report minimal or no mental health treatments before medicalized interventions.<sup>63</sup>

Several other circuit courts have recognized that WPATH guidelines do not reflect medical consensus. *See Gibson v. Collier*, 920 F.3d 212, 223 (5th Cir. 2019) (“WPATH Standards of Care do not reflect medical consensus”); *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”); *Kosilek v. Spencer*, 774 F.3d 63, 88 (1st Cir. 2014) (en banc) (holding “[p]rudent medical professionals ... do reasonably differ in their opinions regarding [WPATH’s] requirements”); *cf. Keohane v. Fla. Dep’t of Corr. Sec’y*, 952 F.3d 1257, 1296 (11th Cir. 2020) (acknowledging district court and others have found WPATH standards “authoritative for treating gender dysphoria in prison,” without evaluating merits of WPATH standards); *Edmo v. Corizon, Inc.*, 935 F.3d 757, 787, 788 & n.16 (9th Cir. 2019) (per curiam) (holding WPATH standards are the “established standards” for evaluations of the necessity of transitioning surgery and the “undisputed starting point in determining the appropriate treatment for gender dysphoric individuals”), *reh’g en banc denied*, 949 F.3d 489, 497 (9th Cir. 2020) (O’Scannlain, J., joined by seven judges, respecting the denial of rehearing en banc) (rejecting panel’s characterization because “WPATH Standards

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<sup>63</sup> *See, e.g., The Evidence*, *supra* note 25 (testimony of Prisha Mosley, who reported receiving “one 15-minute [mental health] appointment before I was given testosterone”).

are merely criteria promulgated by a controversial private organization with a declared point of view”).

**D. The lack of medical consensus is reflected internationally.**

Many countries that initially embraced gender-transition interventions reversing course. For example, Sweden’s National Board of Health and Welfare commissioned an extensive evidence review and concluded in 2022 “that the risks of anti-puberty and sex-confirming hormone treatment for those under 18 currently outweigh the possible benefits.”<sup>64</sup> Finland likewise revised its protocols: the Finnish Health Authority performed an extensive literature review then issued new guidelines prioritizing psychotherapy as the first-line treatment for gender-dysphoric minors.<sup>65</sup>

In the United Kingdom, whistleblower complaints exposed the inadequate psychological care for gender-dysphoric minors at the National Health Service’s

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<sup>64</sup> Socialstyrelsen, Support, Investigation and Hormone Treatment for Gender Incongruence in Children and Adolescents (2022), <https://web.archive.org/web/20221121222721/https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-2-7774.pdf>; *see also* Lisa Nainggolan, *Hormonal Tx of Youth with Gender Dysphoria Stops in Sweden*, Medscape (2021), <https://www.medscape.com/viewarticle/950964>.

<sup>65</sup> 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), *available at* [https://segm.org/sites/default/files/Finnish\\_Guidelines\\_2020\\_Minors\\_Unofficial%20Translation.pdf](https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf). COHERE works in conjunction with the Ministry of Social Affairs and Health.

(NHS) gender clinic.<sup>66</sup> A landmark case against the NHS in 2020 by “de-transitioner” Keira Bell found that minors lacked capacity to consent to transitioning treatments that cause sterility and impair sexual function. The NHS initially suspended the use of puberty blockers and instituted new procedures to ensure better psychological care.<sup>67</sup> (The decision was later reversed on procedural grounds.)

Two separate evidence reviews assessing the impact of puberty suppressing drugs and cross-sex hormones to treat gender dysphoria were published in 2021 by the UK’s National Institute for Health and Care Excellence (NICE). The NICE evidence review found little evidence of benefit and substantial risk of harm from “gender affirming” treatment in minors.<sup>68</sup> A 2022 independent review commissioned by NHS England (the “Cass Review”), found that “[a]t present the professional community does not have a shared understanding about the meaning of gender dysphoria in young people,” its cause, or best treatment approaches.<sup>69</sup> The Review noted that “[m]uch of the research base is observational,” with little “longer term

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<sup>66</sup> 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>.

<sup>67</sup> Becky McCall, *NHS Makes Child Gender Identity Service Changes After High Court Ruling*, Medscape (Dec. 4, 2020), <https://www.medscape.com/viewarticle/941781>.

<sup>68</sup> NICE, Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria (2021); NICE, Evidence Review: Gender-Affirming Hormones for Children and Adolescents with Gender Dysphoria (2021), [hereinafter “NICE Evidence Review” collectively].

<sup>69</sup> Hilary Cass, *Review of Gender Identity Services for Children and Young People*, BMJ 376 (2022), <https://www.bmj.com/content/376/bmj.o629>.

follow up data,” resulting in a “weak evidence base.”<sup>70</sup> It concluded, “[t]here is lack of consensus and open discussion about the nature of gender dysphoria and therefore about the appropriate clinical response.”<sup>71</sup>

Psychotherapists in Australia and New Zealand issued a 2021 policy statement emphasizing mental health treatment for gender-dysphoric minors, rather than “gender affirmation.” They stressed the importance of assessing the “psychological state and context in which gender dysphoria has arisen,” before any treatment decisions are made.<sup>72</sup> In February 2022, France’s National Academy of Medicine warned medical professionals that the increase in young people seeking transitioning treatments may be due to social contagion and urged “great medical caution.”<sup>73</sup> Most recently, in March 2023, the Norwegian Healthcare Investigation Board restricted the

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<sup>70</sup> *Id.*

<sup>71</sup> Cass Review, Interim Report (Feb. 2022), <https://cass.independent-review.uk/publications/interim-report/>.

<sup>72</sup> Position Statement, The Royal Australian and New Zealand College of Psychiatrists, Recognising and Addressing the Mental Health Needs of People Experiencing Gender Dysphoria/Gender Incongruence, Aug. 2021, <https://www.ranzcp.org/news-policy/policy-and-advocacy/position-statements/gender-dysphoria>.

<sup>73</sup> 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>.

use of puberty blockers for gender affirmation, deeming their use “experimental” and lacking in evidence-based support.<sup>74</sup>

**E. The federal government has recognized the lack of medical consensus.**

Despite the efforts under the current administration to push gender-transition interventions, the federal government has never formally determined that such treatments are the appropriate standard of care.

In June 2020, HHS regulations acknowledged that “there is no medical consensus to support one or another form of treatment for gender dysphoria.”<sup>85</sup> Fed. Reg. 37160, 37198 (Aug. 4, 2022). Prior HHS regulations regarding gender-transition surgeries “relied excessively on the conclusions of an advocacy group (WPATH) rather than on independent scientific fact-finding,” such as the CMS factfinding 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.”<sup>75</sup> “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

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<sup>74</sup> A summary of the Norwegian report by the Society of Evidence-based Gender Medicine is available here: @segm\_ebm, Twitter (Mar. 9, 2023, 8:24 PM), [https://twitter.com/segm\\_ebm/status/1634032333618819073](https://twitter.com/segm_ebm/status/1634032333618819073).

<sup>75</sup> CMS Decision Memo, *supra* note 4646.



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.”<sup>76</sup>

Similarly, a 2018 Department of Defense (DOD) report on gender dysphoria 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.”<sup>77</sup> 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, and the National Institutes of Health only began investigating the long-term outcomes of transitioning treatments for youth in 2015.<sup>78</sup>

**F. 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 transitioning interventions, especially for minors.

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<sup>76</sup> *Id.*

<sup>77</sup> Dep’t of Defense, Report and Recommendations on Military Service by Transgender Persons 5 (Feb. 22, 2018).

<sup>78</sup> See Juliana Bunim, *First U.S. Study of Transgender Youth Funded by NIH*, U.C.S.F., Aug. 17, 2015, <https://perma.cc/URA6-CERX>.

For instance, a growing number of states have passed laws prohibiting gender-transition interventions on minors.<sup>79</sup>

State executives have weighed in as well. For example, in February 2022, the Texas Attorney General issued an opinion letter stating that sterilizing treatments and other permanent “sex-change procedures,” including puberty suppression, cross-sex hormones, and various surgeries, “can constitute child abuse when performed on minor children.”<sup>80</sup> Texas’s governor subsequently directed the Texas Department of Family and Protective Services to “conduct a prompt and thorough investigation of any reported instances of these abusive procedures in the State of Texas.”<sup>81</sup>

Florida has taken multiple actions to restrict the provision of gender-transition interventions. In February 2023, the Florida Board of Medicine and Florida Board of Osteopathic Medicine finalized rules prohibiting the provision of gender-transition

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<sup>79</sup> See Ala. S.B.184 (2022); Ariz. S.B.1138 (2022); Ark. H.B.1570 (2021); Ark. S.B.199 (2023); Ga. S.B.140 (2023); Idaho H.71 (2023); Ind. S.B.34 (2023); Iowa S.F.538 (2023); Ky. S.B.150 (2023); Miss. H.B.1125 (2023); S.D. H.B.1080 (2023); Tenn. H.B.0578 (2021); Tenn. S.B.126 (2021); Tenn. H.B.0001 (2023); Utah S.B.16 (2023); W.V. H.B.2007 (2023).

<sup>80</sup> Tex. Att’y Gen. Op. Letter No. KP-0401, from Ken Paxton, Attorney General, to Matt Krause, Chair, House Committee on General Investigating 1-2, Feb. 18, 2022, <https://www.texasattorneygeneral.gov/sites/default/files/opinion-files/opinion/2022/kp-0401.pdf>.

<sup>81</sup> 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>.

interventions for minors, eliminating an earlier exception for research.<sup>82</sup> Responding to an HHS document promoting “gender-affirming care” for young people, the Florida Department of Health issued guidelines in 2022 that clarified that treatment of gender dysphoria for children and adolescents should *not* include social gender transition, puberty blockers, cross-sex hormones, or transitioning surgeries because of “the lack of conclusive evidence, and the potential for long-term, irreversible effects.”<sup>83</sup> Florida’s Agency for Health Care Administration issued rules in August 2022 eliminating state Medicaid coverage of gender-transition interventions.<sup>84</sup> The rules responded to a request from the Agency’s secretary seeking a determination whether gender-transition interventions were “consistent with generally accepted professional medical standards.”<sup>85</sup> The agency review, published June 2022, found

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<sup>82</sup> AP, *Puberty Blockers and Hormone Replacement Therapy Will Be Banned for Minors, Even During Clinical Trials*, WUSF Public Media (Feb. 10, 2023), <https://wusfnews.wusf.usf.edu/health-news-florida/2023-02-10/florida-boards-of-medicine-confirm-ban-on-gender-affirming-care-for-transgender-youth>.

<sup>83</sup> Press Release, 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](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 [HHS] for the coverage of ‘gender affirming’ care, for children and adolescents”).

<sup>84</sup> Brooke Migdon, *Florida Publishes Rule Barring Medicaid Coverage for Gender-Affirming Health Care*, The Hill (Aug. 12, 2022), <https://thehill.com/changing-america/respect/equality/3598274-florida-publishes-rule-barring-medicaid-coverage-for-gender-affirming-health-care/>.

<sup>85</sup> Florida Medicaid Report, *supra* note 3535, at 2.

that gender-transition interventions “are not consistent with widely accepted professional medical standards and are experimental and investigational with the potential for harmful long term affects [sic].”<sup>86</sup>

## II. Gender-transition interventions can lead to serious harms.

Gender-transition interventions can cause significant harms, including loss of fertility and sexual function. Long-term outcomes for individuals who undergo transitioning treatments are not promising. Those who have had genital surgery are nineteen times more likely than the general population to die by suicide,<sup>87</sup> and studies show that transitioning treatments fail to reduce suicide risks and mental health issues in the long-term.<sup>88</sup>

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,

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<sup>86</sup> *Report Overview*, Florida Agency for Health Care Administration (2022), <https://ahca.myflorida.com/letkidsbekids/>.

<sup>87</sup> Cecilia Dhejne et al., *Long-term Follow-up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden*, 6 PLoS ONE e16885 (2011), <https://pubmed.ncbi.nlm.nih.gov/21364939/>.

<sup>88</sup> 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/10.1111/acps.13164>; *Correction to Bränström and Pachankis*, 177 Am. J. Psychiatry 734 (2020) (correcting Richard Bränström et al., *Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study*, 177 Am. J. Psychiatry 727 (2020)).

Europe, Scandinavia, and elsewhere.”<sup>89</sup> 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.<sup>90</sup>

For years, gender dysphoria in children was addressed through “watchful waiting” or family therapy. About eighty-eight percent of the time, the child’s gender dysphoria resolved naturally by puberty without transitioning interventions.<sup>91</sup> The “gender-affirming” approach changed that pattern dramatically, as most children affirmed in their transgender beliefs persist in those beliefs and are likely to pursue transitioning treatments that irreversibly modify their bodies—and lead to regret.<sup>92</sup>

Clinical concerns over the outcomes of gender-transition interventions have escalated.<sup>93</sup> Puberty blockers, originally described as safe and fully reversible, are known to have negative effects on bone density, social and emotional maturation, and

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<sup>89</sup> Kenneth J. Zucker, *Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues*, 48 *Archives Sexual Behav.* 1983 (2019), <https://pubmed.ncbi.nlm.nih.gov/31321594/>.

<sup>90</sup> *Id.*

<sup>91</sup> Singh et al., *supra* note 1212.

<sup>92</sup> Carmichael et al., *supra* note 1919 (study by Tavistock and Portman NHS Gender Identity Development Service (UK) finding 98% of adolescents who underwent puberty suppression continued on to cross-sex hormones); *see also* Lisa Littman, *Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners*, 50 *Archives Sexual Behav.* 3353 (2021), <https://pubmed.ncbi.nlm.nih.gov/34665380/>.

<sup>93</sup> 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/>.

other aspects of neuro-development.<sup>94</sup> They generally fail to lessen the child's gender dysphoria, and deliver mixed results for mental health.<sup>95</sup> Long term effects remain unknown.<sup>96</sup>

Nearly all children who begin puberty blockers go on to receive cross-sex hormones, the next step in transitioning, with life-altering consequences.<sup>97</sup> Blocking a child's natural puberty prevents maturation of genitals and reproductive organs; subsequently introducing cross-sex hormones renders the child permanently sterile.<sup>98</sup> Gender clinicians also admit that puberty suppression may impair the child's later sexual functioning as an adult.<sup>99</sup> These losses cannot be fully comprehended by a child, precluding the possibility of informed consent.

Cross-sex hormones carry numerous health risks and cause significant irreversible changes in adolescents' bodies, including genital or vaginal atrophy, hair loss (or gain), voice changes, and impaired fertility.<sup>100</sup> They increase cardiovascular

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<sup>94</sup> NICE Evidence Review, *supra* note 54.

<sup>95</sup> Carmichael et al., *supra* note 13.

<sup>96</sup> Diane Chen et al., *Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Pubertal Suppression in Transgender Youth*, 5 *Transgender Health* 246 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7759272/>.

<sup>97</sup> *Id.*

<sup>98</sup> Stephen Levine, *Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria*, 44 *J. Sex & Marital Therapy* 29 (2018), <https://pubmed.ncbi.nlm.nih.gov/28332936/>.

<sup>99</sup> Shrier, *supra* note 61 **Error! Bookmark not defined.**

<sup>100</sup> Levine et al., *supra* note 2020.

risks and cause liver and metabolic changes,<sup>101</sup> The flood of opposite sex hormones has variable emotional and psychological effects as well. Females taking testosterone experience an increase in gender dysphoria, particularly regarding their breasts, which heightens the likelihood they will undergo double mastectomies—as young as thirteen.<sup>102</sup> Far from an evidence-based standard of care, transitioning treatments for gender dysphoria amount to unethical human experimentation, including on *children*. One Swedish teen who underwent medical transition, suffered serious bodily harm, and then de-transitioned describes gender-transitioning treatments for gender dysphoria in stark terms: “They’re experimenting on young people ... we’re guinea pigs.”<sup>103</sup> Or, as psychotherapist Alison Clayton warns, this is nothing less than “dangerous medicine.”<sup>104</sup>

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<sup>101</sup> *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/>.

<sup>102</sup> 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/> (Figure: Age at Chest Surgery in the Post-surgical Cohort).

<sup>103</sup> 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>.

<sup>104</sup> 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/>.

Despite the harms of gender-transition interventions, especially for minors, and the lack of medical consensus regarding the treatment of gender dysphoria and gender-transition interventions, HHS seeks to impose a medical standard of care through Section 1557, a nondiscrimination provision. But there is no standard of care that is based on an authoritative review of the evidence, weighing the risks and benefits of proposed interventions and alternative care options, and using evidence-based outcome measures to optimize patient outcomes.

Without reversal, Plaintiffs will be forced choose between providing, insuring, and promoting harmful gender-transition interventions, including for minors, or violating their religious beliefs and best ethical and medical judgments.

## CONCLUSION

The Court should reverse and remand as stated in the Plaintiffs-Appellants' brief.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

This brief complies with the word limit of Fed. R. App. P. 29(a)(5) because this brief contains 6,342 words, excluding parts of the brief exempted by Fed. R. App. P. 32(f) and 6 Cir. R. 32(b).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in Microsoft Word Version 2303 using a proportionally spaced typeface, 14-point Garamond.

Dated: April 6, 2023

s/ Eric N. Kniffin  
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## CERTIFICATE OF SERVICE

I hereby certify that on April 6, 2023, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit using the appellate 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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