No. 23-0697

### In the Supreme Court of Texas

#### THE STATE OF TEXAS, et al. Appellants,

v.

LAZARO LOE, et al. Appellees.

APPEAL FROM THE 201<sup>st</sup> Judicial District Court, Travis County, Hon. Maria Cantú Hexsel, Presiding

#### BRIEF OF AMICUS CURIAE ETHICS AND PUBLIC POLICY CENTER SUPPORTING APPELLANTS AND REVERSAL

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#### 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 has a strong interest in promoting the Judeo-Christian vision of the human person, protecting religious liberty, and responding to the challenges of gender ideology.

Gender ideology has permeated culture with stunning speed, influencing medicine, business, media, entertainment, government, and education. Because gender ideology is sowing confusion and undermining personal well-being, especially among children, its rise has created an urgent need for clarity, education, and compassionate guidance.

To meet this need, EPPC launched the Person & Identity Project, led by Director Mary Rice Hasson.<sup>2</sup> Many EPPC Fellows also write and advocate on issues related to gender ideology.<sup>3</sup>

 $<sup>^{\</sup>rm 1}$  No party's counsel authored, and no one other than a micus and its counsel contributed money for, this brief.

<sup>&</sup>lt;sup>2</sup> EPPC, Person & Identity Project, <u>https://personandidentity.com/</u>.

<sup>&</sup>lt;sup>3</sup>Relevant publications from EPPC Fellows include:

#### INTRODUCTION AND SUMMARY OF ARGUMENT

A central claim in Plaintiffs-Appellees' case is that the irreversible medical interventions<sup>4</sup> for minors prohibited by S.B. 14 represent the "standard of care" for addressing minors' "gender dysphoria"—a standard

- Ryan T. Anderson, WHEN HARRY BECAME SALLY (Encounter Books 2018);
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- Rachel N. Morrison, *Gender Identity Policy Under the Biden Administration*, 23 FED. Soc. REV. 85 (2022), *available at* SSRN: <u>https://ssrn.com/abstract=4104566</u>;
- Theresa Farnan, *Our World Has Lost the Catholic Understanding* of *Human Anthropology*, Our Sunday Visitor, June 2, 2023, <u>https://www.oursundayvisitor.com/our-world-has-lost-the-catholic-understanding-of-human-anthropology</u>;
- Amicus briefs on gender identity authored by EPPC fellows are available at EPPC, Amicus Briefs: "Gender Transition" Interventions, <u>https://eppc.org/amicus-briefs/#16-</u> %E2%80%9Cgender-transition%E2%80%9D-interventions-.

<sup>4</sup> Consistent with the State's usage, amicus here uses "medical interventions" to include pharmaceutical interventions (generally known as puberty blockers and cross-sex hormones) and surgical interventions intended to change the child's body so that it more closely resembles the child's expressed gender identity. reflected in what Plaintiffs-Appellees call "established" and "evidencebased" clinical guidelines from the World Professional Association of Transgender Health (WPATH) and the Endocrine Society.

Contrary to Plaintiffs-Appellees' contentions, however, medical "gender transitioning" interventions in minors, such as those prohibited by S.B. 14 (e.g., puberty suppression, cross-sex hormones, and surgery), reflect neither a medical consensus nor the standard of care. There is not today, nor has there ever been, a national or international medical consensus in favor of permanent medical interventions on children experiencing gender dysphoria.

Furthermore, recent studies confirm that these medical interventions lead to serious harm, especially in minors. Even proponents of puberty blockers are backing off claims that these drugs are "safe and fully reversible." Today, the drugs are known to have negative effects on bone density, social and emotional maturation, and other aspects of neuro-development. Cross-sex hormones likewise affect irreversible changes in children's bodies, including genital or vaginal atrophy, hair loss (or gain), voice changes, impaired fertility, and cardiovascular risks, among others. Surgeries to amputate primary and

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secondary sex organs—performed on children as young as thirteen—are obviously irreversible.

A growing number of victims are now testifying to the dangers of the medicalized approach touted by Plaintiffs-Appellees. Hundreds of "gender dysphoric" youth and "de-transitioners" have become unwilling witnesses to, and victims of, the damage done by these harmful medical gender-transitioning interventions and medicine's failure to abide by its most basic duty: "do no harm."

This amicus brief compiles recent scientific, medical, and political developments to demonstrate that the Texas Legislature acted reasonably and lawfully to pass S.B. 14. The Legislature reasonably concluded that S.B. 14 would advance its compelling interest in protecting Texas' children from harm. Based on the evidence collected here and the arguments of parties, Amicus urges this Court to uphold the challenged law.

#### ARGUMENT

# I. There is no established 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 treating minors' gender dysphoria or supporting medical interventions for minors' gender transitions.<sup>5</sup> 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-transitioning interventions.

#### A. There is no consensus within the medical profession.

Until recently, medical professionals responded to a child experiencing gender dysphoria with "watchful waiting" or family therapy; this protocol was not controversial because, in most cases, the child's gender incongruence resolved by puberty.<sup>6</sup> In contrast, the use of medical gender-transitioning treatments for minors, as sought by

<sup>&</sup>lt;sup>5</sup> Amicus uses the common term "gender transition" to denote efforts to change a child's appearance or body so that it more closely resembles the child's expressed gender identity. A person can change his or her sex.

<sup>&</sup>lt;sup>6</sup> Devita Singh et al., A Follow-Up Study of Boys with Gender Identity Disorder, 12 Front Psychiatry 632784, 12-13 (2021), https://doi.org/10.3389/fpsyt.2021.632784.

Plaintiffs-Appellees in this case, has been controversial since its inception and remains so, leaving no clear medical consensus regarding the "standard of care" for gender dysphoric minors.

The first medical interventions for gender transitions in minors began in the late 1980s and early 1990s in the Netherlands.<sup>7</sup> As the Dutch program grew, so too did opposition. By 1999, a "wave of negative publicity" threatened the fledgling program: Dutch gender clinicians were publicly castigated as "Nazis experimenting with children."<sup>8</sup> Leiden University Professor Heleen Dupuis, a progressive ethicist, described the Dutch youth gender program as "reckless" and an "abuse of medicine."<sup>9</sup> Criticism continued through the early 2000s, as prominent Dutch psychiatrists worried that a child's "wish for sex change" might mask other psychiatric illnesses, including early psychoses.<sup>10</sup>

No "consensus" emerged to support medicalized treatment of gender dysphoric minors; instead, the Dutch clinicians faced persistent

<sup>&</sup>lt;sup>7</sup> Alex Bakker, The Dutch Approach: FIFTY Years of Transgender Health Care at the VU Amsterdam Gender Clinic 120 (2021).

<sup>&</sup>lt;sup>8</sup> *Id*. at 116.

<sup>&</sup>lt;sup>9</sup> *Id.* at 127.

<sup>&</sup>lt;sup>10</sup> *Id*. at 13.

skepticism and worry over peer "disapproval," "reactions of the correctional medical boards, or litigation."<sup>11</sup> Feeling great "urgency" to prove that medical interventions benefitted minors, psychiatrist Annelou de Vries initiated the first follow-up research on puberty-suppressed adolescents.<sup>12</sup> Her studies in 2011 and 2014 touted positive outcomes<sup>13</sup> and "launched the experimental practice of pediatric gender transition into mainstream medical practices."<sup>14</sup> For nearly a decade, advocates for so-called "gender-affirming care" touted these Dutch studies as evidence that transgender minors benefitted from medical interventions.

Inspired by the Dutch, Dr. Norman Spack opened the first U.S. pediatric gender clinic at Boston Children's Hospital in 2007, offering

<sup>13</sup> *Id*. at 160.

<sup>&</sup>lt;sup>11</sup> Peggy Cohen-Kettenis et al., *The Treatment of Adolescent Transsexuals: Changing Insights*, 5 J Sex Med 1892, 1893 (2008), https://doi.org/10.1111/j.1743-6109.2008.00870.x.

 $<sup>^{12}</sup>$  Bakker, supra n.7, at 158.

<sup>&</sup>lt;sup>14</sup> Stephen B. Levine and E. Abbruzzese, *Current Concerns About Gender-Affirming Therapy in Adolescents*, 15 Curr Sex Health Rep 113, 118 (2023), <u>https://doi.org/10.1007/s11930-023-00358-x</u> (citing ALC de Vries, et al., *Puberty suppression in adolescents with gender identity disorder: a prospective follow-up study*, 8 J Sex Med 2276 (2011), <u>https://doi.org/10.1111/j.1743-6109.2010.01943.x</u>., ALC de Vries, et al., *Young adult psychological outcome after puberty suppression and gender reassignment*, 134 Pediatr 696 (2014), <u>https://doi.org/10.1542/peds.2013-2958</u>.)

puberty suppression for gender transition. With scant research to guide him, Spack perceived "stopping puberty" as "diagnostic."<sup>15</sup> If this drug regimen brought psychological relief, that confirmed that the child was "transgender." Spack quickly disregarded the Dutch age protocol and began using cross-sex hormones in 13-year-olds.<sup>16</sup>

Dr. Spack, along with several Dutch gender clinicians, developed the Endocrine Society's 2009 Clinical Practice Guidelines, which were touted as the first official clinical recommendations supporting puberty suppression and cross-sex hormones for minors. Early on, critics pointed out that the Endocrine Society's guidelines lacked "rigorous evaluation of the effectiveness and safety of endocrine protocols."<sup>17</sup> Even in 2017, the

<sup>&</sup>lt;sup>15</sup> Pagan Kennedy, Q & A with Norman Spack, Boston Globe, Mar. 30, 2008,

http://archive.boston.com/bostonglobe/ideas/articles/2008/03/30/qa\_with \_norman\_spack/?page=full.

<sup>&</sup>lt;sup>16</sup> Beth Schwartzapfel, *How Norman Spack Transformed the Way We Treat Transgender Children*, Boston Phoenix, Aug. 10, 2012, <u>https://thephoenix.com/boston/life/142583-how-norman-spack-transformed-the-way-we-treat-tran/</u>.

<sup>&</sup>lt;sup>17</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 Homosex 321, 323 (2012), https://doi.org/10.1080/00918369.2012.653302.

Endocrine Society's guidelines continued to rely almost exclusively on the Dutch studies, even though the supporting evidence was of "low" and "very low" quality,<sup>18</sup> and despite new concerns that had emerged since 2009, including unknown "effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain."<sup>19</sup>

WPATH's guidelines similarly have never reflected a medical consensus. WPATH demonstrated its ideological commitment to medicalized treatment early on, adding puberty suppression to its "standards" in 2001, well before the key Dutch studies that purported to justify this treatment were even published (encouraged no doubt by several Dutch gender clinicians who served on the WPATH Board).<sup>20</sup> Even so, in 2012, WPATH acknowledged that the use of medical interventions for gender dysphoric minors "differs among countries and centers. Not all clinics offer puberty suppression . . . . The percentages of

<sup>&</sup>lt;sup>18</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), <u>https://doi.org/10.1210/jc.2017-01658</u>.

<sup>&</sup>lt;sup>19</sup> *Id.* at 3874.

<sup>&</sup>lt;sup>20</sup> Michael Biggs, *The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence*, 49 J Sex Marital Ther 348, 354-55 (2023), https://doi.org/10.1080/0092623X.2022.2121238.

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>21</sup> Thus, even WPATH acknowledges that its "standards" were never meant to represent a medical consensus on how to treat children with gender dysphoria.

As noted above, the strongest case for performing medical gendertransitions on minors came from the 2014 Dutch study, which reported positive psychological functioning in fifty-five medically transitioned adolescents.<sup>22</sup> For nearly a decade, this study received little scrutiny. It was cited to justify WPATH's "flexible" guidelines and the Endocrine Society's support for medicalized interventions (despite the low quality of evidence.<sup>23</sup> In effect, the thin research produced by Dutch clinicians created the veneer of a "standard of care."

<sup>&</sup>lt;sup>21</sup> WPATH, Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, Ver. 7, 13 (2012), [hereinafter "WPATH SOC7"], <u>https://www.wpath.org/publications/soc</u>.

 <sup>&</sup>lt;sup>22</sup> Annelou L.C. de Vries et al., Young Adult Psychological Outcome
 After Puberty Suppression and Gender Reassignment, 134 Pediatr 696,
 702 (2014), <u>https://pubmed.ncbi.nlm.nih.gov/25201798/</u>.

<sup>&</sup>lt;sup>23</sup> See Hembree, et al., supra n.18, at 3880.; see also WPATH, Standards of Care for the Health of Transsexual, Transgender, and Gender

But today, that veneer has been shattered. The methodology and the ethics of the Dutch protocol have drawn fierce criticism.<sup>24</sup> A 2021 UK study designed to replicate the reportedly rosy outcomes from the 2014 Dutch study failed to do so, finding instead "no changes in psychological function."<sup>25</sup> A 2023 re-analysis of the UK data reported that while most "participants experience no reliable change in distress across all time points," a substantial portion (15-34%) actually saw their mental health

Nonconforming People, Ver. 7, 13 (2012), [hereinafter "WPATH SOC7"], https://www.wpath.org/publications/soc; J. Rafferty, APP Comm. on Psychosocial Aspects of Child and Family Health; Comm. on Adolescence, APP Comm. on Adolescence; APP Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness, *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142 Pediatrics 1 (2018), https://doi.org/10.1542/peds.2018-2162.

<sup>&</sup>lt;sup>24</sup> Biggs, *supra* n.20 at 362. ("Evidence for the benefits of puberty suppression must be acknowledged as slender." "The decision to rely on uncontrolled studies was exacerbated by other decisions. The Dutch clinicians chose incommensurable scales to measure gender dysphoria, which calls into question their finding that dysphoria declined following cross-sex hormones and surgery.").

<sup>&</sup>lt;sup>25</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 1 (2021), <u>https://doi.org/10.1371/journal.pone.0243894</u> (failing to replicate Dutch study).

outcomes "reliably deteriorate," an outcome that contradicts the earlier

Dutch reports.<sup>26</sup>

Several veteran researchers recently warned:

[The gender industry] has a penchant for exaggerating what is known about the benefits of [youth medical gender transition], while downplaying the serious health risks and uncertainties .... As a result, a false narrative has taken root. It is that "gender-affirming" medical and surgical interventions for youth are as benign as aspirin, as wellstudied as penicillin and statins, and as essential to survival as insulin for childhood diabetes-and that the vigorous scientific debate currently underway is merely "science denialism" motivated by ignorance, religious zeal, and transphobia .... This highly politicized and fallacious narrative, crafted and promoted by clinician-advocates, has failed to withstand scientific scrutiny internationally, with public health authorities in Sweden, Finland, and most recently England doing a U-turn on pediatric gender transitions in the last 24 months. In the U.S., however, medical organizations so far have chosen to use their eminence to shield the practice of pediatric 'gender affirmation' from scrutiny.<sup>27</sup>

<sup>&</sup>lt;sup>26</sup> Compared to the 15-34% who deteriorated, between 9-29% reliably improved. Susan McPherson & David E. P. Freedman, *Psychological Outcomes of 12–15-Year-Olds with Gender Dysphoria Receiving Pubertal Suppression in the UK: Assessing Reliable and Clinically Significant Change*, J Sex Marital Ther (2023), <u>https://doi.org/10.1080/0092623X.2023.2281986</u>.

<sup>&</sup>lt;sup>27</sup> E. Abbruzzese, Stephen B. Levine & Julia W. Mason, *The Myth of "Reliable Research" in Pediatric Gender Medicine: A critical evaluation* of the Dutch Studies—and research that has followed, 49 J Sex Marital Ther 673 (2023), <u>https://doi.org/10.1080/0092623X.2022.2150346</u> (internal citations omitted).

Even in the Netherlands, the façade of consensus surrounding the Dutch protocol and medical interventions for minors is collapsing. Dutch legal advocates, ethicists, journalists, and clinicians have expressed growing alarm over the stark evidence of irreversible harm to minors and the vanishingly small evidence that minors benefit from these interventions. A recent documentary, The Transgender Protocol, turned its spotlight on the "fundamental flaws" of the original Dutch research and the crucial questions—such as the effect of puberty suppression on brain development-that remain unexplored.28 A scathing November 2023 critique of the Amsterdam Gender Team's clinical lesson on "gender incongruence" in minors was bluntly critical: "The first and most fundamental problem is that treatment with puberty blockers and crosssex hormones (hormones of the opposite biological sex) are still given as regular treatment in the Netherlands, while the scientific basis is very weak."29 Contrasting the growing numbers of young people seeking

<sup>&</sup>lt;sup>28</sup> Bernard Lane, In the Dark: A major documentary in the Netherlands shakes the foundations of gender medicine, Gender Clinic News, Oct. 28, 2023, <u>https://www.genderclinicnews.com/p/in-the-dark.</u>

<sup>&</sup>lt;sup>29</sup> Jilles Smids & Patrik Vankrunkelsven, Uncertainties surrounding current gender care: Five Problems with the Gender Incongruent Youth Clinical Lesson, Ned Tijdschr Geneeskd, Nov. 7, 2023,

medical gender-transitioning interventions with the alarming results of substantive evidence reviews in Sweden, Finland, and the UK, Dutch ethicists have called for immediate, radical reform.<sup>30</sup>

Several prominent researchers argue that "[f]or children and adolescents, the debate is not whether such transformations are possible, but 'at what age can youth meaningfully consent,' 'upon fulfilling which criteria,' and perhaps most importantly, 'just because we can—should we?<sup>31</sup> They warn that the "intensity of divisiveness within and outside of medicine rarely seen with other clinical uncertainties" has hindered research and left critical questions unanswered, a result that "reflects decidedly different prioritization of *scientific evidence*, *medical ethics*, and *social values*.<sup>32</sup>

<sup>&</sup>lt;u>https://www.ntvg.nl/artikelen/onzekerheden-rond-de-huidige-</u> <u>genderzorg?check\_logged\_in=1</u> (translation on file with amicus counsel).

<sup>&</sup>lt;sup>30</sup> These reviews, and the subsequent calls for reform, have focused primarily on the fact that puberty blockers and cross-sex hormones have become the standard first-line treatment for adolescents expressing gender dysphoria, though the scientific basis supporting these treatments is very weak.

 $<sup>^{31}</sup>$  Levine, et al., supra n.14, at 114 .

 $<sup>^{32}</sup>$  Id. (emphasis in original).

It is certainly true that medical gender-transition interventions for minors have become more popular in recent years. In the fifteen years since U.S. gender clinicians began offering medical gender-transitioning interventions for minors, the number of minors seeking and receiving them has skyrocketed. So too has the number of gender clinics for minors, from one clinic in 2007 to "more than 100."<sup>33</sup> In 2019, Boston Children's opened the first pediatric center for gender surgery, dedicated solely to removing minors' breasts, ovaries, testicles, and genitals as part of medicalized transition.<sup>34</sup> The surgery center reflects gender medicine's risky extension of irreversible interventions to younger and younger adolescents—controversial decisions unsupported by consensus.<sup>35</sup>

<sup>&</sup>lt;sup>33</sup> Chad Terhune, Robin Respaut, and Michelle Conlin, As more transgender children seek medical care, families confront many unknowns, Reuters, Oct. 6, 2022,

<sup>&</sup>lt;u>https://www.reuters.com/investigates/special-report/usa-transyouth-</u> <u>care/</u>.

<sup>&</sup>lt;sup>34</sup> Center for Gender Surgery: Conditions & Procedures, Boston Children's Hospital, <u>https://www.childrenshospital.org/programs/center-gender-surgery-program/conditions-and-treatments</u>.

<sup>&</sup>lt;sup>35</sup> See Hembree, et al., supra n.18, at 3872. See also Christine & Dan Karasic, Age Is Just a Number: WPATH-Affiliated Surgeons' Experiences and Attitudes Toward Vaginoplasty in Transgender Females Under 18 Years of Age in the United States, 14 J Sex Med 624, 625 (2017), <u>https://pubmed.ncbi.nlm.nih.gov/28325535/</u> (urging lowering of recommended age for surgeries); Elizabeth R. Boskey & Judith A.

But market expansion should not be mistaken for a medical consensus. To the contrary, experts continue to warn that "given the substantial uncertainties about best practice care for these youth, the frontline clinician will have to weigh carefully the benefits and risks of various treatment options and proceed with caution."<sup>36</sup> In short, there has never been a consensus within the medical community on the appropriate standard of care to address gender dysphoria in minors.

#### B. There is a lack of evidence to support medical gendertransitioning interventions.

Plaintiffs-Appellees' claim that medical guidelines supporting medical gender transitioning interventions for minors are "evidencebased" falls short. 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

Johnson, Ethical Issues Considered when Establishing a Pediatric Gender Surgery Center, 143 Pediatr 1, 2 (2019), <u>https://pediatrics.aappublications.org/content/143/6/e20183053.figures-only</u>.

<sup>&</sup>lt;sup>36</sup> Kenneth J. Zucker, Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues, 48 Arch. Sex Behav. 1983 (2019), <u>https://doi.org/10.1007/s10508-019-01518-8</u>.

research funding.<sup>37</sup> Experts admit that the "field of gender-affirming medicine is characterized by a . . . relatively slim (biomedical) evidence base.".<sup>38</sup>

In 2021, Dutch gender clinician Dr. Thomas Steensma acknowledged the lack of research: "Little research has been done so far on treatment with puberty blockers and hormones in young people. That is why it is also seen as experimental . . . . This makes it so difficult, almost all research comes from ourselves."<sup>39</sup> Lawrence Tabak, while serving as the 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

<sup>&</sup>lt;sup>37</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/journalofethics.2016.18.11.stas1-1611.

<sup>&</sup>lt;sup>38</sup> Karl Gerritse et al., *Decision-making approaches in transgender healthcare: conceptual analysis and ethical implications*, 24 Med Health Care Philos 687 (2021), <u>https://doi.org/10.1007/s11019-021-10023-6</u>.

<sup>&</sup>lt;sup>39</sup> Grace Williams, *Dutch puberty-blocker pioneer: "Stop blindly adopting our research,"* 4th Wave Now (March 16, 2021), <u>https://4thwavenow.com/2021/03/16/dutch-puberty-blocker-pioneer-stop-blindly-adopting-our-research/</u>.

dysphoria."<sup>40</sup> Diane Chen, a leading psychologist with Lurie Children's Hospital gender clinic, has 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>41</sup>

Dr. Johanna Olson-Kennedy leads The Trans Youth Research Network, a collaborative, multi-million-dollar research project involving four major gender clinics. The project is necessary, Olson-Kennedy wrote in 2019, because "there is a consensus gap about the 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>42</sup> But in 2023, after five years and nearly \$8 million in federal grants, Dr. Olson-Kennedy's grant renewal

<sup>&</sup>lt;sup>40</sup> Florida Agency for Health Care Admin., *Florida Medicaid: Gen. Accepted Prof'l Med. Standards Determination on the Treatment of Gender Dysphoria*, at 14 (June 2022) [hereinafter Florida Medicaid Report],

https://ahca.myflorida.com/letkidsbekids/docs/AHCA\_GAPMS\_June\_20 22 Report.pdf.

<sup>&</sup>lt;sup>41</sup> Frieda Klotz, *The Fractious Evolution of Pediatric Transgender Medicine*, Undark.org (Apr. 6, 2022), <u>https://undark.org/2022/04/06/the-</u> <u>evolution-of-pediatric-transgender-medicine/</u>.

<sup>&</sup>lt;sup>42</sup> Johanna Olson-Kennedy et al., Creating the Trans Youth Research Network: A Collaborative Research Endeavor, 4 Transgend Health 304, 305 (2019), <u>https://liebertpub.com/doi/full/10.1089/trgh.2019.0024</u>.

application continues to describe a "scant evidence-base currently guiding the clinical care of [transgender/gender diverse] youth," and a continued need for "rigorous scientific evidence outlining the longer-term impact and safety of early treatments based on pubertal development stage."<sup>43</sup>

Other clinicians seeking federal grant funding similarly reference the lack of evidence to support medical interventions in gender-dysphoric minors. A 2022 funding request to research the effect of puberty blockers on minors admits that "[t]he overall impacts of [puberty suppression] have not been systematically studied."<sup>44</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

<sup>&</sup>lt;sup>43</sup> NIH Reporter, *The Impact of Early Medical Treatment in Transgender Youth*, NIH Proj. No. 5R01HD082554-08 (2023 Renewal), <u>https://reporter.nih.gov/search/XpRRv6FfvUGhJqpvQKxCZQ/project-details/10615754</u> (multi-year, four-center study led by Dr. Johanna Olson-Kennedy received \$8,711,908 to date).

<sup>&</sup>lt;sup>44</sup> Eric Nelson et al., *The Impact of Pubertal Suppression on Adolescent Neural and Mental Health Trajectories*, NIH RePORTER (2022), <u>https://reporter.nih.gov/search/Xr4WhUWe906AqRywwpsXVA/project-details/10442698</u>.

understanding the longitudinal impact of treatments that are *already* being used in clinical settings."<sup>45</sup>

A 2023 grant of over half a million dollars to Boston Children's Hospital—where the first U.S. youth gender clinic opened 16 years ago aims to investigate youth skeletal health and bone mass because "[l]ittle is known about how pubertal blockade, the first step in the medical management of a young transgender adolescent, affects bone health and psychological well-being."<sup>46</sup>

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

Plaintiffs-Appellees' reliance on guidelines by WPATH and the Endocrine Society is misguided. Endorsements neither create a standard of care nor imply a fundamental right to access controversial medical treatments. Gender clinicians, like Plaintiffs-Appellees, promote the

<sup>&</sup>lt;sup>45</sup> David S. Hong et al., Sex Hormone Effects on Neurodevelopment: Controlled Puberty in Transgender Adolescents, NIH RePORTER (2020),

<sup>&</sup>lt;u>https://reporter.nih.gov/search/XPR7Y2lFAEC3glQp53hqPw/project-details/9940793</u> (emphasis added).

<sup>&</sup>lt;sup>46</sup> NIH Reporter, *Skeletal Health and Bone Marrow Composition Among Youth*, NIH Proj. No. 5R01HD101421-04 (2023), <u>https://reporter.nih.gov/search/XpRRv6FfvUGhJqpvQKxCZQ/project-details/10611431</u>.

WPATH guidelines as a dispositive summary of the prevailing standard of care for treating "gender dysphoria." Aside from its title "standards of care" (currently, Standards of Care 8 or "SOC 8"), the WPATH document never makes an outright claim that it sets forth a legal, ethical, or professional standard of care. Instead, the guidelines repeatedly emphasize their "flexible" and "adaptable" nature, with "flexible" guidelines, "flexible" expectations, "flexible" assessment models, and "flexible decision-making."47 Indeed, the Centers for Medicare & Medicaid Services (CMS) cited the "flexibility" of WPATH's previous version (SOC 7) when it declined to endorse WPATH guidelines for Medicare coverage determinations.<sup>48</sup> Further, although WPATH states that its recommendations are based on "data derived" from systematic evidence reviews "where available," (emphasis added), it also admits that its recommendations otherwise rely on "background reviews and expert

<sup>47</sup> E. Coleman et al., *Standards of Care for the Health of Transgender* and Gender Diverse People, Ver. 8, 23 Int'l J. Transgend Health S1, S3 (2022), <u>https://doi.org/10.1080/26895269.2022.2100644</u>.

<sup>48</sup> CMS, Decision Memo for Gender Dysphoria and Gender Reassignment Surgery, CAG–00446N, Aug. 30, 2016 [hereinafter "CMS Decision Memo"], <u>https://www.cms.gov/medicare-coverage-database/view/ncacaldecision-memo.aspx?proposed=N&NCAId=282</u>. opinions."<sup>49</sup> Unlike true evidence-based standards, SOC 8 fails to align the quality of the evidence it cites with the chosen strength of its recommendations. Nor does SOC 8 evaluate the available evidence according to "risk of bias, imprecision, inconsistency, indirectness . . . or publication bias," unlike reliable substantive evidence reviews that use GRADE methodology.<sup>50</sup>

WPATH SOC 8 appears to place little emphasis on diagnosing a particular condition for which treatment would be warranted. Indeed, a 2023 narrative review of literature pertaining to the use of "feminizing GAHT" (gender-affirming hormone therapy) noted that the WPATH SOC 8 no longer requires GAHT to be prescribed in the context of "a diagnosis of gender dysphoria."<sup>51</sup> Instead, WPATH SOC 8 describes GAHT as an

<sup>&</sup>lt;sup>49</sup> E. Coleman, et al., *supra* n.47 at S3.

<sup>&</sup>lt;sup>50</sup> See, e.g., the more rigorous approach of the Swedish evidence review: Jonas F. Ludvigsson, et al., *A systematic review of hormone treatment for children with gender dysphoria and recommendations for research*, 112 Acta Paediatr 2279 (2023), <u>https://doi.org/10.1111/apa.16791</u>. *See also*, Reed Siemieniuk and Gordon Guyatt, *What is GRADE*, BMJ Best Practice, Evidence-based medicine Toolkit,

https://bestpractice.bmj.com/info/us/toolkit/learn-ebm/what-is-grade (last visited Dec. 11, 2023).

<sup>&</sup>lt;sup>51</sup> Deepshika Sudhakar, et al., *Feminizing gender-affirming hormone* therapy for the transgender and gender diverse population: an overview

"aid" in "the development of secondary feminine sex characteristics" and "suppressing secondary male sex characteristics" and permits "nonspecialists" to prescribe GAHT, thus eliminating not only the previously required "gender dysphoria" diagnosis but also eliminating the required provider expertise to assess mental health stability or differential diagnoses.<sup>52</sup>

The WPATH "standards of care" fail to measure up in other ways as well. They lack the rigor and evidence base necessary to qualify as authoritative standards of care or clinical practice guidelines (CPGs).<sup>53</sup>

of treatment modality, monitoring, and risks, 42 Neurourol Urodyn 903, 905 (2023), <u>https://doi.org/10.1002/nau.25097</u>.

<sup>52</sup> Id.

<sup>&</sup>lt;sup>53</sup> Deutsch et al., *supra* n.37, at 1099. ("Over the years, [WPATH's SOC] has evolved substantially, yet it remains largely based on lower-quality evidence (i.e., observational studies) and expert opinion, and with a scope that remains limited primarily to describing best practices for the diagnosis of gender dysphoria and assessing readiness and appropriateness for interventions. SOC v7 lacks any rating of the quality of the available evidence or strength of the recommendations or description of how expert contributors are selected to participate in the process of developing the guidelines.").

According to the U.S. Institute of Medicine ("IOM"), 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

According to a 2021 first-of-its-kind systematic analysis<sup>54</sup> of international CPGs for "gender minority/trans health" published in the British Medical Journal (BMJ), "WPATH SOCv7 *cannot* be considered 'gold standard" (emphasis added).<sup>55</sup> None of the twelve international gender medicine guidelines assessed in the BMJ review met the rigorous standard for clinical practice guidelines (or standards of care), but WPATH guidelines were singled out for particularly strong criticism and fell far short of an authoritative standard of care.<sup>56</sup>

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." IOM Comm. on Standards for Developing Trustworthy Clinical Practice Guidelines, *Clinical Practice Guidelines We Can Trust* 3 (Robin Graham et al. eds., 2011). <u>https://www.ncbi.nlm.nih.gov/books/NBK209546/</u> (cleaned up).

<sup>&</sup>lt;sup>54</sup> Sara Dahlen et al., Int'l Clinical Practice Guidelines for Gender Minority/Trans People: Systematic Review and Quality Assessment, 11 BMJ Open 1 (2021), <u>https://doi.org/10.1136/bmjopen-2021-048943</u> ("This is the first systematic review using a validated quality appraisal instrument of international CPGs addressing gender minority/trans health.").

<sup>&</sup>lt;sup>55</sup>*Id*. at 8.

 $<sup>^{56}</sup>$  Id. (referencing the "incoherence" of WPATH SOCv7).

The Endocrine Society's guidelines are similarly inadequate. Like the WPATH "standards," the Endocrine Society guidelines rely on "low" and "very low" quality evidence and include a disclaimer stating that its "guidelines cannot guarantee any specific outcome, nor do they establish a standard of care."<sup>57</sup>

In sum, no current guidelines for treating gender dysphoria, much less the guidelines by WPATH and the Endocrine Society, qualify as an authoritative CPG or standard of care. Indeed, clinicians with diverse perspectives on transitioning treatments for minors recognize that no medical consensus exists. For example, in 2015, medical "proponents and opponents of early treatment (pediatric endocrinologists, psychologists, psychiatrists, ethicists) of 17 treatment teams worldwide"<sup>58</sup> convened to discuss ethical concerns surrounding the WPATH and Endocrine Society recommendations supporting medical transitioning for minors. The convening identified seven areas of debate regarding the controversial

<sup>&</sup>lt;sup>57</sup> Hembree, et al., *supra* n.18, at 3895.

<sup>&</sup>lt;sup>58</sup> Lieke Josephina Jeanne Johanna Vrouenraets et al., *Early Medical Treatment of Children and Adolescents with Gender Dysphoria: An Empirical Ethical Study*, 57 J Adolesc Health 367 (2015), <u>https://doi.org/10.1016/j.jadohealth.2015.04.004</u>.

treatments and concluded that "as long as debate remains on these seven themes and only limited long-term data are available, there will be no consensus on treatment."<sup>59</sup> Not surprisingly, Gordon Guyatt, a renowned expert on GRADE methodology and standards of care, has sharply criticized the U.S. practice of medicalized interventions for minors as "untrustworthy."<sup>60</sup>

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>61</sup> Indeed, Mount Sinai eventually developed its own criteria

<sup>61</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 Transgend Health 166, 170 (2020), <u>https://doi.org/10.1089/trgh.2019.0066</u>.

 $<sup>^{59}</sup>$  *Id*.

<sup>&</sup>lt;sup>60</sup> Gordon H. Guyatt (@GuyattGH), Twitter (Mar. 29, 2023, 3:00 PM), <u>https://twitter.com/GuyattGH/status/1641183448063967233</u> ("Current American guidelines for managing gender dysphoria in adolescents [are] untrustworthy. Don't acknowledge the very low certainty evidence regarding alternatives and do not make the very guarded weak/conditional recommendations appropriate for such evidence.").

for transitioning treatments—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>62</sup>

Several federal 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) ("WPATH's Standards of Care are not universally endorsed"); Kosilek v. Spencer, 774 F.3d 63, 88 (1st Cir. 2014) (en banc) ("[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) (criticizing district court for finding WPATH standards "authoritative for treating gender dysphoria in prison" without considering arguments over the 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 evaluating 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 are merely criteria promulgated by a controversial private organization with a declared point of view").

Furthermore, as detailed in the Family Research Council's amicus brief filed in this case, proponents of medical interventions in genderdysphoric minors routinely overstate the clinical impact of WPATH's guidelines, particularly the recommendation that a mental health provider diagnose a minor's gender dysphoria.<sup>63</sup>

## D. Proponents of medical gender-transitioning interventions for minors have suppressed evidencebased research and discourse.

Plaintiffs-Appellees claim that WPATH and Endocrine Society guidelines are "widely accepted," yet any dissenting views are routinely suppressed. For example, in February 2023, transgender activists succeeded in pressuring a renowned journal, the Archives of Sexual Behavior, to retract an original research article on "Rapid Onset Gender

<sup>&</sup>lt;sup>63</sup> Brief for Family Research Council as Amicus Curiae Supporting Appellants and Reversal at 8-18, *State of Texas v. Loe*, No. 23-0697 (Tex. Oct. 26, 2023).

Dysphoria: Parent Reports on 1655 Possible Cases."<sup>64</sup> The authors, researchers Michael Bailey and Suzanna Diaz, were informed that journal editors retracted the article because it lacked advance, specific permissions from survey respondents, a spurious reason. In a public essay, Bailey explained the real reason: "It was retracted because it provided evidence for an idea that activists hate."<sup>65</sup>

Scientific inquiry is stunted when activists, clinicians, or medical associations attempt to silence or punish those who question medicalized transition, produce research that does not align with favored conclusions, or caution against rushing children into transitioning treatments without adequate psychological assessments. Dr. Kenneth Zucker, a highly regarded researcher, clinician, and journal editor, was deplatformed at several national transgender health conferences after activists denounced his caution regarding transitioning treatments for minors as "transphobic."<sup>66</sup> Zucker's emphasis on psychotherapy for

<sup>&</sup>lt;sup>64</sup> Michael Bailey, *My research on gender dysphoria was censored, but I won't be*, Free Press (July 10, 2023), <u>https://www.thefp.com/p/trans-activists-killed-my-scientific-paper</u>.

 $<sup>^{65}</sup>$  *Id*.

<sup>&</sup>lt;sup>66</sup> Jesse Singal, *How the Fight Over Transgender Kids Got a Leading Sex Researcher Fired*, The Cut, N.Y. Mag. Magazine, Feb. 7, 2016,

minors was demonized as "conversion therapy," and his gender clinic shuttered.<sup>67</sup> (Zucker later prevailed in a defamation claim against his former employer.<sup>68</sup>) Similarly, when Brown University physicianresearcher Lisa Littman published a study describing how peers and social media might influence the onset of gender dysphoria in adolescent females (a phenomenon dubbed "rapid onset gender dysphoria"), activists sought to silence her and discredit her work. Her published study was withdrawn and subject to additional scrutiny before being republished; her research contract was not renewed.<sup>69</sup>

A 2022 *New York Times* article highlighted growing divisions among gender clinicians over the appropriate care for adolescents seeking transitioning treatments.<sup>70</sup> Drs. Anderson and Edwards-Leeper

<sup>&</sup>lt;u>https://www.thecut.com/2016/02/fight-over-trans-kids-got-a-researcher-fired.html</u>.

 $<sup>^{67}</sup>$  Id.

<sup>&</sup>lt;sup>68</sup> Id.

<sup>&</sup>lt;sup>69</sup> Jonathan Kay, An Interview with Lisa Littman Who Coined the Term "Rapid Onset Gender Dysphoria," Quillette (Mar. 19, 2019), <u>https://quillette.com/2019/03/19/an-interview-with-lisa-littman-who-</u> <u>coined-the-term-rapid-onset-gender-dysphoria/</u>.

<sup>&</sup>lt;sup>70</sup> Emily Bazelon, *The Battle Over Gender Therapy*, N.Y. Times Mag., June 15, 2022, <u>https://www.nytimes.com/2022/06/15/magazine/gender-therapy.html</u>.

are applauded by colleagues who share their concerns, but other clinicians deride their emphasis on pre-transition psychological assessments as "discriminatory" and "reek[ing] of some old kind of conversion-therapy-type things."<sup>71</sup>

The toxic climate that seeks to impose a false medical consensus regarding the appropriate standard of care for gender dysphoria or gender-transitioning treatments impedes quality research and undermines sound clinical practice.

## E. The lack of medical consensus is reflected internationally.

Plaintiffs-Appellees' assertion that medical interventions for gender dysphoria are safe, effective, and medically necessary is undercut by the international medical community. Many countries that initially embraced gender-transitioning interventions, including for minors, are now reconsidering. 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

<sup>&</sup>lt;sup>71</sup> *Id.* (quoting psychologist and physician Colt St. Amand).

treatment for those under 18 currently outweigh the possible benefits."<sup>72</sup> Finland likewise reversed course. Following an extensive literature review, the Finnish Health Authority issued new guidelines prioritize psychotherapy as the first-line treatment for gender-dysphoric minors.<sup>73</sup>

In the United Kingdom, whistleblower complaints exposed the inadequate psychological care for gender-dysphoric minors at the National Health Service's (NHS) gender clinic.<sup>74</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

<sup>&</sup>lt;sup>72</sup> Socialstyrelsen, Support, Investigation and Hormone Treatment for Gender Incongruence in Children and Adolescents (2022),; see also Lisa Nainggolan, Hormonal Tx of Youth with Gender Stops in Sweden, Medscape (2021), <u>https://www.medscape.com/viewarticle/950964</u>.

<sup>&</sup>lt;sup>73</sup> PALKO/COHERE Finland, Recommendation of the Council for Choices in Health Care in 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\_Un official%20Translation.pdf. COHERE works in conjunction with the Ministry of Social Affairs and Health.

<sup>&</sup>lt;sup>74</sup> Lauren Lewis, NHS's Only Gender Service Children Believes All Girls Who Don't Like 'Pink Ribbons and Dollies' Must Be Transgender, Whistleblower Claims, Daily Mail, Nov. 22, 2021, <u>https://www.dailymail.co.uk/news/article-10231507/NHSs-gender-service-children-believes-girls-dont-like-pink-transgender.html</u>.

of puberty blockers and instituted new procedures to ensure better psychological care.<sup>75</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>76</sup> A 2022 independent review commissioned by NHS England (the "Cass Report"), found that "[a]t present the professional community does not have a shared understanding about the meaning of gender

<sup>75</sup> Becky McCall, *NHS Makes Child Gender Identity Service Changes After High Court Ruling*, Medscape, Dec. 4, 2020, <u>https://www.medscape.com/viewarticle/941781</u>.

<sup>76</sup> NICE, Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria (2021) (https://cass.independent-review.uk/wp-

content/uploads/2022/09/20220726\_Evidence-review\_GnRHanalogues For-upload Final.pdf); NICE, Evidence Review: Gender-Affirming Hormones for Children and Adolescents with Gender Dysphoria (2021) (https://cass.independent-review.uk/wpcontent/uploads/2022/09/20220726\_Evidence-review\_Gender-affirminghormones For-upload Final.pdf), [hereinafter, collectively, "NICE Evidence Review"]. dysphoria in young people," its cause, or best treatment approaches.<sup>77</sup> 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."<sup>78</sup>

Denmark recently confirmed reports that it, too, has adopted a more cautious approach to treating gender-dysphoric minors. Because of the evidence reviews conducted by Sweden and Finland, the rise in adolescents presenting with significant psychiatric issues, and the resulting ethical concerns over the use of medicalized interventions in minors, Denmark now prioritizes the use of psychotherapeutic treatments as it moves towards a revision of its clinical guidelines.<sup>79</sup>

<sup>&</sup>lt;sup>77</sup> Hilary Cass, *Review of Gender Identity Services for Children and Young People*, BMJ 376 (2022),

https://www.bmj.com/content/376/bmj.o629.

 $<sup>^{78}</sup>$  Id.

<sup>&</sup>lt;sup>79</sup> Denmark joins the list of countries that have sharply restricted youth gender transitions, Soc. Evidence-based Gender Med. (Aug. 17, 2023), <u>https://segm.org/Denmark-sharply-restricts-youth-gender-transitions</u>. Here, the Society of Evidence-based Gender Medicine, which collects social science related to treatments for gender dysphoria, offers a synopsis of and an English translations of parts of the has offered an English translation of sections of the Danish report. One such section reads as follows:

Several countries, including Denmark, have adopted a more cautious approach to hormone therapy until more evidence of its beneficial effects is available [2, 17]. In particular, there is

Psychotherapists in Australia and New Zealand have also issued a new policy statement emphasizing mental health treatment for genderdysphoric minors, not "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>80</sup>

Finally, in February 2022, France's National Academy of Medicine likewise warned medical professionals that the increase in young people seeking transitioning treatments may be due to social contagion and accordingly urged "great medical caution [with] children and adolescents, given the vulnerability, particularly psychological, of this population and

a lack of knowledge about the increasing proportion of young people with onset of gender-related discomfort after puberty [2, 17, 23] and the presumably increasing proportion with mental disorders, as new studies suggest that the positive effects are not replicated in this group [22, 29]. There is a need for healthcare services that can be flexibly adapted in the future and systematic international cooperation in research and exchange of experience.

<sup>&</sup>lt;sup>80</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, <u>https://www.ranzcp.org/news-policy/policy-and-advocacy/positionstatements/gender-dysphoria</u>.

the many undesirable effects, and even serious complications, that some of the available therapies can cause."<sup>81</sup>

# F. The federal government has recognized the lack of medical consensus.

Despite the efforts under the current administration to push gender-transitioning interventions for youth, the federal government has never formally determined that such treatments are the appropriate standard of care. As recently as June 2020, Department of Health and Human Services (HHS) regulations acknowledged "there is no medical consensus to support one or another form of treatment for gender dysphoria."<sup>82</sup> The Department explained that 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

<sup>&</sup>lt;sup>81</sup> Press Release, French National Academy of Medicine, Medicine and Gender Transidentity in Children and Adolescents (Feb. 25, 2022) <u>https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/?lang=en</u>.

<sup>&</sup>lt;sup>82</sup> Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160, 37,198 (Aug. 4, 2022).

National Coverage Determination.<sup>83</sup> After its fact-finding, 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>84</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 Medicare beneficiaries [which includes non-seniors] with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively."<sup>85</sup>

Similarly, a 2018 Department of Defense report 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

 $^{85}$  Id.

 $<sup>^{83}</sup>$  *Id*.

<sup>&</sup>lt;sup>84</sup> CMS Decision Memo, *supra* n.48, at 49.

dysphoria."<sup>86</sup> Indeed, none of the drugs used to block puberty and induce cross-sex 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>87</sup>

### G. State action reflects the lack of medical consensus.

State actions also reflect the lack of medical consensus for the appropriate standard of care for gender dysphoria and gendertransitioning treatment, especially for minors. For instance, in addition to Texas, at least twenty-two states have passed laws that prohibit

<sup>86</sup> Dep't of Defense, Report and Recommendations on Military Service by Transgender Persons 5 (Feb. 22, 2018), available at <u>https://media.defense.gov/2018/Mar/23/2001894037/-1/-1/0/MILITARY-SERVICE-BY-TRANSGENDER-INDIVIDUALS.PDF</u>.

<sup>&</sup>lt;sup>87</sup> See Juliana Bunim, First U.S. Study of Transgender Youth Funded by NIH, U.C.S.F., Aug. 17, 2015, <u>https://perma.cc/URA6-CERX</u>.

providing minor children with gender-transitioning treatments.<sup>88</sup> Other states are considering similar bills.<sup>89</sup>

State executives also have weighed in on the issue. Most notably here, the Texas Attorney General issued an opinion letter in February 2022 stating that sterilizing treatments and other permanent "sexchange procedures," including puberty suppression, cross-sex hormones, and various surgeries, "can constitute child abuse when performed on minor children."<sup>90</sup> Governor Abbott subsequently directed the Texas

<sup>&</sup>lt;sup>88</sup> See Ala. S.B. 184 (2022); Ariz. S.B. 1138 (2022); Ark. H.B. 1570 (2021); Fla. Admin. Code 64B8-9.019 and S.B. 254 (2023); Ga. S.B. 140 (2023); Idaho H.B. 71 (2023); Ind. S.B. 480 (2023); Iowa S.F. 538 (2023); Ky. S.B. 150 (2023); La. H.B. 648 (2023); Miss. H.B. 1125 (2023); Mo. S.B. 49 (2023); Mont. S.B. 99 (2023); Neb. L.B. 574 (2023); N.C. H.B. 808 (2023); N.D. H.B. 1254 (2023); Okla. S.B. 613 (2023); S.D. S.B. 1080 (2023); Tenn. H.B. 0578 (2021); Tenn. S.B. 1/H.B. 1 (2023); Utah S.B. 16 (2023); W. Va. H.B. 2007 (2023); see also L. W. by & through Williams v. Skrmetti, 83 F.4th 460, 471 (6th Cir. 2023) (listing 19 states that had passed laws similar to the Tennessee and Kentucky restrictions at issue in that case).

<sup>&</sup>lt;sup>89</sup> See, e.g., Emily Sanderson, Ohio lawmakers to return to session early, saying top priority is overriding veto of House Bill 68, WLWT 5, Jan. 4, 2023, <u>https://www.wlwt.com/article/house-bill-68-ohio-lawmakers-veto-</u> <u>dewine-transgender/46276170#</u>.

<sup>&</sup>lt;sup>90</sup> Tex. Att'y Gen. Op. Letter No. KP-0401, from Ken Paxton, Att'y Gen., to Matt Krause, Chair, House Comm. on Gen. Investigating, Tex. House of Reps. 1-2 (Feb. 18, 2022),

https://www.texasattorneygeneral.gov/sites/default/files/opinionfiles/opinion/2022/kp-0401.pdf.

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>91</sup>

Additionally, Florida's Department of Health issued guidelines in 2022 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 surgeries because of "the lack of conclusive evidence, and the potential for long-term, irreversible effects."<sup>92</sup>

<sup>91</sup> Letter from Greg Abbott, Gov., State of Tex., to Jaime Masters, Comm'r, Tex. Dep't of Fam. and Protective Servs. (Feb. 22, 2022), <u>https://gov.texas.gov/uploads/files/press/O-</u>
<u>MastersJaime202202221358.pdf</u>. *Cf. In re Abbott*, 645 S.W.3d 276, 284 (Tex. 2022) (finding the Attorney General's opinion and the Governor's related directive nonbinding).

<sup>92</sup> Office of the State Surgeon Gen., Fla. Dep't of Health, Treatment of Gender Dysphoria for Children and Adolescents (Apr. 20, 2022), <a href="https://www.floridahealth.gov/\_documents/news-room/press-releases/2022/04/20220420-gender-dysphoria-guidance.pdf">https://www.floridahealth.gov/\_documents/news-room/press-releases/2022/04/20220420-gender-dysphoria-guidance.pdf</a>; cf. Setting the Record Straight, Florida Agency for Health Care Administration (2022), <a href="https://ahca.myflorida.com/LetKidsBeKids/page3.shtml">https://ahca.myflorida.com/LetKidsBeKids/page3.shtml</a> ("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").

The Florida Secretary of the Agency for Health Care Administration subsequently requested that the Florida Medicaid program review whether such treatments are "consistent with generally accepted professional medical standards."<sup>93</sup> The report, published on June 2, 2022, found that gender-transitioning interventions 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]."<sup>94</sup>

## II. Gender-transitioning interventions can lead to serious harms, especially in minors.

Recent studies support the Texas Legislature's finding that transitioning treatments can cause significant harms.<sup>95</sup> Long-term outcomes for individuals who undergo gender-transitioning treatments are not promising. Those who have had genital surgery are nineteen

<sup>&</sup>lt;sup>93</sup> Florida Medicaid Report, *supra* n.40, at 2.

<sup>&</sup>lt;sup>94</sup> See Report Overview, Fl. Agency for Health Care Admin. (2022), <u>https://ahca.myflorida.com/letkidsbekids/</u>.

<sup>&</sup>lt;sup>95</sup> Tex. House Rsch. Org., Bill Analysis, SB 14 at 3 (May 12, 2023), <u>https://hro.house.texas.gov/pdf/ba88r/sb0014.pdf</u>.

times more likely than the general population to die by suicide,<sup>96</sup> and studies show that transitioning treatments fail to reduce suicide risks and mental health issues in the long-term.<sup>97</sup>

Equally troubling, the number of children 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."<sup>98</sup> The typical patient profile has changed markedly. In the past, patients seeking treatment for gender dysphoria were usually either adult males or very

<sup>96</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>97</sup> Roberto D'Angelo et al., One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria, 50 Arch Sex Behav 7 (2020), <u>https://doi.org/10.1007/s10508-020-01844-2</u>; 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 Psychiatr Scand 486 (2020), <u>https://doi.org/10.1111/acps.13164</u>; Correction to Branstrom and Pachankis, 177 Am. J. Psychiatry 734 (2020) (correcting Richard Branstrom 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)).

<sup>98</sup> Zucker, *supra* n.36, at 1983.

young children, mostly male. Today, the typical patient is an adolescent, usually female.<sup>99</sup>

For years, gender dysphoria in children was addressed through "watchful waiting" or family therapy. Under this approach, which attended to children's gender dysphoria without gender-transitioning interventions (social or medical), children's dysphoria resolved naturally by the onset of puberty about eighty-eight percent of the time.<sup>100</sup> The "gender-affirming" approach changed that pattern dramatically: 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>101</sup>

 $<sup>^{99}</sup>$  Id.

 $<sup>^{100}</sup>$  Singh et al., supra n.6, at 8.

<sup>&</sup>lt;sup>101</sup> Carmichael et al., *supra* n.25, at 12 (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 Arch Sexual Behav. 3353 (2021), <u>https://doi.org/10.1007/s10508-021-02163-w</u>.

Clinical concerns over gender-transition interventions have escalated.<sup>102</sup> Puberty blockers, originally praised as safe and fully reversible, are known to have negative effects on bone density, social and emotional maturation, and other aspects of neuro-development.<sup>103</sup> They generally fail to lessen the child's gender dysphoria and deliver mixed results for mental health.<sup>104</sup> Long term effects remain unknown.<sup>105</sup>

Nearly all children who begin puberty blockers go on to receive cross-sex hormones, with life-altering consequences.<sup>106</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>107</sup> Gender clinicians also admit that puberty

<sup>&</sup>lt;sup>102</sup> William Malone, *Puberty Blockers for Gender Dysphoria: The Science is Far from Settled*, 5 Lancet Child & Adolescent Health 33 (2021), https://doi.org/10.1016/s2352-4642(21)00235-2.

<sup>&</sup>lt;sup>103</sup> NICE Evidence Review, *supra* n.76, at 6-8.

 $<sup>^{104}</sup>$  Carmichael et al., *supra* n.25, at 12-17.

<sup>&</sup>lt;sup>105</sup> Diane Chen et al., Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Pubertal Suppression in Transgender Youth, 5 Transgend Health 246 (2020), <u>https://doi.org/10.1089%2Ftrgh.2020.0006</u>.

 $<sup>^{106}</sup>$  Id.

<sup>&</sup>lt;sup>107</sup> Stephen B. Levine, *Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria*, 44 J Sex Marital Ther 29 (2018), https://doi.org/10.1080/0092623x.2017.1309482.

suppression may impair the child's later sexual functioning as an adult.<sup>108</sup> These losses cannot be fully comprehended by a child, making informed consent impossible.

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>109</sup> They increase cardiovascular risks and cause liver and metabolic changes.<sup>110</sup> The flood of opposite-sex hormones has variable emotional and psychological effects as well. Females taking testosterone experience an increase in gender dysphoria, which heightens the

<sup>&</sup>lt;sup>108</sup> Abigail Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, Real Clear Politics, Oct. 5, 2021,

<sup>&</sup>lt;u>https://www.realclearpolitics.com/2021/10/05/top\_trans\_doctors\_blow\_th</u> <u>e\_whistle\_on\_sloppy\_care\_553290.html.</u>

<sup>&</sup>lt;sup>109</sup> IMAP Statement on Hormone Therapy for Transgender and Gender Diverse Persons, Intl. Med. Advisory Panel at 9-11 (June 2023), <u>https://www.ippf.org/file/14216/</u>.

<sup>&</sup>lt;sup>110</sup> Gender-Affirming Hormone in Children and Adolescents, BJM EBM Spotlight (Feb. 25, 2019),

https://blogs.bmj.com/bmjebmspotlight/2019/02/25/gender-affirminghormone-in-children-and-adolescents-evidence-review/.

likelihood they will undergo double mastectomies—as young as thirteen.<sup>111</sup>

Far from an evidence-based standard of care, gender-transitioning treatments for gender dysphoria amount to unethical human experimentation—on *children*. One Swedish teen who underwent medical transition, suffered serious bodily harm, and then detransitioned has described her experience in stark terms: "They're experimenting on young people . . . we're guinea pigs."<sup>112</sup> Or, as psychotherapist Alison Clayton warns, this is "dangerous medicine."<sup>113</sup>

## CONCLUSION

The Texas Legislature passed S.B. 14 to advance its compelling interest in protecting minors from harm. As documented above, the Texas

<sup>&</sup>lt;sup>111</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 Pediatr 431 (2018), <u>https://doi.org/10.1001/jamapediatrics.2017.5440</u> (Figure: Age at Chest Surgery in the Post-surgical Cohort).

<sup>&</sup>lt;sup>112</sup> Video, Mission: Investigate: Trans Children ("Trans Train 4"), Nov. 26, 2021, <u>https://www.svtplay.se/video/33358590/uppdrag-</u> granskning/mission-investigate-trans-children-avsnitt-1.

<sup>&</sup>lt;sup>113</sup> Alison Clayton, *The Gender Affirmative Treatment Model for Youth with Gender Dysphoria: A Medical Advance or Dangerous Medicine?*, 51 Arch Sex Behav 691 (2022), <u>https://doi.org/10.1007%2Fs10508-021-02232-0</u>.

Legislature had substantial grounds on which to reasonably determine that there is no medical consensus in favor of medical gendertransitioning treatments, that these medical interventions harm minors, and that, consequently, the known risks of the procedures described in S.B. 14 outweigh any proven benefits. The Plaintiffs-Appellees vigorous advocacy and enthusiastic support for the Endocrine Society's and WPATH's slanted guidelines cannot change this.

For all these reasons, S.B. 14 is a lawful exercise of state power. This Court should therefore uphold S.B. 14 and the Legislature's efforts to protect Texas' children from dangerous, unproven, and irreversible medical interventions that threaten permanent bodily harm and sterilization. January 16, 2024

Respectfully submitted,

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