# UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF FLORIDA TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v.

Case No. 4:22-CV-00325-RH-MAF

JASON WEIDA, et al.,

Defendants.

MOTION FOR LEAVE TO FILE AMICUS CURIAE BRIEF BY ALABAMA, ARKANSAS, GEORGIA, INDIANA, IOWA, KENTUCKY, LOUISIANA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NORTH DAKOTA, SOUTH CAROLINA, TENNESSEE, TEXAS, UTAH, AND VIRGINIA

The States of Alabama, Arkansas, Georgia, Indiana, Iowa, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Dakota, South Carolina, Tennessee, Texas, Utah, and Virginia respectfully move for leave to file the attached amicus curiae brief in support of Defendants' Motion for Summary Judgment.

1. This motion and proposed brief is timely because, consistent with this Court's October 3, 2022 order, it is being "submitted by not later than the deadline for the corresponding filing of the party whose position the amicus seeks to support." Doc. 43 at 1-2. That deadline is April 7, 2023. Doc. 67 at 3.

- 2. Amici States have met and conferred with the parties in good faith as required by the Local Rules. Both Plaintiffs and Defendants consent to the filing of the proposed amicus brief.
- 3. Like Florida, amici States have an interest in protecting their authority to enact health and safety laws, including regulating medicine and determining which treatments are appropriate for Medicaid coverage. As fellow regulators in this field, amici States offer a unique perspective to this Court.

WHEREFORE, amici States respectfully request an order granting leave to file the attached brief.

# **INTERESTS OF AMICI CURIAE**

Amici are 17 States seeking to ensure that their "health and welfare laws" continue to be "entitled to a strong presumption of validity." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022) (cleaned up). Plaintiffs challenge Florida's Medicaid regulation based on its alleged inconsistency with "current medical opinion," which they define largely by relying on position statements of their preferred medical interest groups. But States' authority to regulate health and welfare is not beholden to the views of self-interested medical interest groups. That is true under the Constitution and Medicaid laws. Amici States thus have a strong interest in ensuring that the Court rejects Plaintiffs' challenge.

# MEMORANDUM OF LAW IN SUPPORT OF MOTION

Amici States offer a unique and crucial perspective in this case and believe their briefing will benefit the Court. Many of the Amici States have encountered claims similar to those Plaintiffs push here—claims that the views of certain medical interest groups represent a medical consensus to which State regulators must defer. But Plaintiffs' preferred medical interest groups do not represent an unbiased medical perspective, and they represent only a slice of medical opinion on this issue. In their brief, amici States explain how these medical interest groups (1) have incentives that preclude objectivity in this case, (2) have prioritized politics over science by stifling dissenting medical opinions and rebuffing calls from their members for open, systematic reviews of the medical literature, and (3) have proclaimed a false medical consensus that conflicts with conclusions of multiple governmental healthcare authorities in Europe. Amici States thus explain why Plaintiffs' preferred medical interest groups do not provide a reliable answer to whether the treatments at issue in this case are experimental (they are), and why these organizations cannot set this Court's standard for determining the validity of Florida's Medicaid regulation.

# **CONCLUSION**

For these reasons, the amici States respectfully request that this Court grant their motion for leave to file their proposed amicus curiae brief (attached) in support of Defendants' Motion for Summary Judgment.

Dated: April 7, 2023

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# **CERTIFICATE OF WORD COUNT**

According to Microsoft Word, the word processing system used to prepare this brief, there are a total of 217 words contained within the Motion, and a total of 340 words within the Memorandum of Law.

s/ A. Barrett Bowdre
A. Barrett Bowdre

# CERTIFICATE OF SATISFACTION OF ATTORNEY-CONFERENCE REQUIREMENT

Pursuant to Local Rule 7.1(B), counsel conferred with counsel for the parties.

Both Plaintiffs and Defendants indicated that they do not oppose Amici States filing the proposed amicus brief.

s/ A. Barrett Bowdre

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# UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF FLORIDA TALLAHASSEE DIVISION

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BRIEF OF ALABAMA, ARKANSAS, GEORGIA, INDIANA, IOWA, KENTUCKY, LOUISIANA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NORTH DAKOTA, SOUTH CAROLINA, TENNESSEE, TEXAS, UTAH, AND VIRGINIA AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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# **INTERESTS OF AMICI CURIAE**

Amici curiae are the States of Alabama, Arkansas, Georgia, Indiana, Iowa, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Dakota, South Carolina, Tennessee, Texas, Utah, and Virginia.

From the Founding, States have exercised their authority to enact health and safety measures—regulating the medical profession, restricting access to potentially dangerous medicines, banning unsafe or unproven treatments. *Abigail All. For Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 703-05 (D.C. Cir. 2007) (en banc). Indeed, independently weighing the harms and benefits of proposed treatments is an important role of government. So it was when the federal government required testing of COVID vaccines before approving them for use. And so it was in countries like the UK, Finland, Sweden, and Norway, whose healthcare authorities recently examined the evidence regarding transitioning treatments and determined, as Sweden's healthcare authority wrote, that "the risks" of the treatments "currently outweigh the possible benefits" for "adolescents with gender incongruence."

And so it was in Florida. After commissioning a systematic review of the literature, the Florida Agency for Health Care Administration (AHCA) determined that

<sup>&</sup>lt;sup>1</sup> Socialstyrelsen, *Care of children and adolescents with gender dysphoria*, at 3 (Feb. 2022), https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf.

current evidence does not support using puberty blockers, cross-sex hormones, and reassignment surgeries to treat gender dysphoria. Based on that review, and in consultation with experts, the agency promulgated a rule excluding Medicaid coverage of these procedures.

The amici States submit this brief in support of Florida's right to regulate medicine and determine appropriate treatments for Medicaid coverage. "[L]ike other health and welfare laws," Florida's decision is afforded a "strong presumption of validity" and "must be sustained if there is a rational basis on which the [agency] could have thought that it would serve legitimate state interests." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022) (cleaned up). Florida's decision is eminently rational.

# **SUMMARY OF ARGUMENT**

In its preliminary injunction order, this Court relied on *Rush v. Parham*, 625 F.2d 1150 (5th Cir. 1980), to frame the issue before it: "whether, based on current medical knowledge, the state's determination that these treatments are experimental is reasonable." Doc. 64 at 4. The Court noted that this question would largely be answered by "current medical opinion." *Id.* at 304 (quoting 625 F.2d at 1157 n.13). Under this standard, Florida's determination that transitioning treatments are experimental easily passes muster.

First, to the extent Plaintiffs rely on medical interest groups to show that Florida's coverage decision was inconsistent with "current medical opinion," that effort fails. For one, *Rush* does not outsource such regulatory decisions to medical interest groups. Neither do cases involving constitutional challenges to state health laws, which also apply rational-basis review. *E.g.*, *Dobbs*, 142 S. Ct. at 2267 (recognizing that the "position of the American Medical Association" ordinarily does not "shed light on the meaning of the Constitution" (cleaned up)). Indeed, it would be strange if interest groups *did* play a role, as though Medicaid laws or the Fourteenth Amendment require States to seek approval from a surgical society before removing coverage of a lucrative surgical procedure. To state the obvious: Medical interest groups, composed of physicians self-interested in Medicaid coverage, are not neutral arbiters of "medical opinion."

Moreover, there is particular reason to be suspicious of the interest groups in this case. See Doc. 34 (proposed amicus brief by medical interest groups). Evidence suggests that the American Academy of Pediatrics (AAP), the World Professional Association for Transgender Health (WPATH), and the Endocrine Society—the three groups that have promulgated guidelines or treatment statements, see Doc. 34-

<sup>&</sup>lt;sup>2</sup> These cases do not apply an idiosyncratic form of rational-basis review turning on "current medical knowledge," but for purposes of this brief amici assume that the standard from *Rush* applies.

1 at 4, 8-9—operate as advocacy groups on this issue, suppressing dissent and rebuffing repeated calls for open, systematic evidence reviews. These groups do not represent "medical opinion," just an outspoken slice of it.

Second, Florida's decision fits comfortably within the mainstream of medical opinion that has conducted or reviewed systematic assessments of the evidence. Perhaps unsurprisingly, the entities that have done this are *not* the medical interest groups, but governmental medical authorities in countries such as the United Kingdom, Sweden, Finland, and Norway. Based on the evidence reviews they conducted (or are conducting), healthcare authorities in these countries have called for curtailing the availability of transitioning treatments for minors. As the council responsible for the assessment of public healthcare services in Finland put it, "[i]n light of available evidence, gender reassignment of minors is an *experimental* practice." Florida's like conclusion was reasonable.

# I. The Court Should Not Defer To Plaintiffs' Preferred Medical Interest Groups.

Medical interest groups are just that—interest groups. They are usually composed of professionals in a relevant field, though some, like WPATH, include non-

<sup>&</sup>lt;sup>3</sup> Michelle Conlin et al., *Gender Imbalance Emerges Among Trans Teens Seeking Treatment*, REUTERS (Nov. 18, 2022), https://perma.cc/Z4QW-CXR3 (emphasis added).

professionals.<sup>4</sup> Their purpose is to advocate on behalf of their members—which is why WPATH recently described itself in court as "an advocacy organization[]." These groups come with their own point of view, their own causes, and—particularly in this case—their own financial interests. As one physician at Vanderbilt University Medical Center's Clinic for Transgender Health explained, transitioning services are a "big money maker." According to the *New York Times*, double mastectomies—euphemistically called "top surgeries"—"cost[] anywhere from \$9,000 to \$17,000, depending on facility and anesthesia fees."

A recent article in the *The BMJ* (formerly *British Medical Journal*) explained that "[t]hree organisations have had a major role in shaping the US's approach to gender dysphoria care: WPATH, the AAP, and the Endocrine Society." These are the same organizations on which Plaintiffs primarily rely. *See, e.g.*, Doc. 1, ¶¶ 29, 37-41, 47, 89. While these organizations claim to represent "[t]he widely accepted

<sup>&</sup>lt;sup>4</sup> See WPATH Membership Information, WPATH, https://www.wpath.org/MembershipInfo (last accessed Apr. 4, 2023).

<sup>&</sup>lt;sup>5</sup> Boe v. Marshall, No. 2:22-cv-184-LCB (N.D. Ala.), ECF 208 at 3.

<sup>&</sup>lt;sup>6</sup> Amanda Prestigiacomo, 'Huge Money Maker': Video Reveals Vanderbilt's Shocking Gender 'Care,' Threats Against Dissenting Doctors, THE DAILYWIRE (Sept. 20, 2022), https://perma.cc/7ZGW-NDY4.

<sup>&</sup>lt;sup>7</sup> Azeen Ghorayshi, *More Trans Teens Are Choosing 'Top Surgery*,' N.Y. TIMES (Sept. 26, 2022), https://perma.cc/9786-V27T.

<sup>&</sup>lt;sup>8</sup> Jennifer Block, Gender Dysphoria in Young People is Rising—and so is Professional Disagreement, THE BMJ (Feb. 23, 2023), https://www.bmj.com/content/380/bmj.p382.

view of the professional medical community" "that gender-affirming care is the appropriate treatment for gender dysphoria," Doc. 34-1 at 8, there is growing evidence that this is far from true.

#### A. AAP

Start with AAP. It would be one thing if its position statement truly reflected either the state of the science or its membership's views. Instead, the organization has apparently suppressed its membership's desire for an updated statement accurately reflecting the science. A recent resolution "submitted to the AAP's annual leadership forum to inform the academy's 67,000 members about the growing international skepticism of pediatric gender transition" was quashed by "the AAP's leadership," "[e]ven though the resolution was in the top five of interest based on votes by members cast." AAP "decried the resolution as transphobic and noted that only 57 members out of 67,000 had endorsed it," but allowed a motion supporting "affirming" interventions to go through the next week with only 53 members supporting it. As AAP member Dr. Julia Mason concluded, "AAP has stifled debate on how best to treat youth in distress over their bodies, shut down efforts by critics to present

<sup>&</sup>lt;sup>9</sup> Julia Mason & Leor Sapir, *The American Academy of Pediatrics' Dubious Transgender Science*, WALL ST. JOURNAL (Apr. 17, 2022), https://www.wsj.com/articles/the-american-academy-of-pediatrics-dubious-transgender-science-jack-turban-research-social-contagion-gender-dysphoria-puberty-blockers-uk-11660732791.

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

better scientific approaches at conferences, used technicalities to suppress resolutions to bring it into line with better-informed European countries, and put its thumb on the scale ... in favor of a shoddy but politically correct research agenda."<sup>11</sup>

Other reporting supports Dr. Mason's concerns. The 2018 AAP statement was "written by a single doctor," who "conceptualized,' 'drafted,' 'reviewed,' 'revised,' and 'approved' the manuscript himself." By 2019," the position statement "was eliciting quiet concern among rank-and-file doctors affiliated with the AAP." And as one researcher explained, the few "references that AAP cited as the basis of [its] policy instead outright contradicted that policy," and AAP "left out" "the actual outcomes [of] research on [gender dysphoric] children"—disregarding 10 of the 11 studies on this cohort. But "[r] ather than promoting dialogue or compromise," AAP leadership "sought to stifle dissent," "urg[ing] the Department of Justice to investigate critics of 'gender affirming care,' arguing that they were spreading 'disinformation,'" "barr[ing] the Society for Evidence-based Gender Medicine, which advo-

<sup>&</sup>lt;sup>11</sup> *Id*.

<sup>&</sup>lt;sup>12</sup> Aaron Sibarium, *The Hijacking of Pediatric Medicine*, THE FREE PRESS (Dec. 7, 2022), https://www.thefp.com/p/the-hijacking-of-pediatric-medicine; *see* Jason Rafferty, *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142(4) PEDIATRICS (2018).

<sup>&</sup>lt;sup>13</sup> Sibarium, *supra*.

<sup>&</sup>lt;sup>14</sup> James M. Cantor, *Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy*, 46 J. SEX & MARITAL THERAPY 307, 307-13 (2019), https://doi.org/10.1080/0092623X.2019.1698481

cates the watchful waiting approach, from being an exhibitor at its national conference," and "block[ing] a resolution calling for a review of the AAP's current guidance on puberty blockers." <sup>15</sup>

#### B. WPATH

Things are, if anything, only worse at WPATH. As Dr. Stephen Levine, a psychiatrist who "helped to author the fifth version of the [WPATH] Standards of Care" has testified, "WPATH aspires to be both a scientific organization and an advocacy group for the transgendered," and "[t]hese aspirations sometimes conflict." *Kosilek v. Spencer*, 774 F.3d 63, 78 (1st Cir. 2014). According to Dr. Levine, "[s]kepticism and strong alternative views are not well tolerated" at WPATH and "have been known to be greeted with antipathy." *Id.* (alteration omitted). This and other testimony led the First and Fifth Circuits—and, until recently, the U.S. Department of Health and Human Services—to find that "the WPATH Standards of Care reflect not consensus, but merely one side in a sharply contested medical debate." 16

<sup>&</sup>lt;sup>15</sup> Sibarium, *supra*.

<sup>&</sup>lt;sup>16</sup> Gibson v. Collier, 920 F.3d 212, 221 (5th Cir. 2019); see Kosilek, 774 F.3d at 90; Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37160, 37198 (June 19, 2020) (warning of "rel[ying] excessively on the conclusions of an advocacy group (WPATH) rather than on independent scientific fact-finding").

Dr. Ken Zucker was one such professional "greeted with antipathy" by activists at WPATH and its U.S. affiliate, USPATH. Zucker is "a psychologist and prominent researcher who directed a gender clinic in Toronto" and headed the committee that developed the American Psychiatric Association's criteria for "gender dysphoria" in the DSM-5.<sup>17</sup> The 2012 WPATH Standards of Care—SOC 7—"cited his work 15 times." In his nearly forty years of research, Zucker discovered "that most young children who came to his clinic stopped identifying as another gender as they got older." Instead, "[m]any of them would go on to come out as gay or lesbian or bisexual, suggesting previous discomfort with their sexuality, or lack of acceptance." Zucker became concerned that socially transitioning children could entrench gender dysphoria that would otherwise resolve.

Zucker's position was not popular with activists at WPATH. In 2017, when USPATH hosted its inaugural conference, Zucker submitted research, "his research passed the peer review process," and he was invited to present.<sup>21</sup> When his panel discussion began, though, protestors "used their voices to drown out Zucker's

<sup>&</sup>lt;sup>17</sup> Emily Bazelon, *The Battle Over Gender Therapy*, N.Y. TIMES MAGAZINE (June 15, 2022), https://www.nytimes.com/2022/06/15/magazine/gender-therapy.html.

<sup>&</sup>lt;sup>18</sup> *Id*.

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

<sup>&</sup>lt;sup>20</sup> *Id*.

<sup>&</sup>lt;sup>21</sup> Erica Ciszek et al., *Discursive Stickiness: Affective Institutional Texts and Activist Resistance*, 10 Public Relations Inquiry, No. 3, pp. 295-310 (2021), at 302.

presentation."<sup>22</sup> "That evening, at a meeting with the conference leaders, a group of advocates led by transgender women of color read aloud a statement in which they said the 'entire institution of WPATH' was 'violently exclusionary' because it 'remains grounded in cis-normativity and trans exclusion."<sup>23</sup> "Activists demanded Zucker's symposium be cancelled and for the WPATH Executive Board to provide an explanation and apology for his presence."<sup>24</sup> "Additionally, activists demanded" "that gender transgressive persons" "be given seats on WPATH committees, including the scientific committees that decide which academic papers are accepted for conferences."<sup>25</sup>

The disruption worked. "Th[e] uprising resulted in the cancellation of Zucker's panels," and "[c]onference organizers and board members publicly apologized for Zucker's presence at the conference.<sup>26</sup> They also "promised to incorporate transgender women of color into each level of WPATH's organization." *Id.* The

<sup>&</sup>lt;sup>22</sup> *Id*.

<sup>&</sup>lt;sup>23</sup> Bazelon, *supra*.

<sup>&</sup>lt;sup>24</sup> Ciszek, *supra*, at 302.

<sup>25</sup> *Id*; see Videorecording of meeting, https://www.youtube.com/watch?v=rfgG5TaCzsk.

<sup>&</sup>lt;sup>26</sup> Ciszek, *supra*, at 304.

public apology ended with the activist protesters on stage, surrounded by "supporters[] and allies" chanting "Trans Power!"" "After th[e] controversy, other providers were on notice that Zucker's methods were no longer acceptable," and "[h]is approach was likened to conversion therapy."

A few years later, in the fall of 2021, a number of articles by and about three WPATH leaders exposed further fissures in the organization. Dr. Marci Bowers, a world-renowned vaginoplasty specialist who currently serves as president of WPATH; Dr. Erica Anderson, a clinical psychologist and a former president of USPATH; and Dr. Laura Edwards-Leeper, the founding psychologist at the first hospital-based children's gender clinic in the United States, voiced their concern that medical providers in America were transitioning minors without proper gender exploratory psychotherapy and other safeguards.<sup>29</sup>

When Anderson, Bowers, and Edwards-Leeper went public with their concerns, they knew their colleagues at WPATH would not welcome the open discussion.<sup>30</sup> As Anderson put it: "[T]his is going to earn me a lot of criticism from some

<sup>&</sup>lt;sup>27</sup> *Id*.

<sup>&</sup>lt;sup>28</sup> Bazelon, *supra*.

<sup>&</sup>lt;sup>29</sup> See, e.g., Abigail Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, THE FREE PRESS (Oct. 4, 2021), https://www.thefp.com/p/top-trans-doctors-blow-the-whistle; Laura Edwards-Leeper & Erica Anderson, *The Mental Health Establishment is Failing Trans Kids*, WASH. POST (Nov. 24, 2021), https://www.washingtonpost.com/outlook/2021/11/24/trans-kids-therapy-psychologist/.

<sup>&</sup>lt;sup>30</sup> Shrier, *supra*.

colleagues, but ... I'm worried that decisions will be made that will later be regretted by those making them."<sup>31</sup> Bowers lamented: "There are definitely people who are trying to keep out anyone who doesn't absolutely buy the party line that everything should be affirming, and that there's no room for dissent."<sup>32</sup> Sure enough, in October, USPATH and WPATH released a joint statement condemning "the use of the lay press ... as a forum for the scientific debate" over "the use of pubertal delay and hormone therapy for transgender and gender diverse youth."<sup>33</sup> "In early November, the board of USPATH privately censured Anderson, who served as a board member. In December, the board imposed a 30-day moratorium on speaking to the press for all board members. That month, Anderson resigned."<sup>34</sup>

In December 2021, WPATH released a draft of the updated 8th edition of its Standards of Care (SOC 8). In addition to adding a controversial "Eunuch" chapter and making other changes,<sup>35</sup> SOC 8 initially retained (some) age requirements for transitioning minors—14 years old for cross-sex hormones (down from 16 in SOC

<sup>&</sup>lt;sup>31</sup> *Id*.

 $<sup>^{32}</sup>$  Id.

<sup>&</sup>lt;sup>33</sup> See Joint Letter from USPATH and WPATH (Oct. 12, 2022), https://perma.cc/X7ZN-G6FS.

<sup>&</sup>lt;sup>34</sup> Bazelon, *supra*.

<sup>&</sup>lt;sup>35</sup> See Genevieve Gluck, Top Trans Medical Association Collaborated With Castration, Child Abuse Fetishists, REDUXX (May 17, 2022), https://perma.cc/NRX5-U85C.

7), 15 for mastectomies, "and vaginoplasty and hysterectomy at 17." Though SOC 8 had been in development for years, WPATH issued a "correction" shortly after publication *removing* the minimum age requirements. Why? According to Dr. Tishelman, lead author of the chapter on children, it was to "bridge th[e] considerations" regarding the need for insurance coverage with the desire to ensure that doctors would not be held legally liable for malpractice if they deviated from the standards. Plus, according to WPATH's president, to "propose" surgeries at defined "younger age[s]" would require "a better political climate."

# **C.** Endocrine Society

While there has been less public reporting about the Endocrine Society, one cause for concern is that the authorship of its guidelines for treating gender dysphoria is composed almost entirely of WPATH leaders. WPATH is an official co-author of the Endocrine Society Guidelines, and of the nine listed authors, it appears that only

<sup>&</sup>lt;sup>36</sup> Lisa Selin Davis, *Kid Gender Guidelines Not Driven by Science*, N.Y. Post (Sept. 29, 2022), https://nypost.com/2022/09/29/kid-gender-guidelines-not-driven-by-science/.

<sup>&</sup>lt;sup>37</sup> Remarkably, this correction has itself since been removed. *See Correction*, 23 INT'L J. OF TRANSGENDER HEALTH S259 (2022), https://bit.ly/3qSqC9b.

<sup>&</sup>lt;sup>38</sup> Videorecording of Dr. Tishelman's WPATH presentation, https://twitter.com/SwipeWright/status/1571999221401948161

<sup>&</sup>lt;sup>39</sup> Azeen Ghorayshi, *More Trans Teens Are Choosing 'Top Surgery*,' N.Y. TIMES (Sept. 26, 2022), https://perma.cc/9786-V27T.

one (M. Hassan Murad) has not served as a leader in WPATH or an author of its standards of care.<sup>40</sup>

Moreover, though Plaintiffs' proposed amici, including the Endocrine Society, boast that "the Endocrine Society's Guidelines were developed following a 26step, 26-month drafting, comment, and review process" that "impose[d] strict evidentiary requirements based on the internationally recognized Grading of Recommendations Assessment, Development and Evaluation (GRADE) system," Doc. 34-1 at 15, Gordon Guyatt, "who co-developed GRADE, found 'serious problems' with the Endocrine Society guidelines, noting that the systematic reviews didn't look at the effect of the interventions on gender dysphoria itself, arguably 'the most important outcome." "He also noted that the Endocrine Society had at times paired strong recommendations—phrased as 'we recommend'—with weak evidence," even though "GRADE discourages strong recommendation with low or very low quality except under very specific circumstances" that "should be made explicit." 42 The Endocrine Society's guidelines do not discuss any of these exceptions.<sup>43</sup>

3, 2023).

<sup>&</sup>lt;sup>40</sup> See generally Wylie C. Hembree et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons, 102(11) J. CLINICAL ENDOCRINOLOGY & METABOLISM 3869 (Nov. 2017), https://academic.oup.com/jcem/article/102/11/3869/4157558 (Endocrine Society Guidelines); Aaron Devor, WPATH, History of the Association, https://www.wpath.org/about/history (last accessed Apr.

<sup>&</sup>lt;sup>41</sup> Block, *supra*.

<sup>&</sup>lt;sup>42</sup> Block, *supra*.

<sup>&</sup>lt;sup>43</sup> Hembree, *supra*.

\* \* \*

These vignettes are necessarily incomplete, and much more could be said. But the point is a simple one: AAP, WPATH, the Endocrine Society, and Plaintiffs' other preferred medical interest groups are not neutral arbiters of science or medical opinion. They are *interest groups*, composed of practitioners whose livelihoods depend on being paid for the treatments at issue. The Court should keep that in mind when reviewing their statements.

# II. Florida's Determination That Transitioning Treatments Are Experimental Comports With The Conclusion Of European Healthcare Authorities.

While Plaintiffs' medical interest groups proclaim a false consensus in the United States, "[i]nternationally, ... governing bodies have come to different conclusions regarding the safety and efficacy of medically treating gender dysphoria." Indeed, in recent years, medical authorities in the UK, Finland, Sweden, and Norway have all looked at the evidence and determined—as Florida did—that transitioning treatments for minors are experimental. (The Department of Health and Human Services seems to have implicitly come to the same conclusion: It is funding an ongoing

<sup>&</sup>lt;sup>44</sup> Block, *supra*.

experiment of transitioning treatments due to "the paucity of empirical research, particularly in the US setting." (45)

# A. United Kingdom

In 2020, following increased concern about practitioners at the National Health Service's centralized gender clinic endorsing transitioning treatments for a skyrocketing cohort of gender dysphoric minors without adequate justification, Britain's National Institute for Health and Care Excellence (NICE) commissioned an independent review of the use of puberty blockers and cross-sex hormones to be chaired by Dr. Hilary Cass. As part of the review, NHS conducted extensive literature assessments of the scientific evidence concerning puberty blockers and cross-sex hormones for children and adolescents. And Neither literature review inspired confidence in the procedures. The review cautioned: Any potential benefits of genderaffirming hormones must be weighed against the largely unknown long-term safety profile of these treatments in children and adolescents with gender dysphoria due

<sup>&</sup>lt;sup>45</sup> E.g., Johanna Olson-Kennedy et al., *Impact of Early Medical Treatment for Transgender Youth: Protocol for the Longitudinal, Observational Trans Youth Care Study*, JMIR RES. PROTOC. (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6647755/.

<sup>&</sup>lt;sup>46</sup> See Evidence review: Gender-affirming hormones for children and adolescents with gender dysphoria, Nat'l Inst. for Health & Care Excellence (Mar. 11, 2021), https://perma.cc/M8J5-MXVG ("NICE Cross-Sex Hormone Evidence Review"); Evidence review: Gondotrophin releasing hormone analogues for children and adolescents with gender dysphoria, Nat'l Inst. for Health & Care Excellence (Mar. 11, 2021), https://perma.cc/93NB-BGAN ("NICE Puberty Blocker Evidence Review").

to the lack of reliable evidence.<sup>47</sup> A similar conclusion followed for puberty blockers: "A key limitation to identifying the effectiveness and safety of GnRH analogues [i.e., puberty blockers] for children and adolescents with gender dysphoria is the lack of reliable comparative studies."<sup>48</sup>

Following publication of the literature reviews, Dr. Cass determined that "the available evidence was not strong enough to form the basis of a policy position."<sup>49</sup> She thus called for experiments to *start* being conducted.<sup>50</sup> In response, and based on the "uncertainties surrounding the use of hormone treatments," NHS England is now "forming proposals for prospectively enrolling children and young people being considered for hormone treatment into a formal research programme," and "will *only* commission [puberty blockers] in the context of a formal research protocol."<sup>51</sup>

<sup>&</sup>lt;sup>47</sup> NICE Cross-Sex Hormone Evidence Review, *supra*, at 14.

<sup>&</sup>lt;sup>48</sup> NICE Puberty Blocker Evidence Review, *supra*, at 12.

<sup>&</sup>lt;sup>49</sup> Hilary Cass, The Cass Review: Interim Report (Feb. 2022) 37, https://perma.cc/RJU2-VLHT

<sup>&</sup>lt;sup>50</sup> Hilary Cass, Letter to Director of Specialized Commissioning (Jul. 19, 2022), https://perma.cc/KS4N-V2GX.

NHS England, *Interim Service Specification* (Oct. 20, 2022), https://perma.cc/N3CY-JYNY, at 16 (emphasis added).

# B. Sweden

In February 2022, following an extensive literature review, Sweden's National Board of Health and Welfare issued a national policy severely restricting puberty blockers and cross-sex hormones to treat gender dysphoric youth.<sup>52</sup> The Board concluded: "For adolescents with gender incongruence, ... the risk of puberty suppressing treatment with GnRH-analogues and gender-affirming hormonal treatment currently outweigh the possible benefits."53 The Board restricted the treatments to "exceptional cases," and explained that its decision was "based mainly on three factors: the continued lack of reliable scientific evidence concerning the efficacy and the safety of both treatments, the knowledge that detransition occurs among young adults, and the uncertainty that follows from the yet unexplained increase in the number of care seekers, an increase particularly large among adolescents registered as females at birth."54 Going forward, puberty blockers and cross-sex hormones may be used to treat gender dysphoric youth in Sweden only in strictly controlled research settings or "exceptional cases."55

<sup>&</sup>lt;sup>52</sup> Sweden National Board of Health and Welfare Policy Statement, Socialstyrelsen, *Care of Children and Adolescents with Gender Dysphoria: Summary* (2022), https://perma.cc/FDS5-BDF3.

<sup>&</sup>lt;sup>53</sup> *Id.* at 3.

<sup>&</sup>lt;sup>54</sup> *Id.* at 3.

<sup>&</sup>lt;sup>55</sup> *Id.* at 4.

# C. Finland

In June 2020, Finland's Council for Choices in Healthcare in Finland also suggested changes to its treatment protocols.<sup>56</sup> Though allowing for some hormonal interventions under certain conditions, the Council lamented the lack of evidence and urged caution in light of severe risks associated with medical intervention. "As far as minors are concerned," the Council stated, "there are no medical treatment[s] [for gender dysphoria] that can be considered evidence-based."57 The Council continued: "The reliability of the existing studies with no control groups is highly uncertain, and because of this uncertainty, no decisions should be made that can permanently alter a still-maturing minor's mental and physical development."58 The Council concluded that further experiments are needed: "Information about the potential harms of hormone therapies is accumulating slowly and is not systematically reported. It is critical to obtain information on the benefits and risks of these treatments in rigorous research settings."59

# D. Norway

In March 2023, the Norwegian Healthcare Investigation Board (Ukom) released a report finding that its national guidelines for treating gender dysphoria were

<sup>&</sup>lt;sup>56</sup> See Palveluvalikoima, *Recommendation of the Council for Choices in Health Care in Finland* (2020), https://perma.cc/VN38-67WT .

<sup>&</sup>lt;sup>57</sup> *Id*.

<sup>&</sup>lt;sup>58</sup> *Id*.

<sup>&</sup>lt;sup>59</sup> *Id*.

inadequate.<sup>60</sup> The existing 2020 guidelines had not been based on a literature review, and the new report found "insufficient evidence for the use of puberty blockers and cross sex hormone treatments in young people, especially for teenagers who are increasingly seeking health services." Accordingly, Ukom "recommended that updated guidelines should be based on a new commissioned review or existing international up-to-date systematic reviews, such as those conducted in 2021 by the UK's National Institute for Health and Care Excellence." At present, "Ukom defines such treatments as utprøvende behandling, or 'treatments under trial'" <sup>63</sup>—i.e., experimental, just as Florida does.

# **CONCLUSION**

The Court should grant Defendants' Motion for Summary Judgment.

<sup>&</sup>lt;sup>60</sup> Jennifer Block, *Norway's Guidance on Paediatric Gender Treatment is Unsafe, Says Review*, The BMJ (Mar. 23, 2023), https://www.bmj.com/content/380/bmj.p697.

<sup>&</sup>lt;sup>61</sup> *Id*.

 $<sup>^{62}</sup>$  *Id*.

 $<sup>^{63}</sup>$  *Id*.

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# **CERTIFICATE OF WORD COUNT**

According to Microsoft Word, the word processing system used to prepare this brief, there are a total of 3,980 words contained within the brief.

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# CERTIFICATE OF SATISFACTION OF ATTORNEY-CONFERENCE REQUIREMENT

Pursuant to Local Rule 7.1(B), counsel conferred with counsel for the parties.

Both Plaintiffs and Defendants indicated that they do not oppose Amici States filing the proposed amicus brief.

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